Innovative finance in the health sector

A GUIDE TO EU AND NATIONAL FUNDING

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INNOVATIVE FINANCE IN THE HEALTH SECTOR: A GUIDE TO EU AND NATIONAL FUNDING – first edition

This book is based on the results of the InnoStars project "Seeking out opportunities for funding interconnectivity with ESIF and National/Regional Funds".

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Preface

I am pleased to introduce "Guide to EU and national funding", which provides you with greater awareness and knowledge regarding widening interconnections between the EIT Health objectives, funding sources and financing schemes of EU/national/regional/local funding entities. The innovation promotion activities of EIT Health are largely funded by the EU budget, the phasing out of these funds requires a gradual replacement from external resources.

EIT Health Regional Innovation Scheme (RIS) programme, which initiated this project, aimed at discovering the main activities and funding sources in the area of Research, Development, Innovation (RDI) with the engagement of EU direct management funds (e.g.H2020), shared management funds (ESIF) and national/regional funding schemes (e.g. targeted programmes and grants), and potential private contributions, if available.

For this purpose, we had to take into consideration and get access to respective EU strategies, health policies and investments in the future EU programming period, the respective regulations, trends, financing plans and decision-makers.

The research covers fives pre-selected regions, namely: Southern Transdanubia, Hungary, Pomorskie Region, Poland, Eastern Slovakia, Continental Croatia and Lithuania. However, the larger part of the document contains relevant information for the whole RIS region.

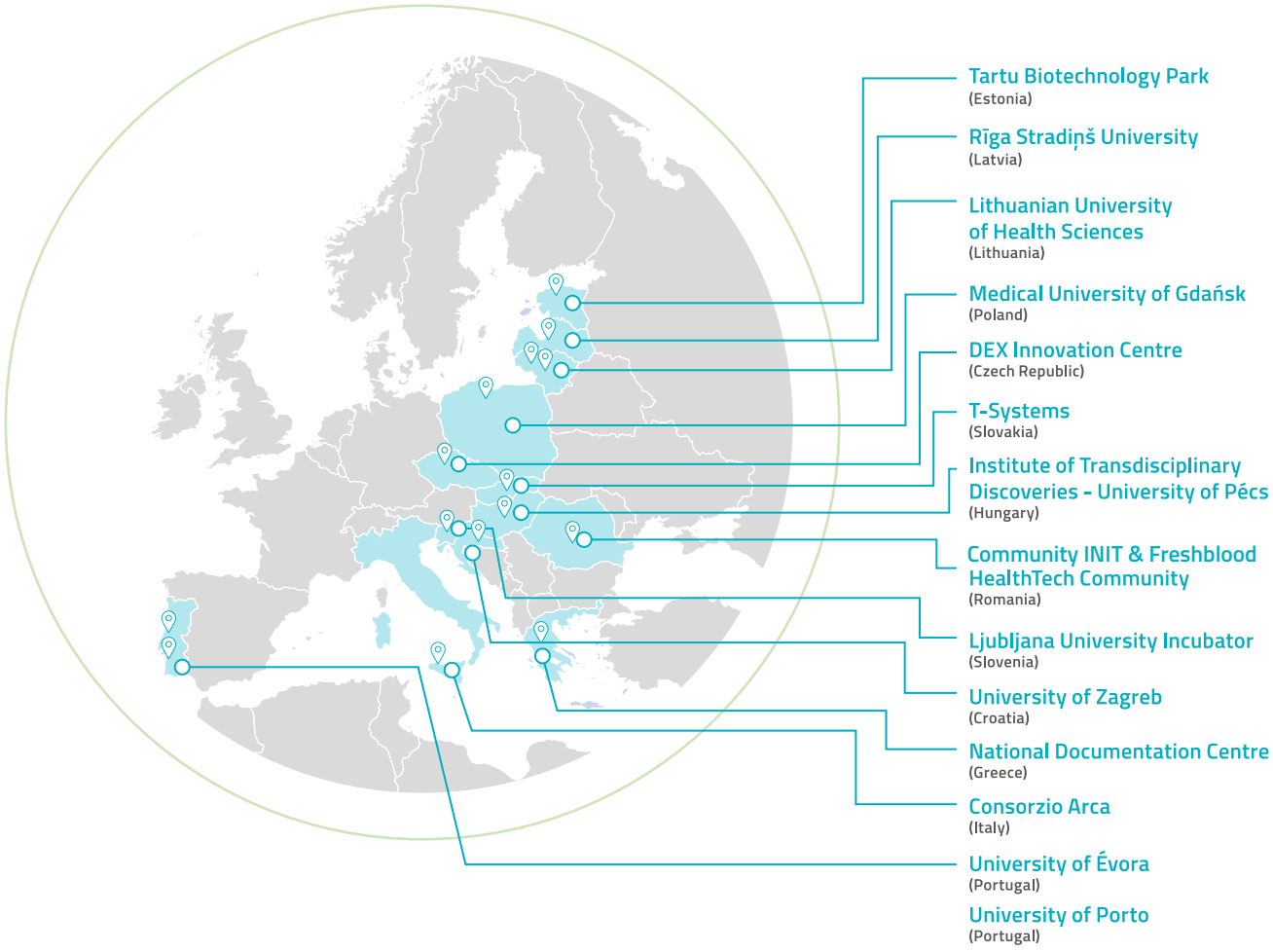
I hope and I am nearly convinced that the main targets of this project i.e. stimulating innovation in different countries, creating a better understanding of the legal and institutional framework of innovation as well as finding possible financial instruments available in Europe will be supported by the outcomes of this study.

This report was prepared as a set of guidelines for EIT Health InnoStars and EIT Health Hubs so that they could fulfil their tasks more effectively. This document gives you valuable insights during this very important period of negotiating the next Framework Programme and the national ESIF Operational Programme. Most of the information will need refreshment in a year, however, we hope that by then — with this guide — our Partners will be firmly positioned in the evolving funding schemes.
Our acknowledgements are directed to the Authors for providing us with valuable, concise and subject-oriented information.

Balázs Fürjes, Managing Director, EIT Health InnoStars

The InnoStars region is one of the seven geographical areas of EIT Health. It covers half of Europe, including Poland, Hungary, Italy, and Portugal, as well as additional regions included in the EIT Health Regional Innovation Scheme programme – the Baltic States, Croatia, Slovakia, the Czech Republic, Slovenia, Greece and Romania. This is a group of countries qualified by the European Innovation Scoreboard (EIS) as moderate innovators. InnoStars is focused on promoting entrepreneurship, innovation and education in the domain of healthcare, healthy living and active ageing in the region.

EIT Health Regional Innovation Scheme Programme (EIT Health RIS) is a European programme that supports more progressing regions in discovering and developing innovations in healthcare and other areas. The programme incorporates 14 Hubs located in 13 countries across Eastern, Central and Southern Europe. These Hubs serve as access points to a pan-European network of the best universities, companies and their projects. The programme aims to incubate the regions where it operates, discovering their unique innovation assets and to engage local innovators to participate in pan-European programmes and competitions. The programme is run by the European Institute of Innovation and Technology (EIT) and is coordinated in the field of healthcare by EIT Health InnoStars.



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List of abbreviations

COSME	Competitiveness of Enterprises and Small and Medium-sized Enterprises
CPR	Common Provisions Regulation
CSF	Common Strategic Framework
DG ECFIN	Directorate-General for Economic and Financial Affairs
DG EMPL	Directorate-General for Employment, Social Affairs and Inclusion
DG REGIO	Directorate-General for Regional and Urban Policy
EAFRD	European Agricultural Fund for Rural Development
EaSI	Employment and Social Innovation Programme
EC	European Commission
ECA	European Court of Auditors
EFSI	European Fund for Strategic Investments
EIAH	European Investment Advisory Hub
EIB	European Investment Bank
EIF	European Investment Fund
ERDF	European Regional Development Fund
ESF	European Social Fund
ESIF	European Structural and Investment Funds
FI	Financial Instrument
FLPG	First Loss Portfolio Guarantee
GBER	General Block Exemption Regulation
HF	Holding Fund
InnovFin	EU Finance for Innovators
JASMINE	Joint Action to Support Micro-finance Institutions in Europe
JEREMIE	Joint European Resources for Micro-to-Medium Enterprises Initiative
JESSICA	Joint European Support for Sustainable Investment in City Areas
MA	Managing Authority
MS	Member State(s)
NSRF	National Strategic Reference Framework
OP	Operational Programme
PPP	Public-Private Partnerships
SMEs	Small and Medium-sized Enterprises
UDF	Urban Development Fund
VC	Venture Capital

Introduction

This report is based on the results of the InnoStars project "seeking out opportunities for funding interconnectivity with ESIF and National/Regional Funds".

This project has been designed to help widening the funding basis so that the local innovation ecosystem and local healthcare innovation projects in the EIT Health RIS covered regions could be effectively promoted. The aim of the research was to provide a fiscal mapping study through

- a detailed review of funding sources which have been financing R+D+I: EU direct management funds (e.g. H2020), shared management (ESIF) funds, national/regional funding schemes (e.g. targeted programmes and grants), and if available potential private contributions. This exercise reveals funding trends in terms of the total magnitude and mixtures of funding available and differences depending on the time period, policy framework/programming structure and geographical location (region),
- nvestigating and describing the corresponding regulatory standards, resource allocation models and the structures and processes employed for the award of finance under the various funding instruments, taking account of anticipated changes in the future,
- identifying and interviewing the key actors involved in the adoption of decisions on (public) investment schemes for local healthcare R&D&I projects and present their mandate and responsibilities.

Besides the European picture, through case studies the book presents the funding situation in 5 pre-selected regions (namely Southern Transdanubia-Hungary, Pomorskie Region-Poland, Eastern Slovakia, Continental Croatia and Lithuania).

We are fully convinced, however, that the results bear relevance to, encourage and make easier the development, preparation and implementation of innovation project for a wide range of innovators in the European healthcare sector. To stimulate innovations in different countries, an understanding of the healthcare system as well as the possible financing solutions available in Europe is necessary for project promoters and policy experts, as well.

It is hard to overstate the importance of employing and using different funding instruments in the most effective and efficient way as well identify clarify the optimal construction for the planned innovative development project. Not only is the innovation ecosystem struck by general capacity constraints, the conversion of an integrated approach into practice, the combination of various public and also private sector funds requires highly specialised knowledge and a particular combination of skills. These, cannot be obtained via the present system of formal education or even by the targeted training interventions offered.

The EIT Health InnoStars is well-placed in the institutional cascade to actively help the bridging of the gap between the various programmes and funding regimes through the provision of technical support for innovators and advice to the managing authorities and other financiers.

This report has been prepared as a guidance. It introduces the findings of the project, which have been translated into strategic recommendations that stakeholders could rely upon in order to optimise presently available and future/planned funding opportunities.

1. Importance of health sector - EU strategies, regulations and decisions

Health is a fundamental human right and key contributing factor to well-being. On the positive side, improved health status contributes to increased economic growth through greater educational investment, improved labour market participation and higher savings. On the negative side, ill-health imposes a significant economic burden on society and public finances, in addition to its human toll[1]. Accordingly, health sector is one of the most important in public spending (accounting for almost 15% of all government expenditure in the EU). It also accounts for 8% of the total European workforce and for 10 % of the EU's GDP. The sector is vital to ensure the health and wellbeing of EU populations and it is at the core of the EU's high level of social protection.

EU action on health issues aims to improve public health, prevent diseases and threats to health (including those related to lifestyle), as well as to promote research. EU action serves to complement national policies and to support cooperation between member countries in the field of public health. Based on the Article 168 of the Treaty on the Functioning of the European Union[2] - which is saying that the *EU has a duty to ensure that a high level of human health protection is guaranteed when EU policies and activities are drawn up and implemented* - the main aim of ***the Council conclusions on the economic crisis***[3] and healthcare as strategic document is to invite European Union (EU) countries and the European Commission, both singly and jointly, to take certain measures to tackle the consequences of the economic crisis on healthcare systems.

EU countries are invited to:

- improve access to high-quality healthcare, especially for the most vulnerable;
- develop health promotion and disease-prevention policies to reduce the need for medical treatment;
- consider ways to better integrate
- hospital care with wider health considerations, such as the environment and lifestyle and,
- health and social care support, such as social work and care home services;
- promote new technological and e-health solutions to improve efficiency and control spending;
- use health system performance assessment to aid policymaking;
- exchange information on healthcare services and strategies, in particular on affordable pricing for medicines and medical devices.

Together, EU countries and the Commission are invited to:

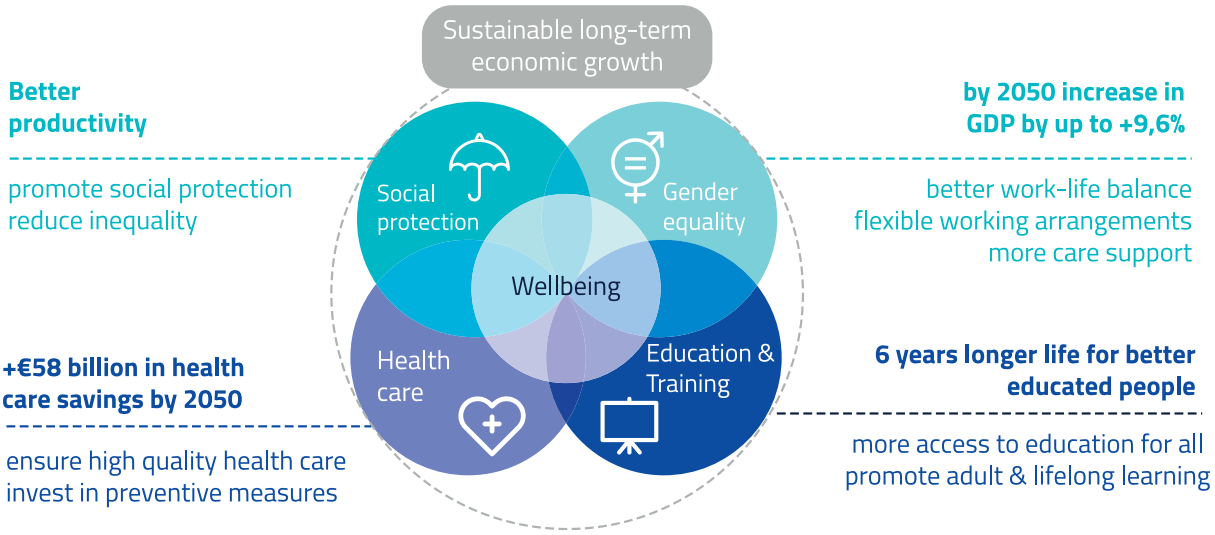
- improve the effective use of European Structural and Investment Funds (ESIF) for health investments in eligible regions of the EU;
- assess the role of healthcare benefits in reducing health inequality and preventing poverty;
- strengthen cooperation on cross-border healthcare, e-health and health technology assessments;
- cooperate on ways to ensure countries have sustainable health workforces with the necessary skills to guarantee that patients have access to care, and the safety and quality of care.

On its own, the Commission is invited to:

- collect and exchange information on equitable access to healthcare;
- encourage cooperation between health services across national borders;
- provide information on the healthcare available under EU countries' national healthcare systems.

For the development of the health sector very important step will be the, when based on policy recommendations an action-oriented ***„Well-being and Sustainability Strategy for the EU"*** will be developed. With a view to the meeting of the Social Questions Working Party on 25 July 2019, a draft Council conclusion on the above subject have been prepared by the Presidency.

Figure 1: The Economy of Wellbeing



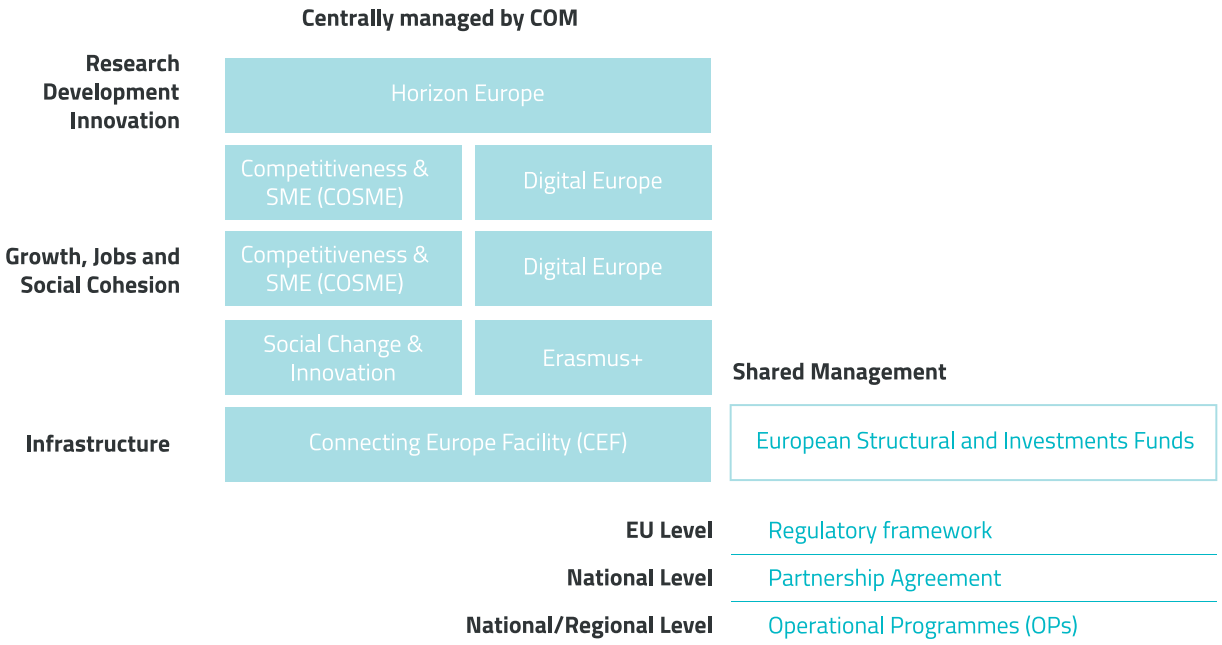
Source: OECD

2. EU direct funding

The Economy of Wellbeing is a policy orientation and a governance approach, which aims to put people and their wellbeing at the centre of policy- and decision-making. It highlights the importance of investing in effective and efficient policy measures and structures ensuring access to all to public services including health services, promotion of health and preventive measures, social protection, and education and training. It emphasises employment, active labour market policy and occupational safety and health as measures to guarantee wellbeing at work.

The European Commission is responsible for the proper and regular implementation of the EU budget. The Commission manages the budget when the projects are carried out by its departments, at its headquarters, in the EU delegations or through EU executive agencies (centrally managed programmes). In other cases, (e.g. cohesion policy), the Commission delegates the management of certain pro¬grammes to EU countries and national authorities under shared management agreements.

Figure 2: Centrally managed and shared management programmes



Source: Nyikos

In this programming period there are 86 central grant call still open for the health area.

The management includes awarding grants, transferring funds, monitoring activities, selecting contractors, etc. A list of open calls for proposals, grouped by area, is available online (https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-search).

2.1. Types of funding

There are different types of funding opportunities, such as grants, loans, guarantees, subsidies and prizes.

A **grant** is non-refundable funding for projects contributing to EU policies. EU grants are awarded to private and public organisations, and excep¬tionally to individuals. The EU usually does not fi¬nance projects up to 100%, accordingly the project have to be co-financed by the beneficiary organisation and/or other supporters.

Financial instruments[4] have been considered[5] more economical than non-repayable capital grants and they may be more effective if market imperfections lead to underfunding of businesses that lack sufficient assets to offer as guarantee. With the same amount of public funds, FIs allow a much larger number of investment projects to be funded.

Box 1: The use of fund-type of FI forms

Loans are the most widely used and well-established form of co-financed FIs. Loans are the main source of private financing for SMEs – over 60 % of SMEs have used them[6]. Loan funds are widely viewed as relatively simple and quick to launch compared to other types of support, and the market uptake also tends to be more rapid[7]. A very wide range of loan sizes is offered in the stocktake countries, and also their terms vary considerably. Generally the loan funds lend at below market interest rates and interest rates, which are subject to the state aid ceilings and are calculated by taking account of the creditworthiness of final recipients.

Guarantees encourage banks or financial institutions to advance credit to SMEs unable to obtain commercial finance (typically loan finance) due to the lack of collateral[8]. Counter-guarantee FIs, where guarantee given by a guarantee agency/bank to another bank issuing a guarantee, secure the guarantees rather than loans, as seen in Italy and Hungary.

Equity FIs are used to support innovative firms and business start-ups with high growth potential (and therefore high returns), but also with high risk (and potentially high losses). Equity and venture capital finance are considered of limited relevance by most SMEs (80%+[9]).

[4] FIs are defined in the Financial Regulation (Article 2(p) of Regulation (EU, EURATOM) No 966/2012 of 25 October 2012) as Union measures of "financial support provided on a complementary basis from the budget in order to address one or more specific policy objectives of the Union. Such instruments may take the form equity or quasi-equity investments, of loans or guarantees, or other risk-sharing instruments, and may, where appropriate, be combined with grants". The CPR uses this definition (see Article 2(11)).

[5] E.g.: Ex post evaluation of cohesion policy programmes 2007-2013, focusing on the European Regional Development Fund (ERDF) and Cohesion Fund (CF) Work Package 3: Financial instruments for enterprise support (2016).

[6] EC, (2013), SME's Access to Finance Survey report

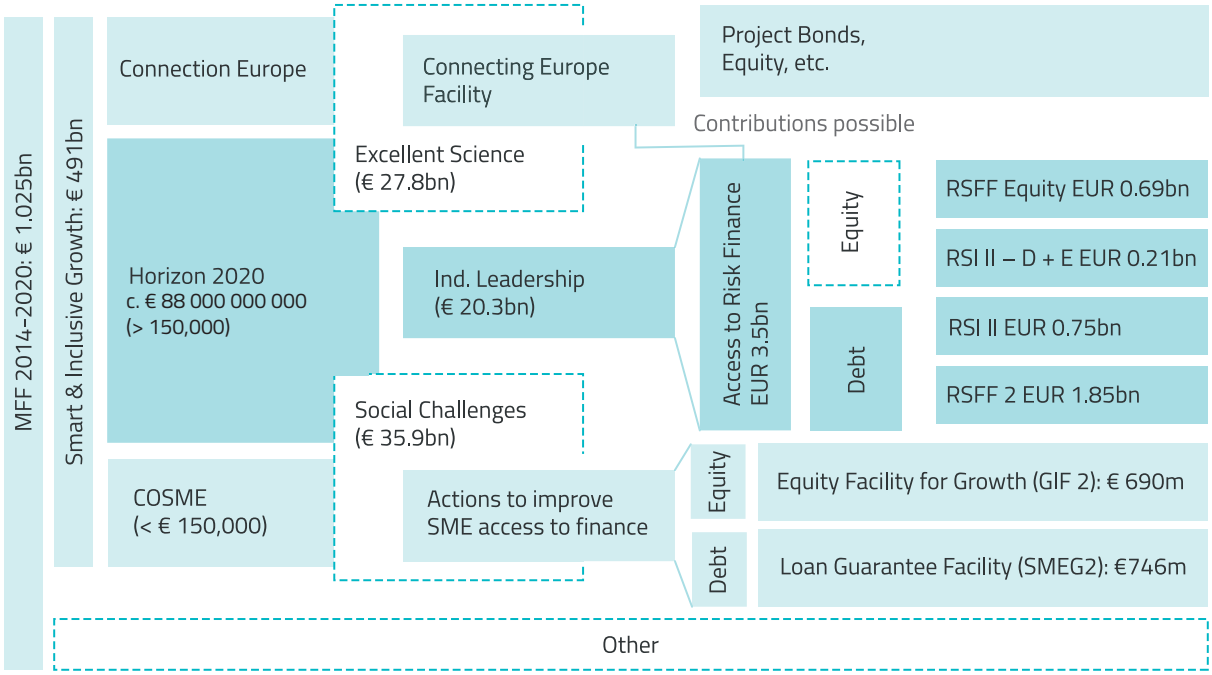
[7] Michie R and Wishlade F, with Gloazzo C (2014) Guidelines for the Implementation of Financial Instruments: Building on FIN-EN – sharing methodologies on FINancial ENgineering for enterprises, Report to Finlombarda SpA.

[8] Collateral is a property or other asset that a borrower offers as a way for a lender to secure the loan. If the borrower stops making the promised loan payments, the lender can seize the collateral to recoup its losses

[9] EC (2013), SME's Access to Finance Survey report

The Investment Plan for Europe strongly **encourages the use of financial instruments** instead of traditional grants in ESIF funding. While the overall amounts delivered through financial instruments should increase, the EC's implicit general policy line is that there should be consolidation of resources into national or supra-regional instruments.

Figure 3: EU Budget Structure - Main logic of the FIs directly and indirectly managed



Source: Nyikos

Subsidies and other types of funding are managed directly by EU national governments, not by the European Commission. For instance, agricultural subsidies are awarded to support farmers.

Prizes are rewards to winners of contests from Horizon 2020. They are also called challenge prizes or inducement prizes.

2.2. Health for Growth: EU health programme (2014-2020)

In 2014, the European Union (EU) launched its third health programme[10].

Figure 4: EU Health Action and Programmes

Source: European Commission

The programme aims to foster health in Europe by encouraging cooperation between EU countries to improve the health policies that benefit their citizens and also encourages the pooling of resources where economies of scale can provide optimal solutions. The programme aims to improve Europeans' health and reduce health inequalities by complementing Member States' health policies in four ways. It is designed to:

- promote good health and prevent disease: here, countries would exchange information and good practices on how to deal with various risk factors such as smoking, drug and alcohol abuse, unhealthy diets and sedentary lifestyles;
- ensure that citizens are protected from cross-border health threats: increased international travel and trade mean that we are potentially exposed to a wider range of health threats than in the past, requiring a rapid and coordinated response;
- support innovation and sustainability in EU countries' health systems: the programme seeks to help capacity building in the health sector, find optimal ways of making scarce resources go further and encourage the uptake of innovations in approaches, working practices, as well as technologies;
- improve access to quality and safe healthcare: this means, for example, ensuring that medical expertise is available beyond national borders by encouraging the creation of networks of centres of expertise across the EU.

In the programme over the 2014-20 period, funding of almost EUR 450 million is available for eligible projects, which must be able to demonstrate the clear value of EU intervention over spending by individual countries (EU added value). There are also rules for projects of exceptional utility when at least 30 % of the budget of the proposed action is allocated to Member States whose gross national income per head is under 90% of the EU average, with at least 14 countries participating in the action. For such cases, the EU contribution may be up to 80 % of eligible costs.

Box 2: Main elements of the Call for Proposals of EU Health Programme 2019 Project Grants

Deadline model	single-stage
Submission open - close	21 May 2019 - 10 September 2019
Who can apply?	**Country eligibility** To receive EU financial support for a project, i.e. to be a coordinator or other beneficiary, the organisation needs to be legally established in: ▪ EU Member States; ▪ Iceland, Norway; ▪ Serbia, Bosnia and Herzegovina, and Moldova. Those countries which have a bilateral agreement with the European Union in accordance with Article 6 of Regulation (EU) No 282/2014 on the establishment of a third Health Programme. Organisations from other countries can only participate as subcontractors or collaborating stakeholders. **Types of organisation** Grants can be awarded to legally established public, non-governmental or private bodies including public authorities, public sector bodies, in particular research and health institutions, universities and higher education establishments. These can submit a project proposal as the coordinator or participate as other beneficiary.
General principles of project funding	**Geographical eligibility** There is no minimum number of partners for a proposal to be eligible. However, a new award criterion is included in the geographical coverage of the proposals: proposed activities must be carried out in at least 3 eligible countries; these activities must be carried out in areas which are particularly affected by the high influx of refugees. ▪ Co-financing rule: own financial resources or financial resources of third parties to contribute to the costs of the project needed; ▪ Non-profit rule: the grant may not have the purpose or effect of producing a profit for you; ▪ Non-retroactivity rule: co-funding possible only for the costs incurred after the starting date stipulated in the grant agreement; ▪ Non-cumulative rule: each action may give rise to the award of only one grant to any one beneficiary (cannot get paid twice for the same cost). All projects should: ▪ provide high added value at EU level, ▪ be relevant to the objectives and priorities defined in the current annual work plan, ▪ be innovative, and last no longer than three years.
How much co-funding?	Projects under the call can receive up to 60-80% co-financing of eligible costs. Overheads (indirect costs) are not eligible for the applicants receiving an operating grant from the Union budget during the period in question.
The allocation of resources for 2019	- for grants (implemented under direct management): €31 750 000 Projects (chapter 2): €5 800 000 ▪ Joint Actions (chapter 3): €15 000 000 ▪ Operating Grants (chapter 4): €5 000 000 ▪ Direct award of grants (International Organisations) (chapter 5): €5 750 000 ▪ Other direct award of grants (chapter 6) €200 000 - for prizes (implemented under direct management) (chapter 7): €300 000 - for procurement (implemented under direct management) (chapter 8): €24 000 560 - for other actions (chapter 9): €7 893 000

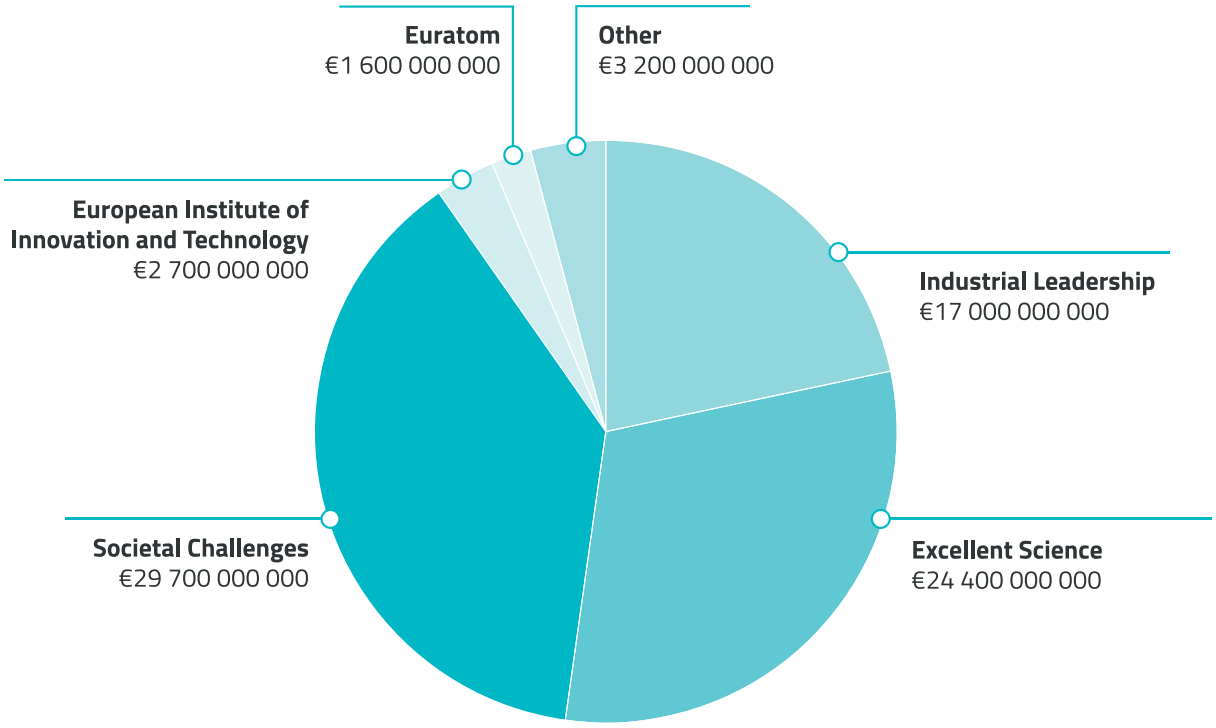
Source: Nyikos compilation

2.3. Horizon 2020

2.3.1. Grants

Horizon 2020 is the EU Research and Innovation programmein the 2014-2020 programming period with nearly €80 000 000 000 of funding available. H2020 is the financial instrument implementing the Innovation Union, a Europe 2020 flagship initiative aimed at securing Europe's global competitiveness.

Figure 5: Horizon 2020 priorities and budget (€78 600 000 000)



Source: European Commission

Two-year work programmes announce the specific areas that will be funded by Horizon 2020. In the H2020 program for standard research projects a consortium of at least three legal entities could apply for grants. In the case of European Research Council (ERC) and SME Instrument the minimum condition for participation is one legal entity. Each entity must be established in an EU Member State or an Associated Country[11].

[11] Agreements between the EU and individual governments have created a number of associated countries, where legal entities can participate in Horizon 2020 on an equal footing to those of EU Member States.For a list of associated countries, see http://bit.ly/H2020AC.Participating legal entities from other countries may also be able to get EU funding in certain circumstances. See http://bit.ly/H2020IPC.

Box 3.: H2020 structure

Euratom
Spreading Excellence and Widening Participation
Science with and for Society
Societal Challenges

- Health, Demographic Change and Wellbeing
- Food Security, Sustainable Agriculture and Forestry, Marine, Maritime and Inland Water Research and the Bioeconomy
- Secure, Clean and Efficient Energy
- Smart, Green and Integrated Transport
- Climate Action, Environment, Resource Efficiency and RawMaterials
- Europe in a changing world - Inclusive, innovative and reflective societies
- Secure societies – Protecting freedom and security of Europe and its citizens

Industrial Leadership

- Leadership in Enabling and Industrial Technologies
  - Information and Communication Technologies
  - A new generation of components and systems
  - Advanced Computing
  - Future Internet
  - Content Technologies and Information Management
  - Robotics
  - Micro- and Nanoelectronics
- Nanotechnologies, Advanced Materials, Advanced Manufacturing and Processing, and Biotechnology

Nanotechnologies

- Space
- Access to risk finance
- Innovation in SMEs

Excellent Science

- European Research Council
- Future and Emerging Technologies
  - FET Open
  - FET Proactive
  - FET Flagships
- Marie Skłodowska-Curie actions

Source: EC, compiled by Nyikos

In Horizon 2020 there is one single funding rate for all beneficiaries and all activities in the research grants. EU funding covers up to 100 % of all eligible costs for all research and innovation actions. For innovation actions, funding generally covers 70 % of eligible costs, but may increase to 100 % for non-profit organisations. Indirect eligible costs (e.g. administration, communication and infrastructure costs, office supplies) are reimbursed with a 25% flat rate of the direct eligible costs (those costs directly linked to the action implementation).

HORIZON 2020 participation gap symptomatic for Innovation Divide; in absolute terms, 68% of Horizon 2020 funding went to Innovation Leaders and Strong Innovators. The roll-up regions are in moderate innovator Member States.

Figure 6: Horizon 2020 participation and contribution per Innovation Performance Group of the European Innovation Scoreboard 2017

	EU MS	GERD	H2020 Contribution	Participations	H2020 Contribution/ GERD	% of H2020 Contribution	% of H2020 Participations
Innovation leaders	SE, DK, FI, NL, UK, DE	€510 480 000	€9 743 000	19,347	1.9%	48%	39%
Strong innovators	AT, LU, BE, IE, FR, SI	€219 546 000 000	€4 158 000	9,446	1.9%	20%	19%
Moderate innovators	CZ, PT, EE, LT, ES, MT, IT, CY, SK, EL, HU, LV, PL, HR	€150 010 000 000	€4 945 000	15,248	3.3%	24%	31%
Modest innovators	RO, BG	€3 346 000 000	€107 000 000	685	3.2%	1%	1%

There are H2020 co-fund actions to supplement individual calls or programmes. For example:

- Calls for proposals between national research programmes (ERA-NET co-fund);
- Calls for tenders for Pre-Commercial Public Procurements or Public Procurement of Innovative solutions (PCP-PPI co-fund);
- Mobility programmes (Marie Skłodowska-Curie co-fund).

The level of **specification of the synergy objectives** is very variable in the H2020 work programmes (WP); in some cases, there is guidance in the main text of the WP, in other cases ESIF and synergy-related issues are only mentioned in the footnotes. In most cases, H2020/ESIF synergies seem more to be offered as an opportunity, to provide space for it in the programme, rather than providing concrete guidance to their set-up and implementation.

There were 114 WP for Horizon 2020 in the two periods 2014-15 and 2016-17, covering all the programme areas plus other areas such as EURATOM; from which 99 work programmes specifically mentioned European Structural and Investment Funds (ESIF) or synergies (86.8%). However, this fund integration is a complicated exercise in the practice (See later in point 4.).

In the whole programming period 3684 call were/are/will be in H2020 programme, from which **438 with health relevance**.

2.3.2. H2020 financial Instruments

The **Horizon 2020 Financial Instruments** are being implemented under the umbrella term 'InnovFin' in the 2014-20 Multi-Annual Financial Framework (MFF) period. InnovFin aims to facilitate and accelerate access to finance for innovative businesses and other innovative entities in Europe.

InnovFin consists of a debt instrument and an equity instrument, and is broken down into individual products. While primarily funded by H2020, the InnovFin programme has also received additional funding under the EFSI. The InnovFin financial products are complemented by InnovFin Advisory.

The European Commission has entrusted the day-to-day management of the programmes to two entities: the EIF manages the SME Guarantee and InnovFin Early-Stage Equities whereas the EIB manages all the other products.

Figure 7: InnovFin product portfolio

Source: EIB

The financial programmes are implemented by **EIB directly** and/or intermediated finance and by **EIF** cooperating with **financial intermediaries**, who could be national development banks as well as commercial banks, fund managers or other financial organizations.

Figure 8: Financial programmes are implemented by EIB Group

2014-2020

- European Fund for Strategic Investments
- CEF Debt Instrument
- CEF Equity Instrument
- Loan Guarantee Facility under COSME
- Equity facility for Growth under COSME
- Innovfin Equity
- Innovfin SME guarantee
- InnovFin Loan Services for R&I Facility
- Private Finance for Energy Efficiency Instrument
- Natural Capital Financing Facility
- EaSI Capacity Building Investments
- EaSI Microfinance and Social Enterprise Guarantees
- Student Loan Guarantee Facility
- Cultural and creative sectors Guarantee Facility

Source: European Commission

Figure 9: EIF intermediaries in the examined MS

Country	What is available?	Intermediary	Initiative
Hungary	Loans	Erste Bank	InnovFin SME Guarantee Facility
	Loans	AVHGA Erste Bank Garantiqa K&H Bank	COSME EFSI-Investment Plan for Europe
	Loans	UniCredit Bank	InnovFin SME Guarantee Facility EFSI-Investment Plan for Europe
	Loans	UniCredit Bank Austria	Risk Sharing Instrument (RSI)
	Micro-loans	Carion Finanszírozási Centrum	Progress Microfinance
Poland	Loans	TISE SA	EaSI
	Loans	PKO Leasing	EFSI InnovFin SME Guarantee Facility
	Loans	Raiffeisen Leasing Polska	EFSI COSME InnovFin SME Guarantee Facility
	Loans	Innovatoin Nest PKO Leasing S.A.	EFSI InnovFin SME Guarantee Facility
	Micro-loans	Nest Bank	EFSI EaSI
	Micro-loans	Inicjatywa Mikro	EaSI
	Loans	Ideabank	InnovFin SME Guarantee Facility
	Loans	BGK Bank Pekao S.A. PKO Leasing S.A.	EFSI COSME
	Loans	Alior Bank	EFSI
	Loans	Deutsche Bank Poland Pekao Raiffeisen Leasing Polska	Risk Sharing Instrument (RSI)
	Micro-loans	Biz Bank FMBank Inicjatywa Mikro TISE	Progress Microfinance
	Micro-loans	Lublin Development Foundation Warmia and Mazury Regional Development Agency Kujawsko-Pomorski Loan Fund	JASMINE

Country	What is available?	Intermediary	Initiative
Croatia	Guarantee	Cordiant	EFSI InnovFin
	Guarantees	Erste&Steiermärkische Bank	EFSI InnovFin
	Guarantees	Erste&Steiermärkische Bank	EFSI InnovFin
	Guarantees	HBOR	EFSI InnovFin
	Guarantees	Zagrebačka banka PBZ	EFSI InnovFin
	Loans	PBZ	EFSI COSME InnovFin
	Loans	Raiffesen Bank	WB EDIF
	Micro-loans	Zagrebačka banka Sberbank	Progress Microfinance
	Micro-loans	Vaba Bank's Inc. Varzadin	RCM
	Loans	UniCredit Bank Austria	Risk Sharing Instrument (RSI)
	Equity	South Central Ventures	WB EDIF
Lithuania	Loans	Capitalia	EFSI EaSI
	Loans	Swedbank	EFSI COSM
	Loans	Trind Ventures	InnovFin Equity
	Loans	OP Corporate Bank plc Šiaulių bankas UniCredit Leasing	InnovFin SME Guarantee Facility EFSI - Investment Plan for Europe
	Loans	Šiaulių bankas	EREM CBSI
Slovakia	Micro-loans	OTP Banka Slovensko	EaSI
	Loans	CSOB UniCredit Bank	InnovFin SME Guarantee Facility EFSI
	Loans	UniCredit Bank Austria	Risk Sharing Instrument (RSI)
	Loans	Slovenská záručná a rozvojová banka (SZRB) Tatra banka UniCredit Bank Slovakia a.s.	JEREMIE

Source: EIF, compiled Nyikos

InnovFin targets research and innovation (R&I) investment projects such as:

- Deployment of innovative technologies (in particular key enabling technologies), including capital expenditure related to commercial launch
- R&I activities including investments in ICT infrastructure and R&I investments made by research institutes/organisations or universities
- R&I infrastructures (both multi-country and national) and enabling infrastructures
- Activities falling under the scope of the EUREKA network or the European Research Area (ERA)
- nnovative demonstration projects and pre-commercial innovative solutions

Box 4: Short introduction of InnovFin products

Start-ups and SMEs financing	Intermediated financing Early-stage SMEs and small mid-caps < 500 Employees
	Intermediated financing SMEs and small mid-caps < 500 Employees
Corporate financing	Direct and intermediated financing Innovative SMEs and mid-caps, large caps and entities investing in R&I activities and R&I infrastructure Recipient located in EU Member States classified as Modest and Moderate Innovators according to the European Innovation Scoreboard and in Horizon 2020 Associated Countries
InnovFin MidCap Guarantee	Intermediated financing Mid-caps < 3 000 Employees
InnovFin Corporate Research Equity	Direct and intermediated equity-type financing in conjunction with the EFSI Large R&I programmes and innovative mid-caps
InnovFin Science	Direct financing Research institutes/organisations and universities
Thematic financing	Project finance and/or direct corporate lending (including equity-type) SMEs, mid-caps and large caps as well as special purpose vehicles (SPVs)
InnovFin Energy Demo Projects	
InnovFin Infectious Diseases	Project finance and/or direct corporate financing (including equity-type) SMEs, mid-caps and large caps as well as SPVs
InnovFin Thematic Investment Platforms	Intermediated financing (including equity-type) through investment platforms focused on specific thematic areas SMEs, mid-caps and large caps as well as SPVs
Advisory	Financial advisory Public and private sector promoters
InnovFin Advisory	

Source: EIB, compiled Nyikos

The take-up of InnovFin in EU Member States in Central and Eastern Europe has lagged behind. Many enterprises in the region do not have a strong enough balance sheet to borrow from the EIB. There is also a problem in terms of what constitutes innovative companies. However, it should also be noted that many firms have not applied for InnovFin support due the availability of other EU funding, mainly the Structural Funds (ESIFs).

In the SME Window, EFSI funding (See next chapter) has been used to 'top up' the SMEG, and the funding has therefore been complementary. However, within EFSI's Infrastructure & Innovation Window, there is evidence of overlaps and competing funding available through the IIW for large projects and MidCaps on the one hand, and InnovFin on the other. One way to address this could be to clearly delineate the two programmes, for example, in terms of geographical coverage, where InnovFin is wider in scope than EFSI or to make possible integrated finance with clear rules.

2.4. European Fund for Strategic Investments (EFSI)

The European Fund for Strategic Investment (EFSI)[12] is to help overcoming the current investment gap in the EU by mobilising private financing for strategic investments. EFSI as one of the three pillars of the Investment Plan for Europe should unlock additional investment.

> **EFSI provides financing for economically viable projects using loans, guarantees and equity investments.**

Box 5: EFSI functioning – eligibility of operations

Preliminary verifications for project eligibility:

- the project is a new investment (no refinancing)
- it is consistent with the EU policy and the EIB policy objectives
- it is not an 'excluded activity'

Eligibility criteria (Article 6 of EFSI Regulation) for the use of the EU guarantee – projects which:

(a) are economically viable according to a cost-benefit analysis following Union standards, taking into account possible support from, and co-financing by, private and public partners to a project;
(b) are consistent with Union policies, including the objective of smart, sustainable and inclusive growth, quality job creation, and economic, social and territorial cohesion;
(c) provide additionality;
(d) maximise where possible the mobilisation of private sector capital; and
(e) are technically viable

Source: Nyikos

[12] Regulation (EU) 2015/1017 of the European Parliament and of the Council of 25 June 2015 on the European Fund for Strategic Investments, the European Investment Advisory Hub, and the European Investment Project Portal and amending Regulations (EU) No 1291/2013 and (EU) No 1316/2013 – the European Fund for Strategic Investments, OJ L169, 1.7.2015, p. 1 (the "EFSI Regulation") entered into force on 4 July 2015.

There shall be no restriction on the size of projects eligible for EFSI support for the operations conducted by the EIB or the EIF via financial intermediaries."

2.4.1. EIB direct finance and EIF programmes

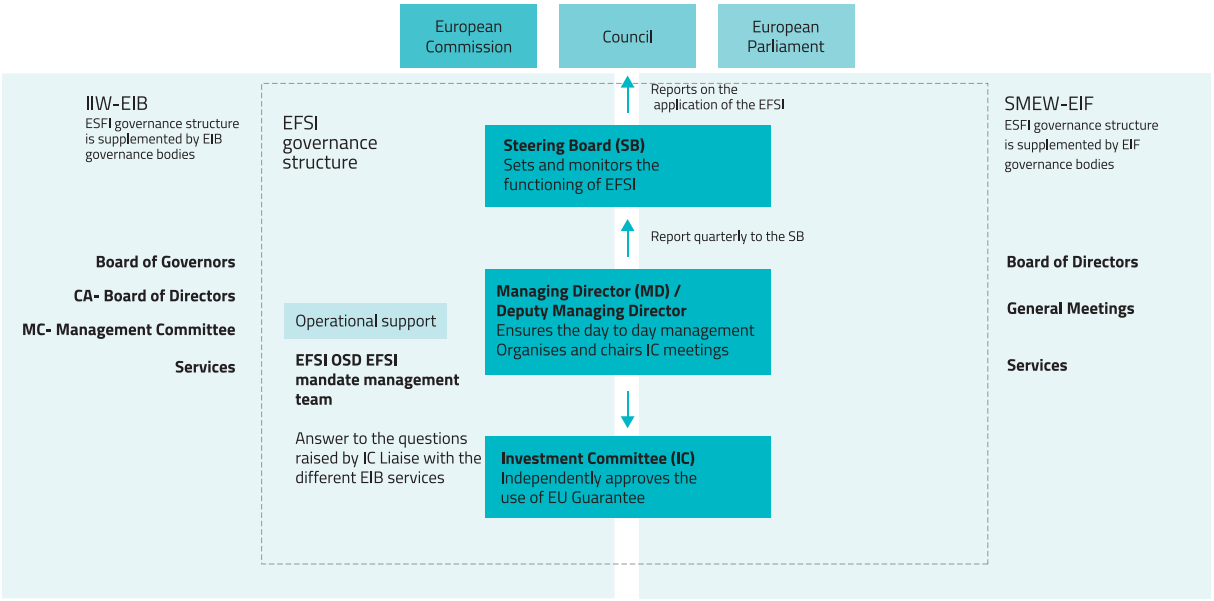
EFSI had two channels to support projects:

- an **Infrastructure and Innovation Window (IIW)** to be deployed through **EIB** and
- an **SME Window (SMEW)** to be deployed through the **EIF** to support SMEs and mid-caps[13].

Since late 2016, there is additionally a third and fourth window through the EFSI Equity Instrument. This consists of two further windows:

- **Expansion & Growth Window** – equity investments to, or alongside funds or other entities focusing on later stage and multi-stage financing of SMEs and small mid-caps.
- **Stage Window (InnovFin Equity)** – early-stage financing of SMEs and small mid-caps operating in innovative sectors covered by H2020. EFSI Equity also contributes to the new Pan-European Venture Capital Fund-of-Funds programme within InnovFin Equity.

Figure 10: EFSI functioning – governance structure

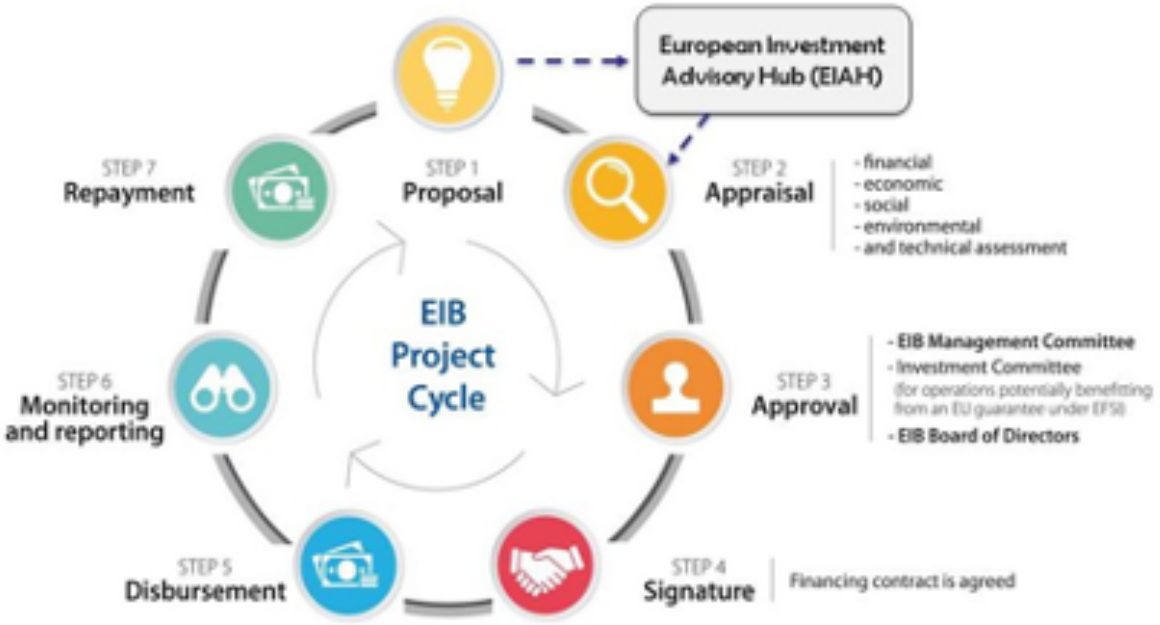


Source: EIB

Health project promoters from the public and the private sectors, can benefit from the Investment Plan by getting financing under the European Fund for Strategic Investments, registering a project to the European Investment Project Portal (EIPP) to reach potential investors, and making use of the advisory services of the European Investment Advisory Hub (EIAH).

13 There is no common EU definition of mid-cap companies. While SMEs are defined as having fewer than 250 employees, mid-caps are broadly said to have between 250 and 3000 employees.

Figure 11: EIB project cycle



Source: EIB, The Investment Plan for Europe (EFSI) 5th October 2015, Prague.

EIB supports projects in various health areas, recognising the importance of infrastructure investments but also the role of innovation in health systems, research and medical education:

- Medical research, education and training
- Innovative products, services and delivery solutions (including by SMEs, mid-caps and start-ups)
- New models of health infrastructure and services (especially for primary and integrated forms of care)

Table 1: Health investments financed by EIB in the analysed Member States

Project	Country	Signature date	Signed Amount
RIJEKA GENERAL HOSPITAL (KBCRI)	Croatia	30/04/2019	€50 000 000
UNIVERSITY HOSPITALS POLAND	Poland	28/02/2019	€90 510 339
POZNAN MEDICAL UNIVERSITY	Poland	28/06/2018	€13 152 864
MAZOWIECKIE REGIONAL INFRASTRUCTURE	Poland	15/12/2017	€34 861 384
BRATISLAVA REGIONAL INFRASTRUCTURE II	Slovakia	21/08/2017	€2 500 000
KUJAWSKO- POMORSKIE HEALTHCARE PROGRAM III	Poland	17/11/2016	€53 658 207
KOSICE REGIONAL INFRASTRUCTURE II	Slovakia	11/11/2016	€4 200 000
VILNIUS URBAN INFRASTRUCTURE	Lithuania	15/09/2016	€500 000
KUJAWSKO-POMORSKIE HEALTH PROGRAM II	Poland	22/12/2015	€38 110 296
PULA HOSPITAL	Croatia	11/06/2015	€40 000 000
POLAND HEALTH INVESTMENT PROGRAMME	Poland	08/11/2013	€400 000 000
DOLNOSLASKIE PUBLIC HOSPITAL	Poland	21/06/2013	€25 734 710
HUMAN CAPITAL CO-FINANCING FL	Hungary	06/12/2012	€80 000 000
MAINLAND INFRASTRUCTURE FACILITY	Croatia	18/10/2011	€3 000 000
HEALTH SECTOR DEVELOPMENT LOAN	Hungary	20/06/2011	€55 000 000
REGIONAL OPERATIONAL PROGRAMS 2007-13	Hungary	29/11/2010	€21 000 000
NDP FRAMEWORK LOAN II	Slovakia	16/11/2010	€26 000 000
KUJAWSKO- POMORSKIE HEALTHCARE PROGRAM	Poland	03/11/2010	€106 730 286
POZNAN MUNICIPAL INFRASTRUCTURE III	Poland	30/07/2010	€20 255 606
ZACHODNIOPOMORSKIE REGIONAL FRAMEWORK	Poland	04/12/2009	€21 114 355
REGIONAL OPERATIONAL PROGRAMS 2007-13	Hungary	07/10/2008	€42 000 000
HEALTH SECTOR DEVELOPMENT LOAN	Hungary	03/06/2008	€45 000 000
PAN-EUROPEAN DIALYSIS CENTRES	Poland	19/12/2006	€10 260 000
PAN-EUROPEAN DIALYSIS CENTRES	Hungary	19/12/2006	€8 550 000
PAN-EUROPEAN DIALYSIS CENTRES	Slovakia	19/12/2006	€2 160 000
KOSICE REGIONAL INFRASTRUCTURE	Slovakia	07/12/2006	€1 970 166
PRESOV REGIONAL INFRASTRUCTURE	Slovakia	11/07/2006	€3 389 831
BUDAPEST - INFRASTRUCTURE&SERVICES-AFI	Hungary	31/03/2006	€36 800 000
STRUCTURAL FUNDS CO-FINANCING FACILITY	Hungary	30/04/2004	€31 150 000
LODZ HEALTH AND EDUCATION	Poland	21/12/2001	€19 000 000

Source: EIB, compiled by Nyikos

EIB offers financing under its Health and Life Science line. Additional EIB financing is available under the Horizon 2020 InnovFin Infectious Diseases Facility.

EIF delivers a wide range of innovative risk financing solutions for SMEs which comprise equity, guarantees, credit enhancement and microfinance, and are delivered through financial intermediaries (including venture and growth capital funds – see in Figure 8). EIF has a unique tripartite shareholding structure combining public and private investors: the European Investment Bank (EIB) 62.1%, the European Union through the European Commission (EC), 30%, and 24 public and private financial institutions, 7.9%.

2.4.2. Investment platform

National development banks – who are often also financial intermediaries of ESI Funds financial instruments - cooperate with EIB group at different level. Besides co-financing at project level they could establish and finance together so called investment platforms as well. The platform could be sectoral or multisectoral and health investments could be the main investments financed by the platform or part of other integrated project such as smart city investments.

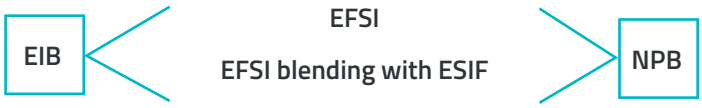
Box 6: National Promotional Banks (NPBs) cooperation and the role of investment platforms in the context of the EFSI

Eight countries announced in 2015 that they would participate in the EFSI project via their NPBs (or similar institutions): Bulgaria, Slovakia, Poland, Luxembourg, France, Italy, Spain and Germany. In addition, the United Kingdom announced in July 2015 that it would make guarantees available to co-finance EFSI infrastructure projects in the UK (€8 500 000 000 (£6 000 000 000)). The UK contribution is not via an NPB.

In detail, the amounts of the announced national contributions via NPBs are as follows:

- Bulgaria, June 2015, €100 000 000, Bulgarian Development Bank,
- **Slovakia, June 2015, €400 000 000, Slovenský Investičný Holding and Slovenská Záručná a Rozvojová Banka,**
- **Poland, April 2015, €8 000 000 000, Bank Gospodarstwa Krajowego (BGK) and another public institution Polish Investments for Development (PIR),**
- Luxembourg, April 2015, €80 000 000 000 via Société Nationale de Crédit et d'Investissement (SNCI),
- France, March 2015, €80 000 000 000 via Caisse des Dépôts (CDC) and Bpifrance (BPI),
- Italy, March 2015, €80 000 000 000 via Cassa Depositi e Prestiti (CDP),
- Spain, February 2015, €1 500 000 000 via Instituto de Crédito Oficial (ICO),
- Germany, February 2015, €8 000 000 000 via KfW.

Figure 12: EIB – NPB cooperation possibilities under EFSI



Infrastructure and Innovation Window (IIW) – EIB				SME Window (SMEW) – EIF		
Bilateral cooperation (with higher EIB risk-taking)			Investment platform	Advisory cooperation	Bilateral cooperation	SME finance platform
Re-finance (e.g.: EIB Global Loan)	Project co-finance	Portfolio risk-sharing	Common investment platform (thematic and/or geographical)	European Investment Advisory Hub EIAH	Cooperation in the preparation and co-finance of tailor-made SME products	Joining multilateral platform (e.g.: Equity Platform)

Source: Nyikos

Investment Platforms are co-investment arrangements structured to catalyze investments in a portfolio of projects with a thematic or geographic focus. IPs are a means to:

- Aggregate investment projects
- Reduce transaction and information costs
- Provide more efficient risk allocation between investors

The main characteristics of EIB-NPI ESFI Investment Platforms is, that it combines resources from EIB, NPIs and private investors and can benefit from EFSI financing under 'Infrastructure and Innovation' and 'SME' windows as well.

The geographic scope could be national, multi-country, regional and multi-regional and the thematic scope mono-sectoral or multi-sectoral. Investment Platform could be offering:

- Equity or quasi equity investment in projects or funds
- Loans or guarantees to projects
- Guarantees or counter-guarantees to intermediaries

Also, it is an important factor that **combining ESI Funds[14] and EFSI** is possible either at individual project or at financial instrument level in cases where the respective applicable eligibility criteria are satisfied (Nyikos 2016). At the project level it is possible to combine national (public/NPB or private) sources with ESIF. However, in case of combining ESIF and EFSI in a single project, **the part of the project supported by ESIF** (consisting of ESI Fund(s) plus the respective national co-financing) **cannot receive support from EFSI**; otherwise this would constitute double-financing. This also means that EFSI support to the project cannot count as national co-financing of the ESI Funds programme and the EFSI supported part of the project consequently cannot be declared as eligible expenditure for ESI Funds' support. However, it is possible to **match sources to finance separate parts of the project**, or to structure the financing in a way that EFSI funds used for the revenue-generating part of the infrastructure project and ESIF for the rest.

2.5. EIT in the present programming period

2.5.1. EIT Regulation and mission

The Regulation of the European Parliament and of the Council establishing the European Institute of Innovation and Technology (EIT Regulation), adopted in 2008, sets out its mission, tasks and the framework for its functioning. The EIT Regulation requires that every seven years the Commission submits to the European Parliament and the Council a proposal for a Strategic Innovation Agenda (SIA) laying down the strategic, long-term priorities and financial needs for the EIT. The SIA needs to be in line with the applicable EU framework programme supporting research and innovation. The EIT Regulation was amended in 2013 in order to align it with Horizon 2020. In July 2019 the European Commission proposed an update of the EIT Regulation as well as its new SIA for 2021-2027. The recast EIT Regulation aligns the EIT with the EU's next research and innovation programme Horizon Europe (2021-2027) delivering on the Commission's commitment to further boost Europe's innovation potential. Furthermore, the initiative aims to improve the functioning of the EIT taking into account the lessons learnt from the past years.

14 See point 3.

The overall **mission of the EIT** is to boost sustainable European economic growth and competitiveness by reinforcing the innovation capacity of the Member States and the EU. In particular, the EIT reinforces the EU's innovation capacity and addresses societal challenges through the integration of the knowledge triangle of higher education, research and innovation. The EIT operates through its Knowledge and Innovation Communities (KICs): large-scale European partnerships addressing specific societal challenges by bringing together education, research and business organisations. In the coming period the EIT will continue to strengthen innovation ecosystems around KICs by fostering the integration of the three sides of the knowledge triangle. Each KIC will keep its organisational structure, based on 'Co-Location Centres', which are the geographical centres bringing together the actors of the knowledge triangle and allowing for geographical proximity and closer collaboration. The EIT provides grants to the KICs, monitors their activities, supports cross-KIC collaboration and disseminates results and good practices.

The **proposal for a recast EIT Regulation** builds on the external evaluation of the EIT carried out in 2017 which confirmed that the rationale behind the establishment of the EIT is valid and its model of innovation-driven knowledge triangle integration remains relevant. The EIT model targets structural weaknesses of the innovation capacities in key thematic areas in the EU, such as the limited entrepreneurial culture, low level of cooperation between academia and industry and insufficient development of human potential, and aims to contribute to closing the innovation gap between the EU and its key competitors.

In delivering on its activities, the EIT will develop synergies and bring added value within Horizon Europe. The EIT is integrated into Horizon Europe as part of its Pillar III ('Innovative Europe'). However, synergies and complementarities with the other components of the programme will be created. The EIT will also contribute to addressing the global challenges under Pillar II ('Global Challenges and European Industrial Competitiveness') and Pillar I ('Excellent Science').

2.5.2. EIT bodies and governance

The main EIT bodies are defined in the proposed EIT Regulation as follows:

- Governing Board composed of 15 high-level members (as opposed to 12 currently) experienced in higher education, research, innovation and business. Its role is to steer the activities of the EIT and take strategic decisions, including the selection, designation, monitoring and evaluation of KICs;
- Executive Committee composed of the Chairperson and selected members of the Governing Board, in order to assist the Governing Board in the performance of its tasks;
- Director, appointed by and accountable to the Governing Board, acting as the legal representative of the EIT, responsible for its operations and day-to-day management. The EIT Director is supported by EIT staff. The human resources of the EIT are limited to 70 full time equivalents per year in the period 2021-2027;
- Internal Auditing Function operating in complete independence, advising the Governing Board and the Director on financial and administrative management and control structures within the EIT.
- The current proposal reinforces the role of the Executive Committee as a specific EIT body, underlines the accountability of the Director to the Governing Board and strengthens the independence of the Internal Auditing Function.

2.5.3. EIT-KIC contractual relations

Partnerships are selected and designated by the EIT to become a KIC following a competitive, open and transparent procedure. The priority fields and time schedule for selecting new KICs are defined in the SIA. The minimum condition to form a KIC is the participation of at least three independent partner organisations,

established in at least three different Member States. The EIT in cooperation with the European Commission shall organise continuous monitoring and periodic external evaluations of the output, results and impact of each KIC. The 2019 proposal updates the reference to the EU framework programme supporting research and innovation as regards the indicators for the continuous monitoring and periodic external evaluations of the KICs.

The EIT may establish a **framework partnership agreement** with a KIC for an initial period of seven years. Subject to a positive mid-term review, the Governing Board may extend the framework partnership agreement for another period of a maximum of seven years. As a new element introduced in the 2019 proposal, subject to the outcome of a final review before the expiry of the fourteenth year of the framework partnership agreement, the EIT may conclude a memorandum of cooperation with a KIC, as a means to frame EIT-KICs relations following the end date of the framework partnership agreement.

In terms of governance, in accordance with the EIT Regulation, KICs shall have substantial overall autonomy to define their internal organisation and composition. KICs shall establish internal governance arrangements, ensure openness to new members, function in an open and transparent way, establish and implement business plans as well as financial sustainability strategies. A KIC business plan is a document describing the objectives and the planned KIC added-value activities. KIC added-value activities are activities carried out by partner organisations contributing to the integration of the knowledge triangle of higher education, research and innovation, including the establishment, administrative and coordination activities of the KICs, and contributing to the overall objectives of the EIT.

In the period 2021-2027 the EIT will implement activities aiming at:
- Strengthening sustainable innovation ecosystems across Europe;
- Fostering the development of entrepreneurial and innovation skills in a lifelong learning perspective and support the entrepreneurial transformation of EU higher education institutions;
- Bringing new solutions to global challenges to the market.

The implementation will take place via support to KICs and through EIT-coordinated activities. As regards **support to KICs**, the EIT will consolidate the eight existing KICs, fostering their growth and impact, and accompany their transition to financial sustainability. In particular, this will concern the first wave of three KICs launched in 2010 (EIT Climate-KIC, EIT Digital and EIT InnoEnergy) whose framework partnership agreements will terminate after 2024. The EIT will provide support to KICs that are running portfolios of knowledge triangle activities through:
- Education and training activities with strong entrepreneurship components to train the next generation of talents, including the design and implementation of EIT-labelled programmes, in particular at master and doctoral level;
- Activities supporting innovation to develop products and services that address a specific business opportunity;
- Business creation and support activities, such as accelerator schemes to help entrepreneurs translate their ideas into successful ventures and speed up the growth process.

The EIT will also launch two new KICs in specific thematic areas in order to tackle future emerging global societal challenges and needs (calls foreseen in 2021 and 2024).

In terms o**f EIT-coordinated activitie**s, the EIT will aim at supporting higher education institutions to integrate better in innovation value chains and ecosystems. The EIT will implement, through its KICs, a support action bringing together in projects higher education institutions and other key innovation players such as businesses to work on strategic capacity development areas. The partners will share common goals and work together towards mutually beneficial results and outcomes. The action will ensure an inclusive

approach to attract higher education institutions beyond the KICs' partners; an inter-disciplinary and inter-sectoral approach; and a link with the European Commission Smart Specialization Strategy, relevant thematic platforms and the EIT Health Regional Innovation Scheme (EIT Health RIS).

> **Through the EIT Health RIS and the new EIT-coordinated activities, the EIT will increase its regional innovation outreach and related impact.**

The EIT Regulation lays down the tasks of EIT and KICs respectively.

I. The EIT shall, among others, raise awareness and encourage participation of potential partner organisations; select and design KICs in pre-defined priority fields; provide appropriate support to KICs; continuously monitor and periodically evaluate KIC activities; facilitate communication and thematic cooperation between the KICs; strengthen the recognition of degrees and diplomas awarded by participating higher education institutions; promote the dissemination of best practices for the integration of the knowledge triangle; foster excellence in higher education, research and innovation, ensuring complementarity and synergy between EIT activities and other Union programmes; organise regular meetings with stakeholders as well as EU Member States to inform about the EIT activities and share experiences. Compared to previous versions, the 2019 proposal made some precisions to the above tasks and introduced new elements, such designing and coordinating support actions undertaken by the KICs for the development of entrepreneurial and innovation capacity of higher education institutions and their integration in innovation ecosystems.

II. The KICs shall undertake innovation activities and investments with European added value fully integrating the higher education and research dimensions; conduct innovation-driven research experimentation, prototyping and demonstration in areas of key economic and societal interest to strengthen the EU's competitiveness at international level and find solutions for the major challenges faced by European society; implement education and training activities to expand the EU's talent base, promote the development of innovation-related skills, and the improvement of managerial and entrepreneurial skills; carry out outreach activities and the dissemination of best practices in the innovation sector; seek synergies and complementarities between KIC activities and existing European, national and regional programmes.

2.5.4. EIT sources in the current programming period

Innovation projects carried out by KICs, and funded by EIT, are typically selected by KICs through calls aimed primarily at the respective KIC's partner organisations, where the topics of the calls for proposals launched by the KICs fall under the thematic priorities and/or Strategic Innovation Agendas. As each EIT-supported innovation project means the development of an entirely new product or service, it is a priority of each KIC to ensure that the property rights of these projects are correctly maintained.
The number of calls for projects launched per year varies across the KICs. Potential new partners are informed of the calls through the KICs' websites, events and via the Co-Location Centres (CLCs). At regional level, for the majority of the KICs, it is the CLCs and local partner networks that manage the promotion of the calls for proposals within their local communities. At central level, KICs usually organise matchmaking and annual events to facilitate the forming of project consortia.
For all KICs, the participation in innovation projects is open to non-members. However, it is typically mandatory that projects are led by a KIC member that pays annual membership fees. The projects funded by the KICs must have a clear focus on market uptake. The KICs do not only fund and monitor innovation efforts but actively help the forming of consortia, facilitate the setting up of projects, and provide support for preparation and realisation of the market launch of new products, processes or services.

2.5.5. EIT Digital

EIT Digital's focus is on providing support for European deep tech scale-ups. This addresses an important European challenge in order to grow and nurture large and dominant players in the digital space, which are able to shape the global and local digital markets and positively impact growth and employment.

The flagship component of their entrepreneurship pillar is the EIT Digital Accelerator, complemented by the Industry-start-up Connections / Hackathons. The EIT Digital Accelerator integrates three activities in one market proposition for scale-ups: the Access to Market, the Access to Finance, and the EIT Digital Challenge. Whereas, the EIT Digital Challenge serves to identify new promising candidates for the Accelerator support, the Access to Market and Access to Finance activities directly support the scale-ups admitted to the Accelerator. Differently, Industry-start-up Connections / Hackathons have been designed to support corporates in identifying technology and talents on specific field of interests, which might reside outside of the current EIT Digital portfolio.

The focus areas of EIT Digital are the following:

- Digital Industry covers the seamless process from production to retail and the related supporting functions such as logistics and consumer engagement;
- Digital Cities leverages the digital transformation of cities through disruptive information, mobility and safety services;
- Digital Wellbeing addresses the prevention of and coping with both physical and mental conditions in order to maintain a good quality of life;
- Digital Tech seeks to provide secure, robust, responsive and intelligent networking, computing and security solutions;
- Digital Finance focuses on innovative digital tools and interfaces improving the quality of the services provided by financial service providers to private customers and corporate clients.

1.5.5.1. EIT Digital Accelerator

The EIT Digital Accelerator is composed of a team of business developers and access to finance specialists providing hands-on support to deep tech start-ups in growth stage, i.e. scale-ups. The Accelerator has direct access to a pan European network of over 500 corporate customers and over 300 private investors (venture capital and corporate venture). EIT Digital concretely helps European innovative companies to scale up beyond simply being viable local businesses employing a handful of people and serving a small customer base. The EIT Digital Accelerator facilitates European innovative companies to scale to the whole of Europe, supported by a pragmatic approach of finding them European customers and European private investors.

The EIT Digital Accelerator integrates the EIT Digital Challenge, the Access to Market and the Access to Finance activities:

- The EIT Digital Challenge is a pan-European contest to identify and attract the most promising deep tech scale-ups in Europe, that are ready to scale up their businesses internationally;
- The Access to Market (A2M) service is facilitating scale-up introductions to corporate decision makers across all EU markets with the purpose of enabling fast, easy and international deal making;
- The Access to Finance (A2F) service is to help the scale-ups to raise international financing rounds between €2 000 000 and €15 000 000 (A-B rounds).

The EIT Digital Accelerator is positioned as a service provider to scale-ups for Access to Market and Access to Finance, with a competitive and integrated business model. Scale-ups are companies with market traction, revenues that typically surpass 1 MEUR, and typical investment needs between €1 000 000 and €10 000 000. Scale-ups that benefit from the services of the EIT Digital Accelerator compensate EIT Digital for the provisioning of these services in the following way:

- A fixed service fee of €50 000 paid as base fee for one year of acceleration. This base fee can be paid within three years from the start of the acceleration;
- For each customer deal that is facilitated via the Access to Market service, an average success fee of maximum 10% of the deal value is added to the base fee and due within three years from the start of the acceleration;
- For each investor deal that is facilitated via the Access to Finance service, an average success fee of 2% of the deal value is invoiced and due shortly after.

In line with the five steps characterising the innovation and entrepreneurship strategy of EIT Digital, the Accelerator processes are detailed as follows:

Attract: as the EIT brand is increasingly recognised and the reputation of EIT Digital is growing, the KIC is spontaneously attracting new scale-ups who approach the EIT Digital Accelerator. This is supported with marketing and active scouting. EIT Digital has now fully integrated the EIT Digital Challenge into the EIT Digital Accelerator and established it as the largest European contest in deep tech. The Challenge is much more than a contest, it is a sourcing instrument to attract the best European scale-ups and to serve the whole of Europe with EIT Digital's Acceleration services.

Select: scale-ups can be admitted throughout the year in a stage-gated admission process, where due diligence on their background is performed, deep tech quality and growth potential are confirmed, and alignment with EIT Digital activities is guaranteed. When it comes to the EIT Digital Challenge, five finalists per focus area are selected through a similar stage-gating process, all of which are eligible to the EIT Digital Accelerator.

Shape: the accelerated scale-ups need coaching and support in order to address foreign customer segments or private investors. The EIT Digital Accelerator coaches them with 'customer readiness' and 'investor readiness' workshops early in the acceleration phase, preparing them for customer and investor success.

Grow: the Accelerator program is all about supporting entrepreneurs to rapidly scale their business in Europe. The fact that the scale-ups have already customers (typically in their home countries) helps the Accelerator A2M team to support them in closing new customers elsewhere in Europe. The fact that the scale-ups have rapid revenue growth is a good prerequisite for the Accelerator A2F team to raise funding for them.

Succeed: success is measured by the KPIs, such as number of scale-ups supported, including new ones; amount of funding raised for A2F; number of business leads for A2M with success fee potential; and value of A2M deals closed by portfolio scale-ups.

EIT Digital Challenge

Organised for the first time in 2014, the EIT Digital Challenge is EIT Digital's pan-European contest to identify the most promising digital start-ups and scale-ups in Europe that are ready to scale up their businesses internationally. The winners can join the Accelerator for free for a full year (i.e. the base fee of €50 000 is waived), while the success fees for A2M and A2F deals remain. As a result, the Challenge improves the selection and integration of companies into the Accelerator.

The Challenge remains the biggest single marketing campaign of EIT Digital. Combined with the general marketing activity, a platform was developed to support inbound lead generation campaigns, new marketing material and engaging content for the Accelerator channels. Activities are aligned to strengthen the EIT Digital Accelerator brand as a whole and provide high quality scale-up leads. While the Accelerator marketing activities generate a constant stream of inbound leads and help communicate the successes of the program along the whole year, the Challenge is delivering a highly targeted, highly visible campaign in a short period of time. Ultimately, the goal of both activities is to position the EIT Digital Accelerator as the best program for European deep tech scale-ups looking to grow their business internationally, thus increasing the attractiveness of the program and reducing the time spend on scouting by the business developers.

Access to Market

The Access to Market activity supports companies with qualified lead generation via targeted one-to-one introductions, events and meetings across Europe. It also helps scale-ups developing and defining the go-to-market strategy and facilitate soft landings in new countries. The Access to Market is continuously generating new market leads for the supported scale-ups, while still following up on the market leads enabled previously.

Scale-ups are admitted on a one to one basis for twelve-month acceleration periods. The contracting of scale-ups for EIT Digital's value-added services for a fee requires substantial preparation efforts as well as continued follow-up, beyond the twelve-month of contractual acceleration, to support the scale-ups in the pursuit of the initiated deals.
The Accelerator role of facilitator for scale-ups access to market implies that the successes in closing deals remains with the scale-ups. The Accelerator success fee linked to scale-up's ability to closing deals has led to progressively focusing on contracting higher quality scale-ups (e.g. good product traction and strong ability to appropriately scale-up) as well as on ones with strong readiness to scale their access to market effort across Europe.

To achieve these targets, a dedicated team of international business developers – serial entrepreneurs, business consultants, industry experts – know what it takes to bring a business to the next level. With years of international experience, a deep understanding of digital technologies as well as the cultural particularities of the various European markets, they help scale-ups to make the right decisions. The business developers are operating from nine different European countries as well as from EIT Digital's Silicon Valley Hub.

Business Developers create an individual support plan building on the following pillars:

- Market readiness: customer targeting and segmentation. Provide support to the scale-up to get ready to launch its business in European countries and the US;
- Quality leads and deals: EIT Digital supports the scale-up to identify and open up selected international quality leads with the goal to transform them with the scale-up into deals. The objective of these introductions is to trigger interest from potential buyers who then request for follow-up meetings and discussions;
- Showcase at international events to increase visibility: this enables peer-to-peer networking and access to domain expertise. Furthermore, it supports scale-up to score leads with new international customers and partners through the attendance to international tradeshows, conferences, niche and own events, often collectively with other scale-ups from the community;
- Product launch & soft landing: the business developers and national teams of EIT Digital in ten countries support the scale-up to refine locally the launching strategy and to develop the scale-up business abroad, specifically to organise and enable a soft landing and country launch programme;
- Corporate matchmaking: the scale-up can be selected to meet one or more specific representatives from corporations who are interested in meeting a quality line up of innovative companies.

Access to Finance

The Access to Finance service helps scale-ups to raise financing rounds between €2 000 000 and €5 000 000 (A-B rounds), which are increasingly difficult to raise due to shortage of venture capital across Europe versus the large number of ventures requiring funding during their growth stages.

EIT Digital's team of technology financing specialists are located in the most relevant investments countries in Europe. They know what it takes for digital ventures to secure funding from professional venture capital investors. The knowledge of the funding process and deep understanding of investors' exact requirements are perceived as extremely valuable by the supported scale-ups and help them tailor their pitch which is essential when speaking to business minded investors.

The pan-European A2F team offers direct access to a network of more than 300 digital technology venture capital providers and corporate venture investors. Close relationships with European and global funds and corporates help to connect the supported scale-ups to the most appropriate investors, improving outcomes and dramatically reducing time and effort to get their financing done.

The A2F program is built around two phases:

1. Investors readiness: before meeting investors, it is of paramount importance to prepare well, and have a compelling business case to present. Hence the first phase of the A2F programme focuses on four tasks:
    a. review the funding strategy of the scale-up and calibrate the amounts to be raised and the use of funds;
    b. improve the fundraising documentation (teaser, pitch deck, business plan);
    c. coach the CEOs to deliver a concise and crisp message and present their business case in an appealing way;
    d. prepare a highly relevant list of investors, matching the sector, the geography, the size and the nature of investor the scale-up is seeking for.

2. Introducing investors: only when the company is well prepared and has rehearsed its pitch, the time is right to introduce them to investors. In order to optimise the chances to raise funds, the A2F team is usually proposing to the CEOs to contact investors of different nature, such as financial venture capital investors, corporate venture investors, and national promotion agencies.

Next to Access to Market and Access to Finance there are complementary services which the business developers are delivering or enabling:

- Strategic coaching: provisioning of expert coaching to accelerate growth strategies and go-to market to commercialise mature technologies and innovative solutions;
- Office space: subject to availability, temporary use of office space by the scale-up at selected location in EIT Digital hubs;
- Communications & PR: the opportunity for scale-ups to obtain communications support from EIT Digital through news items on the website of EIT Digital, social media channels, press releases, events and media contacts;
- Access to talent: the opportunity to get access to interns, graduates and employees, amongst others via the EIT Digital Master and Doctoral schools;
- Access to a pan-European ecosystem: the opportunity to get miscellaneous benefits from the access to the EIT Digital European network, such as building strategic alliances, finding technologies, experts, IP, etc.

2.5.5.2. Industry Business Development

EIT Digital developed an activity to support corporates in addressing specific needs regarding the access to forefront technologies and talents in defined markets and beyond the EIT Digital portfolio of activities.

Industry players have broad market access, are intimate with customer needs, and need to keep up with technology trends by engaging with start-ups, scale-ups, research and technology organisations and universities. They are also natural employers for young graduates and need to keep their workforce at the cutting edge of technology.
Most of the above needs are addressed by other pillars of EIT Digital: Master School graduates are a great source of talent supply, industry players can sponsor PhD students at the industrial Doctoral School, the Professional School can train the industry workforce, and finally industry partners can engage in open innovation activities through EIT Digital's annual innovation call.

However, corporates' specific demands may fall outside of EIT Digital's current portfolio of offering. EIT Digital intends to bridge this gap by offering tailor made solutions to identify talent, technology and support their acquisition. On this basis the DeepHack service has been developed.

The DeepHack is a hackathon format with the distinctive feature of focusing on Deep Tech. Its aim is to identify novel solutions to defined challenges as well as talents able to provide highly innovative solutions.

The definition of the challenge is related to specific corporate needs. An EIT Digital team formed by experienced business developers with strong profiles on innovation management, technology and start-up scouting, helps corporate clients across the EU. Their knowledge enables corporates to best frame their needs and best design their DeepHack event. The service is delivered in close collaboration with corporate clients, which means that they can become sponsor of such events and tailor it to their specific needs. In order to deliver the best experience possible, the KIC is partnering with organisations with proven track record in the sector outside of the EIT Digital community.

This service provides corporates with the opportunity of fostering the development of deep tech solutions to critical business challenges. It is also beneficial for EIT Digital, which can increase its visibility among innovators. It can be used as a mechanism of talent matchmaking for its PhD students, and lastly the seed for future innovation activities.

Regarding financing of collaborative innovation projects by EIT KICs, EIT Digital focuses its investments on a limited number of innovation areas called 'Innovation Action Lines', selected with respect to European relevance and leadership potential. Currently, EIT Digital has five Innovation Action Lines: Digital Industry, Digital Cities, Digital Wellbeing, Digital Infrastructure and Digital Finance.

Digital Industry: The Digital Industry Action Line covers the seamless process from production to retail and the related supporting functions such as logistics and consumer engagement.

Digital Cities: The Digital Cities Action Line leverages the digital transformation of the cities through centralised, participative and collaborative interactions between city actors: government, city service providers, industry, and citizens.

Digital Wellbeing: The Digital Wellbeing Action Line leverages digital technologies to stay healthy (prevention and early detection) or cope with an existing chronic condition. Both physical and mental wellbeing are considered.

Digital Infrastructure: The Digital Infrastructure Action Line is the core enabler of the digital transformation by providing secure, robust, responsive and intelligent communications and computation facilities.

Digital Finance: EIT Digital set up the Digital Finance Action Line in 2018 to support the creation of innovative tools and services to help the finance industry adapt to the challenges it currently faces.

2.5.5.3. EIT Digital Innovation Factory

The EIT Digital "Innovation Factory" supports pan-European entrepreneurial teams to launch new start-ups and new products. With their pre-incubation support, selected activities are embedded in their European ecosystem and receive a financial co-investment to package their technology, sign up customers and attract investors. New start-ups or new products created by pan-European teams from education, research and business organisations are a focus for EIT Digital. Market or societal impact on the one hand, and contribution to the financial sustainability of EIT Digital on the other hand, are the two main dimensions of the EIT Digital Innovation Factory. EIT Digital supports entrepreneurial teams that are creating tangible impact. Proposals should therefore address a specific business pain in any of the five strategic areas mentioned above, build a specific plan leveraging a technology solution and presenting a clear go-to-market route by launching a start-up or a product.

Selected activities receive a co-investment from EIT Digital, with a return on investment expectation. Activities are therefore requested to contribute to the financial sustainability of EIT Digital either through equity (for start-up creation) or financial return mechanisms (for product launch).

EIT Digital considers itself a partnership organisation, which implies that proposers of innovation projects are expected to be or become partner of EIT Digital. Organisations that are not yet a partner are expected to submit their application for partnership latest at the moment of submission of the proposal.

New start-ups or new products created by pan-European teams from education, research and business organisations are a focus for EIT Digital. More specifically, an innovation activity proposal needs to be submitted to a specific strategic area by a team of typically 2 to 5 complementary organisations. It should be an agile, entrepreneurial project that belongs to one of two distinct types:

- It intends to create a start-up
- It intends to launch a "Minimum Viable Product" (MVP)

Innovation project proposals are evaluated with respect to (i) their market or societal impact and (ii) their contribution to the financial sustainability of EIT Digital.

Impact

In the EIT Digital Innovation Factory, start-up creation activity proposals are highly appreciated, with the credibility of the founding team from the perspective of a potential investor being an element that strengthens the proposals. Spinoff creation from universities, research & technology organisations, or companies is also a focus for EIT Digital.

Proposers must "begin with the end in mind" and pinpoint the specific "business pain" that they are trying to solve. That could be an explicit, unmet need (e.g. voiced by customers) or an implicit, latent need (that the proposer has identified). Applicants need to describe how they package mature research results and adequate technologies to address that particular need in an impactful manner, and how the solution will concretely benefit the users. The inclusion of a customer or early adopter explicitly engaged in the innovation project proposal is considered as a strength in the proposal.

A key partner in each innovation project proposal is the so-called Business Champion. It is an organisation that knows the customers' needs, designs and packages the product ("product owner") and brings it to the market. Examples of credible Business Champions include: a start-up with an adequate founding team that will be created as an outcome of the project or the business line of a corporation leading the project. The Business Champion needs to commit to the go-to-market in the proposal, based on breakthrough technologies and validated research results provided by the technology provider.

Sustainability

In the context of the EIT Digital sustainability strategy, innovation projects are requested to contribute to the financial sustainability of EIT Digital either through equity (for start-up creation) or financial return mechanisms (for product launch). Sustainability commitments of the projects accepted in the EIT Digital Business Plan are binding.

For the project type "start-up creation", the sustainability principle is for EIT Digital to receive an equity share in the start-up. As a guideline, the level of shares expected to be attributed to EIT Digital is the following: EIT Digital's equity percentage is determined by the EIT financial contribution as relative share of the total budget of the activity.

For example, EIT Digital receives a 32.5% equity in a start-up resulting from an innovation activity with 65% EIT financial contribution and 35% co-funding.

For the project type "new product creation", the sustainability principle is for EIT Digital to receive a financial return to be defined and committed to in the activity proposal. The amount of the sustainability contribution up until five years after the completion of the activity is an important factor in the evaluation process (one such example is revenue sharing).

Project proposals may come up with other financial sustainability mechanisms, which are then evaluated as part of the overall proposal review.

Each innovation project proposal is expected to include the following key elements:

Communication

a. Simple video with elevator pitch included in submission (max 90 seconds).
b. Commitment to cooperate with EIT Digital on communications about the outcomes and results of the activity.

Freedom to operate

a. Commitment to facilitate go-to-market, including establishment of IP licensing agreement (before end of Q2) to allow business champion (or created start-up) to freely operate and commercialise the results of the activity.

Financials

a. Minimum co-funding: All project proposals must have minimally 35% co-funding (for the activity on the whole).

Partners

a. Typically, 2-5 complementary organisations with strong level of involvement and a clear role for each contributing Partner.
b. Set of Partners must come from at least two different countries.
c. At least one business partner involved.

Team

a. A committed team with well identified individual team members.
b. Individual team members should be involved with minimally 50% of their time (i.e. minimally 0.5 FTE).
c. The project leader should be involved with 100% of his/her time, i.e. a full FTE.
d. Commitment to execution approach "run like a venture" (incl. list of key roles and associated names; a setup like a start-up founding team is recommended for both product and start-up creation projects).

Proposal evaluation

Proposals for new innovation activities are evaluated in a three-stage process.
At the first gate, reviews are performed by independent individual experts appointed for each strategic area. Per strategic area, each expert reviewer individually evaluates each proposal's potential. Each reviewer also provides free text comments to each project proposal to explain their assessment, provide recommendations to the Review Gate, or provide feedback to applicants.

At the second gate (Review Gate), experts come together and evaluate impact and sustainability of each proposal based on their own individual experts' assessments. The goal is to reach a consensus recommendation. The combination of the impact and sustainability evaluation, given the competition and the budget constraints, determines the recommendation of the Review Gate.

At the third gate, the Management Committee of EIT Digital reviews the Review Gate outcome from a portfolio perspective. It also addresses the recommendations from previous gates and takes a decision on whether or not to accept the innovation project. In addition, possible budget adjustments and changes in the project descriptions may be requested.

EIT Digital uses the following quality assessment criteria for assessing all innovation proposals.

Question 1: Elevator pitch	How convincing is the elevator pitch (including the video)?
Question 2: Product	Is the product positioning convincing, in terms of competition, differentiation, adequateness to business case?
Question 3: Technology	Is this activity leveraging a sophisticated technology?
Question 4: Business case	Is the business case specific, solid and well presented?
Question 5: Business focus	Is this an innovation with a clear go-to-market focus and commitment?
Question 6: Market & competition	How do you judge the proposed innovation in the competitive landscape?
Question 7: Customers and investors	Do you believe the venture and/or the product launched by the activity will be attractive to customers or investors?
Question 8: Plan	Is the work plan (milestones, deliverables, and way of working) agile and entrepreneurial to make the activity successful?
Question 9: Partners	Is the setup of Partners in this activity convincing, with clear accountability, complementary roles and a good mix of technical and business capabilities?
Question 10: Individual team members	Are individual team members presented in the Activity with a relevant entrepreneurial profile to make the Activity a success?

2.5.6. EIT InnoEnergy

A core business line operated by EIT InnoEnergy is Business Creation Services (BCS), with the goal to nurture innovative start-ups and grow small enterprises in sustainable energy.

2.5.6.1. Highway

The InnoEnergy Highway is a BCS programme for early stage start-ups where entrepreneurs can find the support needed to transform their ideas or ventures into a successful business. The Highway is a one-stop shop offering a tailored service for entrepreneurs, helping them to create their business, working simultaneously in the four key dimensions: technology, market, people and finance.

The scope of Highway support includes the selection, assessment and acceleration of business ideas. As per its nature, this is a recurring activity, where EIT InnoEnergy provides services and support to ventures under the Highway programme. These services are complemented with the value of a trusted ecosystem of international partners including more than 400 key players in the energy field covering the whole value chain and made up of industry, universities and research centres. These players are EIT InnoEnergy's experts, service providers and the early adopters of the innovative solutions that ventures are launching on the market.

The ultimate goal of this activity is to create a stable pipeline of supported companies under the Highway program so InnoEnergy can support them to make their business stronger, bring successfully their solutions to the market and contribute to solve energy challenges and create a sustainable world.

The Highway program is a starting point for a long-term relationship between the venture and InnoEnergy, which may continue if performance is appropriate and market conditions are favourable, as InnoEnergy being a shareholder and with the possibility for the venture to join other InnoEnergy programmes, such as the Boostway which is support for mature ventures in the growth stage.

The main value added of the Highway is part of its value proposition, and it could be summarised in the following unique benefits for potential customers:

- Specialisation in energy: EIT InnoEnergy is an industrial partner within the energy sector, bringing expertise and knowledge all along the energy value chain.
- Becoming partner within a trusted ecosystem: by entering the Highway programme, start-ups can be connected with all relevant actors needed when creating and launching a new business. This network consists of companies, research organisations, potential industrial partners, potential customers, financial actors not just in Europe but in other regions such as the USA and Asia. In such a way, EIT InnoEnergy is also helping supported ventures in creating global impact.
- Tailor made program with a holistic approach, providing services in all key dimensions for the success of the company (market, people, technology and finance), based on the needs of the venture.
- Hands on approach: through its own staff and partners, EIT InnoEnergy actively supports and works with entrepreneurs in raising funds and getting the first customers.

The actions related to Highway Services are structured in different actions/tasks groups, which are presented below.

Support and acceleration of business ideas

The BC units at different offices of InnoEnergy perform the selection, assessment and acceleration of new and existing business ideas by delivering tailored services to the ventures through the Highway following a holistic approach based on four key dimensions for the creation of successful sustainable businesses: market, technology, people and finance.

The support provided is a joint effort at local (innovation hub) and central level. The six offices at InnoEnergy are located in Benelux, France, Germany, Iberia, Poland and Sweden. They implement the different steps of the process, deliver the Highway services and support closely the ventures in the pipeline. It is complemented by continuous improvement initiatives for enhancing the service offered.

The entrepreneurs go through the following process:

- Once the business idea is captured, the BC team does the preliminary analysis, which consists of assessing the idea to decide whether it is interesting for InnoEnergy and if the Highway services fit with the entrepreneur's needs.
- Once the business idea has passed the preliminary analysis and the BCS agreement is signed, InnoEnergy starts the delivery of the services through the Highway program. Firstly, it is important to know where the venture starts from and therefore a deep assessment is needed. This assessment is called Opportunity Assessment (OA) and it is part of the continuous evaluation process that InnoEnergy is doing along the Highway.
- The OA consist of a co-creation process, which includes a deep analysis done by experts on the technology, on the market opportunity and on the team of entrepreneurs (internal or external). It is followed by the adaptation of the feedback from experts to endorse the business idea with the support of the BC teams. Once it is done, the outcome of this process is used by a committee to decide whether to continue supporting the venture or not.
- In case the decision is positive, InnoEnergy and the entrepreneur sign a term sheet.
- Afterwards, a coach is assigned to the venture/team of entrepreneurs and jointly with the BC team, they define the detailed roadmap with the commitments from both parts (i.e. InnoEnergy and the entrepreneur(s)), as well as the deliverables and milestones to accomplish. This is a living roadmap as the market conditions (demand, regulatory framework, etc.) may change and therefore the roadmap is reviewed regularly in order to adapt to the needs of the ventures.
- Tailored services are then delivered to entrepreneurs through the InnoEnergy network of partners with the aim of accelerating the creation and development of the company at its very early stage of maturity. Services could range from advisory in the definition of the business model, technology enhancement, team creation, and support in finding funding resources or connecting with potential customers among other traditional ones.

These services constitute a holistic offering that covers all the dimensions needed in business creation: market, technology, people and finance (access to funding).

Central service development and delivery

Based on the needs identified and the improvement areas detected, and with the aim of increasing the value and quality of the services offered through the Highway and enriching its offering, EIT InnoEnergy implements the following actions:

a) Development and delivery of the 'talent' program: this program encloses common trainings based on common needs of entrepreneurs in the different dimensions where InnoEnergy gives support in order to improve the competences and skills needed to successfully develop their business. It complements the workshops and trainings delivered at local level contributing as well to the sense of community among entrepreneurs at European level. The topics covered by the trainings are linked to sales and commercialisation, or financial planning to help entrepreneurs to create profitable start-ups and provide them with the tools and knowledge needed to run their business successfully.

b) Convention day: the objective of this annual event is to learn from each other, work on internal challenges to improve internal operations which are then reflected in a better delivery of the services which finally increases the added value brought by BC teams to the ventures supported. During a short training the BC teams are able to share good practices, exchange knowledge, reflect and work on specific common issues related to daily work of supporting ventures among different offices and strengthen the links among the BC teams through different team building activities.

Knowledge integration

Within the Highway activity scope, different actions are carried out at central level in order to enable the knowledge triangle integration with other business lines.

The education and business creation areas are working together with twofold objectives:

a) Bring the entrepreneurial spirit to the educational programs by collaborating closely with the Master School and PhD school in providing business cases (e.g. venture case solve problem). Furthermore, it is also a common practice to invite entrepreneurs in order to share their experience with students so they can indoctrinate the entrepreneurial spirit, bring motivation and inspiration to students, create content (e.g. videos about entrepreneurship experience, the life of entrepreneurs, etc.) and/or offer the possibility to run master thesis within a start-up. In terms of supporting students who would like to create a company, the different BC units in coordination and collaboration with education are supporting, advising and guiding those students who want to become entrepreneurs.

b) Provide access to talent for the ventures: BC collaboration with the Human Capital unit and educational programmes facilitates access to talent to the ventures supported in the form of internship or full time positions.

   Actions are designed to find right matching between ventures' needs in terms of manpower and students such as periodic publishing of job offers among students community or proactive distribution of suitable profiles for ventures from the pool of student's candidates.

2.5.6.2. Boostway

The Boostway service is EIT InnoEnergy's offer to contribute to the growth of existing companies by offering specialised and ad-hoc services for the growth phase for existing and new start-ups in a mature stage as well as small enterprises. The service focuses on the manufacturing scale-up and internationalisation of sales and/or increase of the local market share in addition to the main dimensions offered as well under the Highway.

The ultimate goal of this activity is to create a stable pipeline of supported companies under the Boostway program during which EIT InnoEnergy helps them overcome the scale up challenges.

The Boostway process is preceded by the phase of capturing business ideas, the respective actions and work plan are covered by the Acquisition portfolio described previously. The scope of Boostway activities consists of the support and scale up of companies, including the selection, assessment and support of the companies. As per its nature, this is a recurring activity.

The actions related to Boostway Services are structured in different actions/tasks groups, which are presented below.

Support and scale-up of companies

As a recurring activity, the BC units at different offices of InnoEnergy (Benelux, France, Germany, Iberia, Poland and Sweden) carry out the selection, assessment and support of new and existing companies by delivering tailored services to the ventures through the Boostway.

The Boostway process includes a selection and opportunity assessment as well as the delivery of services to companies supported:

a) Selection: an analysis on the candidate with the aim of checking if the company captured fits into the Boostway target and to what extent the company is an attractive case for the KIC according to a predefined set of criteria.

b) Opportunity Assessment (OA): the aim is to identify if there is any opportunity behind the company case, and whether it is worth to support the company and under which conditions. It includes a market research / supply chain report from an independent expert and internal due diligence and a feasibility study where it is identified what kind of services can be provided through what kind of resources.

c) Delivery of the Service: after a positive OA, a project champion is assigned as responsible to the company in order to deliver successfully the services and to obtain the return desired for InnoEnergy. A strategic plan is agreed with the customer and afterwards an implementation plan is prepared including the services needed to achieve the objectives agreed.

The services under the Boostway are grouped under six dimensions with special emphasis on the manufacturing scale-up and internationalisation of sales and/or increase of their local market share:

- Technology
- Industrialisation / Manufacturing
- Market
- Commercialisation & Sales Development
- People
- Finance & other resources

Specific services are selected from these dimensions based on the needs of each case.

2.5.6.3. Financial and New Product Development (NPD) Services

Since sustainable energy is a capital-intensive industry, the implementation of the business plan of ventures supported requires substantial capital. Therefore, EIT InnoEnergy identified the need to develop and maintain close relationships with sustainable energy investors to introduce them to the ventures and eventually attract them to participate in their follow-on funding rounds.

This need was channelled initially through the VC Community, but later extended to other types of investors, including business angels and corporates, and encompasses also the sponsoring of investor forums, conferences and events, agreements with some investor networks and participation in their events.

2.5.6.4. EIT InnoEnergy's funding instruments in the area of business creation

Acceleration Fund

The Acceleration Fund is a sum of money devoted to accelerate the creation of the start-ups supported under the Highway Services. In addition, it may also apply to BCS Strategy for activities such as US Landing or ideation project.
Eligible beneficiaries are entrepreneurs of a venture supported by InnoEnergy. The grant is given to entrepreneurs on a monthly basis in order to ease their life subsistence/ living expenses, and have them fully devoted to their project.
The amount of the financial support is maximum €15 000 per entrepreneur. There are other limitations, such as:

- Maximum €18 000 per venture for the whole supporting period under the Highway;
- Maximum two entrepreneurs per venture;
- Maximum €1 500 per month per entrepreneur;
- Maximum 10 months per entrepreneur;
- Any income that the entrepreneur may have during the duration of the grant must be disclosed and deduced from the grant to match the €1 500/month/entrepreneur limit.

Technology Enhancement

The Technology Enhancement is designed to enhance a product and/or existing technology of a venture to the requirements and feedback obtained after meetings with potential customers. Through the Highway and Boostway services, a Technology Enhancement grant is offered to support the venture based on real commercial feedback following the customer discovery process. The financial need for technology enhancement under Highway or Boostway programs may vary from venture to venture. An estimate amount per venture is set at €30 000 to support the technological development.

Team Creation

The Team Creation is designed for ventures to grow a strongly skilled management team and increase the chance for success. The beneficiaries are ventures supported by InnoEnergy under the Highway and Boostway services. The financial need for Team Creation under Highway or Boostway programmes may vary from venture to venture. An estimate amount per venture is set at €20 000 to support the growth of a venture's team.

Prizes

Prizes are granted to third parties under contests (e.g. PowerUp!) or awards that contribute and promote InnoEnergy Business Creation activities. In general, prizes can be granted to third parties, which can include ventures supported by InnoEnergy, entrepreneurs, students or other external beneficiaries.

Technology fund

The technology fund provides additional financing to ventures that require funding beyond what the Highway provides to develop or test a new technology. From time to time there is a clear financing need to support a venture in its technology or product development, that otherwise cannot be provided through the normal Technology enhancement fund due to its limitations. This applies in particular when:

- The technology is still not mature enough, and requires more (in terms of capital resources) before being commercially deployed; and
- A supported venture requires an extraordinary effort in terms of added value services that normally appear in the phase of technology enhancement or of proof of concept, but which requires extraordinary expenditure

Regarding financing of collaborative innovation projects by EIT KICs, EIT InnoEnergy looks for new products, new solutions and new services to support and develop in the sustainable energy sector. Innovation is a unique process, and EIT InnoEnergy is keenly aware that taking the spark of an idea and turning it into a successful and marketable product can be a long and complex journey, where technical expertise, commercial awareness and access to a variety of skills and resources are critical. To support innovators in this process, EIT InnoEnergy's investment rounds are open to applications all year round, offering investment and support for innovation projects.

EIT InnoEnergy supports innovation projects and businesses with a proven concept that is related to one of their six thematic fields that they believe can help change the future of the energy industry.

a) **Clean coal and gas technologies:** EIT InnoEnergy encourages innovation in waste conversion technologies, flexible power systems, carbon capture and storage, and unconventional gas and oil extraction.

b) **Energy from Chemical fuels:** Biogenic and synthetic fuels, derived from biomass, waste or even excess electricity, can provide both stability and storage capability alongside more conventional fuels.

c) **Smart Grid and Storage:** Energy storage has an important role in future energy systems as it is a vital component in the development of smart grids, smart cities and smart buildings.

d) **Smart and Efficient Buildings and Cities:** Energy efficiency is the most cost-effective way to reduce emissions, improve energy security, make energy consumption more affordable, and enhance competitiveness. The built environment accounts for 40 per cent of the world's energy consumption. Creating smart buildings and cities is therefore crucial to sustainable development.

e) **Renewable Energy:** Renewable energy plays an essential role in reducing dependence on fossil fuels, increasing energy security for Europe, and decreasing greenhouse gas emissions.

f) **Sustainable Nuclear and Renewable Energy Convergence:** Nuclear power remains an important part of a sustainable energy mix, with 60 nuclear reactors under construction around the world.

2.5.6.5. Innovation projects

InnoEnergy understands by innovation projects as the transformation of available knowledge into new marketable products and services related to the field of sustainable energy that create positive impact on market and society by:

- Decreasing energy cost,
- Increasing intrinsic operational safety or reliability, and/or
- Reducing Green House Gas (GHG) emissions

Such projects should normally present a maximum project duration of 3 years and a time to market shorter than 2 years from the end of the project.

The general conditions to access to funding from EIT InnoEnergy are:

1. The commercialization partners are required to present an acceptable return for the investment received from EIT InnoEnergy conditioned by the successful sale of the product in the market. EIT InnoEnergy considers each innovation project in which invests as a risk investment;
2. The consortium members are to provide a sizeable and relevant co – funding to demonstrate the commitment to the action financed by public funding. The co-funding thresholds are defined on a yearly basis and for 2019 the minimum amount of co-funding required is 30%.
3. Beneficiaries of the investment need to become EIT InnoEnergy members. Following the notification of the successful funding application, EIT InnoEnergy members can apply to become partners according to the EIT rules.

Each EIT InnoEnergy innovation project starts with a so called Work Package 0 (WP0). This is a feasibility study dedicated to the analysis and development of the business opportunity. The analysis has to be defended in front of a thematic field assessment committee or the Executive Board which, at a formal gate review, determines if the project can continue or not receiving EIT InnoEnergy funding. Those projects not succeeding at the gate review will be cancelled. The funding allocation for the WP0 is limited to a maximum of €50 000.

Once successful at the gate review, the funding of EIT InnoEnergy projects is decided on a half-yearly basis, subject to two conditions:

1. Performance according to plan

Project performance is assessed by an InnoEnergy thematic field assessment committee at regular mid-year or year-end project reviews, or at gate reviews established upon attainment of milestones previously identified and agreed for each project. Favourable assessments can lead to budget increases, whereas non-favourable assessments can lead to budget decreases, including the total cancellation of the project.

2. Availability of InnoEnergy resources

Every year in September, EIT InnoEnergy has to submit to the EIT the Business Plan proposal for the subsequent year. After assessment of the overall InnoEnergy Business Plan proposal and upon consideration of available financial resources, in November-December the EIT communicates to EIT InnoEnergy the amount granted for the subsequent year. On the basis of such EIT resources and EIT InnoEnergy's own resources, EIT InnoEnergy allocates the available funds to the different activities.

Proposals can be submitted by public and/or private consortia which have a project for an innovative sustainable energy product or service. Participation in consortia is open to any organisations. However, members of the consortia shall undertake towards EIT InnoEnergy that at least one of the Partners is or shall become a Platinum, Gold+, or Gold member to the InnoEnergy Innovation Ecosystem. Alternatively, each commercialization Partner shall be at least a Silver member to the InnoEnergy Innovation Ecosystem.

Proposal evaluation

The evaluation of project proposal consists of two stages.

1. Thematic Field Level Assessment Committee (TLAC): Each Thematic Field appoints an assessment committee in charge of evaluating the proposals corresponding to its own theme (e.g. the committee of the thematic field "Renewables" assesses all proposals related to renewables, irrespective of the affiliation of the partners in the consortium). The TLAC checks both admissibility and eligibility criteria and ranks the proposals according to the assessment criteria. Only those proposals selected by TLAC are considered in the next assessment phase; the TLAC can reject a proposal if the ranking is too low.
2. KIC Level Assessment Committee (KLAC) performs an assessment of the proposals submitted by the TLAC by a committee composed by the thematic leaders as well as representatives from industry and academia. This group reviews and ranks all the eligible proposal evaluations performed at thematic level using the same assessment criteria. Upon presentation by the consortia, the KLAC submits a ranked list to the InnoEnergy Executive Board for final decision.

Eligibility Criteria

If one of these criteria is not fulfilled, the proposal is rejected at the Thematic Field Level Assessment phase:

1. The goal of the project is to develop products or services to be sold on the market.
2. At least one company commercializing the products or services developed in the project must be involved in the project from the beginning.
3. At least one partner from a country of one of EIT InnoEnergy local offices must be involved in the project. At least one partner from another country must have a substantial role in the project.
4. The number of partners is minimum three and maximum seven.
5. The topic falls within one of EIT InnoEnergy's thematic fields.

Assessment criteria

No	Criterion
A1	BUSINESS DEVELOPMENT
A1.1	Very Clear definition of product or service (problem statement, solution benchmark)
A1.2	Feasibility of proposed solution for product or service
A1.3	Innovativeness of proposed solution
A1.4	Business case opportunity assessment (market analysis, competitive analysis, value proposition for customers, ...)
A1.5	Soundness of IP analysis (background, freedom to operate, protections, etc.)
A2	RISK ANALYSIS
A2.1	Availability of required knowledge in the consortium
A2.2	Risks (technical, regulatory, market, consortium) identified and mitigation plan
A3	FINANCIAL VIABILITY
A3.1	Business case of the opportunity
A3.2	Justification of requested KIC investment
A3.3	Assessment of plan for KIC investment return
A4	OPERATIONAL VIABILITY
A4.1	Soundness of project plan (milestones, deliverables, availability of resources, etc.)
A4.2	Soundness of consortium vs. value chain
A4.3	Quality of project management

2.5.7. EIT Climate-KIC

The long-term objective of EIT Climate-KIC is to develop a fertile and self-sustaining ecosystem for climate-relevant start-ups in Europe. This goal is pursued by nurturing a pool of relevant and viable business ideas by empowering, connecting, and inspiring entrepreneurs, and by fostering a support infrastructure that enables market entry and scale-up. In the area of entrepreneurship, EIT Climate-KIC focuses mainly on the Climate Launchpad Programme, Accelerator Programme, Investor Marketplace and the Community Link.

2.5.7.1. Climathon

The Climathon is a year-round programme, with a powerful solutions-hackathon at its core, creating climate action in the form of tangible projects, supporting climate positive businesses, and addressing local policy challenges. The programme revolves around a 12-72 hour hackathon event, which takes place on the Global Climathon Day in hundreds of major cities across six continents. During the hackathon, a diverse group of participants, ranging from entrepreneurs to policymakers, get together to develop solutions to local climate challenges in their city in an engaging format. The solutions developed during the core hackathon event can be taken forward and implemented by the cities with the support of local organisers and EIT Climate-KIC. The city challenges and resulting solutions are categorised into common themes in order to provide collaboration possibilities.

The programme's main outcome is a strengthened engagement among citizens, city officials, and businesses who share a positive common vision to transform hundreds of cities worldwide to be greener and more liveable.

After the hackathon is delivered, local organisers are coaching and incubating selected solutions who have the opportunity to participate in a Global Awards celebration hosted by EIT Climate-KIC. For the finalists of Global Awards competition a €20 000 prize money is awarded.

2.5.7.2. Climate Launchpad

This activity is about the organisation and delivery of the world's largest green business ideas competition. It attracts hundreds of early stage ideas from all over the world and pitches them against each other in a competitive process. The programme consists of a two-day business training boot camp, follow-up coaching sessions over a period of approximately six weeks, ending with a national final. At national finals the top three ideas are selected to attend the grand final which is the closing event where the national winners from all participating countries go head-to-head and compete to be crowned as the winner of Climate Launchpad.

The coaching sessions at national level are aimed at providing the start-up teams with mentoring and support through local expertise of certified trainers. The coaching sessions are designed as the follow-up programme after the boot camp and give time for the teams to work on and develop their initial ideas and to go out there and validate their ideas by talking to their potential customers, and/or suppliers.

An external and competent review board consisting of relevant experts from the field does the selection of the top 2-3 teams at national level, to go through to the grand final. The grand final is the closing event of the Climate Launchpad competition and the moment where all top 2-3 teams from all participating countries come together and present their ideas in front of a global audience and international experts that have relevance to such a start-up event.

The Climate Launchpad competition is open for anyone with a feasible green business idea. Building on the overall selection process of Climate Launchpad competitions, the thematic prizes are eligible only for national winners of the Climate Launchpad competitions who won a chance to present their idea at the global grand final. All national finalists are invited to participate in one of the thematic awards. One winning team per theme competition is selected and receives the award.

All prizes use the same six criteria formats for ranking and selecting the teams:

1. Business or Market Potential
   a. Does the proposition address a real pain?
   b. Is there a clearly identified customer segment?
   c. Is there an opportunity to expand in other markets?

2. Job Potential or Social Impact
   a. Does this business have the potential for strong growth and create jobs doing so?
   b. Does it address an important environmental or social issue?

3. Innovation or Technology Potential
   a. Is there strong new technology?
   b. Is there a strong new business model?
   c. Or an idea with existing technology/business model

4. Climate Impact
   a. Is there a significant climate impact?
   b. Is the climate impact significant in this business sector?

5. Strength Management Team
   a. Is there entrepreneurial spirit in the team?
   b. How complete is the team for the task at hand?
   c. Does the team have prior start-up experience?

6. Quality of Pitch

The main prizes are awarded during the grand final:
- Winner: €10 000
- Runner-up (2nd): €5 000
- 3rd Place: €2 500

The prize money for the overall grand final winners is purposely modest as the main reward for winning/ participating in Climate Launchpad is the international exposure, along with the direct access granted to the top 10 winning teams to the EIT Climate-KIC Acceleration program. For winners outside Europe, specifically EIT Climate-KIC Accelerator locations, an alternative award is found that is of similar value.

2.5.7.3. Accelerator

The Accelerator programme is designed around three stages aimed at progressing start-ups through each stage. Advancing through the process is predicated on successfully complying with each programme step. Each stage requires that the start-ups have a break through idea related to new technology or service with substantial climate impact, a motivated team with at least two founders and the start-up must be a legal entity not older than five years. The distinguishing features of each stage are:
- Stage 1: a basic business model is defined;
- Stage 2: a solid business model is defined;
- Stage 3: a validated business model is defined and early users/ customers/ partners have been identified.

The accelerator programme provides financial support to start-ups via grants at each stage of the programme:

- Stage 1: up to €20 000;
- Stage 2: up to €25 000;
- Stage 3: up to €50 000.

Individual start-ups can receive a maximum total amount of €75 000 if they go through all the three stages in the time span of 18 months, though not necessarily within a single year.

The goal of Stage 1 is to help entrepreneurs translating pro-climate inventions into viable business models. Start-ups work on developing and testing a business model, using an appropriate business model assessment framework, and on presenting a plan for validating that business model by real-world customers. To achieve this goal, start-ups at this stage receive support services and grants up to €20 000. All teams have access to the local coaching pool and a bootcamp is organised centrally. Each location complements this offer with a variety of trainings, mentoring sessions, networking events, peer-to-peer exchanges whose frequency can vary per location.

For Stage 1, EIT Climate-KIC is looking for start-ups that comply with the following criteria:

- Have a breakthrough business model, exponential technology or solution with substantial climate impact (mitigation, adaptation or both). The programme is open to non-traditional entrepreneurship solutions and approaches addressing climate change with significant climate impact potential (e.g. advocacy and policy, organisational and behavioural change, civic engagement, etc.);
- Proposed solution fits with one of the defined thematic challenges in the call. Those who do not fit with any of the thematic challenges, they shall apply to the wild-card access-track;
- For technology companies entry is open from early-stage proposals with technologies successfully validated in lab environment (equal or higher than technical readiness level 5 as reference) to fully operational models ready to expand;
- Core value proposition can be based on digital as well as non-digital solutions;
- A business model is already defined;
- The start-up has already a legal entity to operate or is in an advanced stage to set-up one. The programme is open not only to classical clean-tech ventures based on regular for-profit legal structures, but also open to non-profits or hybrid legal structures;
- The start-up is composed by a motivated team with at least two founders;
- The team is committed to participate in the programme activities;
- The team is capable of working in an English-speaking environment.

The goal of Stage 2 is to help entrepreneurs translating business plans into concrete value propositions, provide evidence of the validation of the business model by real-world customers and develop and present a plan for developing products/services to market-readiness and achieving market entry. Start-ups at this stage receive support services and grants up to €25 000.

In addition to the conditions defined in stage 1, start-up candidates for stage 2 require:

- Successfully absolved stage 1 or coming directly to stage 2;
- The proposed solution has an elaborated case to show the potential climate impact;
- The business model has a solid case to address the sustainability and replicability / scalability of the proposed solution;
- Technology solutions are ready for product demonstration and validation;
- The start-up has a legal entity to operate.

The goal of Stage 3 is to help entrepreneurs to translate validated business models into first transactions with first customers, beneficiaries and/or investors. Start-ups pursue market entry with core product or service and achieve a meaningful number of commercial transactions that validate the core value proposition and/or attract capital to progress into the next stage in the business development. Start-ups at this stage receive support services and grants up to €50 000.

In addition to the conditions defined in stage 1 and 2, start-up candidates for stage 3 require:

- Successfully absolved stage 2 or coming directly to stage 3;
- Early users/ customers/ partners have been already identified;
- Start-up is looking to address main initial barrier to impact, e.g. first substantial funding, address a policy barrier, generate first customer traction, etc.

Community Management

Being an active player in the local start-up ecosystems is key for the competitive market positioning and success of the entrepreneurship programmes. In-house programme managers in the locations therefore engage with local stakeholders to create the best community around the programme. Among others, these may include building relationships with the EIT Climate-KIC start-up alumni, universities and research institutions, investors, public and private corporations, coaches, mentors and experts in relevant fields, other accelerators/ incubators, and start-up/ sector specific events and trade fairs. An investor dinner is organised on annual basis, together with demo days at different locations, an entrepreneurship night, an international corporates day and an impact investor day. The Investor Dinner is an annual event where the very best current and alumni teams of the Accelerator can present their businesses to an exclusive group of investors from across Europe. Because the evening is limited to a select number of individually invited clean-tech investors, the format allows for a very personal engagement and in-depth discussion with potential funders.

2.5.7.4. Investor Marketplace

The investor marketplace is the most comprehensive overview of investment opportunities into early-stage start-ups working on climate innovations. The platform increases access to finance for early-stage cleantech start-ups while providing investors carefully selected and curated start-up investment proposals. The deal flow stems from EIT Climate-KIC's Accelerator programme.

The Marketplace is a core capability that delivers the right information to the right people, in the first instance, investors and start-ups. It accelerates the investment cycle and leverages the power of the community. It is a platform for facilitating access to finance for early-stage cleantech start-ups, while providing investors carefully selected and curated start-up investment proposals. Since launching the platform, numerous start-ups have been successfully showcased on the website.

Regarding financing of collaborative innovation projects by EIT KICs, EIT Climate-KIC is a European has the ambition to support Europe's leaders in tackling climate change, to enable Europe to fulfil its commitments in respect of the Paris Agreement, and to inspire global efforts by creating prosperity and wellbeing in the future economy. Through calls for innovation projects, EIT Climate-KIC looks to support ambitious, and potentially transformative, innovation experiments that can add something unique to their existing portfolio.

EIT Climate-KIC organises its innovation projects within four key themes that are designed to help Europe reduce the likelihood of the dangerous effects of climate change by 2030. These themes are consistent with the United Nations Sustainable Development Goals (SDGs).

The four key themes are as follows:

Urban Transitions: Cities consume 75% of the world's natural resources, produce half the planet's waste and generate 60-80% of global greenhouse gas emissions. EIT Climate-KIC's Urban Transitions experts advise cities and districts on how best to transform urban environments into decarbonised and climate-resilient beacons.

Sustainable Production Systems: Industry emissions account for 30% of total global greenhouse gas emissions. The Innovation Community's mission is to achieve zero-carbon emissions from materials and industrial processes, supporting cities and regions in their transition towards carbon-neutral societies.

Decision Metrics and Finance: This pathway team works with the network of partners to develop the metrics and financial mechanisms to redirect and mobilise the finance needed to quickly scale up climate action.

Sustainable Land Use: Agriculture, forestry and other land uses represent 24% of global greenhouse gases emissions, second only to the global energy sector. EIT Climate-KIC supports new approaches that decarbonise agriculture, making it more efficient and productive.

2.5.7.5. Innovation pipeline: Pathfinder, Demonstrator and Scaler

To achieve its goals, EIT Climate-KIC has created three programmes for innovation projects: the Pathfinder, the Demonstrator and the Scaler.

Pathfinder

The Pathfinder is an ideation programme that helps innovators test, refine and confirm assumptions about their innovation ideas, so that they are suitably developed to be applied and implemented. The Pathfinder programme is designed to enable the collaboration of research and business stakeholders, and typically lasts between three to six months, with potential funding up to a maximum of €50 000.

Open to both partners and interested partners, Pathfinder helps innovators test, refine and confirm assumptions about their innovation ideas, so that they are suitably developed to be applied and implemented.

Pathfinder is an opportunity to scope out and refine the feasibility of early-stage innovation propositions. Applicants can get support in putting together a network of partners, gain access to pre-existing networks, and test out the parameters of their proposition in a safe, de-risked environment. The projects are typically rapid innovation projects: testing an idea or engaging in prototyping. Successful proposals have to explain why they offer a unique contribution to EIT Climate-KIC's portfolio.

The network of Climate-KIC partners includes organisations at the cutting edge of climate innovation, from academic and educational institutions to established businesses and start-ups. Successful applicants are able to share best practice with the wider network, and propel their innovations to maturity.

EIT Climate-KIC believes that Early Stage innovation activities are critical for developing innovation capability and laying the foundations for compelling, high-value propositions that attract investment and deliver impact. The objective of these programmes is to develop high-quality Early Stage proposals that deliver change around the 12 Impact Goals. Complex interconnected challenges like climate change must be tackled by assembling key actors to change systems. Early Stage innovation, therefore, is not about supporting business as usual, but exploring systemic change and the collaborations, innovations and business models needed to achieve it. All this is done at an Early Stage when it is less costly to experiment and learn. The knowledge and understanding acquired by the EIT Climate-KIC community through this experimentation is harnessed to provide feedback loops that inform strategy and implementation.

Demonstrator

The Demonstrator (for EIT Climate-KIC partners with a validated business model) supports climate innovators to demonstrate that their innovation works and is a viable proposition on which to create a "business", whether for profit or not. It is designed to support multiple stakeholders with funding and services to remove project risk. Such later-stage innovation projects can receive a maximum of €1 000 000 of EIT Climate-KIC contribution per year for up to three years. They should be multi-partner, high-ambition innovation projects with a clear strategic argument for how they will create impact and why they offer a unique contribution to EIT Climate-KIC's portfolio. Each innovation project shall embed learning dimensions, whether in terms of capability building or creating the appropriate mind-sets for systems change.

By enabling consortia, the Demonstrator Programme ensures the full range of technical and business knowledge and competencies are brought to play, thereby reducing the financial, technical and business risk associated with the latter stages of innovation and increasing attractiveness to investment and growth. In order to be eligible, Partner consortia must either have validated or clearly described the scaling model that underpins the identified systems innovation opportunity.

Scaler

The Scaler (for EIT Climate-KIC partners with a validated business model) brings together providers with scaling services and innovators in need of support to scale their proven innovations. It provides funding and support for the development and implementation of scaling services that can be applied to proven innovations. EIT Climate-KIC expects project owners to design projects with and on behalf of demand-

owners (e.g. cities, regions, countries, businesses or citizens groups). The most impactful innovation projects are those that are both designed with demand-owners and involve them throughout. In this regard, EIT Climate-KIC does not intend to support traditional supply-driven, research-oriented projects led by universities/teams of researchers where demand-side partners are not engaged. There are other H2020 instruments to support pure research projects.

The financial resources available from EIT Climate-KIC should be seen as a co-investment alongside others. The maximum EIT reimbursement rate is 80% for Pathfinder projects and 67% for Demonstrator and Scaler projects. The maximum EIT reimbursement rate is applied at the project level. Individual Partners may seek EIT reimbursement of up to 100% within a consortium providing the maximum EIT reimbursement rate for the programme is not exceeded by the project overall. For multi-annual projects, a Partners' EIT reimbursement Rate should remain the same each year.

Proposal evaluation

All proposals shall be assessed fairly and transparently in the scope of EIT Climate-KIC's Innovation Impact Goals, programme eligibility, assessment criteria and the current portfolio of activities. EIT Climate-KIC manages the portfolio to achieve the correct balance of projects and funding across the Impact Goals.

Earlier Stage Applications are assessed by a minimum of two EIT Climate-KIC teams. Later Stage Applications are assessed by a minimum of two EIT Climate-KIC teams and additionally, applications are assessed by up to three independent assessors. The assessors are experts from both business and academia. Applications are assessed against the criteria. Assessors provide written feedback for each scored question in the application. The commissioning board makes the final decision regarding funding.

EIT Climate-KIC uses the following quality assessment criteria for assessing all innovation proposals.

Strategic Fit & Contribution to the Climate Innovation Impact Goals	▪ Does the proposal provide a clear narrative substantiating how and why the project aligns with the EIT Climate-KIC Impact Goals? ▪ Does the proposal clearly work in line with the objectives of the relevant programme?
Demand Assessment	▪ Does the proposal convey how it aims to identify or address the challenges and needs of the demand-side (business, society, policy community, etc.) of the innovation? ▪ To what extent are demand side representatives expressing interest in the innovation? ▪ [Demonstrator, Scaler] Are demand-side representatives part of the project consortium and/or expressing concrete interest in the innovation? ▪ [Scaler] Is there evidence that there has been uptake of the innovation?
Systems Innovation Potential	▪ Does the innovation have intention/potential to create transformational change on a systems level? ▪ Does the proposal clearly describe why it is innovative? ▪ Does the proposal clearly describe how the innovation opportunity was identified (e.g. through a Pathfinder project)?
Expected Impact & Speed to Impact	▪ Does the proposal clearly describe the mechanism for how it will contribute to climate change mitigation and/or increasing climate resilience? What is the potential scale of the impact? ▪ How well does the proposal consider socio-economic benefits and risks that the innovation entails? ▪ Is evidence provided to substantiate (if appropriate: quantify) the expected impact? Does the proposal adequately reference other studies? ▪ Does the project encourage diversity and gender equity?
Project Consortium/ Partnership	▪ Do the consortium partners have the appropriate skills and capabilities to successfully deliver the project? ▪ To what extent does the consortium engage organisations from different parts of society (government, academia, industry and civil society)?

Project Plan & Clarity of Outputs	▪ Are the work plan and work packages clearly explained and relevant to support the project objectives and expected impact? ▪ Are the project outputs, deliverables and KPIs clearly stated and linked to the different work packages/project stages identified in the work plan?
Value for Money	▪ How well is the funding spent on activities directly linked to achieving the project objectives, deliverables and KPIs? ▪ How appropriate is the funding request in relation to the anticipated benefits? ▪ How much co-funding is offered to match the EIT funding? ▪ How high is the potential for the innovation to attract further capital/ investment (beyond EIT-funding)?

2.5.8. EIT Health

EIT Health Accelerator is a business creation programme, set up to support the best and brightest health industry entrepreneurs. To tackle the future challenges of European healthcare, EIT Health Accelerator creates a favourable environment for innovation, providing skills and services to get promising business ideas into the market. The Accelerator pillar of EIT Health provides support to healthcare entrepreneurs at every stage of the process. The activities are structured within three segments: Incubate, Validate and Scale. This business creation supply chain supports the acceleration of innovation projects and access to relevant facilities for start-ups and SMEs throughout the EIT Health community. The Accelerator is open to applications from all entrepreneurs, start-ups, scale-ups, and SMEs in Europe. Entrepreneurs are typically distributed across seven regional offices.

EIT Health supports start-ups participating in EIT Health programmes by helping to promote their success stories on the EIT Health webpage. To mark special achievements, EIT Health is willing to support by sharing the start-ups' social media posts, publishing interviews or writing other related articles on a case-by-case basis.

2.5.8.1. Incubate

The INCUBATE! activity line offers support for not-yet entrepreneurs or scientists wanting to develop start-ups. Activities include innovation training and assistance or other Bootcamp programmes that help entrepreneurs create a business plan out of an initial idea or research project.

Bootcamps

Bootcamps are intensive incubation programmes for start-ups and entrepreneurial teams. Over a period of 2-3 months, teams are trained to validate both product-market fit and problem-solution fit in a European context. The Bootcamp programmes invite teams of MSc, MD and PhD students, as well as post-docs and professionals, who have a business idea for a product that is still in the research and development stage.

Each Bootcamp hosts a mix of teams from all over Europe. As regards selection procedure, a committee chooses the most promising start-ups to participate in the programmes. The committee includes diverse experts from each Bootcamp. If chosen for an EIT Health Bootcamp, applicants receive training with a commercial value equivalent to approximately €15 000. There is no equity is asked for in return. Additionally, each programme includes financial grants to support travel and other associated costs incurred during the

programme. The programme also supports funding for a field trip, which an opportunity to pitch an idea across Europe. Generally, a Bootcamp accepts 10 to 15 teams (each composed of 2-3 team members) within one programme.

EIT Health offers the following Bootcamps:

1. **CRAASH**: it is a 12-week programme over a period of six months that helps European research teams to launch successful device, diagnostic and e-/digital health innovations designed to improve health and patient care. Project teams move from research to market through mentoring with experts from Europe and from the USA. CRAASH supports research projects and soon-to-be incorporated or already incorporated start-ups with a proof of concept or proof of feasibility. Teams consist of three members: one entrepreneurial lead, one clinical lead and one technical lead. The training programme includes on-site and off-site sessions, divided into three main phases. Firstly, the teams validate their problem-solution and solution-market fit, specifically for the Healthtech market. Secondly, selected teams join for road trips in Europe to investigate the market potential in different countries, validate clinical need and verify appropriate regulatory pathways and reimbursement methods. Finally, teams successfully completing all the program milestones travel to the US to pitch their deck. This is an opportunity to meet different stakeholders that help to validate or pivot the strategy defined, while exploring collaborations and building a first network.

2. **Validation Lab:** it is a unique two-month programme with intensive elements that allows aspiring entrepreneurs from all over Europe to discover the business potential of their health-tech ideas. The programme helps participants to explore and validate their ideas, market potential and business model, and to launch in markets all over Europe. After the first weeks of the programme, the teams go on a road trip through Europe to learn more about healthcare systems and explore markets in different countries. During the road trip, teams validate their assumptions about their businesses in markets in other European countries as well. After the road trip, a final event takes place where the teams are connected to investors, launching customers etc. As a final result, entrepreneurs gain a solid foundation for the product's market fit, and a validated business plan.

3. **Medtech:** it provides interdisciplinary teams of engineers and health professionals with an individually tailored entrepreneurial toolbox, a convincing business plan and a strong network of investors. Participants can catapult their promising healthcare transforming ideas from sketch to market. Throughout the Medtech Bootcamp, meticulously selected teams transform their start-up ideas in medical technology into successful start-ups within an eight-week programme on business creation and validation. Firstly, the teams are provided with a business design toolkit to develop and implement a sustainable future business plan. They then create prototypes by applying proven methods from design and management. Afterwards, teams focus on validation through specific training in intellectual property, licensing, and medical product legislation. They have access to testbeds and living labs as well as a broad clinical network. Through selective matchmaking, teams are in close contact with healthcare experts and future customers to improve the design and feasibility of their concepts. At the end, the teams tour Europe to pitch their start-up ideas to possible investors, learn market specifics, and challenge their value proposition at roadshow stops.

4. **E-Boat:** it is an accelerator for start-ups with innovative mobile health solutions. It is a unique programme consisting of six weeks distance learning and two weeks of a Cruise Hackathon formula to validate, develop and launch products in the European market. The programme is aimed to support incorporated start-ups with mobile health solutions. The technology should be ready to be demonstrated and to validate the mobile-friendly product/service and business concept.

5. **Digital Health Validator:** it is a two-month digital health incubator providing opportunity for start-ups to explore and validate their ideas. The Digital Health Validator empowers Digital Health entrepreneurs to validate the technology and market potential of their early stage business. Each applying team participates in a two-day problem-solution fit session. The best teams are selected to participate in a Bootcamp to validate product-market fit and revenue model. The Bootcamp immerses teams in the powerful start-up ecosystem and matches them with a mentor. The programme includes a road trip to bring an international context. The programme is targeting Digital Health start-ups, particularly in the focus areas of bringing care home and value from clinical data.

Venture Lab: it is an intensive, healthcare-focused accelerator that helps aspiring individuals and teams to advance their innovative ventures through an extended period of coaching and training. It provides academic, business and industrial expertise to ensure that participants have a unique opportunity to improve all aspects of their businesses. Participants have the chance to build a strong international network by becoming a member of a Europe-encompassing start-up community. The programme targets international teams who are solving a healthcare-related problem and have already built at least an initial prototype. The programme offers a six-month-long acceleration for candidates with an entrepreneurial mind-set who want to develop their personal and team business competencies and explore their health-related business ideas. Throughout monthly workshops provided by expert coaches, participants acquire the knowledge, skills and attitude necessary to develop the strategic, organisational, networking and financial basis of a growth-oriented firm.

Start-ups meet Pharma

It is a challenge-based programme connecting teams of MSc, MDs PhD students, as well as post-docs and professionals, developing innovative solutions for chronic care beyond the pill with key pharma partners in Europe. The programme invites start-ups developing digital solutions, which affect both the Pharma industry and patients, to tackle challenges in collaboration with top pharma partners.

The ideal team profile features a combination of skills, such as business-lead and product-development-lead. Selection of teams is based on the quality of the business idea, their fit for the selected challenge and the team's motivation and level of commitment.

The programme consists of four modules: (i) workshops on innovation, corporate ventures, business development, and start-up collaborations; (ii) tailored trainings on business modelling, marketing and sales strategy, financial planning and forecasting, regulatory hurdles, pitching and presenting skills; (iii) roadshows to pharma partners in different leading innovation areas in Europe with presentations, feedback and interaction for possible collaboration and deal generation; (iv) demo day with industry partners and investors network.

Selected teams receive a training with a commercial value equivalent to approximately €15 000. Additionally, a financial grant of maximum €10 000 is provided to help support in travel and other associated costs incurred during the programme. The funding is intended to support two-to-three team members.

CaixaImpulse

CaixaImpulse is an intensive 18-month acceleration programme for the creation of new products and ventures in the health and life sciences sector. This programme is meant to jump-start the translation of health research projects into market-ready products. The programme targets project leaders from all European countries doing research in the health and life sciences sector. The programme focuses on supporting early-stage projects, to allow the projects to create and develop a valorisation plan and have access to experts and investors to generate new business opportunities. The programme assists projects in completing a commercialisation plan to validate their strategy and attract private investment. EIT Heath's support allows the expansion of the programme to other European countries, for the internationalisation of the activities.

2.5.8.2. Validate

The VALIDATE! line places emphasis on validating products and services. EIT Health's network of Living Labs and Test Beds provides entrepreneurs the means to test products throughout the value chain. Other activities allow entrepreneurs to gain understanding in local/regional regulatory and reimbursement schemes and have access to market experts.

Headstart

The EIT Health Headstart Programme provides funding of up to €50 000 to support early stage companies and SMEs in developing new products and services. Selected companies work on their product launch project with support from the regional managers to access local and EIT Health networks. The maximum duration of a project is 12 months. The funding may be used for any activity necessary and relevant to reach the project's objectives, but cannot be used for pure basic research activities.

The purpose of the EIT Health Headstart Funding Programme is to:

- support applicants in realising next steps towards the market and shorten time-to-market for innovative products and services;
- verify the need/benefit of the product/service for users/customers/payers/partners;
- increase the possibility of attracting further private investment.

The EIT Health Headstart Funding Programme is suitable for micro and small enterprises, spin-offs, and start-ups that have a well-developed prototype and are ready to launch a product. A company must be incorporated/registered to apply. Ideal applicants have an estimated company valuation of less than €1 000 000. An existing relationship between the start-up and EIT Health must be established before the submission of the application. The project or product supported must be within the scope of the main challenges in EIT Health: healthy living, active ageing, and improved healthcare.

Living Labs and Test Beds

This programme provides the benefits of living labs and test beds to entrepreneurs, so they can develop market-ready products with high added value and a high probability of success. Living labs and test beds are open innovation ecosystems where stakeholders, including healthcare professionals and patients, cooperate on solutions to healthcare challenges. Living labs support the innovation process throughout the different phases of the value chain, including ideation, co-creation, validation and scale-up.

The programme is open to any European start-up, SME, entrepreneur or innovation project that aims to improve their product by validating, co-creating and ideating with the end-user in a real environment. It has a wide geographic coverage throughout Europe and wide coverage of thematic areas such as medtech, digital health or e-health, allowing a diverse group of organisations to benefit from the network across Europe. Companies that apply for this funding should be seeking to develop projects that fit the overall EIT Health objectives of healthy living, active ageing and improved health care.

All start-ups and SMEs applying in living lab and testbeds project can be eligible for vouchers in the value of €5 000 that they can use for support of the programme with certain conditions. A group of experts from the project consortium analyses applications, performs a needs analysis, and selects according to the applicant's needs. This is to ascertain which are the most suitable living labs or test beds to help them. The purpose of the matchmaking and connection phase is agree, define and organise the specific service to be provided. A part of follow up activities, both the living lab or test bed and the start-up is monitored by an expert, who is responsible for the project network to accompany the process. Information is collected to evaluate the proper functioning of the programme and make any necessary improvements.
From the signature of the service agreement, start-ups have 12 months for execution. The duration of the services may last two months at the minimum.

Mentoring and Coaching Network

The Mentoring and Coaching Network (MCN) gathers subject matter experts and top-of-the-line mentors from all over Europe to help with the specific needs of start-ups in medtech, biotech and digital health. To create a vast pool of MCN experts, EIT Health has integrated its individual experts, partners, institutions and corporations into one robust, curated platform of quality mentors, coaches and subject-matter experts with specific know-how and relevant track records from around the EU. The programme is aimed at all business maturity levels, ranging from early stage start-ups developing their product to more mature scale-ups with a developed product and in the phase of expanding to new markets. Entrepreneurs may register on an ongoing basis and begin the matching process to find an expert. Start-ups evaluated positively may be selected to receive a small stipend to cover a portion of fees of the chosen expert.

Bridgehead

The Bridgehead programme provides European start-ups and scale-ups with individualised support in expanding beyond their home market. The programme follows an individual and needs-based approach by matching promising start-ups and SMEs to suitable clusters, accelerators and incubators all over Europe. The programme also offers mentoring, services, resources and vacant physical spaces to start-ups that need them. The Programme is suitable for micro- and small enterprises (less than 50 employees) that are active in the fields of medtech, biotech and digital health, and are operating in an EU country. Applicants should have a defined product strategy, proven traction in their home market and a clear internationalisation plan. Start-ups selected travel to accelerators of their choice to speed up access to markets, tap into local networks of partners and clients, access infrastructure and get a first-hand feeling for the local regulatory and business context. They are guided by a trusted and seasoned local support team that can open the right doors to establish and grow cross-border business. Participating teams receive vouchers of up to €30 000 to spend in the programme.

Digital Sandbox

The Digital Sandbox programme supports SMEs in developing relevant products and services by working with biobanks, sample holders and quality registers in Europe. Access to qualitative sample and data collections can give unparalleled insights, paving the way for new medicines, treatments and medical products. The data can be used to create digital solutions that reduce healthcare costs and lead to more efficient working procedures for prevention, prediction, diagnosis, treatment and follow-up. The Digital Sandbox is designed to help realise this potential. The programme gives SMEs as much as €35 000 in funding to help them leverage the possibilities of the health data business by developing new products and services that take advantage of biobanks, sample holders and quality registers in Europe.

2.5.8.3. Scale

The SCALE! activity line focuses on more mature start-ups and SMEs, to facilitate access to tools and networks for financing and market expansion. The European Health Catapult programme awards funding to companies with the best business plans and provides training in pitching and competitiveness. The GoGlobal Programme supports European ventures so that they can expand beyond Europe's borders to the US, China, Brazil and other international markets. The Gold Track programme accepts extremely high-potential start-ups that aim to become global players.

European Health Catapult

European Health Catapult is a training and competition programme that boosts the development of top-notch European health start-ups. The programme exposes Biotech, Medtech and Digital Health start-ups to high-quality experts and international investors through intensive and multichannel involvement of the whole EIT Health community.

The European Health Catapult is open to micro and small enterprises (less than 50 employees), spin-offs and start-ups that are already incorporated and are looking for seed or Series A funding of a minimum €500 000. Participants must be active in the fields of medtech, biotech or digital health, operating in an EU Country, offering innovative business concepts, and connected to the EIT Health community. A strong focus is placed on the innovation's impact in terms of societal challenges.

Participants gain real-world entrepreneurial experience and potential access to an international network of world-leading medtech, biotech, pharma and IT companies. Participants also have early access to an international network of investors (VCs, corporate VCs, business angels, crowd investors) to boost their business ideas, as well as guidance to access unique services offered by EIT Health networks in crucial areas such as clinical validation (living labs and test beds) and the mentor and expert platform.

Interested companies apply to participate at the regional level. Regional competitions are organised based on the EIT Health regional structure. At stage 1, nominees selected in the regions are invited to a compact training programme designed to prepare the teams and a selection day with a competition in each category. Benefits include reviewing of the business plan, pitch training, and exposure to experts and investors. At stage 2, the semi-finalists chosen at the training and selection days are invited to pitch at the finals during the EIT Health Summit. At the third and final stage, at the EIT Health Summit, the best business plans in medtech, biotech and digital health are selected by a panel of experts. The top three finalists in these categories receive an award based on their placing. The maximum amount of all prizes awarded equals to €200 000.

Investor Network

The Investor Network connects European health-oriented investors with promising start-ups to encourage cross-border financing and co-investments. The network brings private and institutional investors together with pre-screened high-potential start-ups, making it possible to leverage greater local and international funding at a faster pace. This is the first pan-European, EU-driven network for investors that is solely focused on financing healthcare innovation.

Start-ups or SMEs participating in the programme must be registered and at minimum seed stage with public grants. For private investors, representatives of a business angel network, or representatives of a venture capital or corporate venture fund, the Investor Network gives the opportunity to screen and select start-ups that are seeking to raise funds and meet the properties of the portfolio. The programme connects start-ups to investors to allow them to access funds for Seed to Series C rounds, by it is a unique networking programme that displays the start-up's funding needs to a variety of investors, including private equity investors. It is also the first programme of its kind in Europe to offer a continuum of investment. It has the ambition to leverage investment by creating a close-knit network of healthcare investors that know and trust each other, and who share the same ambition of bringing smart money to innovative European start-ups.

The Investor Network journey for start-ups starts with an application. Upon approval, start-ups are invited to sign a Memorandum of Understanding which gives them access to a deal flow management platform where they can upload their documents for review by selected investors. Investors contact them if interested to ask for their information and to potentially begin a due diligence. Start-ups are invited to pitch, and then can proceed with individual negotiations.

Crowdfunding

The EIT Health Crowdfunding platform is the first pan-European equity crowdfunding platform for European healthcare companies. By making it easy for anyone to learn about, and invest in, approved healthcare innovations, the platform builds bridges between European citizens, healthcare professionals and healthcare innovators.

The EIT Health Crowdfunding platform can provide promising start-ups and SMEs much-needed funding while allowing other Europeans the opportunity to invest in, and benefit from, the success of these companies. It supports promising start-ups using the classic crowdfunding formula: ventures raise financing from a large number of people, many of whom might invest a relatively small amount.

For retail and institutional investors, the platform gives access to best-in-class companies in the core health sectors biotechnology, medical technology and digital health. As prospectus-based security offerings, investment opportunities go through a thorough approval process. The platform enables investors to participate in handpicked projects that have been reviewed by an independent investment committee. It provides the possibility to take advantage of early stage investments in healthcare. The co-owner model is structured to enable retail investments alongside business angel and venture capital funding.

Open to companies from across the EU, the initial funding focus is on Belgium, Denmark, Germany, the Netherlands, Sweden and the UK.

GoGlobal Programmes

Europe is home to many health and life-sciences start-ups and SMEs that can find it difficult to grow, especially when the introduction of new treatments to the market involves a long, complicated and costly process. GoGlobal aims to provide companies in medtech, biotech and digital health with the competence needed for international expansion. Participants are supported in entering to new markets with knowledge about specific countries' healthcare systems, regulatory environments, key stakeholders and competitors.

Currently the following GoGlobal programmes exist:

- Start.Smart.Global helps European life science SMEs optimise their market entries into the lucrative but challenging business environments of Japan and South Korea;
- GoGlobal Canada provides top European SMEs with a unique gateway to three recognised Canadian innovation hubs;
- GoGlobal Medtech/Digital Health is for medtech and digital health companies seeking their first export market partake in ten days of investigating Europe, the US and China;
- MedTech Exchange Accelerator gives medtech and digital health start-ups first-hand insights about the country specifics of the Chinese healthcare market.

The target participant profile in the GoGlobal programmes are start-ups, scale-ups or SMEs, either possessing a product and have started to sell, or having strong proof of concept advanced in the regulatory/certification process, and having the ambition to expand to the international market within 12 months. The commercial value of these programmes is an estimated at €10 000 and no equity is asked for in return.

Gold Track

Gold Track is an intensive tailor-made scaling programme that offers hands-on individual guidance to help elite start-ups. Gold Track provides the most promising start-ups and SMEs a deep dive assessment, an individualised roadmap built by their personal high-level advisor, implementation support, and access to network resources and programmes. The goal is to enable these enterprises to make advances in their internationalisation efforts. Participating scale-ups that show promise of future high performance are scouted and/or nominated by the EIT Health's local team and selected by an independent panel of experts of high standing and recognisability. Selected companies seeking growth in international markets are granted outcome-oriented advisory support. These start-ups are fully assimilated into the EIT Health network, receiving resources from the EIT Health portfolio, collaborating partners and external sources. Their one-year journey is supervised by a senior mentor, who provides networking opportunities and advice, as well as sets the high-level strategic goals.

Regarding financing of collaborative innovation projects by EIT KICs, EIT Health's Innovation Platform provides comprehensive support for innovations that show the potential of rapid market penetration of innovative products and services, and the testing and implementation of novel organisational and healthcare delivery processes. EIT Health's innovation projects fall within one of the six EIT Health Focus areas as follows.

1. **Bringing care home:** From institutional delivery to health delivered at home – EIT Health will deliver optimal home-based healthcare to older citizens, and consequent financial benefits to society, by designing and demonstrating innovation in home care service and systems.

2. **Harnessing the power of real world date (RWD):** From conceptual vision to tangible value – EIT Health will launch RWD initiatives that are robust, inform valid healthcare decisions and demonstrate potential to be scaled up, thereby establishing a framework for EU leadership in access and analysis of RWD.
3. **Creating the enabling environment for healthcare transformation:** From the current challenge to a sustainable future – EIT Health will deliver an organisational evolution in healthcare management, with value-based benefits for citizens and consequent financial benefits to society, by designing and demonstrating innovation in management models and aligned training.
4. **Towards health continuum care pathways:** From treatment centric limitations to the health continuum breadth – EIT Health will lead the reform of care pathways, undertaking the design and evidence-based implementation of innovative care and health delivery solutions.
5. **Employer leadership in improving health outcomes in the workplace:** From workplace to health place – EIT Health will deliver improved healthcare to employees, and consequent financial benefits to employers, by going beyond the traditional expectation of employer responsibility for health in the workplace.
6. **Fostering healthy lives by introducing behavioural change:** From dealing with disease and disability to healthy lives – EIT Health will supply the tools and incentives to help citizens modify their way of life to prevent early onset of ageing, disease and disability and to profit from more years in health and wellbeing. EIT Health will focus on providing opportunities, especially to children, and other vulnerable and marginalised groups in society.

2.5.8.4. Innovation projects

EIT Health's Innovation Projects Portfolio consists of three types of project:

1. **Innovation by Ideas:** Innovation by ideas refers to innovation that someone has created because it has occurred to them that they can offer something useful. These are new, solution-driven ideas that the creators believe will benefit society by improving healthcare.
2. **Innovation by Design:** Innovation by Design refers to innovation that is meant to address an existing and usually widely known problem. Needs-driven projects that are created to address a recognised market need or societal problem, to deliver tangible results for citizens.
3. **Wild Card Projects:** EIT Health Wild Card Projects are high-risk, innovative projects with transformative potential. The projects are targeted at challenges provided by EIT Health Partners, where the "solution" of the challenge would be a major breakthrough.

Innovation Projects address the societal challenges tackled by EIT Health. These projects bring together new partners from throughout the consortium who are now collaborating to offer better health and healthcare to European citizens. The ultimate objective of the projects should be the rapid market penetration of innovative projects and services, and/or the testing and implementation of novel organisational and healthcare delivery processes.

EIT Health is generally looking for project proposals that demonstrate a clear innovation and present a viable plan to reach the market or – in the case of organisational and process innovations – present a viable deployment strategy. The EIT Health-financed part of the project should result in an innovation that has been technically validated and tested in a relevant environment, bringing the project to a point where it can attract early adopters or additional external financing. Market launch/deployment/regulatory approval for the innovation should be targeted for about three years following the completion of the project, and a clear path to this point should be presented.

A maximum EIT contribution of €3 000 000 can be sought by proposers for each project and is only provided for a maximum of 36 months. The maximum yearly contribution is €1 000 000 per year. All for-profit EIT Health Partners must contribute 30% co-funding (maximum reimbursement rate of 70%) of all costs for all projects or activities of the EIT Health portfolio. However, Partners that are SMEs of the type "small" or "micro-enterprise" shall be able to have a maximum reimbursement rate of 100%.

Proposal evaluation

Eligibility criteria

- All innovation project proposals must be submitted by an EIT Health Core or Associate partner.
- All innovation project proposals must involve Core or Associate Partners from a minimum of two CLCs/ InnoStars.
- Linked third parties or affiliated parties cannot apply as leaders of any innovation project proposal.
- The yearly financial contribution per project may not exceed €1 000 000.
- All EIT financed project activities must be completed within three years.
- In addition, Innovation Proposals must:
  - Demonstrate clear and achievable commercial or implementation end-points (e.g. products and services to be launched, organisational innovations to be implemented, etc.).
  - Include at least one academic and one non-academic Core or Associate Partner.

Evaluation process

All eligible proposals are evaluated in two stages: (1) remote expert evaluations and (2) hearings.

1) Remote evaluation

Each eligible proposal is evaluated based on the criteria indicated below by five independent external evaluators. EIT Health contracts the evaluators and the evaluators receive training on EIT Health strategy, rules and procedures. They are instructed to check for conflicts of interest and to inform EIT Health if necessary, before evaluation of the proposal starts.
A maximum of 100 points are awarded in the remote evaluation by each reviewer. The final remote evaluation score is the average of all remote reviewers' scores.

Invitations to hearings are based on the scoring/ranking from the remote evaluation.

2) Hearings

An Evaluation Board conducts the hearings for each pillar. The Evaluation Board consists of an external expert group and is chaired by a member of the HQ management team. The Supervisory Board appoints the external experts for all Evaluation Boards. The composition of the Evaluation Boards is published before the hearings. Before hearings, the external experts receive training on the EIT Health strategy, rules and procedures.

A maximum of 100 points can be awarded from the hearings by each reviewer. The final hearing score is the average of all reviewers' scores.

Specific evaluation criteria, and relative value of these criteria

Project Excellence, Novelty of Innovation and Strategic Fit (20%)	▪ Projects should use innovative and unique approaches wherever possible. For example, applying existing knowledge in a new way or in a different context, or applying 'new' knowledge to solve challenges with a different approach ▪ Projects should state uniqueness of the proposal compared to the state of the art. In the case of clinical products/services they should be compared to the standard of care, the gold standard. Processes or management innovation should be compared with standard practices, current guidelines, etc. ▪ Added-value of the proposal should be demonstrated. ▪ Projects should address the relevance and fit with EIT Health objectives and indicate how they relate to the focus areas, as described in the Call. ▪ Projects should address in detail why this Innovation Project could not be developed without EIT Health support and demonstrate the role that EIT Health's support will play in the proposed activity. ▪ Projects should address the concept of Knowledge Triangle Integration by listing the specific EIT Health activities from the Education and Acceleration pillar that will be linked to the project.
Solution Readiness, Feasibility and Project Plan (20%)	▪ The prior work demonstrates that the proposed solution (product/ service /process) has reached the desired maturity level and can be appropriately configured for the relevant domain. ▪ Project plans should be feasible in terms of the timeline, resources allocated and deliverables. Budget distribution between partners and between work packages should be relevant to the tasks to be carried out. Budgets will be a mixture of EIT contribution and partners' own contributions. ▪ Project activities should be well spread between partners' organisations and geographical areas (i.e. different countries or regions). Project organisation should be logical with clear and well-defined work packages. ▪ The milestones that have been chosen should be relevant and realistic for the project's objectives.
Strategy for Implementation (Commercialisation and/or Adoption) (20%)	▪ Projects should describe a clear implementation strategy – to take the innovation to market or to adopt it – identifying the necessary resources and describing how these will be secured. ▪ Projects should present a competitive approach with a clearly defined innovation (product, service, process, organisation, management, etc.). In addition, project teams should demonstrate a clear awareness of the competitive landscape. ▪ Known hurdles (i.e. obvious barriers along the project's path) and potential risks to successful implementation/market launch should be identified, and mitigation plans should be clearly defined.

Impact (20%)	▪ Sound KPIs should be defined. Projects need to ensure that the chosen KPIs, deliverables and outputs fit with the activities' objectives. ▪ Projects should identify measurement of impact and contribution to the healthcare system. Projects need to explain and specify the metrics used to measure the impact, to provide evidence of the expected impact or impact already created by the activity. ▪ Projects should address sustainability. Projects need to explain and specify the future of the activity and prove how it will become self-sustainable beyond EIT Health funding. ▪ Projects should ensure knowledge transfer. Projects need to explain plans to scale and disseminate within the partnership and beyond, and how to share learnings. ▪ In the case of products, assuming the technology/science works perfectly, projects have to demonstrate a potential pathway (regulatory, reimbursement, etc.) to reach patient care within the desired timeframe.
Strength and Commitment of Team (20%)	▪ Projects should demonstrate how they will leverage excellence of involved partners' institutions. Partners having worked together before in similar settings will be considered an advantage. ▪ Projects should show experience of the activity leader and involved team members. ▪ Projects should demonstrate synergies and complementarity of the team. ▪ Projects should demonstrate that the team, coupled with the proposed resources is sufficient for its development and/or implementation. ▪ Projects should demonstrate the clear role and dedication of involved personnel in the activities. Each organisation should fulfil a meaningful role in the project, and this should be reflected in the project description. Key personnel whose roles are critical to the success of the project should be clearly identified. ▪ For-profit partners' own resources (cash, FTEs, infrastructure, etc.) should be committed to the activity. ▪ Projects should demonstrate commitment of partners to develop the outcomes into a self-sustaining activity (e.g. creation of a new start-up; one of the partners in the consortium to bring the project results into the market or to support implementation and maintaining; licensing to a third party etc.). ▪ If there is previous Intellectual Property Rights (IPR) involved, projects should demonstrate that the team has secured support from the institution that controls the IPR (company, university, hospital, etc.) to participate in the initiative.

2.5.9. EIT RawMaterials

EIT RawMaterials' mission is to support innovation that develops raw materials into a major strength of Europe. It aims at promoting new solutions that provide a cost-efficient, secure, sustainable supply and use of raw materials throughout the value chain ranging from exploration, mining, and processing of raw materials, to their recycling and integration into a circular economy (e.g. design and manufacturing of tools and equipment, smart products and services, end-of-life product management).

EIT RawMaterials provides funding and entrepreneurship coaching to early stage start-ups, with a focus on idea-to-market with relevance for the first customer. Business creation and acceleration activities are aimed at transforming innovative ideas and projects into new business for existing large and small companies as well as through the creation of start-ups and spin-offs.

Business Creation and Acceleration activities of EIT RawMaterials are designed to:

- Create and develop new game-changing business across Europe;
- Fast track start-ups and support the commercialisation of business ideas;
- Encourage exchange and networking across different disciplines and businesses;
- Create new entrepreneurial education approaches;
- Provide funding to boost innovation from ideas to commercialisation.

The Accelerator Programme supports new businesses to develop raw materials into a major strength for Europe along the whole material value chain as follows:

- Exploration and raw materials resource assessment;
- Mining in challenging environments;
- Increased resource efficiency in mineral and metallurgical processes;
- Recycling and material chain optimisation for end-of-life products;
- Substitution of critical and toxic materials in products and for optimised performance;
- Design of products and services for the circular economy

Start-up and SME Booster

The EIT RawMaterials "Start-up & SME Booster Program" is one of the EIT RawMaterials funding instruments dedicated to supporting third parties' activities, such as business creation by idea holders and growth support by start-ups and SMEs. It provides support to start-ups and SMEs to develop innovative products/services that can produce an impact in the raw materials sector. It supports promising start-ups and SMEs at regional innovation hubs to validate their business models and connects with the networks of partners.

The aim of the Start-up & SME Booster Program is to provide support to established start-ups:

- To develop innovative products/services that can produce impact in the raw materials sector such as job creation;
- To bring technology development to higher readiness stage to secure future funding steps (such as up-scaling, financing loans and other financing instruments);
- To reach faster the market, e.g. finding potential partners, piloting customers or technology validators from the networking events;
- To gain higher visibility via EIT RawMaterials channels;
- To join the EIT RawMaterials network as member and continue working with its partners to fully benefit from the innovation ecosystem.

Start-up and SME Booster calls are open all year long. The maximum amount of financial support is up to €60 000 per start-up. Funding is attributed based on the proposed activities and submitted budget by the start-up and checked during the pitching evaluation.

Projects supported by the Start-up & SME Booster Program should have one of the following targets:

- Drive proof of concept or feasibility study to increase the technical readiness level;
- To build or expand Intellectual Property portfolio to secure next funding steps;
- Carry out customer validation or pilot testing.
- Expand the market and reach global scale, also through business support services provided by EIT RawMaterials.

The award criteria are as follows:

- Technical excellence, technology readiness level and IP status;
- Business relevance, potential and customer readiness level;
- Quality of the team;
- Quality of the project plan, budget and output;
- Quality of the KPIs and backflow

The application procedure is the following:
Online application including a business plan, illustrating technology, customer needs, market and competition, business model, revenue projections, team composition and expertise, work plan for the booster project, budget required for the booster project, potential benefits for EIT RawMaterials against the provided support.

First screening phase performed by the local innovation hub staff to assess the alignment of the application with the underlying objectives of the EIT RawMaterials. The best applications passing the screening are invited to pitch their idea to the Jury.

Online pitching session and selection by EIT RawMaterials staff supported by external experts who evaluate the applications and select the projects that are granted with the support.

As regards to the Booster program, EIT RawMaterials requests a return (back-flow) in case of success of the recipient company of Booster funding. The definition of success is done together with EIT RawMaterials.

Types of backflow when successful:

- Paying back the allocated Booster funding in full;
- Converting the allocated Booster funding into equity in the venture;
- Becoming member of the KIC;
- Further using EIT RawMaterials service offering;
- Suggesting an own back-flow scheme.

2.5.9.1. Accelerator

The Accelerator activities improve the success rate of market entry of scalable start-ups, focusing on addressing market risk. The Accelerator also includes coaching and instructions on a pan-European level to partners of EIT RawMaterials. It supports scientists, researchers and entrepreneurs in developing their concepts for raw materials innovations into market-ready products and services.

The Accelerator is targeting start-ups that consider they already have an innovative offering and see the opportunity in rapidly developing this offering to the exploration, mining, mineral processing, metal, mineral and steel making and recycling industries as well as their suppliers of equipment and tools. It aims to develop start-ups so that they can rapidly become suppliers to, and perhaps future partners of, the EIT RawMaterials network.

The Accelerator program comprises of three phases: Invent, Build, Grow. There are stage gates between each of the phases, where start-ups need to be approved for entering the next phase. Each phase has specific objectives, process, funding and timeline. The support provided in each phase consists of both group work, individual coaching as well as anchoring start-ups in their local and national ecosystems while at the same time opening up introductions on a Pan-European level to partners in the EIT RawMaterials Innovation Community. The combination of local anchoring and Pan-European opportunities is envisaged to increase the success rate and market opportunities of the selected start-ups.

The evaluation of applications is made by EIT RawMaterials at each of the six Innovation Hubs around Europe, in line with the following criteria:

- Technical excellence, technology readiness level and IP status;
- Business relevance, potential and customer readiness level;
- Quality of the team;
- Quality of the project plan, budget and output;
- Quality of the KPIs and backflow.

The specific characteristics of each phase are as follows.

Phase 1: Invent

Phase 1 is about building proof of concept for the business model in the targeted raw materials market segments. It starts with ideas and aims to find a market niche, to develop a financial model, and to build a business model. Selected start-ups receive €15 000 as funding to cover their costs for participating in Phase 1 of the Accelerator.

Objectives for Phase 1:

- Identify beachhead market, market size, customer pain;
- Identify key value drivers, good margin/product and margin/year, estimate financial needs;
- Compose a founding team, identify roles and coming needs for the team.

Phase 1 has a 3-months duration. It starts with a workshop, followed by calls with experts. It ends with a Graduation Day, where the start-ups pitch their idea and which is also the stage gate to Phase 2.

Phase 2: Build

The purpose of Phase 2 is to validate customer needs and verify business assumptions. The offering provided by the selected start-ups should be at a relatively advanced technological readiness level. Selected start-ups receive up to €30 000 funding to cover their costs of participating in Phase 2.

Objectives for Phase 2:

- Validate customer needs, market size and beachhead market, identify regulations and other specific criteria for technical and market entrance;
- Validate key value drivers, build a 5-years financial forecast supporting/financing needs and strategy;
- Complete a team supporting the next step.

Phase 2 has a duration for 3-6 months depending on individual start-ups development, acceleration, constraints and opportunities. It starts with a workshop, continues with calls and Monthly peer-to-peer sessions and experts talks. The progress of the start-ups is evaluated by a mid-assessment and followed by individual assessment for the start-ups to fulfil criteria and stage gate for continuing to Phase 3.

Phase 3: Grow

Phase 3 aims to get business ready for launch. The offering of the start-ups should at start be at an advanced technological readiness level and heading for market entrance. Selected start-ups receive up to €45 000 as a funding to support their participation in Phase 3.

Objectives for Phase 3:

- Move from early adopters to early majority market, start exploring follow up markets;
- Significant sales or financing deals;
- Expand the team.

Phase 3 starts with a workshop aiming to set tailored project plan for each start-up, which comprises goals and support actions, in order to develop the start-Up's activities in the next 6-9 months. In addition to the continued support of a Business Development Manager from the local Innovation Hub, other support actions could be use of the infrastructure of EIT RawMaterials for tests and pilot studies as well as further linking and introduction to EIT RawMaterials industry partners as validation partners and potential customers. These activities are envisaged as a means to prepare the start-up for future investment rounds as well as providing the basis to scale their business.

Regarding financing of collaborative innovation projects by EIT KICs, EIT RawMaterials supports new entrepreneurs and intrapreneurs to turn their innovative ideas into business opportunities through their innovation ecosystem. This aims to leverage impact through the creation of synergies and will provide a powerful way of maximising opportunities in the raw materials sector and securing the raw materials supply for Europe. Operationally the projects are managed through the Innovation Hubs, which also support the partners in their search for new, innovative projects.

EIT RawMaterials' innovation projects are divided among six themes.

1. Exploration and RawMaterials Resource Assessment: Exploration activities are the initial step in the raw materials value chain but the industry faces an increasing number of challenges and must promote a better understanding and acceptance of the exploration industry within wider society, while securing sustainable, efficient and successful exploration for the future
2. Mining in challenging environments: EIT RawMaterials aims to build up Europe's mineral extraction industry, providing opportunities through the development of innovative, smart and efficient technologies, specialist higher education with an added focus on entrepreneurship, and integration of the entire raw material value chain.
3. Increased resource efficiency in mineral and metallurgical processes: When it comes to processing, European industries and research institutions have both long-standing experience and an extensive knowledge base but still these modern-day solutions face a number of challenges. EIT RawMaterials supports and facilitates the improvement and creation of innovative processing methods and technologies.
4. Substitution of critical and toxic materials in products and substitutions for optimised performance: EIT RawMaterials has identified substitution as a pillar of its strategy to turn raw materials into a major strength for Europe. The current portfolio encompasses projects on topics including energy storage, magnetic materials, hard materials, lightweight design, and materials and systems modelling.
5. Recycling and materials chain optimisation of end-of-life products: The Innovation Community supports innovation projects and new businesses that scale up and introduce new technological solutions to the market. These are aimed at improving both the amount and quality of raw materials recovered from secondary sources, that is, end-of-life products, industrial residues, tailings, and urban and landfill mining.
6. Design of products and services for the circular economy: The challenge for EIT RawMaterials is to fully utilise the potential of industrial symbiosis by applying a systemic perspective and revitalising human capital in the raw materials sector through two strategic objectives: designing solutions and closing material loops.

2.5.9.2. Innovation projects financed by EIT RawMaterials

EIT RawMaterials offers two different means of support for Innovation Projects: 1) up-scaling projects, 2) network of infrastructure accelerator programme.

1) Up-scaling Projects

Up-scaling projects are innovation projects based on validated technologies that need additional step(s) for up-scaling, demonstration or implementation. The objective is to bring the technology to market, as a product, service or process. The technology must be at Technology Readiness Level (TRL) of at least five at the beginning of the project, and corresponding to a "technology validated in relevant environment". At the end of the project, the technology is expected to have reached a TRL of at least seven, corresponding to a "system prototype demonstration in operational environment".

Upscaling projects must aim for market introduction and/or a commercial use within 3 years (or less) after the end of project. Upscaling projects must aim to have an educational component, for example, the inclusion of PhD and/or Masters Projects, internships, contribution to demand-driven Lifelong Learning courses, etc. Upscaling projects are requested to reach a non-EIT/EIT funding ratio of 80/20. The co-funding contributed by the project consortium should be minimum 20% of the total funding. The project duration can be from a minimum of 1 year to a maximum of 4 years.

2) Network of Infrastructure Accelerator Programme

The Network of Infrastructure (NOI) Accelerator Programme intends to support the second phase of project development: commercialisation, within a two-year framed programme.

The Network of Infrastructure activity has the following main objectives:

- Foster innovation by acting as broker among partners and customers
- Create a cluster of excellence, providing access to outstanding infrastructure together with the related knowhow
- Offer and promote an attractive service portfolio, e.g. enabling test bets for pilot-lines
- Link customers and experts inside the network and help to identify the best tailored services in an easy and fast way
- Attract additional customers and increase visibility of EIT RawMaterials and its partners
- Become self-sustainable within a two-year period.

Feasibility and Go-to-market Strategy

Innovation projects need to be based on a solid feasibility assessment, covering important aspects, such as: external context (technical, regulatory, social, environmental, political, etc.), user needs and targeted applications, customer value proposition, target market(s) (size, structure, growth potential, segmentation, etc.), risk assessment, design or market studies, and intellectual property exploration. The ultimate goal is to put a new product, service or process to the market, possibly through an innovative application of existing technologies, methodologies, or business processes, state of the art and technology risk, competitors and competitive positioning, IP protection, business model and exploitation strategy, etc.

Proposal evaluation and selection process

There are three types of criteria for evaluation and subsequent selection of proposals according to these guiding principles:

- Eligibility criteria - mandatory requirements (proposals that do not meet such criteria are not considered for further evaluation);
- Quality criteria - quality criteria against which the collected proposals are scored and ranked by external evaluators;
- Strategy criteria - strategy criteria against which the collected proposals are scored and ranked by the EIT RawMaterials Management Team.
- Eligible proposals are selected based on the quality and strategy criteria ranking. Quality criteria (external evaluation) account for the 70% of the final score, while strategy criteria (EIT RawMaterials evaluation) account for 30%.
- Eligibility criteria
- Eligibility is checked against the following criteria:
- The project consortium must consist of a minimum of 3 KIC Core or Associate Partners, coming from a minimum of 2 different Innovation Hubs and a minimum of 2 different countries;
- The project consortium must include KIC partners from at least 2 sides of the knowledge triangle (education, research, industry/business);

- Non-members are eligible to apply only if they submit an EIT RawMaterials membership application;
- The project cannot have one partner as the Work Package leader in all Work Packages.
- All proposals must include a 'Dissemination and Communication Plan' Work Package, following the communications guidelines included in the document 'EIT RawMaterials Communication and dissemination guidance'

Quality criteria

#	Weight	Description of Criteria
		1. Innovation capacity
1.1	4	Overall rationale for the project's importance and innovation capacity compared with current practice Economic importance of the targeted theme/market (market size, breadth of customers/applications) Potential to deliver tangible results and products, processes or services that have not been delivered by other institutions
1.2	2	Dissemination: Clear dissemination strategy and application (to other countries, on-going initiatives and programmes, links to development in other materials, themes, markets, audiences, partners, etc.)
1.3	1	Synergies: Creation of synergies with other actors in the local ecosystem to create an impact beyond the individual project itself
		2. Quality of the project definition
2.1	3	Clear definition of project objective and overall identifiable output
2.2	2	Clear definition of work packages (WP) with concrete objectives, tasks and measurable deliverables (including for non-technical aspects of the project, e.g., marketing, finance, IP, stakeholder management, regulatory, etc.)
2.3	1	Clear project schedule, with well-defined milestones
2.4	1	Risk management: Identification of key risks (with regards to technology, market, regulatory, financial, stakeholders, managerial etc.) and effective mitigation measures
		3. Quality of the consortium
3.1	3	Soundness of the consortium: Quality and relevance of the leading partner, presence of complementary partners covering the key elements of the value chain, diversity of countries and Innovation Hubs represented in the consortium, Involvement of relevant industrial partner(s), presence of one or several SME(s) as active Task partners
3.2	2	Roles and governance: Clear definition of roles corresponding to the specific strengths of each partner,
		clear definition of project governance structure and of coordination mechanisms among partners

#	Weight	Description of Criteria
		4. Business potential
4.1	2	Technical feasibility of the solution based on the technology(ies) currently available to consortium partners
4.2	2	Innovativeness of the proposed solution, and expected competitive advantage vs. other solutions (already available in the market or in development)
4.3	1	Business opportunity assessment (preliminary, to be confirmed/deepened at end of WP0): value proposition to target customers, market size and expected growth, ability to bring the solution to the target customers, etc.
4.4	1	Clear description of the IP management: background IP, ability to generate new IP, ability to protect, and valorise IP among partners and eventually with the support of the KIC
4.5	3	Quality of the project budget definition: clear explanation and justification of costs, proper balance of costs among partners in line with their assigned roles.
4.6	2	Eligible KCA and KAVA co-funding: relevance of the proposed KCA in support of the upscaling project, and balance in the amount of financial resources (KCA and KAVA co-funding) brought by the different partners (in relevant proportion to the importance of their respective roles in the project).

Strategy criteria

Weight	Description of criteria
7	Strategic importance for the KIC Overall rationale for the project's strategic importance to the KIC Economic importance of the targeted theme/market (market size, breadth of customers/applications) Contribution to de-siloing (countries, Innovation Hubs, disciplines, partner categories, value chain segments, activities) Contribution to building and expanding the reach of the KIC community Effective and comprehensive communication and dissemination plan Clear dissemination strategy and application (to other countries, on- going initiatives and programmes, links to development in other materials, themes, markets, audiences, partners, etc.) Benefit to the partnership beyond the Consortium Creation of synergies with other actors in the local ecosystem to create an impact beyond the individual project itself Involvement of partners from RIS and ESEE region countries Leveraging effect on other KIC activities Collaboration with other proposals, also from other KIC activities Contribution to an overall EIT RawMaterials portfolio that is in line with its strategic objectives Novelty relative to other projects submitted by the same consortium Novelty relative to other projects in the portfolio
7	Expected impact (return on KAVA investment) Realistic assessment of the expected contribution that the project will make to the impact of the KIC in relation to the requested budget With specific reference to the activities, stakeholder interactions, deliverables and objectives, include a clear explanation of how this impact will be achieved Project plan should include a description of expected stakeholders benefiting from the project along with a justification, and details of communication and dissemination plans to stakeholders Other expected quantitative contribution to specific output KPIs and/or scoreboard numbers Clear Description of financial and non-financial benefit provided to the KIC. Support to other KAVA activities, to KIC Customers, or other stakeholders (e.g. public authorities, NGOs, etc.).
3	KCA and other contributions from partners Relevant KCA amount (€) KAVA co-funding brought by partners Balance in the level of resources committed by the different partners Expected financial sustainability for the continuation of the program, if relevant
3	Quality of the proposal relative to requirements Completeness and accuracy of information provided in the proposal Compliance with EIT requirements Alignment with feedback given by EIT RawMaterials on previous submissions (if applicable)

2.5.10. EIT Food

EIT Food supports new businesses across the entire agriculture, fisheries as well as food manufacturing, distribution, consumption and disposal sectors (collectively called agrifood-tech). It aims to provide a full range of programmes and services to support different target groups from students to SMEs, in the creation and the development process of innovative agri-food companies.

EIT Food's services are structured in three segments to match the different target groups of entrepreneurs and SMEs: Explore, Nurture and Scale. In addition, EIT Food provides access to finance services.

2.5.10.1. Explore

Explore activities support talented innovators, entrepreneurs and early-stage start-ups in the pre-seed stage to transform their great ideas and innovations into sustainable agri-food tech businesses. The activities bridge the gap between ideas and results and promote the creation and/or growth of new start-up ventures.

SeedBed Incubator

The SeedBed supports aspiring entrepreneurs interested in building a business in the agri-food sector with a structured scheme to further develop their business idea and validate their business model utilising the lean start-up approach. Graduates of the programme are eligible for the Innovation Grants Scheme where the most promising business ideas can pitch for further financial support from EIT Food.

This multi-location pre-accelerator programme trains and supports teams over a four-month period. Selected teams are provided with the tools, expertise, connections and mentors to help them better understand the needs of their customers and validate their business idea. Through conversations with numerous relevant customers, participants gain invaluable insights to help them build something that customers are willing to pay for, the key requirement to successfully launch a scalable business. At the end of the programme, participants pitch their idea to a panel of industry experts, receiving constructive feedback and the chance to win one of three equity-free cash prizes.

Concretely, participants benefit from:

- A training at a four-day residential bootcamp based on unique customer-oriented methodology, supporting the development of a start-up business model;
- Reimbursement of travel costs to go out and speak to potential customers;
- An invitation to a final event where they pitch their validated business ideas to a panel of industry experts;
- Mentorship by leading agri-food sector players with specialised knowledge and skills to develop food sector innovation;
- The opportunity to win up to €20 000 equity-free cash prizes.
- In terms of requirements, the programme is targeting teams fulfilling the following criteria:
- Composed of at least two highly-motivated and committed members;
- Developing an innovation set to make a big impact on any part of the food sector including the way we produce, deliver, consume and recycle food;
- Not awarded previously significant funding to support market validation of their idea or innovation.

Change Makers

The EIT Food Change Makers programme is a collaborative initiative which gives diverse talent the chance to become agrifood-tech innovators or entrepreneurs through a series of events, mentorship and training. The programme encourages and supports entrepreneurs and start-ups from underrepresented backgrounds (female, persons of colour, etc.) who are currently not well represented in the agri-food start-up ecosystem. Part of this activity involves identifying the core issues limiting participation of underrepresented beneficiaries across all the business creation programmes and implement activities to better support this specific group of talent.

The bulk of the activity focuses on building and nurturing a European community of diverse talent, specifically from the STEM and business sectors, interested in solving challenges facing the agri-food system. Through community activities, diverse talent across Europe is brought together to collaborate and co-create. Structured workshops are offered consisting of training and mentorship, catered to the needs of the community.

Furthermore, access to funding is provided via a grant mechanism. The selected applicants are supported to launch an idea, find co-founders, learn new skills, get a greater understanding about food system issues, connect with an amazing community and pitch for €10 000 worth of support.

2.5.10.2. Nurture

Nurture is for entrepreneurs and registered start-ups who are on their way to transforming the food system and would benefit from EIT Food's high-level support to boost their new business.

Selected start-ups benefit from a structured four-month programme with expert coaching from EIT Food partner companies, investors, and experienced entrepreneurs. The programme runs in parallel in all six acceleration hubs. The start-ups going through the selection process are invited to the EIT Food Venture Summit to compete for three financial prizes. Promising graduates of the EIT Food Accelerator Network may be invited to apply to become members of the RisingFoodStars association and as such become part of the EIT ecosystem and contribute to EIT Food's innovation strategy. Furthermore, those start-ups can also receive additional support in the form of business services.

Innovation prizes

The Innovation Prizes competition is one of Europe's largest start-up competitions in the agri-food sector. Prizes are awarded to entrepreneurs and early-stage start-ups to support the development of new products and services which can help transform the food system, making it healthier, more sustainable and more trusted.

The Innovation Prizes are open to entrepreneurs and start-ups from across the whole of Europe. In each of the finals, there is a €10 000 and a €5 000 prize available. In addition to the cash prizes, participating start-ups benefit from access to investors, high-quality training and EIT Food's community of mentors and experts.

In terms of eligibility, any resident, citizen or legal entity based in an EU Member State or associated countries can apply. However, the proposed products or services must align with one or more of EIT Food's strategic objectives:

- Making the food system better for people's health;
- Making the food system better for the environment;
- Making the food system more trusted and transparent.

EIT Food Accelerator Network

The EIT Food Accelerator Network is a multi-location accelerator programme delivered across Europe, to support high impact agri-food start-ups in order to maximise their success.

The programme is open to agri-food start-up or spin-off companies having less than €1 000 000 in sales and less than €500 000 in investment capital (excluding university and research body funding) with an operative branch in the EU or EU associated countries. Applicants go through a rigorous selection process, judged by a series of experts including successful entrepreneurs, investors and experts from the agriculture and food industries. Successful candidates are invited to join an accelerator programme at their preferred location, either in Germany, Israel, Spain, Switzerland or the UK. Over a four-month acceleration period, they have access to a buffet of tools, connections, mentors and expertise to help to succeed.

At each location all start-ups receive:

- Coaching and mentorship by leading food sector players and world renowned academics with specialised knowledge and skills to develop food sector innovation expertise;
- Both a broad entrepreneurship curriculum and a food focused syllabus, to equip food space start-ups with the knowledge they need to succeed;
- Co-working space for four months;
- Access to technology, pilot sites and international markets through EIT Food's network of partners.

Various amounts of travel grants are awarded to bringing start-ups together from multiple locations and connecting them with EIT Food corporate partners which strengthens the appeal of the programme overall, but also allows the partners to meet start-ups. This creates not only interaction but also the opportunity to explore potential partnerships (e.g. investments, pilot projects, etc.).

2.5.10.3. Scale

Scale elevates high-potential agri-food mature start-ups and early scale-ups to the next level in becoming international game changers.

Rising Food Stars

As an affiliate of EIT Food, the association RisingFoodStars (RFS) allows impactful mature start-ups and early scale-ups to actively engage in EIT Food's activities. This unique network provides outstanding young companies access to knowledge and networks. By joining RFS, companies benefit from access to EIT Food's expert network of partners, programmes, technological infrastructure and entrepreneurship support as well as potential customers and distribution channels. All of this provides the opportunity to significantly accelerate international growth potential. The collaborations between RFS and the other EIT Food partners provide an entrepreneurial and agile innovation culture bringing complementary competences from the entire food ecosystem and unprecedented value to the table, in terms of cutting-edge technologies and innovative business models.

The main benefits of being part of RisingFoodStars Association are as follows.

- Easy access to an unparalleled network of main European companies, universities and research organisations;
- Enhanced European reach to new markets and develop internationally;
- Backing from a trusted network;
- Increased visibility by participating at best-in-class agri-food and start-up events, both in Europe and globally;
- Tailored support in scaling up, investments and the typical pains of a scale-up during membership.

2.5.10.4. Access to finance services

One of the cornerstones of EIT Food's unique smart entrepreneurial development approach is to provide start-ups with access to finance by connecting them efficiently with the right funding opportunities and investors.

EIT Food builds and leads an Investors Community to better connect agrifood-tech start-ups with investors (VCs, Corporate Venture funds, Angel networks, etc.) and facilitate their access to finance at later stages, but also support investors to identify and back the investments that contribute positively to the transformation of the food system. The central component of the Investor Community is planned to be an online, searchable database of EIT Food start-ups, with the objective to facilitate the matchmaking between the investors offer and the start-ups funding needs. The other component is the organisation of personalized thematic events to allow investors to interact with start-ups in a more personal way.

Finally, all members of the Investors Community are invited to the annual EIT Food Venture Summit, where start-ups of the last cohorts from SeedBed Incubator, EIT Food Accelerator Network and RisingFoodStars are made visible to the entire Investors Community, with the organization of workshops, marketplace and one-on-one meetings.

Regarding financing of collaborative innovation projects by EIT KICs, EIT Food has defined six Strategic

Objectives to create impact using a carefully selected portfolio of activities:

- Overcome low consumer trust,
- Create consumer-valued food for healthier nutrition,
- Connectivity and transparency – build a consumer-centric connected system,
- Enhanced sustainability through resource stewardship,
- Educate to engage, innovate and advance,
- Catalyse and support food entrepreneurship.

2.5.10.5. Innovation programmes

EIT Food has four Innovation programmes targeting societal challenges through technology-based products and services with breakthrough potential. Activities are carried out by teams of experts who share an entrepreneurial way of working and an open innovation mind-set.

The four programmes are:

1) EIT Food Assistant

This innovation programme will develop non-invasive tools and on-line information services, and market novel technology that will empower people to self-monitor their Preferences, Acceptance, and Needs (PAN), to make healthier decisions and increase the environmental sustainability of their consumption habits. The activities prioritised in this segment include tools and services to function as:

- Interactive systems to empower consumers allowing them to customize their diet
- Self-monitoring of consumers´ preferences, acceptance and needs

2) Your Fork2Farm

This innovation programme aims at a consumer-centric "fork-to-farm" approach to deliver personalised healthy food at economies-of-scale associated with mass production. It includes and concentrates in people-driven co-creation as a means to boost the development of nutritionally-customised food products with an improved eco-footprint. The activities prioritised in this segment include:

- Natural and functionalised ingredients to produce healthy and customized products
- Fostering novel collaborations between consumers and the food value chain for new, healthier food products
- New food processes to improve the safety, nutritional and sensory profile of healthier food products
- New strategies for reduction of fat, sugar and salt in consumer products

3) The Web of Food

This Innovation programme aims to catalyse the digitalisation of the food system to boost a demand-driven, resource- efficient food production and build trust by increasing the traceability and auditability of food quality, safety and authenticity. The activities prioritised in this segment include:

- Combining digital and sensor technologies to acquire and transmit information through the food value chain
- New engagement solutions using information technologies to increase consumer trust

4) The Zero Waste Agenda

This programme will explore and utilise circular bio-economy pathways by identifying favourable tracks for:

- Optimizing resource efficiency and environmental sustainability
- Generating consumer relevant functionalities
- Creating economic and societal value, and
- Developing novel solutions for future food security.

The activities proposed will develop exemplary and innovative nature-inspired circular bio-economy pilot solutions, serving for up-scaling into wider food system domains. At the same time, they will provoke at the same time a circular-economy mind-set and global engagement to reduce and valorise waste. The activities prioritised in this segment include:

- Recycling strategies, by-products valorisation and the bio-refineries of the future
- New technological solutions to increase the environmental efficiency of the food value chain

Principles applicable to all innovation projects

All proposals for innovation projects need to be aligned with EIT Food's overall vision, mission, and set of KPIs. They must contribute to one of the Strategic Objectives of EIT Food as primary objective to achieve impact; they may specify impact on a secondary Strategic Objective if appropriate. The activity proposals must articulate market need, output and impact, and demonstrate a realistic prospect for market and/or societal success of the proposal including the competitive landscape. The proposals must also include a roadmap for implementation of the results, milestones with measurable go/no-go criteria, expected risks and a dissemination plan. All innovation activities are expected to have a mechanism in place to ensure impact can be sustained beyond the duration of the project itself – this can be financial and/or societal in nature.

Each activity of EIT Food is executed by a consortium of partners of EIT Food, from both academia/ research institutes and industry, representing different areas of the food system, and include at least three members representing a minimum of two different CLCs. Each partner is expected to play a key role in the consortium towards achieving the defined objectives. Consortia of more than five partners are discouraged.

One partner organisation needs to take the lead partner role. The Activity Leader of the Activity has to be an employee of this partner. The Activity Leader is responsible for the project management, and to ensure all outputs, deliverables, impact and financial requirements are achieved and reported. Due to the amount of work this role represents, SMEs and start-ups are discouraged to take this role is Activities.

The Activity structure needs to be broken down into tasks (work packages) including start and end date, milestones with measurable go/no-go criteria and related cost items. The management of each Activity is a mandatory first task. Further tasks can be defined according to the activity purpose. Multiple partners can collaborate in one task, and the same partner can be active in multiple tasks.

The deliverables of the activity (in effect reporting documents) should describe critical achievements in order to be meaningful. They have to be assigned to at least one of the tasks. One Deliverable is compulsory and it is a Dissemination report (including a publishable executive summary of key project findings). Each partner in each task has to specify the costs they will have for that task, broken down into a number of cost categories (such as personnel, travel, equipment depreciation, sub-contracting, etc.).

In addition to the task and budget breakdown, partner consortia must specify how their Activity will contribute to the financial sustainability of EIT Food (e.g. in case the objective is to commercialise a product or process), or will create positive societal impact. This can be done by suggesting a specific mechanism to share with EIT Food a fraction of the value generated by the activity, e.g. by revenue sharing, or by describing the societal impact in a quantified terms. All proposals must demonstrate a dissemination plan including an external communications strategy, as well as a list of risks and associated mitigation measures for the activity.

Proposal evaluation

All proposals are reviewed by panels of well-qualified and experienced reviewers, who have been selected from a pool of reviewers based on criteria for a balance of background (industry, academia, communications, entrepreneurship), and demonstrated expertise in, respectively, food systems, innovation processes, communication, business creation, and/or education, as required for each panel.

Proposals are grouped by Functional Area and then by segment or Strategic Objective before being allocated to a Review Panel. Each Review Panel consists of 3-4 reviewers, one of whom acts as the Chair. Each proposal is reviewed first by reviewers working individually, using the evaluation criteria provided in section 4.2; they also write feedback comments reflecting on pertinent aspects of the proposal. The scores of different reviewers are aggregated before the Review Panel meetings in June.

During Review Panel meetings, proposers are invited to pitch their proposal to the external reviewers, which also includes a Q&A session. The scores for the pitch are added to the scores from the individual reviews. The overall aggregate scores lead to a ranking of proposals, which is then discussed by the reviewers. This leads to the Panel giving a recommendation for each proposal based on the scores and the discussion. The results of the expert review are taken into consideration by the Management Board of EIT Food when making the final decision on which proposals to be selected. The proposals need to form a well- balanced portfolio matching expected available budget and the strategic expectations of EIT Food. Preference is given to proposals which integrate aspects of two or more of the functional areas (innovation, education, communication and business creation).

EIT Food's Supervisory Board takes an active interest in ensuring that the calls for proposal deliver an ambitious, balanced portfolio that makes significant progress towards EIT Food's Strategic Agenda. Independent Supervisory Board members are invited to the Review Panels to act as observers to gain a thorough understanding of the rigour of the review process. Once the portfolio has been constituted by the Management Board, the Supervisory Board is consulted about the results to verify that it is meeting the ambitions and the Supervisory Board approves the Draft Business Plan before it is presented to the Partner Assembly.

Evaluation criteria

Proposals are evaluated using the criteria provided in the table below. Scores range from 0 (not provided) to 5 (excellent).

Excellence	Impact	Quality and efficiency of implementation
Soundness/credibility of the concept, including demonstration of societal or market need	Ambitions of the proposal and contribution to EIT Food's Strategic Objectives (e.g. scope and scale of market or societal impact)	Coherence and effectiveness of the work plan, including appropriateness of the allocation of budget, tasks and resources
Extent to which the proposed activity has innovation potential, and is beyond the state of the art (e.g. breakthrough, novel concepts and approaches)	Contribution to EIT Core and EIT Food specific KPIs, and demonstration of Knowledge Triangle Integration	Appropriateness of the management structures and procedures, including quality management and risk management
Quality of the proposed solution/offering, including appropriate consideration of inter/multidisciplinary aspects	Extent to which the activity strengthens the competitiveness and growth in the context of the European Food System and global markets	Competences, experience and complementarity of the participating organisations and their commitment to the project
Extent to which planned outcomes are achievable within timeframe and budget	Quality of the proposed measures to exploit and disseminate results, including external communication	Robustness of implementation plan beyond the work plan, scale of impact (e.g. route to market, numbers of citizens benefiting)

3. Health policies and investments in the future EU programming period (2021-2027)

3.1. Health innovation and sources for it in the next MFF

The proposal for the new Multiannual Financial Framework (MFF) for 2021-2027 places a strong emphasis on innovation, which is identified as a crucial driver of productivity and economic growth as well as a key means of addressing societal changes.

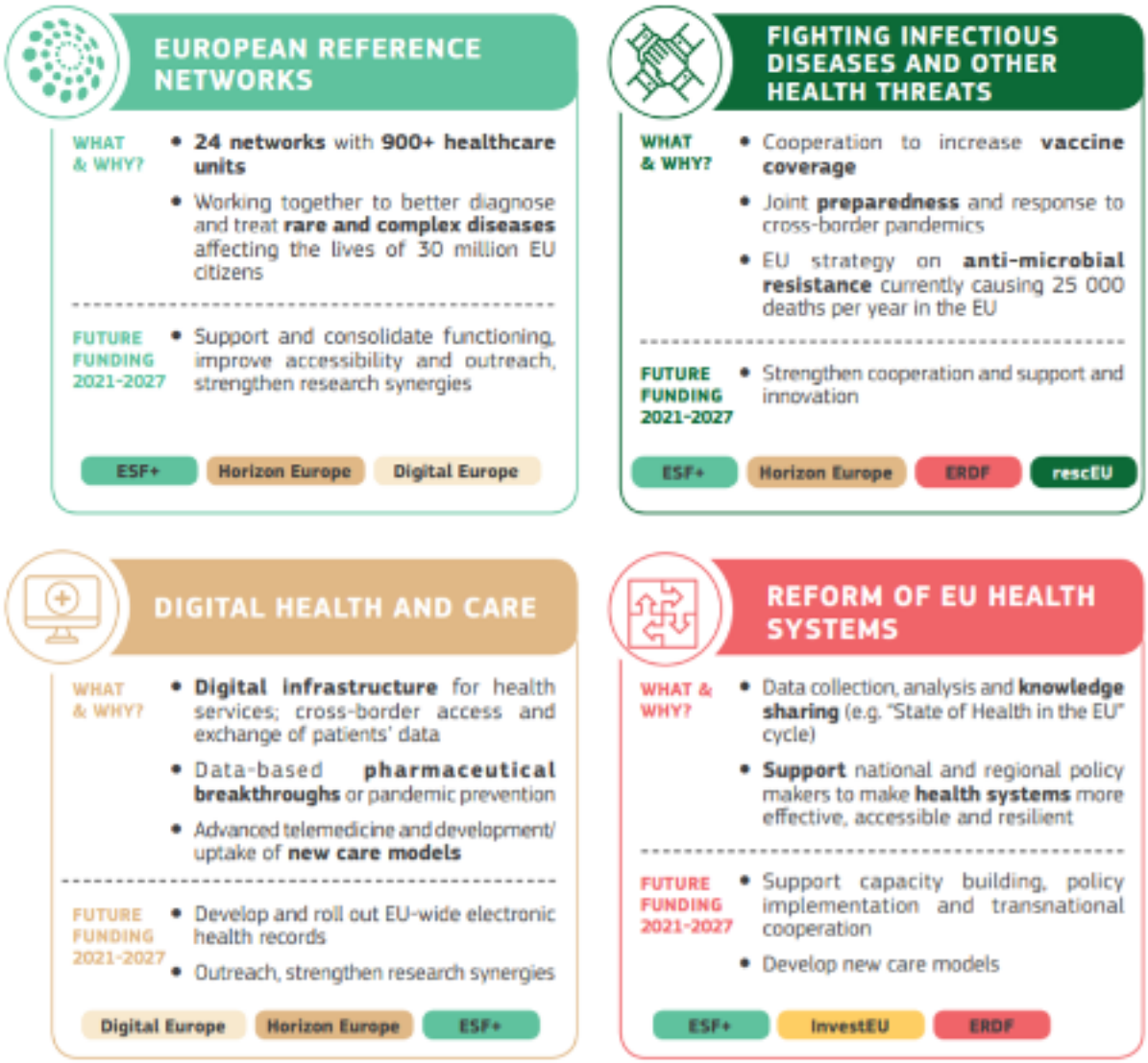
Table 2: Current and proposed MFF headings, 2018 prices

MFF 2014-2020	Commitment	MFF 2021-2027	Proposal	Key shifts
1a Competitiveness & growth for jobs	€144 330 000	I Single market, innovation & digital	€166 303 000	Losses Erasmus+ to II (€26 680 000) Losses nuclear safety to V (€1 190 000 000)
1b Economic, social & territorial cohesion	€373 596 000	II Cohesion & values	€391 974 000	Gains Erasmus+ (€26 368 000) EMU reform tool support (€22 282 000)
2 Sustainable growth: natural resources	€428 783 000	III Natural resources & environment	€33 623 000	Directly comparable
3 Security & Citizenship	€18 023 000	IV Migration & border management €30 829	€30 829 000	New heading, some shifts from 3 to I and II
		V Security & defence	€24 323 000	New heading, some shift from 1a and 3 to V
4 Global Europe (including EDF)	€96 648 000	VI Neighbourhood and the world	€108 929 000	Broadly comparable
5 Administration	€70 812 000	VII Administration	€75 602 000	Comparable
Total	**€1 134 031 000**		€1 134 583 000	

Source: European Commission

To boost the innovation potential of Europe EU funds will assist identifying and eliminating bottlenecks for innovation in the EU. The EU can make a meaningful contribution by identifying structural weaknesses, coordinating research efforts and networks, providing guarantees and funds, and enhancing quality by creating a competitive environment. Additionally, the MFF proposal has a strong health dimension as well: health policies will be funded both through dedicated funding (strand within the ESF+) as well as across other key financial instruments. Financing for health-related activities will be available through the social fund as well as through research, digital market, regional and cohesion funds, and other support mechanisms increasing the impact of health policies.

Figure 13: Financial sources and supported areas of Health in the next MFF



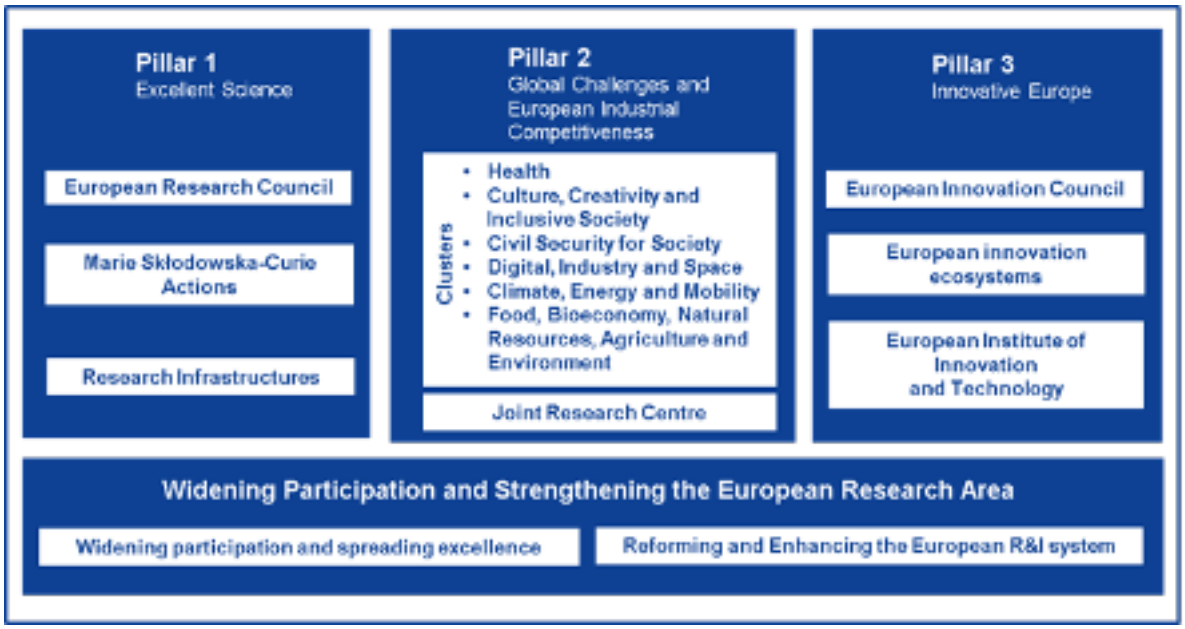
Source: European Commission

3.1.1. Horizon Europe

The EU institutions have reached a **partial political agreement on Horizon Europe**[15]. Namely, it will continue to drive scientific excellence through the European Research Council (ERC) and the Marie Skłodowska-Curie fellowships and exchanges, and will benefit from the scientific advice, technical support and dedicated research of the Joint Research Centre (JRC), the Commission's science and knowledge service. New features including the European Innovation Council (EIC) will be introduced: a one-stop shop to bring disruptive and breakthrough innovations from lab to market application, and help start-ups and SMEs scale up their ideas. In addition to the current activities of the European Institute of Innovation and Technology (EIT), as a new mechanism it will provide direct support to innovators through two main funding instruments, one for early stages and the other for development and market deployment (it is similar to the current SME instrument, however for innovation).

In the framework of the program, health sector will be supported in the following areas:
- Health throughout the life course
- Non-communicable and rare diseases
- Tools, technologies and digital solutions for health and care, including personalised medicine
- Environmental and social health determinants
- Infectious diseases, including poverty-related and neglected disease
- Health care systems

Figure 14: Horizon Europe - Preliminary structure



Source: European Commission

15 subject to formal approval by the European Parliament and Council

3.1.2. European Social Fund Plus

Opposite of the previous programming periods in the 2021-2027 period will be no dedicated health program managed by EC. Instead European Social Fund Plus (ESF+) Programme as cornerstone will serve as the EU's main financial instrument guiding investment in people and implementation of the European Pillar of Social Rights, including health policies. The health aspects of the ESF+ Programme will facilitate synergies with other EU instruments that provide financing to health-related projects. €413 000 000 for the Health strand will finance the next activities:

- Strengthen crisis-preparedness and response in the EU to protect citizens against cross-border health threats
- Strengthen health systems, by supporting the digital transformation of health and care, the development of a sustainable EU health information system and the national reform processes for more effective, accessible and resilient health systems addressing, in particular, the challenges identified in the European Semester
- Support EU legislation on public health (medicines, HTA, tobacco, cross-border care)
- Support integrated work: implementation of best practices to support structural innovation in public health (e.g. ERNs, HTA and implementation of best practices in health promotion, disease prevention and management).

The ESF+ Programme merges existing funds and programmes. Health policies will be funded both through dedicated funding (strand within the ESF+) as well as across other key financial instruments. Besides ESF+ finance for health-related activities will be available through research, digital market, regional and cohesion funds, and other support mechanisms as well.

3.1.3. Digital Europe

The European Commission has proposed Digital Europe programme with a planned overall budget of €9 200 000 000, for building the strategic digital capacities of the EU and facilitating the wide deployment of digital technologies. It have to shape and support the digital transformation of Europe's society and economy and boost investments in supercomputing, artificial intelligence, cybersecurity, advanced digital skills, and ensuring a wide use of digital technologies across the economy and society.
The supported areas and sources for it will be the next:

Supercomputers: €2 700 000 000 will fund projects to build-up and strengthen supercomputing and data processing in Europe, which is crucial for the development of many areas – from health care and renewable energy to car safety and cybersecurity.

Artificial intelligence (AI): €2 500 000 000 is planned to help spread AI across the European economy and society.

Cybersecurity and trust: €2 000 000 000 will be invested into safeguarding the EU's digital economy, society and democracies through boosting cyber defence and the EU's cybersecurity industry, financing state-of-the-art cybersecurity equipment and infrastructure as well as supporting the development of the necessary skills and knowledge.

Digital skills: €700 000 000 will ensure that the current and future workforce will have the opportunity to easily acquire advanced digital skills through long-and short-term training courses and on-the-job traineeships. The Digital Innovation Hubs will carry out targeted programmes to help small and medium-sized enterprises and public administrations to equip their personnel with the needed advanced skills to be able access the new opportunities offered by supercomputing, artificial intelligence and cybersecurity.

Ensuring a wide use of digital technologies across the economy and society: €1 300 000 000 will ensure the digital transformation of public administration and public services and their EU-wide interoperability and facilitate access to technology and knowhow for all businesses, notably SMEs. Digital Innovation Hubs will be 'one-stop shops' for small and medium-sized enterprises and public administrations, providing access to technological expertise and experimentation facilities, as well as advice to better assess the business case of digital transformation projects. A network of Digital Innovation Hubs will be supported.

3.2. EIT in the next programming period

3.2.1. Budget and funding model

In terms of financial resources, the proposed budget for 2021-2027 is €3 000 000 000, which represents an increase of €600 000 000 or 25% compared to the current 2014-2020 multiannual financial framework. The vast majority of this amount (over 95%) shall be devoted to operational expenditure implemented mostly through grants to KICs. The SIA lays down rules for earmarked allocations dedicated to policy areas of specific importance. In terms of indicative annual allocations, the pattern is a slightly upwards curve during the 2021-2027 period, starting with a €403 000 000 budget for commitments in 2021, gradually increasing to €455 000 000 in 2017. This may cause some disruptions in operations as it represents a significant decrease in 2021 compared to 2020, the last annual allocation under the current Horizon 2020 framework programme.

As for financing KICs, apart from financial contributions from the EIT, the following sources are identified in the EIT Regulation:

- contributions from partner organisations, which shall constitute an important share of funding;
- voluntary contributions from Member States, associated countries or third countries or public authorities within them;
- contributions from international bodies or institutions;
- revenue generated by the KICs' own assets and activities and royalties from intellectual property rights;
- capital endowments;
- bequests, donations and contributions from individuals, institutions, foundations or any other national bodies;
- financial instruments, including those funded from the general EU budget.

As a new provision introduced in 2019, the EIT Regulation provides the principle for the revised EIT funding model in the sense that the EIT contribution to the KICs may cover up to 100 % of the total eligible costs of KIC added-value activities only in the initial stages of the KIC life. Such contribution shall gradually decrease over time in compliance with the co-funding rates defined in the SIA (see below). It also emphasizes the importance of financial sustainability of KICs within the EIT's competitive allocation mechanism.

3.2.2. EIT Strategic Innovation Agenda

This Strategic Innovation Agenda (SIA) sets out the strategy and priorities for the European Institute of Innovation and Technology (EIT) for the period 2021-2027, building on lessons learned over the last years of operation of the EIT and the results of a wide consultation process with key stakeholders. The SIA also reflects the Horizon Europe proposal of the Commission that was published in June 2018.

The SIA recognises the strengths of the EIT such as the fact that no other EU action on innovation includes higher education in the innovation value chain to the extent the EIT does. The EIT's education agenda is key for developing highly entrepreneurial and skilled innovators. The focus on global challenges through the integration of the knowledge triangle distinguishes the EIT from other innovation instruments. By providing a grant for up to 15 years to KICs, the EIT is delivering on its long-term objective of tackling global challenges through innovative products and services and bringing concrete benefits to our society and citizens. The EIT also has set the objective to the KICs to become financially sustainable after 15 years, which is a unique feature that leads to a business and result oriented innovation instrument. Through the EIT Regional Innovation Scheme, the EIT has expanded its activities across Europe and offers now opportunities for regions with low innovation performance to engage in knowledge triangle activities as part of the a KIC community.

Notwithstanding the strengths of the EIT model and the EIT Community, the EIT also faces challenges. First, today's economies are increasingly driven by the skills and abilities of people and organisations to turn ideas into products and services. Innovation skills and an entrepreneurial culture make all the difference today, in particular in the technological and scientific domains but increasingly also in other disciplines. There is a strong need to further boost the innovation capacity of higher education institutions in Europe. Second, physical proximity is a key enabling factor for innovation. Initiatives aiming at developing innovation networks and providing services that support the creation, sharing and transfer of knowledge, play a key role in fostering the interactions between business, academia, research organisations, governments and individuals. Still, research and innovation performances across the EU, as reflected in the annual European Innovation Scoreboard, vary considerably. It is of crucial importance that innovation is inclusive and rooted in the local territories. Finally, vibrant innovation ecosystems require a mix of knowledge, infrastructure and talent. Framework conditions for cooperation between European research, education and innovation along with strong synergies need to be in place to ensure proper and efficient investment of scarce resources into research and innovation.

The EIT will continue to support its KICs in order to strengthen the innovation ecosystems that help to tackle global challenges. It will do so by fostering the integration of education, research and business, thereby creating environments conducive to innovation, and by promoting and supporting a new generation of entrepreneurs and stimulating the creation of innovative companies. In line with the challenges identified above, the specific strategic objectives of the EIT in the period 2021-2027 will be as follows:

- Increase the impact of KICs and knowledge triangle integration;
- Increase the innovation capacity of the higher education sector by promoting institutional change in higher education institutions (HEIs);
- Increase the regional outreach of the EIT in order to address regional disparities in innovation capacity across the EU.

3.2.3. Increasing the impact of KICs and knowledge triangle integration

The EIT will continue to support the existing KICs. The integration of the knowledge triangle by the EIT and KICs at EU, Member States, regional and local levels will remain a core task for strengthening innovation ecosystems and making them sustainable, as well as for developing new solutions to global challenges. The KICs will continue to pursue financial sustainability in order to achieve financial independence from the EIT grant in the long-term. The EIT will dedicate a large share of its budget to support KICs. It will monitor and analyse their performance and ensure they deliver towards the objectives of the EIT and of the Horizon Europe Programme. Beyond financial support, based on lessons learned, the EIT will provide strategic supervision to KICs, as well as guidance on horizontal and specific issues. The EIT will facilitate shared services towards the KICs and exchanges of experiences and good practices between KICs and foster collaboration between them. The EIT will take an active part in defining the content and structure of the cross-KIC activities and it will monitor their implementation as well as the results achieved.

The EIT will further increase its regional impact through an enhanced openness towards potential partners and stakeholders and a better articulated regional strategy of KICs, including links to the relevant Smart Specialisation Strategies. From 2021 on, the EIT Health RIS will become an integral part of the KIC' multi-annual strategy. The EIT will continue to provide guidance and support to KICs in the preparation of multi-annual EIT Health RIS strategies and in their implementation. EIT Health RIS activities will continue with improved support to the innovation capacity of countries and regions that underperform in terms of innovation. The EIT budget devoted to implementing EIT Health RIS activities will be at least 10% of the overall EIT support funding to KICs. Activities supported through EIT Health RIS will aim to improve the innovation capacities of the local ecosystem, via capacity building activities and closer interactions between the local innovation actors, as well as to link local innovation ecosystems to pan-European innovation ecosystems through cooperation with KICs and their co-locations centres.

In order to contribute to addressing new and emerging global challenges, the EIT will also launch new KICs. A first KIC in the field of Cultural and Creative Industries (CCI) is proposed to be launched in 2022 with a call for proposals to be published in 2021. This priority field has the strongest complementarity with the eight KICs that have already been launched by the EIT. CCI are still a very fragmented sector and the innovators and business creators lack the needed entrepreneurial and innovation skills. These bottlenecks would be best tackled by a KIC based on the knowledge triangle integration approach. Based on the proposed budget for the EIT, a second new KIC could be launched in 2025 with a call to be published in 2024. The thematic field of that KIC will be selected taking into account the priority areas to be identified in the Horizon Europe Strategic Research and Innovation Plan and the criteria set in the Horizon Europe Regulation for the selection of European Partnerships.

3.2.4. Supporting the innovation capacity of higher education

A new strategic objective and line of action proposed for the EIT is to develop Higher Education Institutions (HEIs) into more innovative and entrepreneurial organisations. EIT has helped to bridge the persistent gap between higher education, research and innovation. In particular, the EIT is a key tool for the development of human capital through its distinctive focus on entrepreneurial education. However, the impact of the EIT remains limited to the KICs' partners. Activities under the new action will be implemented by the EIT through the KICs in an open and targeted way which will aim at increasing the innovation capacity in higher education in order to integrate a wider number of HEIs in innovation value chains and ecosystems. Thereby, the impact of the EIT will reach beyond the KICs and their partner universities. The EIT will in particular target HEIs from countries that are moderate and modest innovators and other low performing regions that wish to strengthen their innovation footprint and Smart Specialisation Strategies. The EIT will allocate to this measure at least 25% of the overall budget allocated to these activities.

3.2.5. EIT cross-cutting activities

The EIT will reinforce its communication and visibility. With a growing number of KICs and the new action supporting the entrepreneurial development of HEIs, the EIT will boost its efforts to increase its recognition as a quality brand for innovation. In order to ensure that a large stakeholder community across the knowledge triangle at EU, national, regional and local levels are aware of all EIT and KIC calls and funded projects, they will appear also in the European Funding and Tender Opportunities Portal, under Horizon Europe.

The EIT will continue running the EIT Stakeholder Forum and the EIT Awards in order to promote the interactions with European actors of the knowledge triangle and recognise the most promising entrepreneurs and innovators in Europe. The EIT will continue to steer and provide strategic guidance to the EIT Alumni Community (in collaboration with the EIT Alumni Board) to maximise its entrepreneurial and societal impact and the continuous involvement of its members in EIT-supported activities.
The EIT will continue to identify and share good practices and will further develop its role as an innovation institute able to detect, analyse, codify, share and ensure the take-up of innovative practices, learnings and results from the EIT-funded activities.

The EIT will seek greater impact of its activities through international cooperation and will coordinate international EIT-funded activities by the KICs.

3.2.6. Changes to the operational and funding model

The SIA proposal by the Commission contains a number of changes to the way the EIT and KICs currently operate.

Measures ensuring continuous openness and transparency of the KICs will be improved notably by including common provisions for new members that add value to the partnerships. They will also run their activities in a fully transparent way. The procedure for the preparation of the Business Plan, including the identification of priorities, the selection of activities and the allocation of funds, will be made more transparent and inclusive. Furthermore, KICs will increase the share of calls, in particular for innovation projects that are open to third parties. KICs' operations will be implemented through a lean, efficient and cost-effective structure that would keep administrative and overhead costs to a minimum.

The EIT will introduce a co-funding rate in order to increase the levels of private and public investments. The adaptation of the funding model will facilitate the KICs in the transition towards financial sustainability. Fixed decreasing co-funding rates will be applicable across phases of the entire KICs' life cycle (start-up, ramp-up, maturity, exit from the EIT grant) as follows:

	Start-up	Ramp-up	Maturity	Exit from EIT grant
Years	1-4	5-7	8-11	12-15
EIT co-funding rate	Up to 100%	Up to 80%	Up to 70%	50% at year 12, decreasing by 10% p.a.

The grant allocation process will be geared more strongly towards competitive performance and results and the use of multiannual grants. The EIT Governing Board will provide stronger incentives to KICs in particular based on their individual performance in order to ensure the highest level of impact.

The EIT will apply strict rules for reinforcing the review mechanism prior to the expiry of the first 7 years initial period of KICs' operations. This mid-term review will be carried out in line with Horizon Europe criteria for the monitoring and evaluation of European Partnerships and will take place before the expiry of the initial seven years period. As a result of the review, a decision will be made by the Governing Board to either continue the financial contribution to a KIC, or to discontinue it.

Finally, the EIT will continue its efforts towards simplification in order to alleviate unnecessary administrative burden of the KICs, allowing the implementation of their annual Business Plan and multi-annual strategy in an agile and efficient way. This will include the use of lump sum or unit costs for relevant KIC activities. Moreover, in order to provide a better planning of the resources, in particular of innovation activities, as well as facilitate stronger commitment and long-term investment from participating partners in KICs activities, the EIT will sign multi-annual grant agreements with KICs, when appropriate, under the respective framework partnership agreements. These multi-annual grant agreements should not exceed 3 years.

3.2.7. EIT relation with KICs after the termination of the framework partnership agreement (after 15 years)

The terms of the EIT's relationship with KICs with which the framework partnership agreements will come to an end in the 2021-2027 period are not fully defined in the Commission's SIA proposal. The Commission proposes that the EIT will define the relations after an in-depth independent study has been carried out in close cooperation with the Commission by the end of 2023. Subject to a positive outcome of a final review, the EIT may conclude a "Memorandum of Co-operation" with each KIC, aiming to maintain cooperation with KICs after the termination of the framework partnership agreement.

3.2.8. Synergies and complentarities with other programmes

Building on its broad scope of action and distinctive role, the EIT will continue to create synergies and provide complementarities with other EU programmes or instruments. Erasmus and EIT will establish synergies between their respective communities in order to ensure access for Erasmus students participating in KIC partner higher education institutions to KICs' summer schools or other relevant training activities. KICs' co-location centres will collaborate with the European Digital Innovation Hubs to support the digital transformation of the industry and public sector organisations. KICs, through their co-location centres

and EIT Health RIS entities, will promote regional and cross-regional cooperation between the knowledge triangle actors and managing authorities, along value chains in related smart specialisation priority areas and the work of the thematic smart specialisation platforms. KICs will contribute to feed the InvestEU Portal in order to bring investors closer to ventures supported by KICs.

3.2.9. Budget needs

The EIT's budget needs in the period 2021-2027 are €3 000 000 000 and are based on three main components: 1) the expenditure for the existing eight KICs (reflecting that for three of them the framework partnership agreements will come to an end by 2024) and the launch of two new KICs (in 2022 and 2025); 2) the launch of a new EIT support and coordination action; and 3) administrative expenditure.

Around €2 500 000 000 is envisaged to fund existing and new KICs, which includes €200 000 000 for the Regional Innovation Scheme. The budget for the launch of two new KICs will be around €300 000 000. The EIT will launch a new support action to help develop the entrepreneurial and innovation capacity of HEIs. This action will require horizontal project management and monitoring services. Around €400 000 000 of the EIT budget is needed to implement these activities.

The EIT will continue to be a lean and dynamic organisation. The costs of administrative expenditure, covering necessary staff, administrative, infrastructure and operational expenses, will increase but on average not exceed 3% of the EIT budget. On this basis, administrative expenditure will therefore be approximately €73 000 000 for 2021-2027.

3.3. EU cohesion policy health funding – present and future

The European Commission delegates the management of certain pro¬grammes to EU countries under shared management agreements. In collaboration with the European Commission, each country prepares an agreement, setting out how the funds will be used during a funding pe¬riod, normally covered by a multiannual financial framework. The current framework runs from 2014 to 2020. EU countries assign the management of EU funding mainly to managing authorities such as ministries and other public bodies. These institutions are responsible for organising and publishing calls for proposals or tender procedures. Health investments under ESIF 2014-2020 should support Member States in achieving EU goals in the health area. ESIF funding can contribute strategically to health goals and health actions can contribute to ESIF objectives aiming at boosting competitiveness and growth and improving quality of life, while ensuring social and territorial cohesion.

3.3.1. Country specific recommendations

In the framework of the European Semester mechanism the Commission proposes health recommendations as well. The latest country specific recommendations included on health and investments in health as part of its ongoing assistance to Member States in implementing their health systems reforms in the light of an ageing population. The Commission recommends that the governments of 16 Member States invest in their national health systems or improve their effectiveness, increase accessibility and strengthen their resilience, with the following recommendations. This year, identifying and addressing investment needs has been a key priority – also with a view to the negotiations about the future Multiannual Financial Framework, the EU's budget for 2021 to 2017:

Table 3: Country specific recommendations on health issues for the examined countries

Country	Recommendation
LT	Increase the quality, affordability and efficiency of the healthcare system.
HU	Improve health outcomes by supporting preventive health measures and strengthening primary health care.
PL	Focus investment-related economic policy on… , healthcare, … taking into account regional disparities.
SK	Safeguard the long-term sustainability of public finances, notably that of the healthcare and pension systems. Focus investment-related economic policy on healthcare, …. taking into account regional disparities.

The adoption of proposals for country specific recommendations is a key step in the European Semester, the EU's yearly cycle of economic, fiscal and social policy coordination.

3.3.2. Ex-ante conditionality and thematic objective

The 2014-2020 ESIF regulatory framework sets out obligatory requirements for compliance with horizontal and sector specific ex-ante conditionalities for the start of the operative programmes' implementation. Health investments in ESIF 2014-2020 must be justified within a coherent policy strategy, based on a needs assessment, and should also demonstrate cost-effectiveness. Ex-ante conditionality 10.3 requires the existence of a strategic policy, budget and monitoring framework in health; as well as the mapping out of current infrastructure and needs for infrastructure investments . Ex-ante conditionality 8.4 on active and healthy ageing requires inter alia to engage with the relevant stakeholders in the design and follow up of policies with a view to retaining elderly workers on the labour market and promote their employment, and to have measures in place to promote active ageing; ex-ante conditionality 2.1 on digital growth (see specific guidance note) requires that a strategic policy framework for digital growth is in place that covers, inter alia, e-health.

In compliance with these ex-ante conditionality health investments can be foreseen under several TOs. According to the ERDF and ESF Regulations, investments in health can be supported under seven of the eleven TOs; five TOs (2 - ICT, 3 - SMEs, 8 - Employment, 9 – Social Inclusion and 11 – Institutional Capacity) explicitly include health interventions as key priorities for ESF and ERDF. In the case of TO1 health is not explicitly covered in this thematic objective; interventions to be financed in the area of health should contribute to Member States' actions in innovation in health, health products and services.

Table 4: Health investments linked to thematic objectives and funds

ERDF	ESF	CF	Thematic objective	Health investments
			1. Strengthening research, technological development and innovation	Innovation in health, health products and services in those cases where health is one of the areas on which innovation efforts are concentrated in the national or regional smart specialisation strategies of Member States Support research in development of new detection methods and treatments; Support collaborative research Support research and related IT infrastructures, including to support health information systems..etc
			2. Enhancing access to, and use and quality of, information and communication technologies	E-health technologies/services (including electronic health care records) Set-up e-health solutions which are compatible with EU standards, ensuring (cross-border) interoperability of IT systems. Support the use of uniform electronic health care information system, electronic prescription system (medicines, referrals etc.), patient electronic medical records, telemedicine and telecare. Create legal basis for e-health (including quality standards/ certification for applications and data management, data protection). Improve IT tools for coordination of response to health threats and for health information systems for EU-level reporting. Support the development of new ICT based solutions and services to address the needs of an ageing population and empower users to use them to remain active and independent for longer…etc
			3. Enhancing the competitiveness of small and medium-sized enterprises	The development of SMEs [for] innovative services reflecting new societal demands or products and services linked to ageing population, care and health Promote awareness among SMEs on "white sector" business opportunities and know-how. Support SMEs' businesses addressing the needs of old people, or 'age-friendly' businesses (e.g. providing personalised care, assisting in functional physical or cognitive decline, improving old people's health literacy), including senior start-ups and entrepreneurship. Encourage private and public enterprises to play a larger role in public-private partnerships in 'age-friendly' areas… etc.
			4. Supporting the shift towards a low-carbon economy in all sectors	

			5. Promoting climate change adaptation, risk prevention and management	
			6. Protecting the environment and promoting resource efficiency	
			7. Promoting sustainable transport and removing bottlenecks in key network infrastructures	
			8. Promoting employment and supporting labour mobility	Member States' actions in relation to the health workforce, to promote active and healthy ageing, to promote people's health as human capital, and to ensure health and safety at the workplace. To support workforce planning in the sector; To support the training and adaptation of the health workforce, and encourage continuous professional development and life-long learning, to match future demanded skills and services; To support measures to enhance the attractiveness of the health professions in rural and remote areas to improve access to healthcare and territorial cohesion within a Member State; To support measures to encourage, train and offer young people work experience in the wide range of healthcare occupations [see also TO 10]. To support measures for good working conditions, career advancement of the health workforce; Promote age-friendly environments to enable older workers to remain at work for longer, and healthier, and utilise the advantages of the elderly workforce; Strengthen prevention, screening and early diagnosis…etc.

		9. Promoting social inclusion and combating poverty	Interventions to enhance access to healthcare services by all with special attention for vulnerable or disadvantaged groups, to reduce health inequalities (thus combating poverty), to modernise mental healthcare, to implement reform and adaptation processes in favour of the transition from institutional-based to community-based and more integrated forms of care, as well as to increase cost-effectiveness and sustainability of health care. Investments in health should contribute to the achievement of the poverty target and increase social inclusion in relation to the Europe 2020 Strategy[16]
		10. Investing in education, skills and lifelong learning	Interventions in relation to formal education and lifelong learning of healthcare professionals. Increase pool of primary care practitioners through, for example, promoting the option at university education level or specific training programmes [also under TO 8] Develop protocols on and include/reinforce in professional education and (lifelong) training programmes, for health professionals and other healthcare workers…etc
		11. Enhancing institutional capacity and an efficient public administration	Interventions to enhance cross-border cooperation and in support of institutional and management capacities of health administration and stakeholders, including in particular to design and implement the necessary reforms (which are recommended under TO 9) to increase health systems' cost-efficiency, quality and sustainability, and to reinforce health systems including in specific areas such as public health surveillance, health security, and, where relevant, major disease management and patient safety.

Source: compiled Nyikos

The European Commission in the new cohesion policy regulation 2021-2027 proposed simplification on thematic objectives; as the 11 objectives will be simplified and consolidated to 5 presented below:

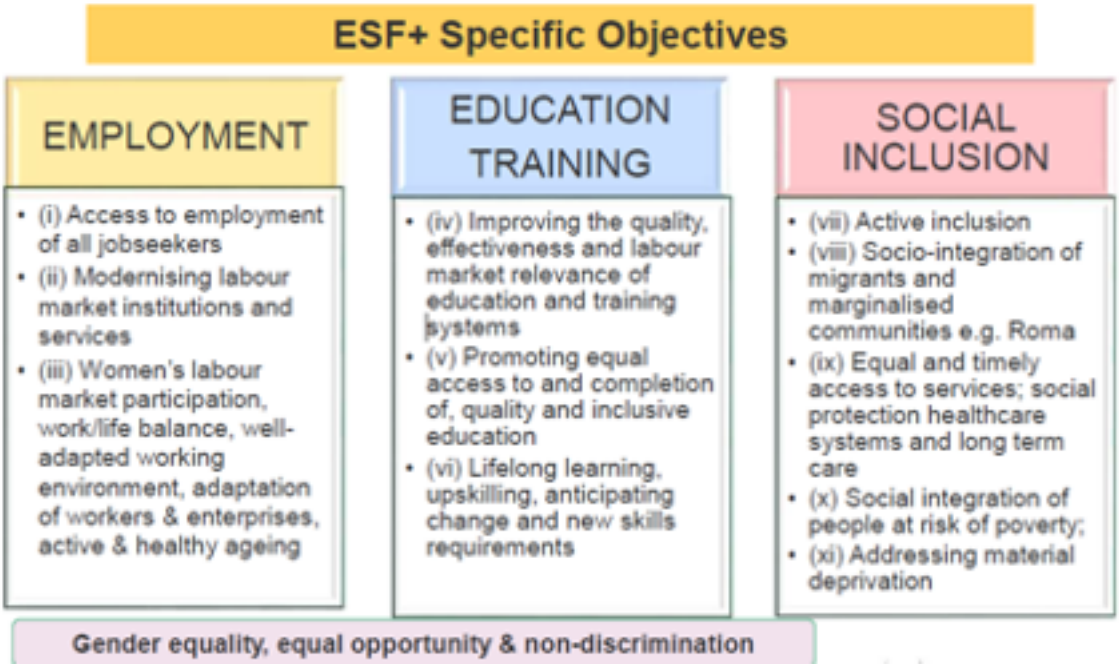
[16] Guidance on Ex Ante Conditionalities for the European Structural and Investment Funds (ESI), DG Regional and Urban Policy

Figure 15: Objective 1 - A smarter Europe by promoting innovative and smart economic transformation

Objective 2 - A greener, low-carbon Europe (including energy transition, the circular economy, climate adaptation and risk management)

Objective 3 - A more connected Europe (mobility and ICT connectivity)

Figure 16: Objective 4 - A More Social Europe – Implementing the European Pillar of Social Rights



Objective 5 - A Europe closer to citizens (sustainable development of urban, rural and coastal areas and local initiatives) with 2 horizontal objectives:

- Administrative capacity building
- Co-operation between regions and across borders (embeds co-operation in mainstream)

Health investments in the 2021-2028 period can be foreseen under thematic objective 1. and 4. and both of the horizontal objectives.

From the ESI Funds the European Regional Development Fund and the European Social Fund could finance health investments. For the 2021-2027period the European Regional Development Fund will maintain spending in the key areas for growth and jobs and European Social Fund + will have three priorities linked to the pillar of social rights

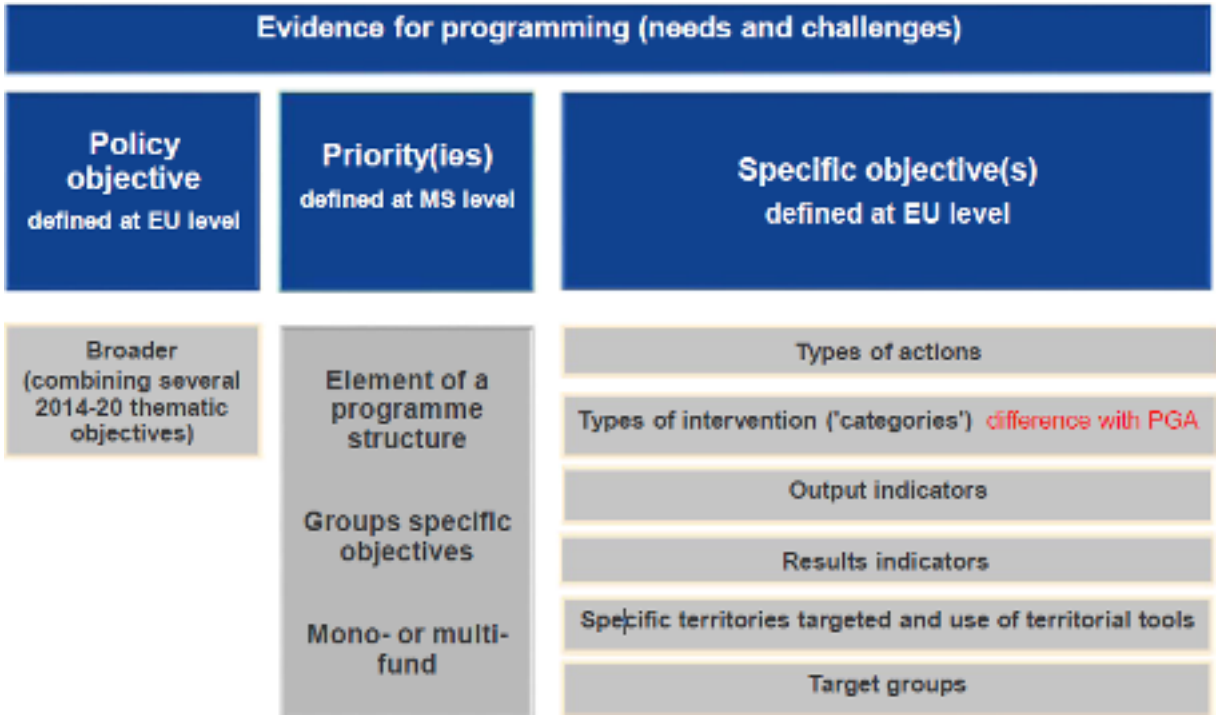
1. Equal opportunities and access to the labour market (including quality and inclusive education and training systems)
2. Fair working conditions and
3. Social protection and inclusion.

and all of them could be relevant for health development project.

3.3.3. Operational programmes

Operational programmes are detailed plans in which the Member States set out how money from the European Cohesion Policy ESI Funds will be spent. They can be drawn up on geographical bases for a specific region or a country-wide horizontal thematic goal as sectoral operational programme (e.g. Environment). Member States submit their operational programmes on the basis of their Partnership Agreements. The calls are based on the operational programmes thus in this cascade programming documents the strategic decisions and the main conditions of the grants are laid down in the Ops. Most part of the calls (objectives, indicators, eligibility rules … etc.) are already determined either by regulations or by the programming documents (Partnership Agreement and operational programmes).

Figure 17: Programme structure post 2020



Source: European Commission DG REGIO

The legislative proposal for the period 2021-27 illustrates the continuation of efforts to advance synergies between Horizon Europe ("European excellence") and ERDF ("regional relevance", smart specialisation, innovation diffusion). In this aspect, great importance has been attached to the reinforced seal of excellence mechanism. "For operations awarded a Seal of Excellence certification, or selected under the programme co-fund under Horizon Europe, the managing authority may decide to grant support from the ERDF or the ESF+ directly, provided that such operations are consistent with the objectives of the programme." This tool is not applicable to H2020 only but can be employed for also other Union policies, e.g. Life+, Single Market Programme, Digital Europe or Erasmus+ programmes. Practical implications are as follows:

- there is no need for subjecting the project in question to a formal selection procedure under the operational programme, provided that the project contributes to the programme's objectives
- the co-financing rate of the other Union policy applies, and otherwise the CPR rules apply (also programme co-fund)
- progamme co-fund under Horizon Europe may receive support from the ERDF, ESF+ and the EMFF
- joint financing of an operation may the form of splitting by costs or applying a pro-rata split, whereas the rules governing each Fund apply to respective contributions

An operation may receive support from one or more Funds or from one or more programmes and from other Union instruments. In such cases expenditure declared in a payment application for one of the Funds shall not be declared for either of the following:

(a) support from another Fund or Union instrument;

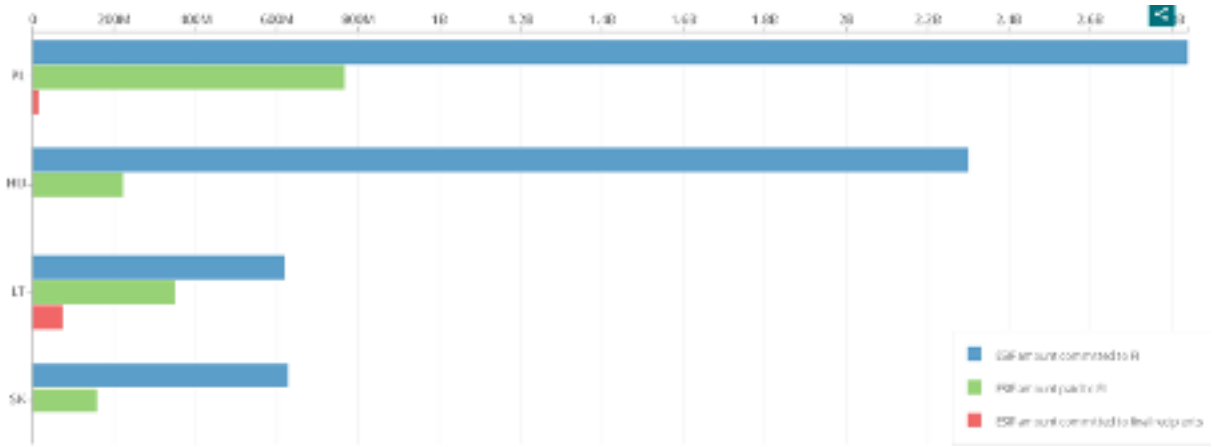
(b) support from the same Fund under another programme.

The amount of expenditure to be entered into a payment application of a Fund may be calculated for each Fund and for the programme or programmes concerned on a pro rata basis, in accordance with the document setting out the conditions for support.
Financial instruments

The using of the cohesion policy sources for financial instruments is not a completely new phenomenon. Financial instruments have been used for delivering investments for Structural Funds since the 1994-1999 programming period. Their relative importance has increased during the programming period 2007-2013 and 2014-2020 as well, and according to several experts and policymakers these are expected to be the future of the cohesion policy (Nyikos-Soós 2018).

Their use has been promoted because of the added value of revolving instruments compared to that of grants in terms of the efficiency of use of public resources. Secondly, by unlocking other public sector funding and private sector resources through co-financing and co-investment, FIs aim to increase the overall capital available (Nyikos 2016). Additionally, the private sector participation enables policymakers to make use of private sector skills and expertise in areas such as identifying investment, decision-making, management of commercial operations and the ability to achieve returns.

Figure 18: ESIF Amounts committed / paid to Financial instruments by Member State



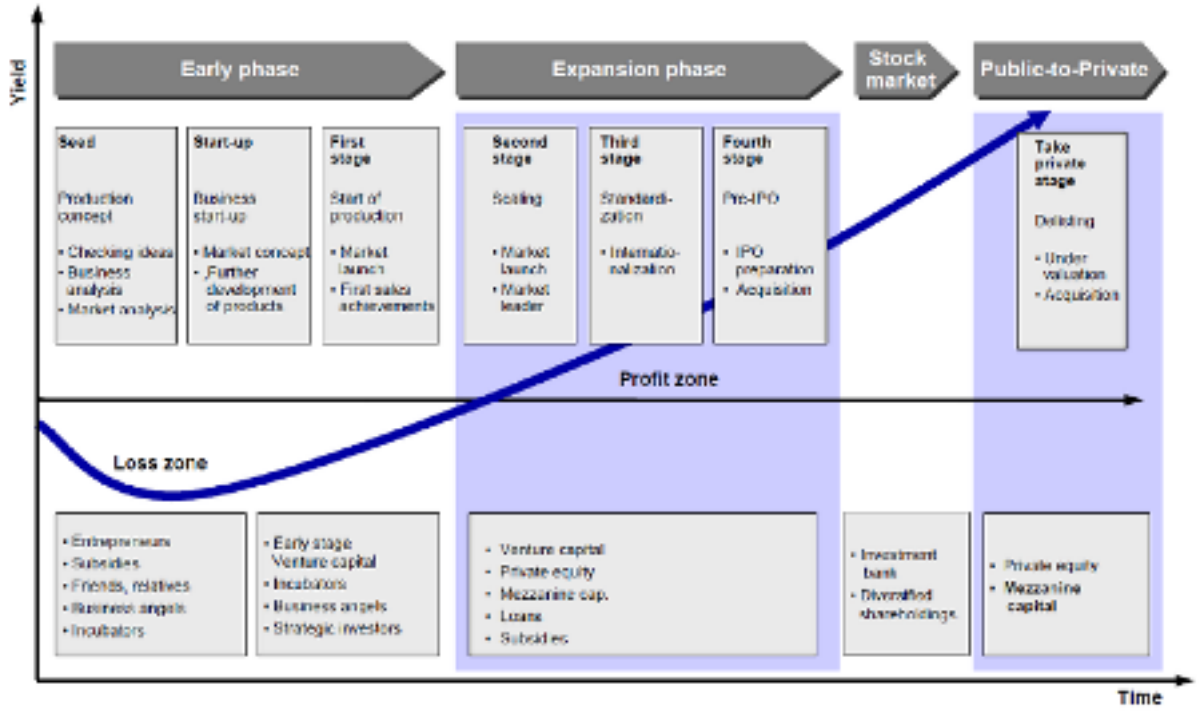
Source: Nyikos, data from the European Commission

However, because of these repayable natures at the use of financial instruments a shift from traditional grant financing is necessary: the project should be revenue-generating and financially/economically sustainable. For the preparation of this kind of economic viable project besides the knowledge of the functioning of the different funds also market analysis and business planning is needed. For a revenue-generating investment project as a starting point a business idea is a must: a product with market potential. The preparation starts with consideration of potential market, customers and price (revenue), competitors, costs, risks and obstacles, implementation process and possible funding sources.

Because of the funds are coming from the EU budget via operational programmes there are several rules for what and how the use of these sources are possible. They are coming from EU financial rules, cohesion policy rules, state aid rules and occasionally from national regulations as well as from the exact conditions of the bank's/fund manager's finance.

Also the project and the firms behind them are different and accordingly the access to finance has different conditions: as firms move from seed and early stage to later stages of development or the project is more mature and economically viable, the investment risks so the risk of the non-paying decline. However, there are also potential market failures at the later stages of a company's development and a number of countries have programmes addressing the growth and expansion stages.

Figure 19: Life-cycle of a firm and stages of financing



Source: Policies for Seed and Early Stage Finance FINDINGS FROM THE 2012 OECD FINANCING QUESTIONNAIRE 2013

Very important development at the use of financial instruments is that the Common Provisions Regulation (CPR)[17] makes it clear that more types of combination may be possible[18]:

- combination of different programme contributions and different funds in one financial instrument; and
- combination of financial instruments and grants and other forms of assistance.

The advantage of using the combined solutions can be the achievement of critical mass and economies of scale as well as a wider spectrum of policy objectives. In the "Guidance for Member States and Programme Authorities on Combination of support from a financial instrument with other support" the Commission presented two types of combination of support: within a financial instrument operation (a single operation) and at the level of the final recipient (combination of two separate operations). According to the guidance, grants can be combined with the FI in a single operation if they are directly related to the FI and target the same final recipients. However, separate records must be kept for each form of support. Alternatively, final recipients supported by an ESI Fund FI may also receive assistance from another ESI Fund priority or programme or from another instrument supported by the EU budget. Yet again, separate records shall be maintained for each source of assistance[19].

[17] Regulation (EU) No 1303/2013 of the European Parliament and of the Council of 17 December 2013 laying down common provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund, the European Agricultural Fund for Rural Development and the European Maritime and Fisheries Fund and laying down general provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund and the European Maritime and Fisheries Fund and repealing Council Regulation (EC) No 1083/2006.

[18] Art. 37(7) CPR

[19] NYIKOS, Research for REGI Committee - Financial instruments in the 2014-20 programming period: First experiences of Member States, European Union, 2016.

4.4. InvestEU

For the 2021-2027 programming period the Commission proposed to create the InvestEU Programme, bringing EU budget directly managed financing instruments (loans and guarantees) under one roof (see in 2.4. section). InvestEU has to bring together financial programmes currently available and boost job creation, investment and innovation.

The new programme will consist of the InvestEU Fund, the InvestEU Advisory Hub and the InvestEU Portal. The Commission proposed €15 200 000 000 for the InvestEU Fund, which would allow the EU budget to provide a €38 000 000 000 guarantee to be used to support strategically important projects across the EU. The InvestEU Fund supports four policy areas – sustainable infrastructure; research, innovation and digitisation; small and medium-sized businesses; and social investment and skills.

The budget guarantee is divided between the policy areas as follows:

Sustainable infrastructure:	€11 500 000 000
Research, innovation and digitalisation:	€11 250 000 000
SMEs:	€11 250 000 000
Social investment and skills:	€4 000 000 000

The InvestEU Advisory Hub will integrate the 13 different advisory services currently available into a one-stop-shop for project development assistance. It will provide technical support and assistance to help with the preparation, development, structuring and implementation of projects, including capacity building. The European Investment Project Portal brings together investors and project promoters by providing a database, giving projects more visibility and enabling investors to find investment opportunities in the sector or location of their interest.

When blending grants from other programmes like Horizon Europe, the Single Market Programme or the Connecting Europe Facility with support from InvestEU, InvestEU rules will apply for the entire project.

4. Project-financing by using different funds together

4.1. Integrated funding and programming

An important question is how to use the limited resources available in the most efficient and sustainable way. The assessment of development policy interventions and the question of successful absorption of development funds shifted clearly towards stronger enforcement of aspects efficiency and effectiveness. There is clearly a need for an integrated approach to deliver an effective and sustainable response.

Accordingly, an important principle of 2014-2020 programming period is integrated funding and programming. This serves not just to provide improved coordination, but also to achieve integrated development.

In the health sector, integrated funding can help ensure the more effective interlinking of actions to address problems. For example, activities comprising equipment purchase, disease prevention programmes, screening examinations, training for medical staff, etc. could be combined. Indeed, it is unlikely that systemic change and improvement in the way services are delivered can be achieved within the confines of a single fund.

The improvement of the effectiveness of R+D+I included health initiatives through improved coordination, synergies and complementarities between cohesion policy, H2020 and other direct managed programmes (e.g. Health for Grow or European Union Programme for Employment and Social Innovation ("EaSI")) has been long on the agenda.

Table 5: Differences between Horizon and Cohesion Policy

Horizon	Cohesion Policy
Focus on European research and innovation excellence	Focus on regional relevance and economic transformation, based on smart specialisation strategies
Focus on frontier research, generation and exploitation of new knowledge and disruptive, market-creating innovations	Broad innovation concept; focus on diffusion and exploitation of existing knowledge & technology to places that need it
Quality-based competition for funds, incl. beyond EU	Focus of support on where it is most needed inside the EU
Predominantly trans-national projects and consortia	Predominantly "mono-beneficiaries" or actors in the same country/region (exception: Interreg)
Focus on R&I activities and "R&I community" in view of contributing to other policies	Focus on R&I capacities and innovation ecosystem development, as one part of a comprehensive policy with sustainable& inclusive growth and a broad partnership

Source: Peter

Despite the clear and useful goal, the practical implementation of it is complicated mostly because of the not harmonized different regulations and the lack of knowledge needed for this.

"The potential for different grant based funding sources is presently limited. This is due to different regulatory and administrative requirements as well as different timings for funding calls and subsequent evaluation of applications. The instrument specific regulations can be difficult to reconcile with the CPR.

- *Different implementation rules of ESI Funds and other EU instruments delivered through grants can hamper complementarity.*
- *The content and timeline of interventions, selection criteria for projects financed from the operational programmes do not allow giving support to projects that have passed successfully the Horizon 2020 evaluation threshold but could not be funded for lack of Horizon 2020 budget. The same applies to other centrally managed programmes.*
- *Different cost categories may apply to projects funded e.g. by H2020 and ESI Funds (different items are eligible for funding).*
- *Differing reporting obligations increase administrative costs for beneficiaries.*
- *Auditing projects jointly financed from an operational programme and centrally managed funds requires different knowledge (e.g. options for synergies, extra-territorial funding, eligibility issues).*
- *Inefficiencies and inconsistencies between ESI Funds and certain other instruments arising from overlapping grant regimes.*
- *Difficulties in accessing user-friendly information and guidance hinders the leveraging of funding opportunities[20]"*

[20] For further details see „Study on the coordination and harmonisation of ESI Funds and other EU instruments, Final Report"

The fine-tuning of the 2014-2020 EU legislation and allowed for more harmonised terms, definitions and principles. Specifically, the cohesion policy regulation (CPR) enabled the

- cumulating of grants which means the financing of the same project or beneficiary from various funds,
- alignment of cost models, namely the employment of simplified cost options (scales of unit costs, lump sums and flat rates) for corresponding costs and similar types of operations and beneficiaries in Horizon 2020 and other EU programmes,
- within limits, the use of funds outside the programme area.

Synergy is about building meaningful interactions between investment strategies and interventions. It implies joint or coordinated efforts to achieve greater impact and efficiency. Synergy in relation to joint ESIF and H2020 contributions is "*combining place-based innovation investments in smart specialisation priorities with world-class research and innovation initiatives, thus ensuring a higher impact of the funds*"[21].

Synergies may be of strategic nature (e.g. alongside the realisation of S3 priorities) or achieved at the project level in various manner:

- **up-stream**: national authorities may decide to funding actions that build research and innovation capacities of actors aimed at participating in the Framework Programme/Horizon 2020 or other internationally competitive research and innovation programmes, including among others,
  - research infrastructure: universities, competence centres, etc.
  - innovation infrastructure and equipment: pilot lines, LivingLabs, FabLabs, Creative Factories, science and technology parks etc.
  - upgrading skills base: creative thinking, design, e-commerce etc.
  - advisory services for potential Horizon 2020 applicants
- **down-stream**: national authorities fund market uptake for the results of H2020 or other internationally competitive research and innovation programmes including, among others
  - early product validation, first production actions, pilots, prototypes
  - supporting the development of advanced manufacturing capabilities
  - funding collaborative research actions linking SMEs and universities/public research bodies
  - market introduction and expansion of productive capacities
- **parallel projects** where operational programme and H2020 funded projects complement each other
- **single project**: national authorities may choose to contribute to the same project financed from H2020
- **take-over projects**: national authorities may decide to take up high quality, positively evaluated project applications from centrally managed programmes in short of finance.

The need for actual and proven complementarity should be re-emphasised here, a pure and technical combination of ESIF and H2020 sources in the same project does not meet the term.

[21] Synergies between H2020 and ESIF and CEF, https://www.transport-ncps.net/wp-content/uploads/2018/12/Synergies.pdf

The Omnibus regulation[22] offers an additional option for combined projects. The expenditure can be reimbursed from the ESIF funds and centrally managed programmes on a pro-rata basis as set out on a written agreement (usually the grant contract which sets out the conditions for support) concluded at the time of the grant signature.

However, certain constraints have remained valid, these include the prohibition of

- substituting national/regional or private co-funding (own resources) to EU projects under direct Commission management by ESIF money (and vice versa),
- double financing: in no circumstances shall the same cost (element) be financed twice by any budget
- diversion of funding from the purpose of the respective instrument or ESIF programme
- cumulating grants in the same projects under the Erasmus+, Creative Europe, CEF and COSME rules.

Organising joint contributions to R+D+I activities pre-supposes a systemic approach. For that reason, the arrangements for coordination between ESIF and other EU and national funding instruments and with the European Investment Bank had to be **outlined in the programming documents**.

Also the "*MLE on National Practices in Widening Participation and Strengthening Synergies: Summary Report*"[23] recognised and articulated importance of governance structures to unlocking potential at a systemic level. The document proposed to improve communication and coordination between the relevant managing authorities and the bodies responsible for H2020-related activities so that optimally targeted actions enhance skills base, business-research-university networks and participation in H2020.

4.2.Project financing – financing the project

To finding appropriate and eligible financing for development investment project a proper baseline analysis needed.

One important evaluation element is whether the project is sustainable and possible economically viable or not: for this, a basic factor is income-generating ability. The next step measurement of the possible income compared with the investment and operating costs to be decide about necessary type of financing (grant versus financial instruments or commercial tools). For both grants and FIs the starting necessary examination steps are the following:

1. Market potential. Project targets a clear and validated need (including a market/technology gap) with demand/market (commercial value that can be addressed).

2. Value proposition - Offers a credible and well evidenced unique value proposition, consistent with the need identified and current solutions (competition)

3. Risk - technical and operational risks have been identified and addressed as far as possible in relation to the stage of project implementation. Risk are sound and their estimation is presented and clearly investigated.

[22] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 66/2012

[23] https://rio.jrc.ec.europa.eu/en/library/mle-national-practices-widening-participation-and-strengthening-synergies-summary-report

4. Financial coherence has an established or proposed operational cash flow model (costs and revenues) which is consistent with the objectives and ambitions of the project.

5. Investment proposition – Project demonstrates actual or potential "sustainability" for grants and/or 'bankability' i.e. return on investment for loans/equipment/guarantees

For financial instrument financing the project should be revenue-generating and financially sustainable. For the preparation of this kind of economically viable project besides the knowledge of the functioning of the different funds also market analysis and business planning is needed. For a revenue-generating investment project as a starting point, a business idea is needed: a product with market potential. The preparation starts with consideration of potential market, customers and price (revenue), competitors, costs, risks and obstacles, implementation process and possible funding sources.

Table 6: Indicative list of services needed for project finance preparation

Service	Service content	Further content
Business advisory services		
Product/service/ market	Review of product/ service and early adopters	Assessment of the product/ service to isolate and analyse key features, such as market position, paths to market, features that differentiate it from the competition etc. To include information on early adopters including strategic information on their success to date, and their potential to provide ongoing user feedback.
	Review of the market	Research and summary of market trends and conditions (national, European, global) with a focus on macroeconomic trends, demand drivers, emerging technology and key IP holders, geopolitical developments, and other commercially-relevant considerations.
	Review of the competition	Development of a competitor matrix with an overview of the positioning of the competition, together with their strong points and weaknesses, as well as identification of new entrants and impact of innovative / disruptive technologies in the short and medium term.
Product/service/ market	Review of the Unique Value Proposition (UVP)	Market research focussed exercise to isolate and understand the UVP, identifying scope for additional value creation.
	Review of unfair advantages and IPR	Assessment of blocking IP rights from state aid, subsidies and other similar advantages considered unfair to free competition with incumbent competitors.
	Review of the investment project	Reviewing the investment project that has been put forward. Understanding the capital expenditure, its implementation period, costs (opex), operational life cycle, and projected revenues. The investment has to be reviewed as a whole. Different scenarios will be modelled out in order to compare them. Understanding how the investment project will help to increase (actual or new) market size, the company's market share, profitability or steps to preventing it being put out of the (current) market.

Business model	Financial business plan review	Understanding of the initial Financial Business Plan and review of the mathematical correctness, structure, flexibility / adaptability and readability of the model: checks of inputs, calculation and outputs to understand and control that the model is logically built with no material errors (financial model review).
	Review the business model	Discussion, understanding and assessment of the initial business model and listing of additional/alternative prioritised business models options and components to be elaborated.
	Business model improvement	Discuss and propose improvements to the Business Model and its translation in the Financial Model projections: getting concise, motivated and clear outputs for the base case.
Operations	Review of the operations	Information on turnover rate, segregation of responsibilities related to accounting and finance, protections against fraud and misconduct, inventory turnover, human resources plan and policies.
Team/HR	Review the Team/ HR	Assessment of the Human Resources development plan. The information provided in the respective business plan will be used to review the project team and provide recommendations to integrate, further develop it, including motivate and retain key personnel.
Marketing and sales	Review of the marketing strategy	Assessment and refinement of project marketing strategy (if it exists); or development of a unique marketing strategy. To include where appropriate: balanced scorecard, sales and price policy, customer relationship, management strategy.
	Review of distribution and sales channels	Critical analysis of downstream channels and end-user needs, with the aim of identifying logistical cost savings/ efficiency improvements, scoping additional paths to market, refining distributor networks (where applicable), and diversifying platforms utilised.
	Monitoring process and KPIs	Reviewing feedback mechanisms to improve the responsiveness of marketing and sales to changing user demands and/or underperforming marketing/sales activities. Revising the utility of current KPIs and/or introducing and setting new KPIs where appropriate.
Revenues	Review of revenue streams	Identifying the different types of revenue streams. For every revenue stream the volume driver and the price driver has to be identified. These can then be used to analyse the revenue stream and to create different scenarios for business modelling purposes.
Costs	Review of cost components	Identifying the different types of costs (fixed or variable). Identifying cost drivers and the volume drivers. The drivers can be used to better understand the cost items.

Cash flow analysis	Review of cash flow statements and of indicators such as the financial internal rate of return (FRR)	Calculation of the financial profitability of the rates of return to the holders of equity, therefore providing indications about improvements in the financing structure of the project.
Investment plan	Review/analysis of pre money valuation, including intangible assets	Auditing with technological, legal and market dimensions, to assess the quantity and the quality of intellectual property assets owned by the investee/promoter and an estimation of the importance and value of these IP assets based on their capacity to generate future revenues.
	Analysis of the financial mix with advice on the best available options and the combination of existing funding instruments	Analysing the business model, the available sources, the current company structure and identifying the optimal financing structure for the project based on the company's current situation.
	Information on the costs of funding	Assisting in the market sounding, or in proposals through talks with financial institutions/other sources of funding, with respect to the cost structure of funding.
	Market sounding	Analysing feedback from the market to ascertain whether there is appetite for a certain way of financing, and under which conditions this could be done.
	Analysis of the availability of other sources of funding at regional and national level; identification of difficulties/eligibility criteria	Checking whether a company can apply for a certain subsidies, grants, tax incentives for innovations, research or investments. Identifying EU incentives and/or financing solutions
	Risk analysis and advice on improvements to minimise investment risk for investors	Identification of risk factors and determining maximum risk thresholds. Analysing how risk can be avoided (e.g. through alternative financing structures). Quantification of the risk, where possible.

Legal services		
The investment vehicle/fund management company	Review of the investment vehicle	Identification of the contractual and legal structure (i.a. within existing structures, new company as affiliate or joint venture between parties, legal jurisdiction, limited liability, minimal capital requirements, limited recourse structure, shareholder structure, fiscal treatment of profits and profit disbursement policy)
	Review of governance rules	Identification of governance structures with powers and delegations at the level of Shareholders, Board of Directors and Management Team; Role for independent directors; Control structure; Internal and external audit; Reporting process.
	Advice to project promoters on appropriate project governance and management;	Based on the identified legal structure and governance rules, advising on the areas of potential improvements to project governance and management from a bankability point of view
	Legal advice on implementing innovative governance approaches	Identification of and recommendations on how to remove regulatory obstacles to innovation and investment. Based on the identified legal structure and governance rules, advising on the areas of potential improvements on removing regulatory obstacles from a bankability point of view.
Regulation	Legal advice on sectoral regulations, regulations related to the execution of the project, intellectual property rights, permitting procedures and other regulatory issues related to the investment project	Identification of areas of improvement from a legal framework point of view to improve project management, IPR and regulatory issues.
	Legal advice on potential options for regional innovation grants related to the execution of the project;	Identification of legal actions necessary to facilitate and obtain regional Innovation grants.

Assistance in the planning implementation of the investment and in the application for financing		
Road-mapping	Preparation and review of an implementation roadmap for the execution of the project (including identification of main milestones for all stages).	Identification of the relevant steps based on the chosen financing solution, including identifying and shortlisting potential financial institutions/investors, sending out NDAs, teasers and Information Memorandum, project presentations and Q&A process with financial institutions/ investors; progressing the due diligence process, getting credit / investment committee approvals, evaluating proposals, selecting the most favourable offer, drafting and negotiating of legal documentation, and contract and financial closure.
Due diligence preparation	Preparation of project promoters for due diligence process by financial institutions, information about usual expectations of financial institutions;	Performing preparatory due diligence on the company and project to see whether it complies with financial institution and/or the EIB requirements for a certain loan/warranty.
Contacting financial institutions	Assistance to project promoters in contacts with public or private financial institutions.	Setting up contact between the clients and the possible financiers: MAs, NPB, EIB Group, fund managers or financial intermediaries in order to obtain financing for the projects.
Presenting to financial institutions	Support in the preparation of the pitch desk to present to selected investors.	Assisting and improving the pitch presentation in order to clarify the core message by providing complete and relevant information, focussing on key investment highlights, explaining risk mitigating actions, anticipating questions and delivering the message in an attractive manner that increases the attention of the financial institutions (e.g. by organising a 'dress rehearsal' of the presentation with management).

Source: Ecorys and Nyikos

With all these additional layers the preparation of revenue-generating investment projects for possible financing by loans, guarantees, equity and other risk-bearing mechanisms, with a possibly of combination of grants are a complicated exercise where clearly technical assistance for the project-owner definitely needed.

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REGULATION (EU) No 1295/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 establishing the Creative Europe Programme (2014 to 2020) and repealing Decisions No 1718/2006/EC, No 1855/2006/EC and No 1041/2009/EC

Case studies
1. Hungary

1.1. Health situation[24]

Life expectancy in Hungary has increased by almost four years since 2000 to 75.7 years in 2015, but still lags almost five years below the EU average. Large gaps exist in life expectancy between men and women, with men living on average nearly seven years less than women. The gap in life expectancy by socioeconomic status is even larger: Hungarian men with the lowest level of education live on average about nine years less than men with the highest level of education. These large gaps in life expectancy by gender and socioeconomic status are not new. They continue to be driven mainly by greater exposure of men to risk factors to health, such as smoking, harmful alcohol consumption and obesity.

Figure 20: Amendable mortality per 100,000 pop

Source: State of Health in the EU: Companion Report 2017

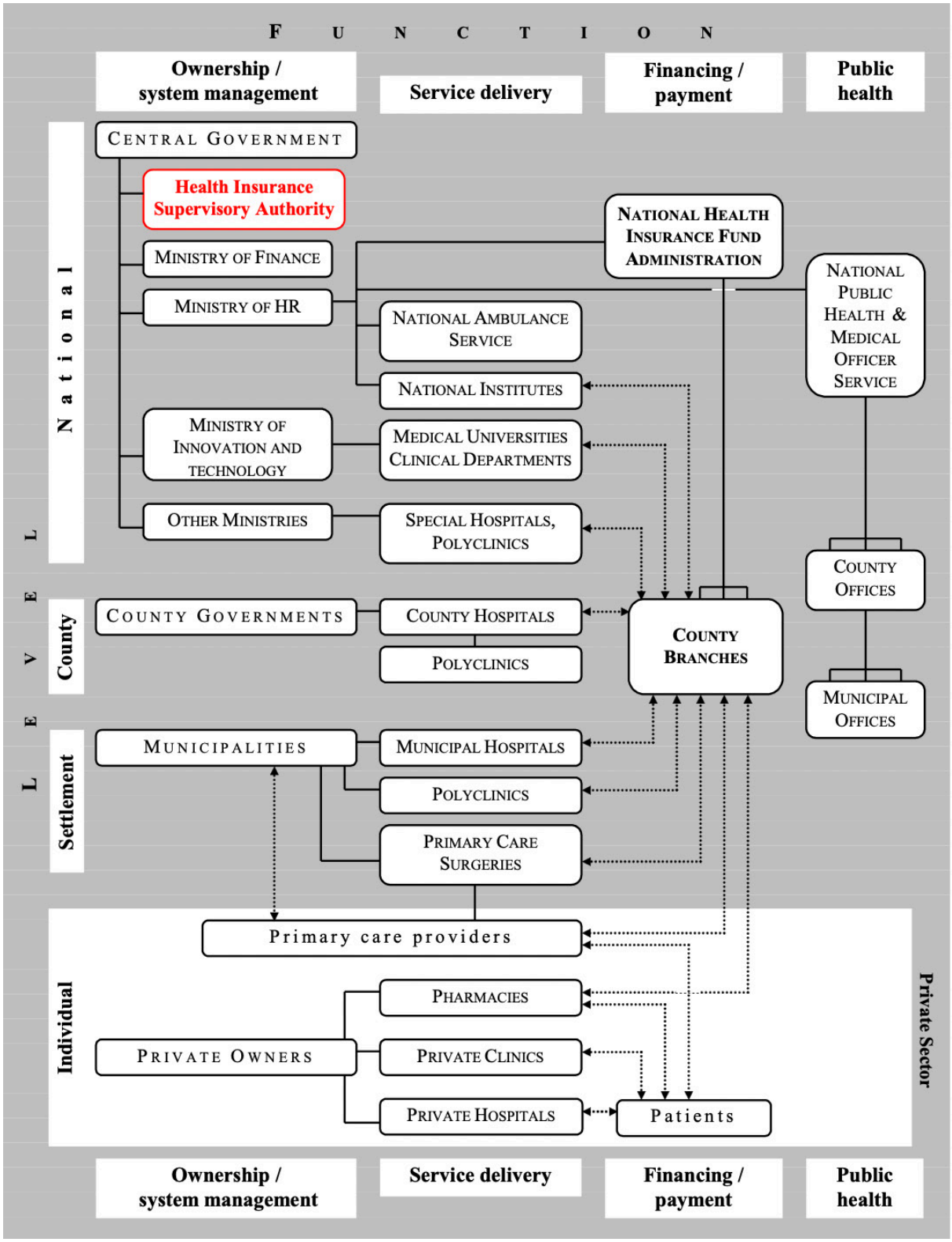
The Hungarian health system is underfunded. Health spending per capita is among the lowest across the EU, and only about half the EU average (€1 428 per capita in Hungary compared to the EU average of €2 797). Only two-thirds of health spending in Hungary is publicly funded (compared to nearly 80% across the EU), leaving the system highly reliant on direct out-of-pocket spending. Consequently, a relatively high share of low-income households reports unmet medical care needs due to financial reasons. More than 25% of such households face catastrophic out-of-pocket expenditure for health care, a higher share than in most other EU countries. Pharmaceuticals account for substantial shares of both public spending and out-of-pocket spending by households. Pharmaceutical spending may be reduced by making more effective use of public procurement practices and encouraging the prescription of generics.

[24] State of Health in the EU: Companion Report 2017

Cancer care and outcomes in Hungary may be improved through greater prevention, early detection and timely access to quality care for different types of cancer. Hungary reports among the highest mortality rates for both preventable cancers (e.g. lung cancer) and treatable cancers (e.g. breast, cervical and colon cancers). National programmes are in place to promote regular breast and cervical cancer screening, but the screening rates among women in the target age group remain low. A new national screening programme for colorectal cancer will be implemented in autumn of 2017. Greater public spending on cancer care would help achieve further progress in early detection and treatment, thereby increasing survival rates.

The Hungarian health system remains highly hospital-centred, as shown by above-EU average rates of hospital discharges, length of stay and avoidable hospitalisations for chronic conditions.

Figure 21: Overview of the Hungarian health care system



Source: Szocska

Not only does this point towards a weak gatekeeping system of primary care providers, but incentives and capacities to provide the appropriate care outside of hospitals are also lacking. Shifting care towards the community while simultaneously strengthening primary care delivery can promote more equal access to care, drive further efficiency gains and improve quality.

1.2. The legal and institutional framework of Innovation in Hungary

In December 2014, the Parliament passed the **Law LXXVI. of 2014**[25]. The legislation aims to ensure enabling legal and financial frameworks for scientific research, development and innovation. Its specific objectives contained

- to reinforce institutional structures for intra-governmental coordination, the provision of predictable, transparent and efficient forms of R+D+I funding as well as for assuring adequate support for basic (exploratory) research,
- to lay ground for further development and innovation processes through assisting applied research and experimental development, built upon the results of basic research,
- to boost sustainable economic growth via facilitating the delivery and exploitation of R+D+I results,
- to advance business competitiveness and the creation of new jobs that generate greater value added,
- to advance the skills base and recognition of R+D+I specialists,
- to stimulate the shift towards knowledge and innovation based economy and sustainable, smart growth.

Within Hungary's administration, responsibility over research, development and innovation is assigned to the Ministry of Innovation and Technology (ITM). In line with Hungary's ultimate strategic goal of boosting economic competitiveness necessitating a different approach to human capacity development, a recently adopted Government decision subjected the higher education sector to supervision by the ITM Minister, as well.

Following the adoption of the Law on R+D+I the rather fragmented institutional setting of innovation support was replaced by the newly set up National Research, Development and Innovation Office (Hungarian abbreviation is NKFIH). In accordance with the centralised R+D+I support model, the NKFIH is in charge of policy making, monitoring and impact assessment, coordination of R+D+I issues nationally and in international organizations. It manages the Research, Development and Innovation Fund, operates a principally competition-based financing system. The NKFIH facilitates the design and launch of innovation support services and collaboration platforms, continued dialogue between the private, research and business sectors as well as it maintains databases to back up its strategic analysis function. The NKFIH's remit includes coordinating the use of the national budgetary resources vis a vis the operational programme funds. This implies close collaboration with the Economic Development and Innovation Operational Programme (EDIOP) Managing Authority, including policy advice on financial planning and scheduling of calls launched under EDIOP, engagement in the elaboration of these calls as well as providing expertise for the appraisal of applications.

[25] Law LXXVI. of 2014 on scientific research, development and innovation

1.3. National strategies and funds

1.3.1. Public policy design and operationalisation in Hungary

European Union resources play a **pre-decisive** role in funding public investments in Hungary. For that reason, the policy planning framework shows some important similarities with the Cohesion Policy regiment in terms of its timeline, content, methodology, communication and coordination modalities, the latter including the engagement of socio-economic and territorial partners. Adopted, legitimate public policy documents lend themselves, to differing extent though, to an overarching programme of private sector as well as public – both EU and national budget financed – investments. While the reasonableness of regularly[26] revisiting the policy framework in a fast changing context is beyond any doubt, the above specific circumstances imply that the formalised policy updating **derives from external pressure**, rather than satisfies an inner demand for honestly assessing progression and establishing a firm grounding for future interventions. Consequently, fulfilling the pre-defined criteria[27], that guarantees the acceptance of a policy document as a basis for future funding, acts as the main driver of the process. Whereas, real ownership itself may thus be instantly weakened, the policy formulation, the corresponding consultation and decision-making processes are likely to create **temporary uncertainties** about the future **path of the policy** among its stakeholders, too. To interpose another layer of difficulty, the preparation of the forthcoming round of programming documents coincides time-wise with the "wrapping up" of the currently running operational programmes. The rather complex course of actions fully ties up the policy practitioners (managing authorities) and typically prevents their active involvement in the policy and subsequent programme formulation exercise. At this point in time, planning may rely on mid-term evaluations of the policy interventions which shed light on whether the policy interventions are on the right track but offer little guidance on their impact. In case the outcome of ex-post impact assessments are also taken into account, they always refer to the preceding programming period (creating a 3-5 years' gap at minimum).

While the present study intends to draw attention to the partly inevitable problems in the conceptual, theoretical, analytical framework of policy formulation compounded by an uneven skills base across the public administration and the re-occurring challenges of involving high-quality external expertise, this time interval also grants a unique **opportunity to present well-grounded proposals** which the evolving policy documents could accommodate. A similar window may open up in the last years of the programming period when through drop-outs, financial corrections etc. "new" funds that must be committed and spent relatively fast become available. In this case though, a more in-depth level of elaboration may be required so that the proposed intervention could be converted into a call for proposals quickly.

In relation to the global policy framework, what we have to look at is how they relate to, in particular help advancing innovation in the health sector. Meanwhile a policy document is expected to ensure certain flexibility so that relevant, prospective ideas which were yet unknown at the time of its adoption could receive acknowledgement, approval and support over the entire police cycle. At the same time, the document has to offer sufficient rationale and justification for the individual interventions being either measures or projects. The relationship, preferably of a direct nature, between policy objectives and the traits of the intervention in question should be captured and illustrated in a convincing manner (intervention logic).

However, it is not possible to establish a direct match between one and only specific policy document and the promotion in innovation in the health sector, it is clearly cross-sectoral and impacts all governance levels.

[26] The EU budgetary period presently covers 7 years.
[27] Ex-ante conditionalities in the period 2014-20, enabling conditions in the perspective 2021-27.

1.3.1.1. Global strategic framework

The National Development and Territorial Development Strategy, which the Parliament approved in January 2014 occupies the highest level in Hungary's hierarchy of policy documents. This strategy sets out the principles, ultimate goals and long-term priorities of development policy, placing a strong emphasis on economic development meanwhile R+D+I as well as societal health and well-being constitute specific objectives. Nonetheless, the interpretation and operationalisation of the rather broad, ultimate objectives has created insurmountable difficulties. Whereas, its objectives have been formally embedded in Hungary's Partnership Agreement, the strategy had indeed limited influence on the content of either public policy documents or the 2014-20 operational programmes. By the mid-2010s, the perception that the strategy was practically shelved became wide-spread in the administration. In view of the pace of preparation for the 2021-27 programming period, the impact of the strategy on defining Hungary' development priorities is likely to remain unchanged (marginal). According to the working hypothesis the Parliament will receive the updated strategy in September 2020. Meanwhile the submission of the operational programmes to the Commission is foreseen for June 2020.

1.3.1.2. Strategic framework for innovation

Whereas the acceptance of the R+D+I Strategy and the S3 Strategy preceded the announcement of the new legislation, the law has affected both their implementation and updating.

The R+D+I Strategy 2013-2020[28] aimed at advancing innovation performance and progression towards a sustainable knowledge-based economy via the complete renewal and reinforcement of Hungary's innovation system. The document gives special attention to the harmonisation of its goals with Hungary's **science policy**; it advocates the creation of **internationally competitive knowledge centres** through supporting the development of research infrastructure and human capital, whereas "future-technologies" – including **biotechnology** – receive priority. Setting the gross domestic expenditure on R&D as 1.8% of the GDP by 2020 to be further increased up to 3% by 2030 stated the political commitment to invest in the innovation ecosystem as well as it projected the availability of a **growing size of public finance**, too.

The mid-term evaluation undertaken in 2017, contributed significantly to the amendment of the R+D+I strategy. Systemic problems has hampered Hungary's innovation performance, which currently ranks 21st on the European Innovation Scoreboard. The corresponding reports[29] observes

> Innovators, Intellectual assets and Finance and support are the weakest innovation dimensions. Hungary's lowest indicator scores are on Design applications, SMEs innovating in-house, and SMEs with marketing or organizational innovations.

Whereas productivity plays a critical part in fostering competitiveness, it shows great variation according to company size and ownership structure. Productivity of small and medium-sized firms lags far behind the EU average. Also indigenous companies markedly underperform multinational corporations and/or their affiliates. R+D+I policy interventions (supporting technological development, organisational, service and marketing innovation) are instrumental to productivity improvement in the SME sector.

[28] Befektetés a jövőbe – Nemzeti Kutatás-fejlesztési és Innovációs Stratégia (2013-2020)/Investment in Future : National R+D+I Strategy

[29] European Innovation Scoreboard 2019, Hungary, available at https://ec.europa.eu/docsroom/documents/35894

Due to establishment of the Innovation Fund in 2003, the growing magnitude of EU support and expanding R+D+I activities of multinational companies R+D+I spending by companies has steadily risen since 2003 both in absolute terms and in GDP ratio. However, almost half of the spending is born by 10 companies confirming the widely acknowledged duality in Hungary's private sector. Smaller companies have shown resistance to innovation, which constitutes an important barrier for their engagement in global value chains. Besides, the achievement of the 2020 target (1.8%) necessitates that R+D+I expenditure is considerably raised[30].

Companies struggle with high innovation costs compounded with scarce resources, difficulties of obtaining public finance and the acute shortage of qualified labour force. Meaningful collaboration with universities implies real partnerships among equal partners.

Academic and higher education institutions suffer from the general underfinancing of operational costs which jeopardises the sustainability of their R+D+I capacity, in particular the retaining of expertise and the maintenance of infrastructure.

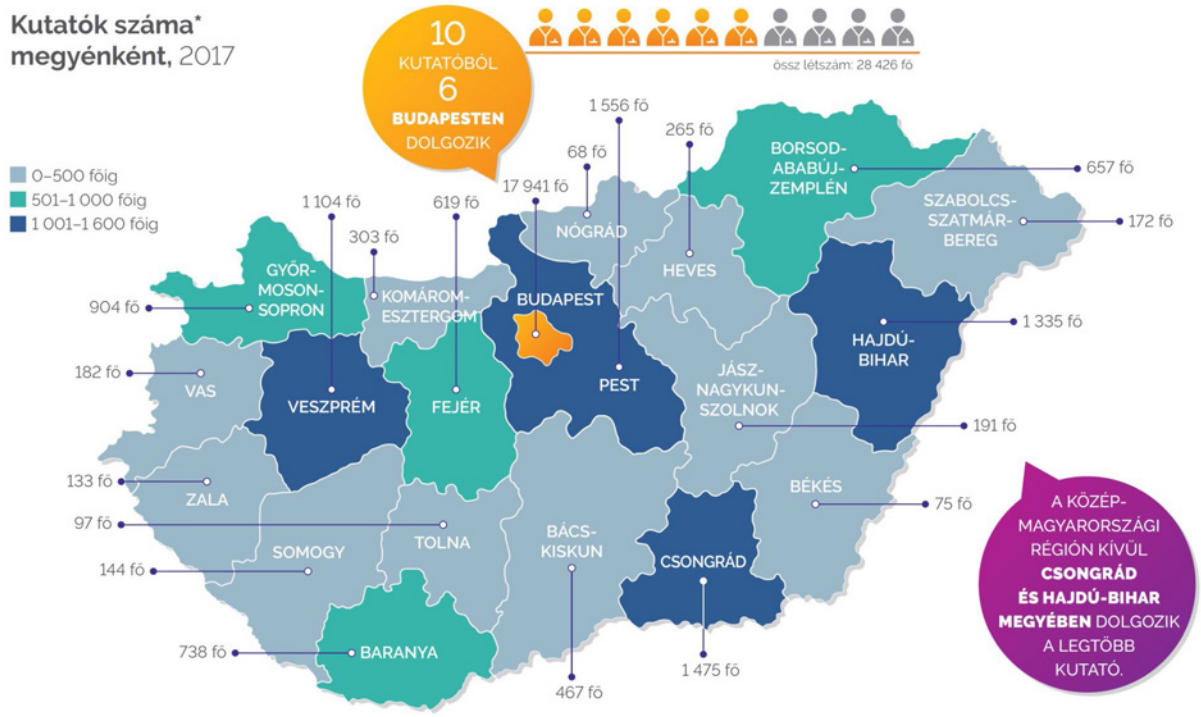
> The shortage of financial resources is detrimental to the career opportunities of researchers in the public sector and their number fell by 1.5 % since 2010. This trend is accompanied by a decrease in the number of research units, and a falling proportion of highly cited publications. The proportion of science and engineering graduates has also declined since 2014 and is among the lowest in the EU.[31]

The distribution of R+D+I capacity presents strong territorial concentration, the dominance of Budapest followed by university-industry poles of regional importance.

[30] Estimates by the NKFIH suggest that the drying up of the 2014-2020 requires, at minimum, the doubling of the allocation from the national budget.

[31] Country Report Hungary 2019, SWD(2019) 1016 final, available at https://ec.europa.eu/info/sites/info/files/file_import/2019-european-semester-country-report-hungary_en.pdf

Figure 22: The number of researchers per counties



Source: NKFIH

The 2019 Country Specific Recommendations invite Hungary to prioritise R+D in her investment-related economic policy taking into account regional disparities.

The renewed strategy visionalises Hungary to turn into a leading innovator and SMEs to become widely capable to generate and apply innovation. It contributes to addressing outstanding social challenges via a stable and supportive environment. It promotes a deeper international, first and foremost European embeddedness and also fosters public sector innovation. It supports excellence-based research and development, alongside with horizontal, non-technological innovation and shaping attitude to innovation. Focused R+D+I activities coupled with solidified R+D+I collaboration will promote sustainable and increasing competitiveness.

The strategy includes horizontal and vertical objectives as illustrated below.

Table 7: Objectives of the Hungarian RDI Strategy

Horizontal objectives		
1. Responsiveness to innovation, creativity and value added creation 2.)Enabling legal and business environment 3. Promotion of territorial, social and economic cohesion 4. Stable, stimulating financing regime 5. Challenge (mission) oriented, demand driven innovation 6. Gender equaliy in R+D+I		
Knowlege creation	**Collaboration and knowledge flow**	**Application of knowledge, company innovation**
1. Develop future research capacity 2. Practical, demand-driven education and R+D+I 3. Needs based doctorial programmes, industrial PhD 4. Collaboration between higher education, research and external innovators 5. Strengthened and better utilised state research capacity 6. Increased company R+D+I 7. Knowledge based services	1. Active knowledge and technology transfer in the innovation ecosystem 2. Open innovation and access 3. Cross-sectoral mobility of academic researchers 4. International mobility of academic resarchers 5. Access to R+D+I infrastructure 6. Interfirm cooperation in R+D+I 7. International R+D+I cooperation	1. Intellectual property management and application 2. Promoting start-up eco-system and spin-offs 3. Encouraging company innovation 4. Promiting technology and non-technology (organisational, marketing) 5. Fostering new innovation infrastructure 6. Strengthening universities third mission

Source: Kondor compilation

- Not only do policy aims accord with the ultimate goals of EIT Health InnoStars' aspirations, but specific objectives fully coincide with the focus of EIT Health Hubs and their partners'.

- Moreover, to approximate domestic innovation capacity to those of leading hubs, a specific measure concentrates on "*Involvement research, education and business in joint projects, strengthening of the knowledge triangle via EIT resources and structure*".

The approval of Hungary's S3 Strategy has been the outcome of a long, painful process, whereas the outstanding importance the European Commission - attaches to the document led to a lengthy course of consultations and several draft versions before finalisation and adoption[32] could take place. This strategy intends to carve out a trajectory for counties – and regions – to organise their specialisation and R+D+I focus around. The policy papers do not set forth absolutely binding provisions: strategic and specific priorities have remained unweighed. Being fairly balanced, the policy documents do not contain any other modes of ordering substances for future rounds of funding. It may not have been the initial intention either. Nevertheless the absence of funding prioritisation leaves significant room for manoeuvre in terms of converting the goals into actual interventions and match funding to them. Key funding channels include the Cohesion Policy regime, national budget funding through NKFIH and to a lesser extent EU direct management funds, in particular Horizon 2020 each working according to a different regimen.

1.3.1.3. Strategic framework for health development

Hungary's ultimate health goals are explicitly set forth in Article XX of the Constitution.

> (1) Everyone shall have the right to physical and mental health
> (2) Hungary shall promote the effective application of the right referred to in paragraph (1) through agriculture free of genetically modified organisms, by ensuring access to healthy food and drinking water, by organising safety at work and healthcare provision and by supporting sports and regular physical exercise as well as by ensuring the protection of the environment.

By its Resolution 1039/2015. (II. 10)[33], the Government launched the 'Healthy Hungary 2014-2020' Healthcare Sector Strategy. The strategy was adopted for the 2014-2020/2022 period, since it is primarily linked to the EU macro level policies and comprehensive strategies as well as to financing opportunities the ESI Funds offer. The document stresses that population health has a significant effect on economic performance and competitiveness. Improving health, prevention and regular health screenings, efficient and effective health systems are needed to ensure that people reach and preserve their optimal health.

Given the experience of pursuing reforms and undertaking expensive developments in a rather disconnected mode over the past decades, unsurprisingly without achieving the intended transformation, the Government chose to take a systemic and concerted approach to dealt with the key health problems and healthcare gaps.

Overall aims contain

- increasing e the number of healthy life years by 2 years until 2020, and achieving the EU average by 2022,
- increasing life expectancy for women from 78.3 years to 80 years and for men from 70.3 years to 72 years,
- reducing the standardised death rate (per 100,000 inhabitants) by 10%,
- raising the social recognition of the value of physical and mental health,
- promoting health-conscious behaviour, encouraging individual responsibility,
- lessening territorial inequalities and differences in life expectancy.

The strategy calls for the harmonised implementation of actions under four key strands.

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[32] In order to improve Hungary's R+D+I performance the Government adopted the Smart Specialisation Strategy (S3)In November 2014.

[33] 1039/2015. (II. 10.) Government Resolution

Table 8: Key strands of the Healthy Hungary Strategy

development programmes	infrastructure upgrading	human resource development	health insurance development
▪ national health programmes ▪ primary health care services ▪ public health programme ▪ emergency care ▪ health technology development	▪ Healthy Budapest ▪ Semmelweis University ▪ family-friendly maternity units	▪ pay increases for, doctors, pharmacists, nurses/allied health professionals/ ancilliary staff, technical staff, finance staff ▪ training and development, ▪ scholarships	▪ raise financing of Health Insurance Fund

Source: Kondor

The policy document gives only modest attention to promoting innovation in their health sector. Innovation is principally noted in relevance to encouraging new approaches to reach desired outcomes in basic health and social services, namely the introduction of innovative methods across the health sector. The document also refers to the need to embrace innovative ways to finance health services development and provision, including the upgrading of medical technology.

In order to operationalise the strategy, a set of national health programmes were launched in December 2018[34]. As the overwhelming majority of early deaths are due to chronic non-communicable diseases, the aim of preventing the leading causes translates into specific intervention packages.

[34] 1722/2018. (XII. 18.) Government Decree on the national health programmes, and corresponding 2019-22 intervention packages

Table 9: National Health Programmes 2019-22

Programme	Allocation		Intervention areas
Pillar 1: Prevent and develop health of priority target groups			
National Cancer Prevention Programme	HUF31 177 000 000	cca. €94 500 000	diagnostic technology, tumor surgery, chemotherapy equipment, drug therapies, oncology informatics, rehabilitation and hospice networks, oncology specialty training and technological development, revision of oncology finance
National Circulatory System Programme	HUF22 270 000 000	€67 500 000	risk factor reduction, end-of-treatment target level improvement, risk factor avoidance in childhood, modifying cardiovascular risk factors in children, reduce/approximate to EU average cardiovascular mortality, reduce stroke morbity and mortality, reduce lower body amputation, increase quality of life and healthy years for patients
National Locomotory System Programme	HUF8 781 000 000	€26 600 000	prevention, preserve/restore work capacity, physical activity for disabled people, enhanced rheumatology services, increase quality of life for patients, medical rehabilitation, neurosurgery, traumatology-orthopedics, sports medicine and surgery
National Mental Health Programme	HUF15 778 000 000	€47 800 000	improve psychiatric care delivery, child and youth mental health services, treat substance abuse and drug addiction, develop psychotherapy services
National Child Health Programme	HUF19 760 000 000	€59 900 000	prevent lifestyle diseases, pre-natal and early primer and intervention, equality in access to primary health care, establish child care centres, reduce premature births, sustainable capacity development
Pillar 2:			
National Primary Healthcare Programme	HUF42 688 000 000	€129 400 000	foster access, quality standards, better patient pathways, unified coordination regime, reorganise finance, operations and administration, expand capacity and skills base
National Public Health Programme	HUF 8 178 000 000	€85 400 000	healthy start in life, health prevention in childhood, reducing burden of chronic diseases, prevent epidemics, reduce environmental health hazards
Intra-sector cooperation, development of health communication[35]			

Source: Kondor

[35] Further information is not available yet.

The integrated approach to interventions is expected to contribute to increased efficiency in the healthcare sector. It enables the strengthening of public health and basic health related as well as close to home specialised clinical services while harmonising them with investment-intensive in-patient servicing. Whereas the programmes set forth the medium-term development agenda for the above priority intervention areas, details of the financing arrangements (funding sources) are unattended.

1.3.2. National funding schemes (direct financing targeted programmes and grants, e.g. NKFI Fund, Proof of Concept (PoC)) and local public sources

The approach the NKFIH has taken to R+D+I finance is driven by the intention to improve long-term international competitiveness of Hungary's economic actors, which is essentially shaped by their position in the global value chain. Consequently, the fundamental funding principle dictates that assistance should concentrate on high-value added RDI activities and programmes, catalysed predominantly by the NKFIH.

The concept is to offer predictable and transparent financing for projects which involve

- **world-class**, excellent scientific background,
- **talented** researchers and other professionals,
- **competitive** infrastructures.

The NKFIH allocates approximately HUF80 000 000 000 (cca. €240 000 000) per year to R+D+I support, mainly in the form of grant finance. These resources come from the National Research, Development and Innovation Fund, the implementing rules of which were renewed as of 1st of January 2015. Financial assistance is awarded to different disciplines, institutions, researchers and companies on a competitive basis. In December 2016 the Government published a new decree regulating the project selection system.

Table 10: Currently open calls

Call	Allocation	Support per project	Estimated no. of beneficiaries	Type of beneficiary	Project implementation period
Competence centre, research infrastructure development -basic research, industrial (applied) research, experimental development	HUF 8.5 billion	HUF 1-5 billion	3-5	university, company research units, (non research) companies, non-profit research institutes lead applicant = budgetary organ	36-48 months
Hungarian participation in EUREKA -industrial (applied) research, experimental development, industrialproperty rights, commercialisation	HUF 0.5 billion	HUF 20-70 million	7-25	companies	36 months
Hungarian participation in H2020	HUF 80 million	HUF 1.5-3 million	30-60	university, other budgetary research institutes, (non research) companies, non-profit research institutes lead applicant: budgetary organ, companies, non-profit research centres	12 months
Participation in H2020 SMS Instrument	HUF 100 million	HUF 25 million	4	(non research) companies rejected by H2020 due to lack of finance	6 months

Table: Planned Calls for Proposals

Call	Allocation	Support per project	Estimated no. of beneficiaries	Type of beneficiary
SME START Innovation	HUF10 000 000 000	HUF 10-20 000 000	650-700	SMEs
Market-led RDI	HUF 45 000 000 000	HUF 50-700 000 000	160-200	SMEs, large companies, universities/research and knowledge transfer organisations
Open Innovation	HUF1 500 000 000	HUF 10-150 000 000	15-20	large companies & SMEs
University-industry cooperation	HUF20 000 000 000	HUF 1 - 6 000 000	4-8	large companies, research and knowledge transfer organisations, SMEs
Intellectual property rights	HUF500 000 000	HUF100 000 -7 100 000	20-40	SMEs, large companies, research and knowledge transfer organisations, state bodies, nonprofit organisations, natural persons

Source: NKFIH

1.3.3. Cohesion Policy funding

The policy formulation process started in parallel with the drafting of the Cohesion Policy funded operational programmes. As a consequence, the planning of innovation measures in the Economic Development and Innovation Operational Programme could not rely on the solid basis of an approved policy. Evaluations were only available to a limited extent and covered the 2007-13 programming period partially. Nonetheless, the analyses brought to light some important considerations for supporting innovation in the health sector.

The "**Evaluation of NSRF funded Developments in the Health Sector**" [36], among others, underlines

- the need to adopt an integrated approach and broad focus to the upgrading of Hungary's healthcare system, implying that the impact of EU aided investments is compounded by
  - structural reforms, changes in the regulatory and financing framework,
  - the pressing issues of human resource planning, management and continued development in the health sector: EU-funded projects proved adequate to resolve or mitigate local discrepancies. However, challenges at a sector level (turnover, training needs) require reaction at policy and political levels,
  - the strong influence of adequate territorial targeting of public assistance and calls for tailoring interventions to well-defined local needs. "Controversial" territorial statistics[37] on preventable deaths suggest that more detailed analyses are needed for efficiency gains in health care provision.

[36] Egészségügyi tárgyú NSRK-fejlesztések értékelése (2013), Hétfa Kutatóintézet, Budapest Intézet, Revita Alapítvány, available at https://www.palyazat.gov.hu/egeszsegugyi_fejlesztesek_ertekelese#

[37] Important differences between the levels of socio-economic development and exposure to preventable deaths in a similar territorial context.

- the introduction of new (innovative) type of care provision – e.g. one-day ambulatory services – has triggered a rising take-up. Nevertheless, the study also warns of the under-utilised IT developments[38],
- the difficulties beneficiaries meet and rarely overcome when they attempt to match funds under various operational programmes for complex measures.

The "**Evaluation of Tertiary Education Development Programmes**"[39] among others, highlights

- that the logic which a managing authority employs to the use of the funds – characterised by pre-defined and controlled inputs and outputs, relatively short project delivery timeframe and a financing model reinforcing these elements – clashes with the operational modalities of service-providing universities – whereas performance is hard to measure, motivational instruments illustrates a greater degree of complexity and long-term perspective,
- the value infrastructure upgrades in the less developed regions has played in creating proper conditions for research. Active R+D collaboration between universities and the private sector had a beneficial influence on applied research capacity and services,
- ESF funds helped to retain young research scientists through enabling advanced remuneration and scientific career development
- the need to explore the co-existence and relationship between R+D+I activities which universities pursued with funding from the human development operational programmes and collaboration with companies, innovation in the private sector whereby company projects benefitted from support under the Economic Development OP and the Central Hungary OP. The review shows that
    - o R+D+I opportunities at university evolve separately from particular services and/or one-off assistance which companies demand. Indeed direct links proved rare. What is more, (EU-funded) innovation projects companies had undertaken fell beyond the direct focus and perception of universities,
    - o a basic problem rests with the incompleteness of the innovation process. The phases at the two extremes, namely that of basic research as well as satisfying specific company needs to commercialise are well provided for which does not apply to the phases between including prototype development, pilot application, testing, development are not. This underperformance derives from
        - insufficient funding allocation and unattractive aid intensity for companies, whereby support for universities principally addresses the basic research function,
        - a lack of mechanism and funding to manage knowledge and innovation transfer,
        - state aid rules ignore the inherent risks R+D+I projects hold.
    - o parallel capacity building by universities reflects the absence of coordination, which is also prevalent for technology transfer offices. Rather than institutionalised, collaboration of universities with private firms is largely dependent on personal relationships and confidence,
    - o a strategic framework for resource allocation, performance-based financing, in particular requirements for universities to fulfill applied research needs and to advance their integration into the global science community were found indispensable to promoting Hungary's economic competitiveness.

[38] A delay in delivering the E-Health component of the Social Infrastructure OP prevented a full-scale appraisal of overall effectiveness though.

[39] A felsőoktatást célzó programok értékelése/ Evaluation of Tertiary Education Development Programmes (2013), Hétfa Kutatóintézet, Budapest Intézet, Revita Alapítvány

The "**Evaluation of R+D+I measures under the Economic Development**"[40] OP, among others reveals

- the critical importance of institutionalised support (e.g. mentoring, innovation management) for innovative start-up companies, at present, this role is exclusively fulfilled by venture capital companies,
- that companies perceive collaboration with universities as a risk: joint implementation of projects is frequently hindered by bureaucracy and slow reaction, lack of structural and managerial stability,
- that demarcation between national and OP schemes in terms of thematic focus and territorial coverage proved essential to avoiding overlaps and encouraging synergies,
- the value of a one to one matching between a distinct phase of the innovation process and a dedicated support scheme,
- the extreme length of the project selection process and the uncertainty this causes for applicants,
- that the project selection regime attaches greater weight to project implementation considerations in detriment to innovation perspective as well as focuses on business appraisal rather than investigation the innovation potential the project offers.

The **renewed Cohesion Policy** regulations significantly reduced the liberty of the Hungarian administration to prioritise financial allocation. Thematic objectives and the corresponding earmarking obligations to a large extent predetermined where most of the funding were to go. Addressing the crux of the low level of knowledge use, creation or modification in the business sector is central to the EDIOP. Planners of EDIOP had to venture into "unchartered land". The radically augmented magnitude of economic development funding[41], and within this the substantial allocation for R+D+I, implied the definition of measures and allocations the spending and transformative reality of which could not be adequately explored. Surprisingly, just the opposite approach proved valid too when programme objectives have been converted into measures: to mitigate absorption risks, which are inherently higher for innovative projects anyway, the tendency to reach back to already tested schemes has been prevalent.

The intervention logic in the programme implies that as a result of increasing dynamism in innovative companies, the need for R+I, networks and relations helping innovation will markedly improve.

The **Priority 2 R+D+I** under the EDIOP concentrates on i.) strengthening R+I infrastructure and capacity, ii.) promoting R+I in the business sector and iii.) supporting strategic R+I cooperation. Quantified performance targets predict the support of 760 firms by the end of 2018 and 3,800 by the end of 2023. As R+D activities involve the business sector which falls into the remit of the EIDOP and academic-educational sphere in the focus of the Human Resources Operational Programme (HRDOP), a demarcation line had to be drawn.

- As a main rule, the EDIOP uses ERDF monies to support the modernisation of research infrastructure, mobility (e.g. cooperation with centres of excellence) as well as preparations for accessing H2020 - consortium leadership and fully-fledged project design.
- The HRDOP (Priority 3) finances educational infrastructure development, ESF mobility actions as well as preparation, training for H2020 and other programmes.

[40] Értékelés a Gazdaságfejlesztési program Kutatásfejlesztés és innovációt célzó beavatkozásairól/ Evaluation of R+D+I measures under the Economic Development (2013), KPMG, available at https://www.palyazat.gov.hu/a_kutatas_fejlesztesi_es_innovacios_tamogatasok_ertekelese_gop_1_prioritas#

[41] The budget of the EIDOP accounts for 34% of Hungary's total allocation, compounded by the Competitive Central Hungary Operational Programme (CCHOP) 4%.

The **allocation of HUF 523.3 billion** is outstanding, the second highest in the operational programme as the most sizeable budget goes to the Priority 8 Financial Instruments.

Priority 8 centralises financial instruments across the remit of the Partnership Agreement and offers refundable or combined assistance to projects fitting into the priorities of the operational programmes. A budget of HUF 202 million has been earmarked to support R+I activities in the business sector.

Table 11: Financial Instruments 2014-2020 in Hungary

TO	Loan programs	Combined loan programs	Venture capital programs	
TO1	Loan program for supporting RDI activities of enterprises (EDIOP)	Combined loan program for supporting RDI activities of enterprises (EDIOP)	National technological and intellectual property venture capital program (EDIOP) Smart specialisation venture capital program (EDIOP, CCHOP)	National Fund
TO2	-	Loan program for the development of NGA and area networks (linked to grant; EDIOP) Combined loan programs for supporting ICT development (4 programs; EDIOP)	Specialized seed and pre-seed investment fund for start-up ICT companies venture capital program (EDIOP) Digitalisation Fund (EDIOP)	
TO3	Loan program for enhancing competitiveness of SMEs (EDIOP, CCHOP)	Combined loan program for supporting capacity expansion of SMEs (EDIOP) Combined loan program for supporting medium-sized food companies (EDIOP)	Irinyi venture capital program (EDIOP)	
TO4	Energy loan program for SMEs (EDIOP) Loan program for improving energy efficiency in the housing sector (EDIOP, CCHOP)	Combined loan program for improving energy efficiency of SMEs' buildings with the use of renewable energy (EDIOP, CCHOP)	-	
TO8	Loan program for promoting employment (EDIOP)	-	-	

Source: Nyikos

To resolve the problem of late programme start, the Government decided to apply a very steep spending profile for all the operational programmes. This has practically meant a very compressed timeframe, accelerated project selection and contracting which has doubtless brought about positive absorption impacts. At the same time, by to date grant assistance allocations under the operational programme has been depleted by to date, there is no open call for proposal for companies wishing to innovate.

The geographical scope of the Competitive Central Hungary Operational Programme is limited to Budapest and Central Hungary. As in the period 2014-20 these territories are not eligible for support under any of the other operational programmes, the CCHOP essentially includes measures which supplement interventions in the less developed regions by the sectoral operational programmes including EDIOP. The CCHOP allocation is very restricted, national funding has had to be mobilised to meet the acute need of development in Pest county.

The Commission's legislative proposal for the budgetary period 2021-27 has given a firm impetus to preparations. As many of the sectoral policies largely coincided with the EU present financial perspective, the need to revisit these documents became evident. Accordingly, the R+D+I strategy has been recently undergoing an updating process. The new strategy for the post 2020 period, among others encourages creativity and generation value added, collaboration within the innovation ecosystem and reinforces R+D resources and activities at the universities.

Setting out the new framework for Cohesion Policy implementation is underway, too. The formal launch of the planning process in February 2019 was accompanied by carving the key principles into stone too. The Government called for a stronger emphasis on

- long term positive impacts on efficiency and productivity, business environment, human capacity and well-being,
- effectiveness of the interventions paid by the operational programmes,
- concentration of objectives and interventions,
- the working out of simplifications and prepare applicants to ease access to funding.

Discarding the approach of polishing the existing set-up, the idea of assessing sectoral and to a lesser extent territorial needs and reconciling the deriving intervention strands with top-level priorities has prevailed so far. An elaborate programming structure was set up whereas main consultative/decision-making platforms include

- programming working committees[42]
- thematic working committees covering 37 thematic intervention areas,
- the Coordination Committee for Development Policy,
- the Strategic and Family Policy Cabinet, and the ,
- the Economic Affairs Committee

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[42] 1024/2019. (II. 11.) Korm. határozat a Programozási Munkacsoport létrehozásáról

n July 2019, the Government discussed its global goals for 2030 and the contribution of the next round of Cohesion Policy funding to their realisation. The national strategic concept for long-term socio-economic development assigns utmost priority to, among others,

- **Improving growth, health and labour market competitiveness of the population**
- **Creating a demographically sustainable life concept and lifestyle**
- **Achieving world-class, innovative, highly-value added economic – production – performance**

Consequently, the key strands for using Cohesion Policy resources includes, among others

- **business development and innovation:** this intervention area concentrates on Hungary's international competitiveness and aims to significantly raise its level as well as industrial production both in absolute[43] and relative[44] terms.
    - The objective of better value adding, which leads to widened participation in global value chains, brings about the need to improve the position of indigenous firms.
        - These companies are become capable of forming supplier integrations and raising their share in GDP production[45] and total exports[46].
- sustainable labour market development: this intervention area focuses in increasing employment (also involving the mobilisation of the retired population groups) and advancing labour market performance.
    - Productivity of the labour force is expected to attain an annual average growth level of 2% in the period 2020-2030.
- improve human capital for renewal in the labour market: this intervention area presents strong links to overall competitiveness based on the achievement of a demographic change, a region-wide leading educational system and reduced inequalities. Targets are also relevant to health and innovation including
    - The total number of births should amount to 90.000 per year, meanwhile the birth rate-death rate relationship is improved too. Longetivity is aimed to be extended by 2 years. The early mortality rate is reduced by 50%.
    - Mandatory health screening, good-quality and accessible basic services will be provided. Home-based social and health services will be made accessible for the entire ageing population. The health sector will be endowed with motivated and highly-qualified health personnel.

Resource allocation has been defined at a macro level. The weight of the business and innovation strand is well reflected by its share, which equals 33% of the country's financial allocation (as compared to the present 28%). Competitiveness linked labour market and social policy interventions hold a share 24% (presently 31%) and infrastructure development accounts for 41%.

The setting forth of ambitious aims induced a notably altered approach in financing policy interventions. The intervention area of business and innovation support will benefit from more targeted financial assistance, marking a break with the provision of support for general economic development purposes. Moreover, the proportion of refundable support will increase, as well. The Government has recently approved the preparation and introduction of a pilot convertible loan scheme which allows the partial conversion of refundable loan assistance into non-refundable grant assistance in case the beneficiary meets the pre-defined performance targets.

[43] An increase in industrial output by 40% is set out.
[44] An increase from a share of 25% to a share of 35% in the total economic output is set out.
[45] An increase from the current 50% to a share of 65% is set out.
[46] An increasefrom the current 30% to a share of 50% is set out.

The successful pilot is intended to be rolled out to a broader range of business and innovation promotion schemes in the period 2021-27. This could turn out as a particularly relevant model for health innovation projects, where due to the novel nature of projects, beneficiaries carry a much higher risks.

The Government is firmly committed to improve Hungary's innovation performance. The system of priority objectives under Cohesion Policy offers an adequate context for supporting the delivery of innovation policy goals from both the EU and national resources. Correspondingly

- the new mission-oriented innovation policy will be continued. This enables responding to outstanding socio-economic challenges by tailoring assistance (through content, deadlines, indicators etc.) to addressing of specific problems
- the National Innovation, Research and Development Fund enables multiannual project funding from national budgetary sources,
- the three pillars of Hungary's innovation policy – SME innovation, academic and educational sector, priority projects (e.g. science parks) - will ensure a direct link to the progression towards excellence. Broadly set and long term open calls for proposals will make certain the utilisation of multiple – EU and national level - funding sources for high-potential projects,
- exploiting the Seal of Excellence mechanism will bring about a fast track route for projects of outstanding quality. This means that EU regulations allow for direct take-over of project proposals from centrally managed EU programmes (e.g. Horizon Europe) into the relevant operational programmes in case the project has been judged of sufficiently high quality nonetheless rejected in the absence of funding. The commitment of the Hungarian authorities (in charge of either policy or implementation of the operational programmes) is unclear at this stage. General transfer modalities as well as the technicalities of taking over projects, which are generally launched by international consortia, and charge them against the national operational programmes requires more analysis yet,
- also the efficiency and effectiveness of R+D+I support needs to be increased. The ratio of R+D+I support to R+D+I spending by firms, which is relatively low by international comparisons, reveals significant unlocked potential.
- human services promotion schemes will target persons rather than institutions. (Under ESF financed schemes the preparation of studies and methodologies will become ineligible. Rather than creating new services, access to the existing portfolio of technologies and services should be promoted.)

The next milestone was initially fixed for 31st October 2019 when the Government was to take a decision on priority axes, operational programmes and the breakdown of finance. Also the mode of addressing complex territorial problems was to be determined. Although tby the above deadline the Government's final formal position has not been established, the continued strategy formulation process has led to some important clarifications.

The Government aims at introducing a simple, straightforward architecture for the operational programmes. Namely, the concept of three operational programmes seems to have consolidated greatly to date; this implies the launch of a(n)

- Competitive Economy Operational Programme: This operational programme is foreseen to include a priority focusing on fostering innovation whereby projects will benefit from ERDF funding and a higher education, vocational education priority which will be supported by the ESF.
- Infrastructure Development Promoting Competitiveness Operational Programme, and

- Renewable Human Resources Operational Programme: this operational programme is foreseen to comprise a priority which is dedicated to health sector development with funding to come from ESF.

R+D+I as well financial instruments will enjoy a greater share of funding. This goal is clearly shared by the European Commission and the Government of Hungary and its details will be put in place and finalised during the negotiation of the operational programmes, in the second half of 2020.

Hungary's current Partnership Agreement for the period 2014-20 takes note of the economic growth potential which involvement in the H2020 programme could help to unlock and calls for the EDIOP and HROP to improve access to H2020 via helping the preparations of prospective applicants.

Accordingly, the EDIOP R+D+I priority has been planned to aid companies in their innovative actions, to promote R+D+I strategic collaboration and initatives, to support the research sector in attaining excellence as well as to advance their capacity, domestic and international collaboration.

- Not only specific measures have been outlined, aimed at narrowing the gap between the preparedness of the Hungarian innovation actors vis a vis H2020 requirements ; measures to follow up successful H2020 projects promised the exploitation of their results.
- Besides, the operational programme projected a preferential approach in project selection to companies and Widening participants which have met the respective H2020 call requirements[47] and have been only rejected due to the shortage of funds.
- The wording of the programme also allowed for parallel financing of complementary actions[48].
- The performance framework for the priority does not exert any pressure for a paced realisation of the above objectives.

The HROP deploys its ESF monies for the academic and higher educational sectors to further strengthen their existing research capacity and to build the future research leaders, and the programme also promotes their integration into the global and international research communities.

- Similarly to the EDIOP, the outline of the priority and the measures do not translate the aim of advancing synergies either into the broadly defined key selection criteria or the performance targets.

In accordance with the demarcation line drawn between the EDIOP and HROP, project preparation can only be funded from the former.

The responsibility to coordinate the various funding streams is clearly assigned to the line ministry. Additionally the Partnership Agreement describes the role of the Development Policy Coordination Committee (FKB) in discussing issues and progress. The presentation of the coordination regime with internal and external financiers is standardised, again not provoking a real thinking process about how the use of the various funding instruments could be effectively approximated.

Whereas, operational programmes funds have been practically depleted (fully committed), new opportunities for funding may arise even in the last years of the programming period (e.g. replacement of projects affected by financial corrections, withdrawals, exchange rate fluctuations etc.).

[47] .Kiválóságot szolgáló K+I kapacitások megteremtése/Reinforcing excellence focused R+I capacity;

[48] With the exception of the same expenditure element, whcih the EU regulations excluded at the point in time when the programme was adopted.


TEMMUZ
AĞUSTOS
EYLÜL
EKİM
KASIM
ARALIK
OCAK
ŞUBAT
MART
NİSAN
MAYIS
TEMMUZ
EYLÜL
EKİM
KASIM
ARALIK

1.3. Project implementation: experiences, obstacles and best practices

1.4.1. Project preparation

The experience of exploiting synergies, which the combination of ESIF and H2020 (or other centrally managed programmes) enables, is practically missing. Just the opposite, the use of the ESI Funds gives abundant experience and food for thought.

Without any doubts regarding the positive side of obtaining public contribution, especially grant assistance for R+D+I projects, both applying for and implementing Cohesion Policy funding effectuates major risks for a project promoter.

The first risk relates to the preparing a fully-fledged project for finance under any of the operational programmes. This requires massive investments from the project promoter which only pays off if the project is (i.) selected and (ii.) successfully implemented so that the public support is fully released. Small surprise, instead of mature, well grounded concepts applicants tend to reach out to broadly defined, immature project ideas which are then massaged into an acceptable form. This means that the application has to meet the dictated – at least minimally required - technical-professional as well as project quality standards and to conform to all the administrative conditions which the use of the EU funds implies.

The difference between the case when an organisation is planning a project for its own purpose and when the project is devised against a call for proposals is hard to illustrate. Public contribution involves/may involve

- additional obligations for the beneficiary, which would otherwise not be provided for within the project (extra activities, extra expenses, nonetheless they are eligible),
- worded exclusion of activities or expenditure (which may be necessary for the project),
- the assignment of maximum/minimum limits to the value of certain project components or activities, e.g. setting a percentage for the purchase of equipment, project management etc. (which in reality may cost more),
- the attachment of deadlines to project components, deliverables, e.g. milestones (which may be tight or unreal)
- a lack of reference to/clear guidance on activities, expenditure necessary for the project,
- a series of administrative tasks, e.g. reporting, payment application, whereas the timeline for approving their satisfaction is unknown.

Working with the ESI Funds necessitates that the applicant, later beneficiary secures a rather unique combination of skills. The applicant's capacity should include

- discipline/subject matter specialists relevant to the topic area of the call,
- broader sectoral policy understanding - and preferably expertise,
- Cohesion Policy implementation – knowledge and experience,
- general project management skills and experience.

Without a critical mass of OP funded projects which would have instigated the setting up of a dedicated project implementation/management unit, **most organisations struggle** with ascertaining the above skills base. They can usually come up with the technical expertise, besides heir functional managers (legal, financial, HR etc.) can contribute to project preparation in a meaningful manner. For Cohesion Policy grant application and management, the probability that external expertise has to be engaged is quite high. Its expensiveness is compounded by strict admission deadlines which gravely increase the intensity of the project preparatory efforts.

Competition is limited to domestic actors. It is all the fiercer though as it is timely compressed, due to the dominance of one-off type calls for proposals, the unpredictability of future funding options, absorption pressure motivating a rapid commitment of the funds.

Networking, lobbying is assumed to be relatively widespread.

The grave risk of **failing the award of assistance** may come from various factors:

- Despite a step of simplification steps, submitting a grant application still comes along with enormous requirements for administrative-regulatory compliance.
    - There is a serious disparity between the admission deadline and the requirements.
    - The magnitude and complexity of the call and all the corresponding documents makes a misstep relatively easy.
        - Some of the missteps are incorrigible. (A missing documents leading to instant rejection.)
- As mentioned earlier, grant application goes hand in hand with probable delays, among them rather serious ones, in the appraisal process.
    - New applicants have to familiarise themselves with such a situation and learn how to handle the undesired pause properly, e.g. keeping the project on the agenda, proceed with the preparation as possible.
- Imbalance between the grant scheme funding volume (total allocation) and the total requested funding repeatedly leads to the suspension or even closure of the call.
    - Regulations oblige the managing authority to provide some “buffer time” before the call is closed, so that applications with a maturity close to submission standards can be completed and uploaded into the electronic grant application system.
    - However, this short period of time proved insufficient for many of the less progressed applicants. Not only was their chance to obtain grant assistance nullified, they lost the monies they had invested in the working out of the application, as well.

Project promoters can only meet the first outstanding challenge of obtaining the funds if they have sufficient information about the requirements, on the basis of which they can measure the pros and cons, secure the necessary resources (financial and human), last but not least set in motion and control a project for the preparation of the project.

- Many applicants just have not got enough experience to do it. Moreover, applicants are likely to keep their experience to themselves and rarely share the details with potential or real competitors.

- Although mystified by inexperienced applicants and private consultants (even to some extent by the OP delivery bodies) writing up a grant application is far from rocket science. To understand this, applicants are in strong need of straightforward, very pragmatic support especially in the orientation and early stage of project preparation.
    - Support could be – partly - institutionalised for R+D+I projects as private consultancy companies rarely if ever can present the highly specialised technical knowledge.
    - Advice and information should be supplemented by bridging the gap between the applicant and the grant provider organisation (managing authority, NKFIH), which is usually done by private consultancy companies.
    - Technical support can include the organisation of sharing experience.
- Capability gaps of innovators were early recognised by the EIT Health InnoStars. Its local development project scheme offers a combination of project preparatory support and pre-assessment for entities wishing to submit applications for centrally managed EU programmes. Experience has revealed that accessing centrally managed programmes pre-supposes a significantly higher level of quality which innovators could rarely meet without externally arranged technical assistance. Feedback from leading international experts does create value to the project applications. Similar support should form an integral part of the instruments which the new EU operational and national programmes will offer.

1.4.2. Project selection (structures and processes employed for the award of finance)

1.4.3. Cohesion Policy Regime

Annual operational plan

Operational programmes are broken down into annual operational plan (ÉFK)[49], which is discussed by the monitoring committee and the Development Policy Coordination Committee (FKB)[50] and approved by the Government. The approval lists all the call for proposals (budget, mode and date of launch[51]) and the priority projects (name, beneficiary, indicative allocation, main technical requirements[52]) the managing authority will start. It is published on the central website[53], providing indication for applicants on the probable schedule of calls.

Preparation of the call for proposals

The launch of a call for proposal is mandatory for all projects, irrespective of their selection procedure which for R+D+I projects is essentially[54] the standard project selection process. Selection is based on strong competition. Ranking is defined on the judgment of the satisfaction of qualitative criteria. One or more rounds of selection (deadlines) may apply. Besides, a direct award mechanism may be used for priority projects; these are nationally/regionally important investments help the fulfilment of public tasks.

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[49] Abbreviation stemming from the Hungarian term „éves fejlesztési keret".
[50] Abbreviation stemming from the Hungarian term "Fejlesztéspolitikai Koordinációs Bizottság".
[51] The explanatory note to the government also includes information on the particular competitive project selection procedure, total budget, target group, eligible activities and expenditure, founding size, indicator values)
[52] The explanatory note to the government also includes information on total budget, eligible activities and expenditure, founding size, date of launch, indicator values, eligibility and project selection criteria, justification for the use of direct award.)
[53] https://www.palyazat.gov.hu/ves-fejlesztsi-keretek
[54] Other selection modes, irrelevant for R+D+I projects include territorial project selection and CLLD based project selection.

Call for proposals are very prescriptive in Hungary. The 50 pages core document of the call is supplemented by a broad range of annexes easily amounting to 1,000 pages. The major challenge lies with exploring the obligations for application and submission and project delivery. In fact, many applicants rely on external experts, specialised also in screening and processing assistance related information. The highly instructive nature[55] of calls is also caused by the fear of potential irregularities. Draft calls, with the exception of priority projects are placed on the centrally run website inviting observations over a minimum period of 10 days. Calls are being formulated till the day prior to their announcement and even running calls are subject to constant changes.

For R+D+I schemes, applicants may have been requested to attach a recommendation letter (positive expert opinion) from the NKFIH to their application.

Appraisal and selection

Delays in opening up calls are commonplace, not to speak about the uncertainties over the probable demand these funding opportunities will generate and the burden of the implementing criteria they set forth. The perception that "*nothing is certain until a call is published*" increases the attraction of available assistance and spurs applicants to react to any calls they can squeeze their project ideas into. As a matter of fact, applicants have presented a very high level of flexibility in terms of tailoring their project plan to the articulate funding criteria. This widely held attitude compounded with generally short submission deadlines result in huge demand exceeding many times the budget allocation as well as a multitude of immature project applications.

The appraisal process two-staged and starts with the basic administrative-eligibility check. For some of the eligibility criteria, demonstration of their satisfaction must be available at the outset[56] or their absence provokes an outright rejection. For a set of other documents, in case of their absence or incompleteness the applicant is contacted to submit the missing information within a short period of time. Failure leads to an ineligible applicant status. Hence, the first decision is taken at the end of the eligibility checks period and the applicant is sent a confirmation accordingly.

Regarding the second stage, project appraisal is based on the project selection criteria which had been approved by the monitoring committee and published online, as part of the call for proposals. Once announced, these selection criteria should not be changed.

To reduce criticism in relation to the objectivity of the selection process as well as mitigate audit risk, the nature of the selection criteria has changed over time. The result is a fragmented scoring model, whereby all the more complex attributes (e.g. project rationale or quality) are broken down into a numerous little-weight or yes-no criteria. In relation to R+D+I projects, the difficulties of capturing excellence through a checklist type set of quality assessment criteria and purely paper-based appraisal are apparent.

The head of the managing authority decides on the nature – namely internal, external[57] – and the number of assessors. Priority projects should be examined by two experts at minimum. As the eligibility check relates to the application processing rather than application content, the applicant may be invited to send in supplementary information.

[55] The need to find the right balance between overly prescriptive and overly flexible calls has been explained noted int he H2020 mid-term evaluation, too.
[56] The rationale being that the absence of certain basic information prevents efficiently processing the application.
[57] The NKFIH provides specialised assistance for the appraisal of R+D+I projects.

Each assessor evaluates the application and formulates a recommendation for the rejection or support[58] of the application. Their reports are summarised automatically. If there is great variance between the appraisals, or the quality of a project appraisal is unsatisfactory, a new appraisal[59] may be called.

The head of the managing authority can also use a project selection committee to prepare the final decision-making. Such a committee is usually chaired by a managing authority delegate and it is composed of voting members (mainly line ministry, managing authority), observers and experts. If required, the project assessor(s) present(s) the appraisal and respond(s) to questions. The committee may provide various types of funding advice, rejection or approval, the latter including a combination of potential amendments to project content, size and support or referral to the reserve list.
The final, formal decision rests with the head of the managing authority. Although he/she is not bound by the results of pre-appraisal(s), this rarely happens and it is never systemic. The "fate" of an application is practically defined in the project assessment phase.

Prior to their approval by the head of the managing authority, priority projects are endorsed by the Coordination Committee for Development Policy and the Government.

The applicant is entitled to submit an appeal against the decision. There is little prospect of an overturn of the decision. The case is only returned to the managing authority – implying a new appraisal – if procedural violations have been evidenced.

Project appraisal has shown many delays, the length of the waiting period can substantially exceed the official timeline. Such a situation causes uncertainty, makes certain administrative/project components (e.g. availability of experts, validity of bids for conditional public procurement) outdated or it may force the revision of the project plan, postponing the signature of the grant contract.

Regarding the funding allocation under national schemes, the NKFIH employs a multi-step project appraisal process, too. Similar to the operational programme delivery regime, administrative checks constitute the first stage, whereas the satisfaction of 3-5 basic conformity criteria are investigated. Flexibility options are described in the call for proposals, and the opportunity to complete missing documents or information is granted accordingly. Non-compliant or incomplete applications will not be accepted.

R+D+I and innovations schemes aim at promoting excellence via awarding applications offering outstanding quality and a high degree of novelty. To judge applications on these merits, applications are examined by project appraisal groups. Experts are selected from a roster of 15,000 specialists. Each application is subject to a scrutiny of 2-5 experts, who work independently from each other, using the publicly available project selection criteria.

In the next phase, the groups collectively discuss each application and lay down a ranking order in their recommendation. A summary of the project reviews is submitted to the discipline colleges for R+D+I projects and to the innovation boards for innovation project applications. These recommending panels review each application with the corresponding appraisal reports and provide a recommendation to the NKFIH President who makes the final decision. This assessment phase generally takes 20-30 days, with the exception of calls with international or bilateral relevance which require a longer timescale.

Within 10 days applicants are informed of the results of the evaluation of the proposals.

[58] Assessors may propose technical-financial reductions or prescribing additional conditions for the applicant.
59 Modalities correspond to the standard procedure for project appraisal.

Applicants are entitled to file an appeal to contest a violation of the project selection regulations.
The current project selection system cannot prepare innovators for successful application under the centrally managed EU programmes. A change in approach is needed to motivate the preparation of applications of a higher quality and complexity, with the use of English language allowing for appraisal by international experts.

1.4.4. Project implementation

Experience suggests that applicants very much concentrate on getting grant assistance and a lot less thought is given to how the project will be implemented and the requirements met.

- Beneficiaries of unfledged, incomplete projects come across many difficulties during implementation.
- Delays in the course of project appraisal unavoidably lead to the postponement of contracting. Depending on the length of time that has passed since the submission of the application, the signature of the agreement with the funder may require the revision and modification of the project plan. This is usually accompanied by the extension of the project closure date, yet the extension is not necessarily proportionate or cannot prevent disruption to a linking project either. Similarly modification of the grant contract may take much longer than expected.
- The signature of the grant contract enables the release of advance payment for the beneficiary. While an advance is crucial for many organisations for the launch of the project, it has tangibly reduced the pressure for quick spending as disbursements have become less essential for improved liquidity.
- Public procurement has remained a major issue and a dominant source of irregularity. Despite heavily equipped with public procurement lawyers, beneficiaries' vulnerability stays to be high.
    - o The right of interpretation of the EU Public Procurement Directives lies with the Commission's auditors at the first level and the Commission's specialised legal experts at the next level.
    - o When violation of the norms is established, correction rates are massive.
- For R+D+I projects in particular, understanding and properly interpreting State Aid implications (e.g. definition of activities and eligible expenditure) create problems, too.
- Spending public funds comes with accountability implying many controls and auditing.
    - o The disbursement of financial assistance is linked to the approval of payment requests, the ordered presentation of invoices and substantiating materials[60]. Managing authorities are in charge of management verification which means that they have to check the lawfulness of the expenditure, the compliance of the submitted documents with national and EU rules.
        - First of all it takes time, second it may provoke questions, requests for additional information.
        - Depending on the size of public contribution, and the risk the managing authority merits to the project, on-site control checks are carried out, too.
        - A beneficiary has to have a thorough grounding in the principles and rules as well as he/she should be able to interpret them within the confines of the project in order to provide a quick and satisfactory reaction on any concerns that emerge during the checks (or audits as described below)

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[60] When the managing authority employs a simplified payment technique, one of the so-called simplified cost options, the need to submit evidence for the occurrence of expenditure is limited.

- In particular the less experienced beneficiaries underestimate the highness of the stakes which external audits, undertaken by the EUTAF and especially by the European Commission, represent. Beneficiaries often fail to properly prepare for the auditors' visit and efficiently coordinate with them (directly or through the managing authority) before, during and after the audit.
- The level of details may be unusual as well as the difference in the interpretation of legality and regularity which the changes in - the control and audit - personnel (high turnover) may cause.
  The project must contribute to the objectives of the operational programme which is measured through performance targets. To aggrandise the value of the applications and thus enjoy better chances for winning, project promoters may commit themselves to over-ambitious targets, namely milestones (to be met at the end of distinct phases in the project) and indicators (to be achieved by the end of the project). In this aspect, flexibility is fading.
  - First, the release of financial assistance is linked to satisfactory delivery of milestones.
    - A delay in meeting a milestone leads to the suspension of payment to the project.
  - Underperformance of the indicators is likely[61] to trigger a reduction of the assistance.
- The checks the managing authority carries out or auditors' findings may result in the perception[62] of an irregularity. The investigation of an assumed irregularity is a meticulously regulated process, whereas the beneficiary has the opportunity to defend his/her case. The learning is very similar to those related to the need for professionalism to coordinate external audits. The risk is even higher though as
  - the commencement of an irregularity examination may lead to the suspension of the payment to the project which could continue for months.
  - a failure to demonstrate convincing evidence provokes financial correction.
    - A shift towards applying flat-rate corrections rather than calculating the exact loss to the national/EU budget has made irregularities very expensive for the beneficiary.
    - The repayment generates a net loss to the beneficiary as the amount cannot be re-used in the same project (the beneficiary cannot offer to charge another piece of expenditure to the project instead).
    - Irregularities of a very serious nature induce the termination of the grant contract and the recovery of the total public contribution reimbursed to the beneficiary so far.
    - Depending on the nature of the irregularity, it may be taken into account of negatively when other applications of the beneficiary are appraised.
- The complexity of the obligations is hard to capture. From time to time a firm ignores durability requirements (e.g. the result of the investment has to be maintained for a pre-determined set of time, changes in the ownership of a company should not give undue benefit to the firm or impact the project significantly) or the obligation to keep the project related paper or electronic documents until the given deadline.

Consultations with innovators holding projects financed both by the operational programmes and centrally managed EU programmes suggest that the rules for nationally run schemes have been tightened up substantially in the programming period 2014-20. This contraversion requires attention at all levels, decision-makers, implementing bodies and innovators. The latter specifically asked for help[63] to communicate their observations to the regulator (ITM). The EIT Health InnoStars should take up this coordinating role as soon as possible.

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61 Due consideration is given to all factors, including external circumstances.
62 Officially suspicion.
63 Local workshop in Pécs, 5th November 2019

1.4.5. Preparation for 2021-27

At present, little is known about the changes to the modalities of grant application and management. The EU regulatory proposal principally governs the management of the operational programmes. Domestic concepts centre on the strategic planning tasks, yet describe some important principles, too. All currently known and yet fluid ideas factoring in, the following conclusion can be drawn:

- simplification in the EU regulations will essentially impact
    - the financial implementation of projects where the use of simplified cost options will be expanded which coincides full with the priorities of the Government,
    - as well as audits where the number of audits, especially to small projects, will be reduced,
    - combining different funds and/or forms of support via the further harmonisation of their implementing rules.
- also the Government has articulated its commitment to ease the use of assistance. The coordinating ministry (ITM) is seeking and is open to feasible solutions to cut back administrative burden. The timeframe for the adoption of domestic legislation leaves approximately a year[64] for the incorporation of new proposals in the new government decree.
    - The current strategic thinking process does not encompass the aim to closely coordinate the ESIF and centrally managed programme funds and actively help their combination. Correspondingly very little consideration is given to the specific obstacles that need to be overcome.

1.4.6. Institutional capacity

The exploitation of synergies and complementarities between R+F+I projects supported by Cohesion Policy and H2020 or other centrally managed funds needs the understanding, commitment, cooperation and support of all actors involved, at various levels, for the design and implementation of the respective policy initiatives.

Starting with highest level in the cascade, key decision-makers comprise the Government, strategic level leaders in the R+D+I and health policy domains. Whereas the approved conception paper on the 2021-27 policy intervention regime lays down the objective of promoting excellence, there is limited information on the potential which the coordinated use of Cohesion Policy and H2020/other centrally managed programme funds could offer. The Cohesion Policy and central programme delivery structure are perceived as two distinctly different regimes, which are separated in a "Chinese Wall" manner.

Consequently there is a general lack of understanding of the

- beneficial impact the exploitation of synergies could exert on realising the objective of advancing excellence,
- broader context of H2020/centrally managed programmes, in particular their decision-making and operational set up and mechanisms,
- advantages and modes of approximating and linking the Cohesion Policy and H2020/centrally managed programme regimes,
- major systemic discrepancies which have to be addressed and how these issues could be resolved.

[64] Adoption of the national implementation rules is planned for September 2020.

Therefore, information should be disseminated on an on-going basis (e.g. position paper, explanatory brief, short report on key issues, consultation on specific themes).

So far decision-makers in charge of the design and implementation of sectoral policy (line ministries) and operational programmes (managing authorities, intermediate bodies) have had no responsibility and consequently no motivation either to closely coordinate the use of policy/programme funds and H2020/ centrally managed programmes. In terms of motivation, the interests of the line ministries rest with linking policy objectives and OP funds, meanwhile the managing authority focuses on maximising absorption and performance targets, mainly output indicators.

Besides the above mention information gaps, delivery also have missed out on information and experience in

- drawing up a strategy to implement the promotion of excellence – via exploiting synergies with H2020/ other centrally managed programmes in order to help attaining policy/programme objectives,
- adjusting operational programme and implementing provisions to enable such synergies,
- upgrading their skills base to handle the particularities of approximating to and coordinating with H2020 and other centrally managed programmes, including
    - legal-institutional basis: terminology, programme objectives and targets, institutional responsibilities, eligibility (e.g thematic, organisational, geographic, activity and expenditure-wise), financing conditions (e.g. co-financing rate), horizontal policies (e.g. State Aid, public procurement), procedure framework (project selection, contracting, financial implementation, monitoring, financial control and audit)
    - provisions for coordinating with ESIF at the level of implanting rules and provisions, calls, projects, specific coordinating instruments, e.g. Seal of Excellence, joint financing and modes of overcoming systemic differences.

Internal and external auditors, in particular the Audit Authority need the same type of information, yet unavailable.

Since applicants and beneficiaries have shown capacity gaps in relation to accessing operational programme funds (the national system), coordinating with and obtaining funds from H2020/other centrally managed programmes interpose additional shortcomings in knowledge and skills. As a matter of fact, problems start with their motivation and attitude shaped by the domestic grant systems. Beneficiaries tend to give high priority to maximising their funding opportunities, profit gains (companies) on the assistance or fixed costs charged against the project (public and non-for-profit entities), and investing in fixed assets.

As obtaining finance rather than fulfilling long term organisational goals is of the utmost importance, they do not perceive the importance of adopting a strategy. Other important gaps include that the applicants

- are often struggling financially which diverts attention and resources from long term consideration and efforts,
- are accustomed to the formalistic requirements of the OP project selection and implementation regime, and have no insight into the project quality requirements for H2020,
- they lack the experience of managing H2020 projects,

- are endowed with limited administrative resources and weak capacity to secure intra-organisational support or the elaboration of high-quality proposals,
- have shown modest participation in international networks and difficulties in joining - international - consortia,
- are required to invest substantially in the creation of an efficient knowledge triangle cooperation,
- maintain a low remuneration level which erodes research capacity,
- illustrate a moderate command of foreign languages,
- lack the commitment to compete for H2020/centrally managed funds. Accessing operational programme funds is much easier (higher success rate, use of Hungarian language)

Progress in institutional capacity building proved to have been quickly eroded by high turnover. Arrangements for retaining institutional memory in this rapidly changing environments are rarely, if ever put in place.

1.5. Conclusions and recommendations

The above listed policy documents clearly constitute as a generally suitable reference frame for supporting innovation – in the health sector. They do not prioritize though and neither they reflect to problems or financing needs particular to the EIT Health InnoStars and EIT Health Hub.

Regarding the relationship between H2000 and EDIOP funded projects, the dynamic is perceived as one-dimensional. Financial resources in control of the Hungarian administration are employed to support preparations for successful bidding to H2020. Moreover, the time of formulating the operational, in particular project selection mechanisms of H2020 and the barriers Hungarian applicants need to overcome were unaware. The concept of an opposite flow of support, namely taking over projects which have been partly supported or judged worth for support but rejected in the absence of funding under the H 2020 regime, has not received consideration either.

The 2021-27 period will bring important changes. To achieve the ultimate goal of advancing Hungary's economic competiveness business and innovation measures receive an increasing priority and allocation.

- Both labour-market interventions and social-health schemes are closely linked to the targeted sustainable, knowledge-based economic development model.
- The health sector is assigned with a growing responsibility to contribute to bettering demographic trends via dealing with all the key aspects affecting the population growth rate.

The traditionally hectic period when wrapping up the current operational programmes, policy formulation and programme design for the subsequent programming period occur in parallel creates a good opportunity for presenting elaborate ides for decision-makers.

Also many efforts are yet needed,fromn the EIT Health InnoStars, that the proof of concept instrument is understood, incorporated in the 2021-27 operational programme(s) and regulated (in the future national implementing rules).

The EIT Health InnoStars may influence at the following milestones (see detailed action plan):

- policy formulation: consultation, partnership, decision-making
- partnership agreement and operational programmes for 2021-27:
    - thematic working groups, expert meetings,
    - networking: bilateral meetings with planners, decision-makers: umbrella organisations, ministries
    - mandatory partnership platforms, including participation in monitoring committees. contribution to the evaluation of the 2014-2020 operational programmes.

Beneficiaries are at a loss when they attempt to grasp the complexity of accessing and using Cohesion Policy funds. Applicants/beneficiaries in general, highly specialised R+D+I project promoters particularly need more continued, direct, pragmatic yet discipline-specific support than the present, impersonalised managing authority services (e.g. call centre, frequently asked questions, general guidance note or even one-off info days) could offer.

At the time of drawing up the present implementing decree there was no motivation (understanding, intention) to address coordination with funds falling outside the Partnership Agreement.

- Since then combination efforts or intentions in the administration have not achieved a critical mass that would have triggered more attention. The issue and specific obstacles of combining OP and H2020 or other centrally managed funds is still not on the agenda[65].
- The EIT Health InnoStars is now in an ideal position to raise awareness of the combined funding potential and present the particular steps that should be taken to eliminate the obstacles of synergy creation (programming documents, regulations, calls, inter-institutional coordination and collaboration gaps etc.).
- Moreover, the national regulators have had no exposure to well-proven models under H2020. The EIT Health InnoStars could present cases for the overcoming of typical policy delivery problems or reducing administrative burden. This would also help the approximation of the national and H2020 rules.

Beneficiaries usually cite the lack of predictability as the most important problem. This high level of uncertainty applies to the

- launch of calls,
- length of the project selection process,
- timescale of project modification,
- complexity of contract modification,
- exact requirements for the release of payment to the project (information as well as processing deadline),
- judgment of in irregularity.

Any scheme/service the EIT Health InnoStars may offer which eliminates the lack of predictability could attract great demand.

[65] A managing authority keeps its attention to the confines of the operational programme.

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2. Croatia

2.1. Health situation[66]

Croatia has made important progress in recent years in improving the health status of its population, but life expectancy at birth is still more than three years below the EU average. Mortality rates from cardiovascular diseases are almost double the EU average and mortality rates from lung, breast and colorectal cancer are among the highest in the EU. These health challenges point to shortcomings in health care delivery and public health interventions. Moreover, smoking and obesity rates are higher than in many other EU Member States. Investing in public health interventions to address these high rates could yield substantial benefits. Despite a challenging economic context and major fiscal pressures on health expenditure, Croatia has kept publicly funded health services accessible to its population. Although health expenditure per capita is among the lowest in Europe, the share of public expenditure is comparable to the EU average and the benefits package is broad, encompassing most health services. Nevertheless, affordability for some population groups remains a challenge; while the overall prevalence if catastrophic out-of-pocket spending is relatively low (4%), 17% of low-income households face catastrophic out-of-pocket spending.

The sustainability of health financing is a concern, with major fluctuations in per capita expenditure in recent years, due to a challenging fiscal environment and high unemployment rates. In addition, the ageing population is expecting to exacerbate the financial pressure on the health system in the future.
Croatia has pursued a number of important health reforms in recent years, many aimed at improving the effectiveness and efficiency of its health system. Building on and implementing these reforms could help to further improve the performance of its health system. A comparatively large share of health expenditure goes to pharmaceuticals, indicating that efficiency gains may arise if appropriate measures are taken.
One of the focal points for health reforms has been the hospital sector, with efforts to improve the strategic planning of hospital infrastructure and the efficiency of the hospital sector. However, so far results have been mixed, with progress made on a new provider (DRG) payment system but stalled implementation of hospital reorganisation plans and continued accumulation of debts.

The strategic planning of human resources for health is a further challenge. Numbers of physicians and particularly nurses are low compared to the EU average. Following the country's accession to the EU, the outward migration of health workforce to other Member States has increased and further contributed to the workforce shortage in the Croatian health system.

Developing the stewardship function of the Ministry of Health will be crucial for safeguarding achievements so far and addressing the remaining challenges in health care delivery and public health. By building national capacity in health reform, Croatia can ensure that it meets the objectives it has set itself for the health system, including improvements in life expectancy, quality of life and reductions in health inequalities.

[66] State of Health in the EU: Companion Report 2017

2.2. National strategies and funds

2.2.1. National strategic background

Croatia, due to its recent accession to the European Union and the intensive preparation for the implementation of the EU policies in regional development and innovation, has developed a large number of strategic documents in the past nearly ten years, thereof many have relevance for innovation and, particularly, innovation in the health sector.

Most documents base on a similar analytical background, stressing the importance of the health-related sector in the country's R&D performance. Therefore, innovation in health industry has been first defined as a long-term objective in the Action Plan 2007-2010 "Scientific and Technology Policy of the Republic of Croatia" (Vlada RH, 2007). In spite of its significant growth, the health sector is a very concentrated industry: pharmaceutical industry is dominated by a few large companies, making Croatia an important player in generic pharmaceutical manufacturing. On the other hand, health-related innovation in the information and technology sector is less concentrated: besides large multinational companies several domestic IT enterprises are active as well.

2.2.1.1. Sectoral strategies on national level

The National Strategy for Health (Ministarstvo zdravlja, 2012), was prepared by the Ministry of Health and has been adopted in 2012. The document is considered as a sectoral strategy, which is focusing on health primarily as public service. The strategy aims to cope with problems of ageing population, the staff shortage in the health sector and Croatia's accession to the European Union, which is referred as an opportunity to overdo development disparities. The strategy provides in-depth situation analysis, based on various descriptive indicators, pointing out the main challenges of the public health sector. Under analysing the influencing factors, the strategy provides a holistic approach, taking into consideration a wide array of factors. Under these factors informatisation (e-Health), research and innovation in biomedicine is discussed in separate subchapters, just like its connection to tourism, the most innovative economic sector in Croatia. The strategy stresses the relatively good coverage of health institutions in the country and their adequate level of equipment, however most of the tendencies in the population's health status and the staff working in the sector are rather unfavourable. Although the strategy mentions that informatisation has been significantly developed, it can't be considered as complete, therefore development of e-Health system is set as first priority (Ministarstvo zdravlja, 2012). Besides, the strategy does not deal with research and development issues, rather focuses on provision of public service.

The Croatian Parliament has adopted the Industry Strategy for the Republic of Croatia in October 2014, which is focusing on tasks of the state to improve business climate and transfer of technologies that play a key role in the development of the country. The strategy focuses on a limited number of sectors (NACE C – processing industry, F – construction, F – information and communication – Hrvatski sabor, 2014; pp. 3-4). Under processing industry "manufacture of basic pharmaceutical products and pharmaceutical preparations" (NACE C21) have direct relevance from health innovation point of view, however several further processing industry categories and ICT development activities may also have indirect relevance. The analytical part points out the generally low productivity of the Croatian processing industry, however

manufacture of basic pharmaceutical products and pharmaceutical preparations is considered one of the few sectors, which has a positive balance, with growing profitability (Hrvatski sabor, 2014; p. 33). Priorities of the strategy set out institutional interventions in order to improve the investment climate, cooperation between industry, education, science and technology and provision of finance. Among industries, production of pharmaceutical preparations (C 21.2) is considered as the main "trigger" of the Croatian industry (Hravtski sabor, 2014; p. 115), and altogether the strategy defines C21 Manufacture of basic pharmaceutical products and pharmaceutical preparations as strategic industrial activity number one (Hravtski sabor, 2014; p. 119).

The food industry, which is also defined as strategic sector, has also relevance from health innovation point of view. After all, the strategy in its priority structure does not set our distinctive sectors, but rather focuses on improvement of some main indicators and setting up scenarios. Out of the four priorities of the strategy, priority 2 focuses on improvement of strategic cooperation between industry, education, science and technology, which is of particular importance from health innovation point of view.

The Strategy for Encouraging Innovation was prepared by the Ministry of Economy and has been adopted by the government in 2014, with a validity period up to 2020, in line with the EU programming period. The strategy sets the vision to make Croatia an internationally recognised country in science and research, being part of the global innovation value chain. The strategy rather focuses on horizontal institutional issues (innovation climate, public sector investments, role of fundamental and applied research, human resource development, academia-business cooperation) for improving conditions in innovation than specifying sectors of priority. One of the strategic objectives include the increase the contribution of private sector to innovation investments to 50% (Vlada RH, 2014). The strategy sets out the establishment of Innovation Council for Industry, for coordination of the implementation of the strategy. As an umbrella organisation for innovation development the state agency HAMAG BICRO is named, however in each state body a contact person should be defined for innovation. Under development of innovation potential of the economy, the strategy sets out the establishment of competence centres (among them for health and life quality and food and bioeconomy), for the new technologies to be applied key enabling technologies (KET) are mentioned, inter alia biotechnology. Under enhancement of cooperation between the business, the public and the scientific-research sector coping with social challenges is stressed out, including access to healthy food and health services are particularly mentioned (Vlada RH, 2014).

The Development Plan of Research and Innovation Infrastructure of the Republic of Croatia was developed by the Ministry of Science, Education and Sport in 2014. The development plan, or Roadmap, has been designed in line with the Western Balkans Regional R&D Strategy (Ministarstvo znanosti, obrazovanja i sporta, 2014). The Plan mentions manufacture of basic pharmaceutical products and pharmaceutical preparations as an area with industry development potential, just like manufacture of computer, electronic and optical products, which has also health industry relevance. In terms of R&D infrastructure development biomedicine, public health and biotechnology are mentioned as priority areas. The plan sets out list of foreseen key projects, including the Competence Centre in Translational Medicine at the Srebrnjak Children's

Hospital in Zagreb, and a detailed list of research equipment to be purchased at various institutions. Although a relatively old strategic document, but still relevant is the Strategy for Cluster Development 2011-2020, which has been developed by the Ministry of Economy, Labour and Entrepreneurship (Vlada RH, 2011). The strategy should be updated, in line with the smart specialisation strategy and the innovation strategy (S3, 2016; p. 76). In terms of objectives the strategy puts promotion of innovation and new technology transfer into focus, while achievement of objectives should be based on the efficient absorption of EU funding. The strategy promotes national coordination in the cluster policy and specialisation of regions and networking of clusters within a region and in Southeast Europe. Innovation should be strengthened, just as cooperation with the academic society, development of capacities in innovation.

Out of the relevant sectoral strategies the most recent one is the "New Colours of Knowledge – Strategy for Education, Science and Technology", which was adopted by the Parliament in October 2017 (Ministry of Science and Education, 2017), after long debate. The strategy tackles all levels of education – from pre-school to higher education – setting various objectives in order to create an open and innovative society, emphasising the role of human capital and life-long learning, improving the competitiveness of the education sector, from curricula to finance. In the science and technology chapter the strategy promotes the changes in the current system, foster the development of internationally competitive public universities and research institutes and improve the environment for technology transfer, link the national research and innovation infrastructure to the European network. The strategy stresses the relative good performance of Croatia in European R&D cooperation projects (FP7), particularly in health, information technology and biotechnology (Ministry of Science and Education, 2017; p. 232). Among its science- and research-related measures the strategy promotes increase in R&D financing in various terms, inter alia, the increase of R&D expenditure to 1,4%, thereof 0,7% should be provided by public bodies, the rest by the business sector. The strategy does not set sectoral objectives or measures.

2.2.1.2. Smart Specialisation Strategy

Beside the numerous sectoral strategies and development documents the smart specialisation strategy is of primary importance, as the Europe 2020 strategy pushes the member states to support excellence and smart specialisation, in forms of cooperation between players of the triple helix. The General Provisions Regulation (CPR[67]) sets out that smart specialisation strategies should be prepared in order to set priorities to build competitive advantage by matching research and innovation strengths to business needs. Such a strategy may be national or regional and shall be used as a guiding document for selection of projects under thematic objective (TO) 1, investment priority (IP) 1b (promoting business investment in R&I – ERDF Regulation[68] Article 5).

Croatia's strategy for smart specialisation – called "Strategy of Smart Specialisation of the Republic of Croatia for the period of 2016-2020 and Action Plan for the Implementation of the Strategy of Smart Specialisation of the Republic of Croatia for the period of 2016-2017" – addresses the following main challenges for the Croatian economy:

- "Croatia's innovation performance over the last decade has fallen short of expectations. The innovation system is operating below its potential (…).
- Croatia is significantly below EU-average in innovation and belongs to a group of countries considered as moderate innovators.
- Croatia is performing below the EU average in most dimensions but above the EU average in human resources, due to above average performance in new doctorate graduates and youth with upper secondary level education.
- There are three factors that impede innovation: tax regime, lack of early stage financing (…), and business environment[,] (…) volume of business R&D is low (…).
- High-value products and services remain a negligible part of exports, and the country's skills and technological capabilities have remained stagnant. This trend is reflected in Croatia's export and technological performance and competitiveness rankings (…)" (S3, 2016; p. 15).

In the analytical part the S3 strategy also stresses the high added value of C21 Manufacture of basic

[67] Regulation (EU) 1303/2013/EU of the European Parliament and of the Council

[68] Regulation (EU) 1301/2013/EU of the European Parliament and of the Council.

pharmaceutical products and pharmaceutical preparations, which is very export-oriented, partially due to apparent payment problems on the domestic market. Production of medical equipment and devices is significantly smaller, however still a significant branch. Out of the service sectors ICT, in general terms, has significantly increased its export and employment, which may have also health innovation relevance. As a good application for the triple helix model cooperation in the health sector is particularly mentioned, between the large pharmaceutical companies and the academia.

The S3 strategy sets the strategic objective to focus knowledge and research capacities to areas, where Croatia is having the biggest potentials, in order to contribute to social-economic development and efficient research, development and innovation (S3, 2016; p. 75). In order to reach the above objective, scientific and research capacities should be increased, fragmentation of the innovation chain should be decreased, R&D investments should be made in the economy, in order to contribute to the global innovation chain, contribute to the solution of social challenges and development of smart skills.

The strategy sets strategic thematic priority areas (STPA), thereof several are related to the health sector (Figure 1).

Figure 23: The S3 thematic priority areas.

Source: S3 (2016; p. 90).

Figure 24: Health and quality of life sub-thematic priority areas (STPAs).

Source: S3 (2016; p. 92).

The pharmaceutical industry (STPA 1) is – despite its significant role in the export turnover – is a very concentrated industry, which is dominated by three companies working in human medicine (Pliva, Belupo, JGL) and a Genera, one of the world leaders in health products for animals. This way, Croatia is a key player in production of generic medicine and over-the-counter drugs (OTC), which is a tool of diversification for pharmaceutical companies. The S3 strategy refers to a set of comparative advantages Croatia is having in the pharmaceutical industry. Significance of the pharmaceutical industry is reflected in the scientific indicators of Croatian researchers as well.

The STPA 2 Health services, new methods in preventive medicine and diagnostics is an emerging element of the health industry, which is gaining more relevance due to ageing population and rising expenses in the health care services. Developments under this domain include technologies of remote delivery of healthcare services, by integrating mobile health (mHealth) and already existing and further developed eHealth solutions. Croatia has built its information system (CEZIH), with contribution of the public sector, private companies and the academic sector as well. The system involves e-prescriptions, e-referrals and e-appointment modules (S3, 2016; 95), which is often referred as a success story. Similar to the pharmaceutical industry, this sector is also very concentrated, only a limited number of IT companies are involved, however its expansion is expected. Development of diagnostical tools is a good opportunity for cooperation between the health research sector and the IT industry, which is proven by several new tools developed by Croatian companies (S3, 2016). The four university centres – out of them two, Zagreb and Osijek are located in the Continental Croatia NUTS 2 region – are key players in the research activities.
The STPA 3 Nutrition has key significance in the health sector, as bad nutrition habits lead to the dominant death causes, i.e. heart and blood-vessel diseases. Croatia suffers high rate of people with diabetes and overweight. Croatian pharmaceutical companies are very active in production of nutraceuticals, herbal products and various dietary supplements and animal feed. Research and development activities in this regard are usually taken place at large companies with own R&D unit. Many foodstuff producers have started to produce functional food products, increasing the added value of their traditional products on the market. In terms of public institutions universities and several state-run research institutions are operating, including the Croatian Food Agency, which is responsible for coordination of scientific and technical tasks in the field of food and food safety.

Besides thematic priority areas the strategy defines a mix of delivery instruments as well, as shown on Figure 23. The strategy envisages the setting up of action groups for all sub-thematic priority, which will take care of the preparation of action plans for the sub-thematic priority and set up project pipeline. Setting up of the envisaged structures has become part of the financing framework in the 2014-2020 programming period, as it is detailed in Chapter 2.2.3.

Figure 25: Delivery instruments of the Croatian smart specialisation strategy.

Source: S3 (2016; p. 162).

2.2.1.3. Governance of innovation

Implementation of the strategy is based on a multi-level coordination system that involves most of the line ministries and various contributing state bodies. The National Innovation Council – which is co-chaired by the Ministry of Science and Education and the Ministry of Economy – is a coordination body. For each thematic area a sub-council is planned to set up. In case of the health sector 70% of the members are coming from the business sector, 20% from academia, while 10% from the public sector. while most of the activities are carried out inside the centres of excellence.

The main consultancy and supporting body for scientific research, high education and technology development is the National Council for Science, Higher Education and Technological Development (Nacionalno vijeće za znanost, visoko obrazovanje i tehnološki razvoj - NVZVOTR), which is responsible for quality assurance in the research sector. The Agency for Science and Higher Education (Agencija za znanost i visoko obrazovanje – AZVO) has a similar role in the higher education sector. The State Intellectual Property Office (Državni zavod za intelektualno vlasništvo – DZIV) is a state administration body, dealing with the protection of intellectual property rights, coordinates patenting processes, certifications and related consultancy activities (S3, 2016; pp. 44-45).

For financing R&D activities of SMEs, the role of the state agency HAMAG-BICRO should be pointed out, focusing on technology development at enterprises. HAMAG-BICRO is operational implementor of national innovation schemes, EU-funded grant schemes and financial instruments, technology development assistance schemes and business consultancy services. Out of all the financing provided by HAMAG BICRO 7% has been spent to health, biotechnology and biology projects (S3, 2016; 45).

2.2.2. National funding for innovation in the health sector

In terms of domestic funding distinction should be made between research and support to enterprises, as they are regulated by different legal acts and are implemented by two different ministries.

In terms of financing basic research the Croatian Science Foundation (Hrvatska zaklada za znanost – HRZZ) should be mentioned, which – as a public body – has taken over the management of domestic research grant schemes from the Ministry of Science, Education and Sport in 2013. Besides basic research the Foundation finances projects of cooperation between the business and the academic sector and individual career development projects of researchers (S3, 2016; p. 44). The Foundation coordinates the annual calls for research projects that are financed from state budget, including basic research projects, established (post-doctoral) projects, projects for cooperation between academia, the public sector and businesses and scientific terminology development. Besides, the Foundation supports preparation of PhD theses, coordinates international exchange programmes and provides support for participation in European Research Council projects. Annual budget for national projects, depending on yearly allocation is around HRK70 000 000 (approx. €9 450 000). Since the 2013 takeover from the Ministry allocation of funding takes place on a programme basis, through detailed application conditions and peer reviewed evaluation, often with involvement of foreign evaluators, thus former first "first come, first served" approach has been replaced with significant competition. As applied research may be funded from multiple sources, HRZZ focuses more on basis research projects. Similarly, as STEM (science, technology, engineering, and mathematics) related areas of research are generally having better chances to get funded from various sources, in spite of the dominance of STEM-areas, there is a growing interest from SSH (Social Sciences and Humanities) in the past few years.

Analysing the project financed since 2013, altogether HRK679 000 000 (approx. €91 700 000) has been spent for various projects, inter alia for biomedicine and health, amounting to 21% of the dedicated grants. In the calculation shown in Table 1 projects of primary biomedicine and health relevance were taken into consideration.

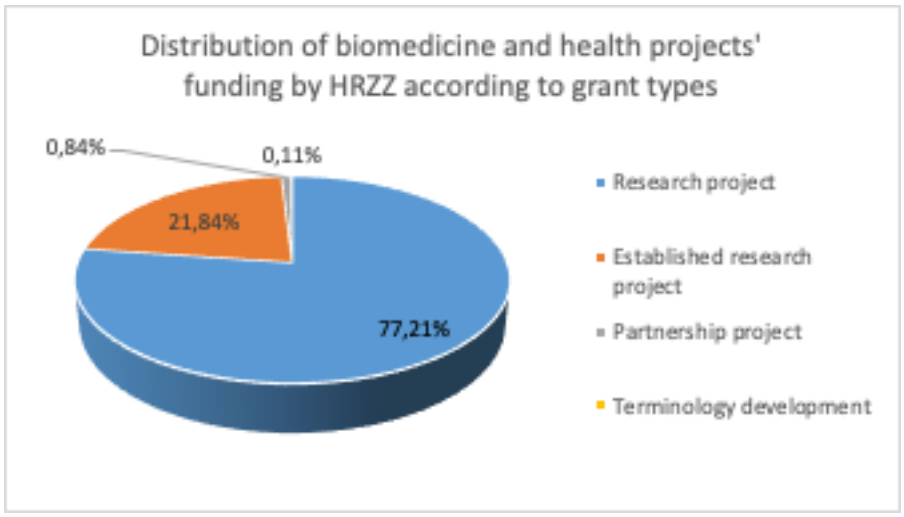
Table 12: Distribution of funding of the Croatian Science Foundation since 2013.

Disciplines	Grant in HRK	Grant in EUR	Share
Biomedicine and health	143 187 230,96	19 340 478,28	21,08%
Biotechnology	80 217 431,70	10 835 068,78	11,81%
Social	36 159 784,53	4 884 147,30	5,32%
Human	50 961 350,91	6 883 413,37	7,50%
Interdisciplinary	837 942,95	113 182,00	0,12%
Nature	226 176 075,40	30 549 885,24	33,30%
Technical	141 655 120,87	19 133 534,26	20,86%
Total	679 194 937,32	91 739 709,23	100,00%

Source: Author's calculations based on HRZZ data: http://www.hrzz.hr/default.aspx?id=2313 (13.09.2019).

According categories of grants, out of biomedicine and health projects founding for (basic) research projects amounted to 77%, while almost all the rest was spent for established research projects (Figure 4).

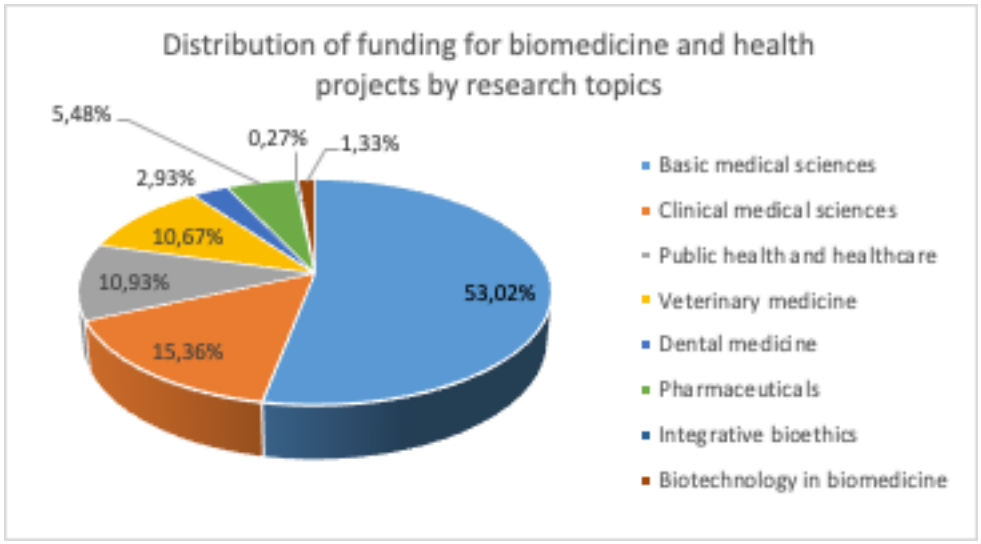
Figure 26: Distribution of biomedicine and health projects' funding by HZZ according to grant types.



Source: Author's calculations based on HRZZ data: http://www.hrzz.hr/default.aspx?id=2313 (13.09.2019).

Analysing distribution of biomedicine and health projects in terms of research topics, more than half of the funding was spent for primarily basic medical science projects, however clinical medical science, public health and healthcare and veterinary medical research projects amounted to also more than 10% of the funding.

Figure 27: Distribution of funding for biomedicine and health project by research topics.



Source: Author's calculations based on HRZZ data: http://www.hrzz.hr/default.aspx?id=2313 (13.09.2019).

The Ministry of Economy, Entrepreneurship and Crafts is responsible for promotion of innovation in the business sector. Since the country's accession to the European Union, SME development funding has been multiplied, therefore national innovation financing plays a complementary role.

The Act on state aid for research and development projects[69] aims at the increasing the number of enterprises investing into research and development. Support is provided through tax breaks, for companies on the profit tax, for natural persons on income tax. Level of tax break depend on the categories of innovation activities: basis research, industrial research, experimental development and feasibility study. For the different categories different percentages apply in case of small, medium and large enterprises, in the range 25% (experimental development for large companies) to 100% (basic research). In each category there is a maximum defined: for basic research 300 000 HRK, while for feasibility studies 50 000 HRK. Application for this category of state aid must take place before the project starts. Implementation of the projects may last up to three years (Zakon, 2018).

Besides tax break subsidies the Ministry of Economy, Entrepreneurship and Crafts, through its implementing agency HAMAG-BICRO, has implemented several programmes with non-repayable grants that are shown in Table 2.

Table 13: Nationally funded schemes for research and development projects.

Name of the scheme	Duration	Aim	Funding (in HRK)
RAZUM (Development of knowledge-based enterprises)	2005 –	Provision of seed money funding for start-up enterprises for product development in the knowledge-based sector.	142 100 000
TECHRO (Programme for technology development infrastructure)	2008 –	Development of competitiveness of the economy through development of support institutions (technology incubators, technology and business centres, competence centres, development and research centres). Eight projects have been financed, thereof five projects in the continental region.	75 900 000
IRCRO programme for R&D	2008 –	Funding for SME for R&D projects with scientific research institutions, in order to improve business and academia links and better utilisation of research infrastructure. Several projects have been funded in biotechnology and medicine.	30 000 000
UTT (Support for technology transfer offices)		Strengthening the role of technology transfer offices at various universities and public research institutions, particularly in commercialisation activities. Financed through loan of the World Bank.	11 000 000

Source: https://hamagbicro.hr/bespovratne-potpore/programi-podrske-inovacijskom-procesu/ (18.09.2019).

[69] Zakon o državnoj potpori za istraživačko-razvojne projekte (NN 64/2018).

Currently available scheme is dedicated for the check of innovation concept. Aim of the scheme is to finance pre-commercial activities in the early phase of product, service or technology development, in order to lower the risks arising in later periods of commercialisation (HAMAG-BICRO, 2018). The latest scheme has been opened in April 2019, under the name PoC8, and available for SMEs and physical persons as well, who are seriously considering the establishment of a company and are not owners of any other business falling under the category of large company. The scheme provides support to prototype development and market analysis or feasibility study. The grant provided is between 100 000 and 500 000 HRK, with a co-financing rate of 70% for micro and small, and 60% for medium enterprises (HAMAG-BICRO, 2019). The scheme is horizontal, i.e. available for all eligible applicants from the health sector as well. As the call has been opened until 2 September 2019, applications are currently under evaluation. Previously seven similar calls have been carried out, in the recent calls (PoC7) with assistance of the "identified centres" that are partner institutions (R&D centres of universities, technology parks, TTOs etc.) of the Ministry all over the country. In the past call the maximum subsidy available was HRK16 300 000 (approx. €2 223 000) (TERA Technopolis, 2018).

2.2.3. EU Structural and Investment Funding

2.2.3.1. Overall strategic framework

As Croatia has accessed the EU a short time before the start of the new financial perspective, there was a certain pressure on the national administration to comply with priorities and policies defined by the key European strategies. During negotiations Croatia faced a strict approach of the European Commission: opening of negotiation chapters had already been bound to certain policy benchmarks. As membership was official from 1 July 2013 on, a very short half-year period strategic framework has been prepared, parallel with starting the preparation of the new programming period.

The EU 2020 strategy aims at smart, sustainable and inclusive growth, setting targets to all member states in the field of employment, spending for R&D, life-long learning and poverty. In case of Croatia spending for R&D out of GDP has been 0,78% at the beginning of the programming period in 2014, in 2017 it reached 0,86%, however the target value to be reached until 2020 is 1,4%. With this data Croatia is in the lowest quartile of the member states, but higher than in Romania, Latvia, Malta, Cyprus or Bulgaria, but below all the Visegrad countries.

The Partnership Agreement signed with the European Union declares €8 610 000 000 for Cohesion Policy, structure of the operational programmes (OP) follow a monofund approach: the OP Competitiveness and Cohesion (OPCC) is financed by the European Regional Development Fund (ERDF) and the Cohesion Fund (CF), while the OP Efficient Human Resources (OPEHR) by the European Social Fund (ESF) and the Youth Employment Initiative (YEI) (EC, 2014). For analysis research and innovation funding through Cohesion Policy will be further analysed through the OPCC.

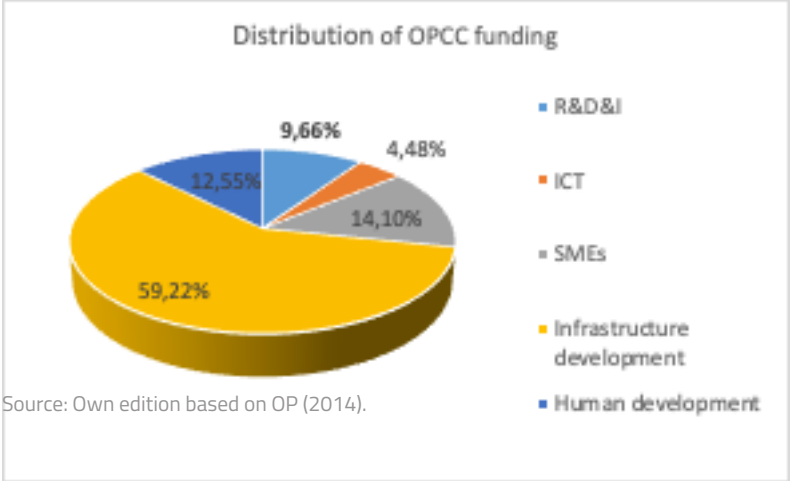
The OPCC covers all TOs defined by the CPR, apart from TO8 Employment, which is solely governed by the OPEHR. The TO1 covering R&D and innovation amounts to nearly 10% of the OP's allocation (Table 3), while with further TOs combined relevant from innovation point of view allocation is beyond 28% (Figure 6). In general, priorities of the OP completely reflect the logic of the CPR, which makes tracking and monitoring of performance relatively easy.

Table 14: Distribution of funding between TOs of OPCC.

TO no.	TO description	Allocation	Share
1	Research, technological development and innovation	€664 792 165,00	9,66%
2	Information and communication technologies	€307 952 676,00	4,48%
3	Small and medium-sized enterprises	€970 000 000,00	14,10%
4	Low-carbon economy	€531 810 805,00	7,73%
5	Climate change adaptation	€245 396 147,00	3,57%
6	Environment and resource efficiency	€1 987 360 608,00	28,88%
7	Sustainable transport	€1 310 205 755,00	19,04%
8	Employment	€0,00	0,00%
9	Social inclusion	€356 500 000,00	5,18%
10	Education and training	€270 914 791,00	3,94%
11	Cooperation	€236 112 612,00	3,43%
Total		€6 881 045 559,00	100,00%

Source: Own edition based on OP (2014).

Figure 28: Distribution of OPCC funding by major topics.



Source: Own edition based on OP (2014).

Inside Priority (or TO) 1the programme distinguishes two specific objectives (SO), which are in line with the relevant investment priorities defined by the ERDF regulation[70].

[70] Regulation (EU) No 1301/2013 of the European Parliament and of the Council of 17 December 2013 on the European Regional Development Fund and on specific provisions concerning the Investment for growth and jobs goal and repealing Regulation (EC) No 1080/2006.

Table 15: Distribution of funding between specific objectives within TO1 of OPCC.

Investment priority 1a	Enhancing research and innovation (R&I) infrastructure and capacities to develop R&I excellence, and promoting centres of competence, in particular those of European interest	
Specific objective 1a1	Increased R&D capacities of R&D sector to perform excellent research and to serve the needs of economy	€334 321 739
Investment priority 1b	Promoting business investment in R&I, developing links and synergies between enterprises, research and development centres and the higher education sector	
Specific objective 1b1	Increased development of new products and services resulted from R&D activities	€205 000 000
Specific objective 1b2	RDI activities of business sector increased through creation of favourable innovation environment	€125 470 426

Source: Own edition based on OP (2014) and MRRFEU (2017).

SO 1a and SO 1b are differing in their target groups. SO 1a1 is focusing on the public bodies and research structures, scientific organisations and transfer institutions. Main indicator of this objective is the number of scientific publications published in journals indexed by the Web of Science (OP, 2014; 48). On the other hand, SO 1b1 puts businesses into focus (SMEs and large companies as well), in order to increase their innovation activity. Main indicator is measured through number of patent applications and share of newly developed innovations' sales in turnover (OP, 2014; 58). SO 1b2 targets the Ministry of Economy and clusters operating in the strategic S3 sectors, measured through business expenditure on research and development (OP, 2014; 58).

Implementation of SO 1a is delegated to the Ministry of Science and Education, as first level intermediate body, based on contract with the coordinating Ministry of Regional Development and EU Funds. Similar coordination role has the Ministry of Economy, Entrepreneurship and Crafts for the SO 1b. In case of SO 1b operational management of calls, evaluation and contracting is carried out by the Croatian Agency for SMEs, Innovations and Investments (HAMAG-BICRO) (Uredba, 2014).

2.2.3.2. Financing of R&D capacity development (SO 1a)

For SO 1a1 financed projects are selected through various calls and selection methods. The aim is to renew the scientific and research infrastructure (implementation and preparation of technical documentations) and contribute to the informatisation of science monitoring (project "Science and technology foresight" – OP, 2014; 49).

KK.01.1.1.01	Top-notch Research Centres of Excellence	
Objective	Strengthening the capacities of scientific centres of excellence	
Beneficiaries	Designated centres of scientific excellence	
Max. funding/project	HRK38 000 000,00	~ €5 100 000

Key element among the interventions is to strengthen the role and capacities of centres of scientific centres of research excellence (CoRE) in various disciplines. Altogether 13 CoREs have been set up, thereof ten were eligible for this call. Several has relevance from health innovation (coordinator institutions in brackets – ZCI, 2019)

- Scientific Centre of Excellence for Reproductive and Regenerative Medicine (University of Zagreb, School of Medicine);
- Centre of Excellence for Virus Immunology and Vaccines (University of Rijeka, Faculty of Medicine – not in the NUTS 2 region Continental Croatia);
- Centre for Basic, Clinical and Translational Neuroscience (University of Zagreb, School of Medicine;
- Scientific Centre of Excellence for Personalised Health Care (University of Zagreb, Faculty of Pharmacy and Biochemistry; University of Osijek)

All the four relevant CoREs have applied their projects, with elements of capacity development, equipment and various research activities. In this call for the different types of activities different co-financing rates were defined, however public institutions, as beneficiaries could apply for 100% co-financing.

KK.01.1.1.02	Investing in organizational reform and infrastructure in R&D and innovation	
Objective	Providing support for innovation reform through infrastructure development	
Beneficiaries	High education institutions, scientific institutions, local governments	
Max. funding/project	HRK456 000 000,00	~ €61 600 000

In this call the eligible organisations could apply with 100% co-financing. In fact, beneficiaries could apply basically for physical construction activities, purchase of equipment, but soft elements for organisational development were also eligible. Altogether 13 projects have been started so far, thereof seven projects target directly health innovation. With one exception, the University of Osijek, all beneficiaries of health innovation projects are located in Zagreb.

KK.01.1.1.03	Science and technology foresight	
Objective	Setting up a coherent system for prioritizing research, development and innovation policies in the Croatian scientific space.	
Beneficiaries	Ministry of Science and Education	
Max. funding/project	HRK15 494 132,14	~ €2 000 000

The project has been selected as a strategic project, without open call. The project has been started in December 2017 and finishes in December 2021. Main output of the operation is the setup of an informational system for the beneficiary ministry, in order to make available data about research, development and innovation activities. Moreover, the project will provide in-depth analysis on scientific capacities, with involvement of relevant stakeholders and revision of existing strategic documents (MRRFEU, 2017b). The project has indirect relevance for innovation in the health sector, as health is one of the priority areas of the S3 strategy.

KK.01.1.1.04	Investment into knowledge and innovation	
Objective	Providing support to cooperation projects between scientific institutions and the business sector, in order to improve quality of R&D activities.	
Beneficiaries	Scientific institutions and their partners	
Max. funding/project	HRK6 800 000,00	~ €900 000

Under this call project proposals have been already submitted, however evaluation is still ongoing, therefore no projects are under implementation yet.

KK.01.1.1.05	Centre for advanced laser technology	
Objective	Development of infrastructure based on advanced laser technology at the Institute of Physics	
Beneficiaries	Institute of Physics	
Max. funding/project	HRK121 304 417,38	~ €16 400 000

As a pre-selected project, it has been allocated to the Institute of Physics in Zagreb. Main output of the project is a modern laser technology centre, which, in its research activities, shall focus on key social challenges, including nutrition and health. The project is financed with 100% co-financing.

KK.01.1.1.06	Development and strengthening of synergies with the horizontal activities of the Horizon 2020 programme.	
Objective	Providing support to improvement of innovation capacities, development of infrastructure and equipment for organisations, which have been funded by Horizon 2020.	
Beneficiaries	Pre-defined, beneficiaries of projects under the horizontal activities of Horizon 2020 "Spreading Excellence and Widening Participation"	
Max. funding/project	HRK1 500 000,00	~ € 200 000

The call targets partners of Horizon 2020 projects that have relevance for Cohesion Policy and the smart specialisation strategy. Under this call six projects have been started, thereof one has direct health innovation relevance. The project is owned by the Faculty of Veterinary Medicine of the University of Zagreb, dealing with molecular medicine and innovative diagnostic processes.

KK.01.1.1.07	Capacity development for research, development and innovation	
Objective	Providing support to cooperation projects between scientific institutions and the business sector, in thematic priority areas of the S3 strategy.	
Beneficiaries	Scientific institutions, SMEs and large companies.	
Max. funding/project	HRK6 800 000,00	~ €900 000

The call has been opened in 2018, evaluation of projects is still ongoing.

KK.01.1.1.08	Croatian scientific and education cloud	
Objective	Development of national e-infrastructure, in form of a computing and data storage cloud.	
Beneficiaries	University of Zagreb, University Computing Centre	
Max. funding/project	HRK196 802 600,00	~ €26 600 000

The project HR-ZOO has been started in July 2018 and will be finished in September 2022. Co-financing rate is 100%.

KK.01.1.1.09	Preparation of R&D&I infrastructure projects	
Objective	Development of technical documentations for key infrastructure development projects for R&D facilities. national e-infrastructure, in form of a computing and data storage cloud.	
Beneficiaries	Scientific institutions.	
Max. funding/project	HRK9 120 000,00	~ €1 200 000

Project proposals have been submitted in January 2019, therefore evaluation is still ongoing. It is expected that scientific institutions in the health sector will be active in this call. Co-financing may reach 100%, if activities don't fall under state aid.

KK.01.1.10	Children's Centre for Translational Medicine at the Children's Hospital Srebrnjak	
Objective	Establishment of a competitive and innovative facility for translational medicine and carrying out organisational reform.	
Beneficiaries	Children's Hospital Srebrnjak	
Max. funding/project	HRK432 234 746,80	~ €58 400 000

The project – due to its size – is defined as a major project by the OPCC. The project has been submitted in June 2018, grant contract has been signed in July 2019 (Bolnica Srebrnjak, 2019), the project is currently being launched. Co-financing amounts to 100%. The project has clear relevance to health-innovation, as the hospital is a registered research institution with significant research activities.

2.2.3.3. Financing research and innovation for businesses (SO 1b)

SO 1b (research and development projects targeting the business sector) have been managed by the Ministry of Economy, Entrepreneurship and Crafts. The SO is implemented through open calls and three strategic projects.

KK.01.2.1.01	Increased development of new products and services resulted from R&D activities	
Objective	Support to R&D projects of the business sector, support to research infrastructure development and equipment for businesses.	
Beneficiaries	Large companies, small and medium size enterprises	
Max. funding/project	HRK56 000 000,00	~ €7 600 000

The first call focused on five prioritised S3 areas (health and quality of life, energy and sustainable development, transport and mobility, security and nutrition and bioeconomy), the second call, which was due on 2 September 2019, is opened to all 11 sub-priority areas. By scoring contribution to the improvement of competitiveness in the S3 priority areas is 30%, further 35% is given to the significance of the research carried out to national and global economy (MINGO, 2016a). In the first round 49 projects were selected, which was followed by another selection round. Currently, until end of May 2019, 87 projects are running, thereof nine has relevance for innovation in the health sector.

KK.01.2.2.01	National project for Competitiveness cluster initiatives support	
Objective	Identification and analysis of Croatian position in Global value chains, support to establishment of competitiveness clusters, in order to foster innovation, productivity and diversification.	
Beneficiaries	Ministry of Economy, Entrepreneurship and Crafts; Croatian Chamber of Economy.	
Max. funding/project	HRK67 494 068,00	~ €9 100 000

The project has been selected as a strategic project, in partnership of the Ministry and the Croatian Chamber of Commers, as project partner. The project aims at the development of strategic framework for cluster initiatives and support for capacity strengthening and smart skills development; in the second phase implementation of cluster development activities (CIRAZ, 2016a). Since 2012 in Croatia 12 competitiveness clusters have been established (S3, 2016; 17), one of them is the health industry competitiveness cluster, which includes, besides public bodies, 14 private company members and 13 science and research organisations (S3, 2016; p. 38). The cluster is usually referred as a good example of triple helix cooperation (S3, 2016; 37). Prior to the strategic project each competitiveness cluster has been awarded 100 000 HRK for preparatory studies, promotion and co-financing of various projects. The health competitiveness cluster has been the weakest in absorption, only 25% of the funding was used (MINGO, 2015a). The most recently established competitiveness cluster has been set up for personalised medicine (MINGO, 2015b).

KK.01.2.2.02	Strategic project for development of Innovation Network for Industry and creation of Thematic Innovation Platforms	
Objective	Enhancement of the innovation system, networking its stakeholders and setting up efficient communication between public, scientific and research and the business sector.	
Beneficiaries	Ministry of Economy, Entrepreneurship and Crafts; Croatian Chamber of Economy.	
Max. funding/project	HRK66 294 768,00	~ €9 000 000

The project aims at the setup of institutional platform for research and development, which will serve as a tool for communication and stakeholder involvement. The project also promotes the establishment of innovation council for industry and thematic innovation councils in order to develop long-term RDI sectoral strategies, in line with the S3 priorities (HGK, 2018). Inova Think Thank should be an international advisory council for implementation of industrial, innovation and S3 strategies. Its aim shall be to create and promote new ideas and consult throughout the implementation process of the various strategies (CIRAZ, 2016b). The project will include a project preparation facility as well, through elaboration of a database for projects according to the S3 strategy (HGK, 2018).

KK.01.2.2.03	Strategic project for development of Innovation Network for Industry and creation of Thematic Innovation Platforms	
Objective	Improvement of innovation environment, by increase of research, development and innovation activities in the business sector through development of competence centres, in line with the S3 strategy.	
Beneficiaries	Organisations previously registered and accredited by the Ministry. The cluster might be a separate legal entity (as research institution, innovation cluster or manager of business infrastructure) or consortium of applicants made of companies and scientific institutions.	
Max. funding/project	HRK112 282 500,00	~ €15 200 000

These centres shall be set up as a network of business entities, for providing assistance to improve innovation capacity. Competence centres may be a consortium of enterprises and other business support institutions; may be an innovation cluster or a separate legal entity that is managing research infrastructure on behalf of a public body (local, regional or national government) (MRRFEU, 2017a; 9).

The available funding is divided among five thematic areas defined by the S3, which includes "health and quality of life" and "nutrition and bio-economy". Each of these thematic areas are allocated 157 195 500,00 HRK (~ €21 200 000), which should be divided among the applying clusters under this topic (MINGO, 2017).

The call was opened at the end of 2017, a pre-selection round has taken place, but final project selection and contracting has not been done so far.

2.2.3.4. Performance of applicants from the health sector

Assessment of the performance of the health sector takes place on basis of the list of ongoing operations published by the Ministry of Regional Development and EU funds on its website[71]. The database has been closed on 31 May 2019. The database includes IDs of projects, names of beneficiaries, titles of the operations, a short summary, start and end dates of the projects, the total eligible (committed) funding, the co-financing rate and the place of registration of the beneficiary. The database under Priority Axis 1 (Strengthening the Economy through Application of Research and Innovation) contains 130 approved and ongoing projects. Health-relatedness of the financed projects has been identified on the basis of the short project descriptions. Projects of medicine, pharmaceutics, bioanthropology, biochemistry, veterinary, genetics and e-health solutions were taken into consideration as health sector. Even if health-relevance is unambiguous for some natural science projects (chemistry, physics), they have not been considered as health innovation projects in this analysis. Similarly, horizontal projects were also excluded. Altogether 20 projects have been qualified as health innovation.

Table 16: Occurrence of health innovation projects in different calls.

Call ID	Call	Total no. of projects	No. of health-related projects	Share of health projects in call	Distribution of health projects between calls
KK.01.1.1.01	Research Centres of Excellence	10	4	40,00%	20,00%
KK.01.1.1.02	Infrastructure in R&D and innovation	22	6	27,27%	30,00%
KK.01.1.1.03	Science and technology foresight	1	0	0,00%	0,00%
KK.01.1.1.05	Centre for advanced laser technology	1	0	0,00%	0,00%
KK.01.1.1.06	Synergies with Horizon 2020	6	1	16,67%	5,00%
KK.01.1.1.08	Croatian scientific and education cloud	1	0	0,00%	0,00%
SO 1a total		41	11	26,83%	55,00%
KK.01.2.1.01	Development of new products (IRI)	87	9	10,34%	45,00%
KK.01.2.2.01	Competitiveness cluster initiatives	1	0	0,00%	0,00%
KK.01.2.2.02	Innovation Network for Industry	1	0	0,00%	0,00%
SO 1b total		89	9	10,11%	45,00%
Total		130	20	15,38%	100,00%

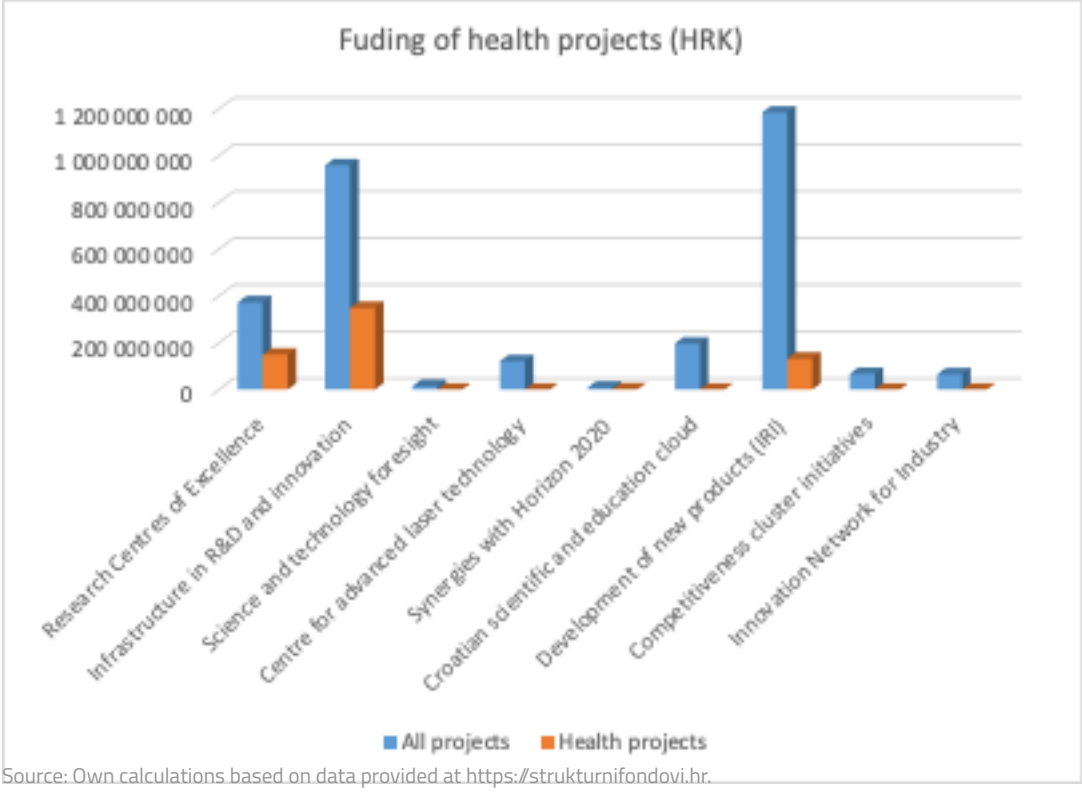
Source: Own calculations based on data provided at https://strukturnifondovi.hr

[71] https://strukturnifondovi.hr/wp-content/uploads/2019/06/Popis-operacija-OPKK-2014-2020_31052019.xlsx (06.08.2019).

The highest share of health projects occurred among the projects for research centres of excellence and for R&D institutions' development (KK.01.1.1.02), which are founding public institutions. Share of health project among the private sector projects (KK.01.2.1.01) was much lower (10,34%). Globally, 55% of the health-related projects are promoted by the public sector, 45% is coming from private enterprises (Table 5).

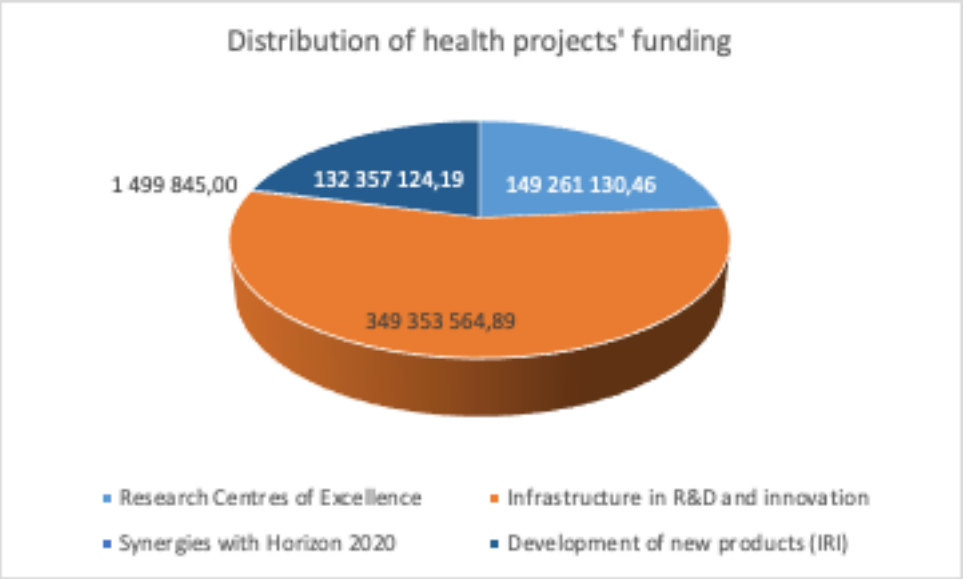
Funding patterns are similar. The highest amount of funding appears under the infrastructure development (KK.01.1.1.02) call. Projects for research excellence and new product development (KK.01.2.1.01 or "IRI") have similar funding performance (Figure 7). Considering distribution among calls, more than half of the funding for health innovation is realised in public R&D&I infrastructure development (Figure 8). Altogether, 21,12% of funding under Priority axis 1 has been spent for health innovation projects.

Figure 29: Funding of health project under the different calls.



Source: Own calculations based on data provided at https://strukturnifondovi.hr.

Figure 30: Distribution of funding of health project between calls.

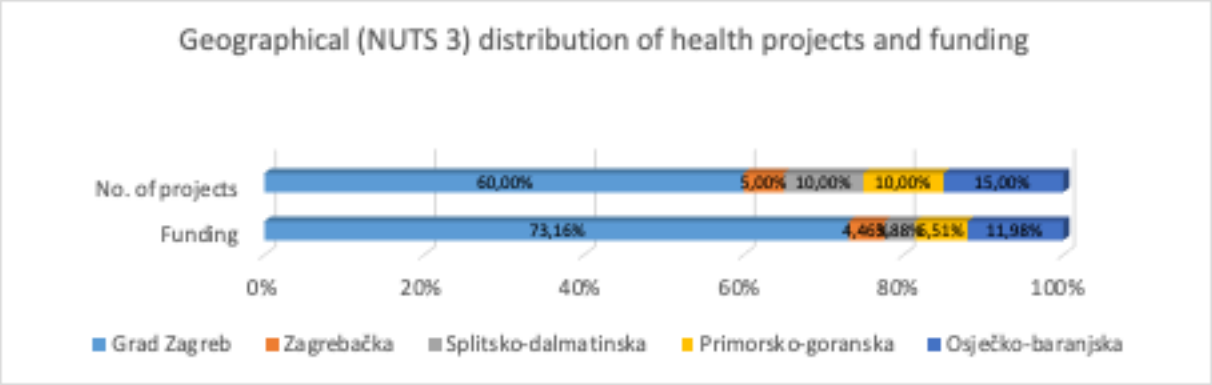


Source: Own calculations based on data provided at https://strukturnifondovi.hr.

Comparing with national funding patterns (Table 1), it can be stated that share of the health sector is very similar (21 vs. 22%). Although, in case of national financing number of projects is higher, while financing is significantly lower. Similar patterns show a stable interest of the health sector in innovation schemes.
In terms of geographical distribution health projects are very much concentrated in counties with medical faculties. The only "exception" is Zagreb county, which belongs to the direct agglomeration of the capital city.

The relative strong position of Osijek (the biggest city of the Continental Croatia NUTS 2 region after Zagreb) must be emphasized: along with two public institutions (university, clinical hospital centre) there is an active private company as well (Genos d.o.o.). In spite of the relatively strong role of the large urban centres outside Zagreb, in terms of financing concentration in the capital city is much stronger: 73% of the funding goes to Zagreb, meaning their projects are of bigger size, while size of projects in the regional centres are smaller and similar to each other (Figure 9).

Figure 31: Geographical (NUTS 3) distribution of health projects and funding.



Source: Own calculations based on data provided at https://strukturnifondovi.hr.

2.3. Project implementation: experiences, obstacles and best practices

Implementation of projects takes place after successful project selection, which is a long way to go, both for beneficiaries and implementing bodies. In line with the regulation different phases of implementation is carried out by different bodies. Submission and administrative check are done by the second level of intermediate bodies, while eligibility and quality assessment, just like decision on project selection is carried out by the coordinating ministries (Uredba, 2014; MINGO, 2016a).

During implementation applying the Act on Public Procurement[72] is obligatory, also for beneficiaries that are not financed from the state budget. During implementation monitoring is carried out by the second level of intermediate bodies (Central Finance and Contracting Agency for SO 1a, and HAMAG-BICRO for SO 1b). During implementation beneficiaries should submit intermediate progress reports and a final report at the end of the project. In three and five years after finishing the project a sustainability check is carried out (MINGO, 2016b). During project implementation particular guidelines is developed for visibility requirements, that should also be taken into consideration.

In order to get acquainted with experience of beneficiaries, two organisations have been interviewed, which represent characteristically different target groups:

1. University of Zagreb, Centre for Research, Development and Technology Transfer. The University is a key player in innovation, it currently implements ten innovation projects under priority axis 1, including the Croatian scientific and education cloud (KK.01.1.1.08) as pre-selected strategic project, and two further public R&D infrastructure development projects, by the Faculty of Pharmacy and Biochemistry (KK.01.1.1.02), and the Faculty of Veterinary Medicine (KK.01.1.1.06).
2. Genera Plc., as beneficiary of an R&D project for developing new poultry vaccines, implemented in the framework of the IRI call (KK.01.2.1.01).

For public R&D infrastructure development projects the most important statements and lessons from implementation were the following:

- On strategic level EU-funded projects are filling an important gap, as national research funding is rather focusing on basic research. ERDF-funded projects, on the other hand, have relatively low contribution to innovation, it is mostly appropriate for organisational reform, infrastructure and capacity development, application of good practices. R&D infrastructure development funding is rather considered as some kind of replacement for national funding. Horizon projects are having a higher added value in developing excellence. There is a lack of financing for pre-commercial development for public institutions, only for businesses.
- Project development: projects for health innovation are usually very well prepared, they are aware what they want to achieve. As many FP7 and Horizon 2020 projects prove, Croatian researchers in health science are in the top level. Main indicator is number of publications or number of patents, which are often defined too ambitious and puts a lot of pressure on the staff during project implementation. Geographical preference in favour of less developed regions was formerly applied in various ERDF-financed schemes, which was disadvantageous for Zagreb-based institutions. This preference in scoring is not used anymore.
- Evaluation is often overlong. Croatia is a small country, often lacks appropriate evaluators, who are not in conflict of interest. Honorary for evaluations is very low, hard to recruit them. For excellence projects, in order to assess global relevance of a project, foreign evaluators are involved. This takes a lot of time.

[72] Zakon o javnoj nabavi. Narodne novine NN 90/11, 83/13, 143/13, 13/14.

- Project implementation: indicators as publications and patents often might misdirect project implementation, putting a pressure to comply with them. ERDF- (and generally EU-) funded projects need significant administrative capacities, which is not available at each research and scientific organisation. This makes team leader professors spending a lot of time with contracting, reporting and administration issues. Professors are also often occupied with teaching, lack motivation to apply. Professional science-managers dealing with intellectual property issues should be trained to ease administrative burden on researchers. On the other hand, they must be motivated, e.g. by additional payment, which is often complicated as they are public servants and paid from budget of the Ministry. Hospitals are practice and teaching base for the university, they are occupied with the health service, but often they are involved in projects. Public procurement makes project implementation very complicated, especially when special equipment should be purchased. Procurements usually last long, which often threat on-time achievements of project goals. Control and revision are also stricter for ERDF projects, everything is defined by administrational compliance, therefore Horizon 2020 is more suitable for real research projects.
- Sustainability: already established research centres of excellence, particular in health innovation are working on European level, most of them are collaborating in FP7 and Horizon 2020 projects as well, so their sustainability is ensured. There are expectations towards the thematic sub-councils currently being established, to set priorities. It would be important to have more centralised programmes (Horizon Europe), in order to maintain the level of excellence achieved.

As for private innovation beneficiaries the following experiences were shared:

- On strategic level: The pharmaceutical sector is based on big companies. It has been a challenge to communicate what they are doing, particularly when they were involved in elaboration of the S3 strategy. Veterinary medicine has been existing for more than 100 years. The company deals with vaccine development for a long time. Projects of the company follow a step-by-step approach, their projects are modular. Limitation of funding to SMEs is a problem for them, as they have become a large company. They consider exclusion of large companies from some grants a problem, and a double standard. In case of funding for public institutions large organisations, e.g. hospitals, are also eligible. Genera is the biggest player in veterinary medicine in Croatia. They are open not only for R&D projects, but other ones as well.
- Project development: as they are not SME anymore, they could not apply for SME grants. They have applied for the last call of IRI in 2016, where large companies were also eligible, albeit with a lower co-financing rate. The project idea was development of vaccines. As they were not able to write the project on their own, must hired consultants, which were selected carefully, after several hearings. Application for a project is an important decision: co-financing is an important element. There must be appropriate people behind a project, as all project must be justified with turnover and profit. Approach of the management must be proactive towards the consultants: they ask what and how project would be eligible. This needs a certain level of confidence and trust. Communication is important between the administrative bodies and the companies. During application phase there are often a lot of questions, which would not be possible to cope with without consultants. They did not foresee combination of different grants.
- Evaluation: long evaluation is a key problem, particularly for the pharmaceutical sector, due to the high value of novelty and patenting. Evaluation was done by scoring: projects have been listed by scores, and have been financed until funding was available.

- Project implementation: main difference between national funding and EU-funding that the latter reimburses the co-financing on basis of invoices, while national funding worked with advance payment. The EU system is more transparent, but also requires more administration. Main problem was public procurement. Procurement is done by consultants, the same ones who made the project. Internal management of projects is done by 15 people. Each employee must have a clear work description and are monitored by time sheet. They have developed a research laboratory, where they also keep files, which is very time and money-consuming. Works are not financed by this project, as it was not needed, only equipment was purchased, but most of the funding goes for human capacity. Often they order studies, which are not possible to do in Croatia, but only by global companies, they must involve the leaders of the industry. IRI has supported this. They are aware of centres of excellence and competence centres, but they need special detailed services, generalised content is not sufficient. These centres had to work more for businesses. For smaller companies it would be a big added value to get such services from these centres than buying on the market.
- Sustainability: they are the biggest player in veterinary medicine in Croatia, their market is global. They have been bought by UK-based company Decra Plc., which is a huge help in commercialisation. Their market is prosperous: they focus on poultry, which is getting more important, as it is the cheapest protein, with growing demand. Large companies are generally more sustainable: they usually don't fail during the sustainability period and give orders to small companies, thus they have a bigger impact on the economy. They have not applied for Horizon 2020 so far.

2.4. Recommendations

2.4.1. Strategic level

Strategic background of innovation in the health sector is well established. There are several sectoral strategies, horizontal strategies are harmonised. Priorities are clearly defined, both in horizontal (innovation policy) and in sectoral terms (high priority given to the health sector, more precisely to pharmaceutics).

In order to better tailor future schemes it would be recommended to prepare action plans for the five prioritised sub-thematic priority areas. Coordination should be carried out by the relevant sub-council of the National Innovation Council. A sufficiently profound action plan would make possible to launch targeted calls, with flexible allocations between the sub-thematic priority areas. Targeted calls would ease evaluation and make it more transparent, as thematically similar projects should be compared.

Steps of implementation:

- Setting up of the sub-council of the National Innovation Council for health and quality of life.
- Public procurement for elaboration of S3 action plan for health and quality of life, with intensive involvement of the relevant stakeholders.
- Adoption of the action plan by sub-council and the relevant ministers.
- Setting up working group for elaboration of targeted call for proposal for health and quality of life innovation projects, both for applicants in the public sector and for businesses.

2.4.2. Project development

The health sector is dominated by large companies that often mobilise capacities of small companies and research institutions. In order to achieve a more intensive involvement of the SME sector, the existing companies shall get assistance by the public sector to appropriately prepare their projects and successfully. In cities where health sector companies are concentrated, technology transfer offices (TTO) must act as bridges between the local research institution and the companies.

Steps of implementation:

- Identify hubs city of health innovation – cities with medical university capacities (Zagreb, Split, Rijeka, Osijek), assessment of their capacities and business background in the wider catchment area.
- Setting up technology transfer offices at the universities and research institutions.
- Hire staff with relevant experience in health innovation policy and practice, including knowledge on intellectual property rights.
- TTOs shall set up communication channels with relevant players of the private sector in the wider catchment area.
- Organisation of networking events for academia and businesses in health innovation, in order to transfer good practices.

2.4.3. Evaluation

Projects targeting global and European excellence in research and innovation should undergo quality assessment on European level. In case of some calls (e.g. KK.01.1.1.01, future targeted thematic calls of KK.01.2.1.01) it would be suggested to replace Croatian in application or parts of the application with English-language application, or bilingual. Supporting documents should be eligible in Croatian, however description of the technical content would be submitted in English. This may ease the shortage of evaluators on one hand, on the other hand projects would be measured on a European standard. A European pool of health innovation project evaluators should be useful and may be applied.

Steps of implementation:

- Starting consultation and debate within the sub-council of the National Innovation Council on application of English language in some parts of the application of health innovation projects.
- Initiating consultations with relevant bodies of European research excellence on setting-up of pool of evaluators for health innovation projects.
- Launching an experimental targeted call with the new requirements.
- Evaluation of the submitted projects and make comparative evaluation with other fields of innovation where calls have been implemented according to the previous practice.

2.4.4. Project implementation

In order to improve efficiency of project implementation, managing experts (project managers) at scientific research institutions should be hired and trained. Training programme shall be developed for these staff, focusing on project management, science management, intellectual property rights and technology transfer. Coordination should be at the Ministry of Science and Education. Upgrading management staff would ease the burden of professors and researchers to deal contracting and financing issues and more capacity would be available for research.

Steps of implementation:

- Development of curricula for innovation project management.
- Launch training course by the Ministry of Science and Education.
- Administrative burden related to project management might be eased by application of simplified costs options in some calls. Simplified cost options are already applicable in the current programming period and will be further extended in the next period. Simplified costs options may be:
- Lum sum: a pre-defined amount of funding for the whole project, where the actual spending is not controlled. This may be used in smaller projects, e.g. national financing schemes.
- Flat rate: either defined as percentage of the project's size or as percentage of research staff costs. In this case the actual spending is also not controlled.
- Standard scale of unit cost: a pre-defined monthly rate of financing for management staff with certain qualification, in line with market prices. In this case only the fact of employment is controlled, but not the number of hours actually spent on the project.

These simplifications may decrease administrative burden on one hand, on the other hand may better motivate innovation management staff, who are usually not benefitting from scientific achievement, but additional payment may be provided.

2.4.5. Sustainability

Successful project applicants should be involved in a network that may be supervised by the sub-council for health and quality of life innovation. Beneficiaries of ERDF-funded innovation projects, particularly businesses, should be diverted to new projects and motivated to participate in European scale research projects (Horizon Europe, European Research Council), as role of these programmes will likely increase from the next period on.

Steps of implementation:

- Setting up of network of innovation project promoters.
- Organisation of networking and informational events for European-scale innovation funding opportunities.
- Providing technical assistance, particularly to businesses, to participate in international research and innovation projects.

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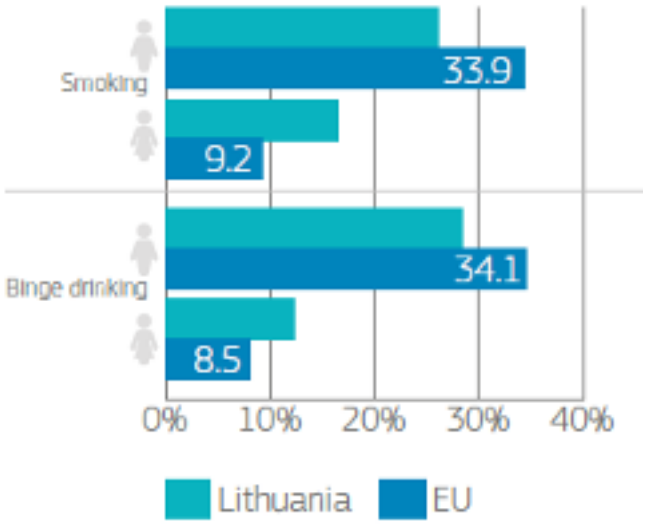
3. Lithuania

3.1. Health situation[73]

Life expectancy in Lithuania is the lowest in the EU, six years below the EU average. Life expectancy for men is nearly 11 years lower than for women, the largest gender gap in the EU. Mortality rates for the two leading causes of death – ischaemic heart diseases and stroke – exceed the EU averages by four and two times respectively. The proportion of people reporting to be in good health is the lowest in the EU, and is particularly low among people in the lowest income quintile.

Lithuanians consume more alcohol than any other people in the EU. Excessive alcohol consumption ("binge drinking") is especially common among men and adolescents. Alcohol-related deaths are more than two times greater than the EU average. Strengthening alcohol control policies is high on the policy agenda in Lithuania, and a new law coming into effect in January 2018 will ban advertising of alcohol products, increase the legal age for consumption to 20 years and restrict sales hours.

Figure 32: Risk factors



Source: State of Health in the EU: Companion Report 2017

Health expenditure per capita in Lithuania is half the EU average. One-third of health spending comes from private sources – largely out-of-pocket payments. Spending on pharmaceuticals forms the largest share of these out-of-pocket payments, as many people pay the full cost of both prescribed and over-the-counter medications. This can create financial barriers to the purchase of pharmaceuticals for some vulnerable groups, especially older and low-income people. In addition, informal payments are not uncommon in Lithuania.

[73] State of Health in the EU: Companion Report 2017

The NHIF, the single purchaser of personal health services, is funded by compulsory income-related contributions and the central government for the non-working population. The Lithuanian health insurance system has an effective counter-cyclical mechanism in place and was successful in protecting public spending on health at the time of the financial crises. Compulsory health insurance fees are covered from the state budget for 19 population groups (as compensations). However, the fee paid from the state budget for those receiving compensations is more than twice lower than that paid by persons covering the fee of compulsory health insurance by themselves. Due to extensive coverage of the compulsory health insurance from the state budget, the state is unable to fulfil its commitments to a full extent and the national health care system is constantly underfinanced[74].

Lithuania has among the highest amenable mortality rates in the EU, indicating that the health care system can improve its effectiveness considerably. Quality indicators provide a mixed picture, but both hospital and primary care services are improving their performance. Notable is Lithuania's exceptionally high suicide rate, despite mental health reform efforts. Reforms are ongoing to cluster acute care in centres with larger catchment areas, create networks of hospitals to provide each service in a more limited number of locations and implement volume thresholds to increase both efficiency and quality. The progress in primary care is following several years of reform, with modernised general practitioner and nursing services and a comprehensive reimbursement system incentivising prevention.

Lithuania has a very large number of hospitals, spread out across most of the country's 60 municipalities. Many reforms have sought to reduce this capacity and shift care to outpatient and primary care services, but Lithuania still has one of the highest number of curative care beds per population in the EU. This is partly due to the shrinking population, which together with urbanisation has left many rural communities with a large hospital capacity.

3.2. National strategies and funds - General Context of Innovation Finance in the Health Sector

This section provides an overview of the general context of financing innovation in the health sector. Firstly, the institutional set-up for decision-making and implementation of innovation policy in Lithuania is presented. It is followed by the definition of the national innovation policy framework based on the principal directions for national strategic development. Finally, the position of innovation in the health sector within this broad policy framework is described.

3.2.1. The Institutional Set-Up for Policy Decision on and Implementation of Innovation

The institutional set-up for decision-making and implementation of innovation policy follows the breakdown of the national science, technology and innovation system by its components, namely science, technology and innovation.

[74] BGI Consulting, Spatial Foresight, t33, Razbor (2018), Assessment of government interventions' impact for the setup and implementation of financial instruments.

The field of science is regulated by the Law of Science and Studies of the Republic of Lithuania[75]. The national policies of research and higher education are formed by the Parliament of the Republic of Lithuania and primarily implemented by the Ministry of Education, Science and Sport of the Republic of Lithuania in concert with the Research Council of Lithuania acting as an advisory body to the Parliament and the Government on the research-related issues.

Its functions include the implementation of research, experimental (social, cultural) development and related programmes, organizing competition-based funding of research programmes and evaluation of research activities carried out in Lithuania.

The fields of technology and innovation are regulated by the Law of Technologies and Innovation of the Republic of Lithuania[76]. The state technology and innovation policies are formed by the Ministry of Economy and Innovation of the Republic of Lithuania. The Science, Technology and Innovation Council acts as an advisory body to the Government on the issues related to research, technology and innovation. It consists of the Minister of Economy and Innovation and the Minister of Education, Science and Sport, as well as associated business and science structures engaged in technology and innovation. Other subjects involved in the implementation of technology and innovation policies are 5 integrated science, studies and business centres (the so-called valleys) and 7 science and technology parks. The valleys are aimed at providing the necessary infrastructure for carrying out applied research and technology development, as well as favourable conditions for establishing new innovative companies[77]. The main function of the science and technology parks is promoting the dissemination of scientific knowledge and technologies, creating the conditions for commercializing the results of the R&D, promoting cooperation between science and business, as well as innovation culture[78].

3.2.2. National Innovation Policy Framework

According to the main long-term national strategic document Lithuania's Progress Strategy "Lithuania 2030"[79], long-term (until year 2030) socio-economic development of the country is determined by the targeted changes in three main areas - smart society, smart economy and smart government. Key initiatives to be implemented in the area of smart society include, on the one hand, improving individual and overall public health as the most valuable asset for personal and societal well-being, and, on the other hand, creating favourable environment for science and research. Similarly, among key initiatives to be implemented in the area of smart economy, funding of science and research institutions for the development of market-relevant innovations is foreseen. Innovation in the health sector constitutes an integral part of national innovation policy. In the period of 2014-2020, the strategic framework of national innovation policy is set in a number of strategic documents, defining directions for both general and sectoral strategic development.

[75] Law of Science and Studies of the Republic of Lithuania, adopted by the Order No. I-1489 of the Supreme Council of the Republic of Lithuania - Reconstituent Seimas of 25 June 1991.

[76] Law of Technologies and Innovation of the Republic of Lithuania, adopted by the Order No. XIII-1414 by the Parliament of the Republic of Lithuania of 30 June 2018.

[77] Information provided by the Ministry of Economy and Innovation of the Republic of Lithuania, available at: https://eimin.lrv.lt/en/sector-activities/innovation/valleys.

[78] Information provided by the Ministry of Economy and Innovation of the Republic of Lithuania, available at: https://eimin.lrv.lt/en/sector-activities/innovation/cooperation-between-business-and-science

[79] Approved by the Resolution No. XI-2015 of the Seimas of the Republic of Lithuania of 15 May 2012.

In the main strategic documents, innovations are mostly referred to as a desired outcome of R&D activities. Lithuania's Progress Strategy "Lithuania 2030" emphasizes lack of RDI investment, particularly from the private sector, and, thus insufficient level of innovativeness in the country. According to the 2019 European Semester Country Report on Lithuania, Lithuania is a moderate innovator. In 2017, it still lagged behind the EU average in terms of both total R&D investment (amounting to only 0.9 % of GDP, compared to the EU average of 2.1%) and private R&D investment (amounting to only 0.3 % of GDP, constituting one fifth of the EU average).

Such challenges as scarce cooperation between businesses and universities or research centres and limited economy's capacity to innovate and absorb RDI were distinguished[80]. The National Progress Programme for Lithuania for the period 2014-2020[81] envisages RDI support under different priority axes describing strategic development in the areas of education and science, economy and health. All of these priority axes indicate various ways of creating favourable conditions for conducting R&D activities, including development of necessary RDI infrastructure, human capital, services, and promotion of cooperation among different RDI stakeholders.

Under the programme's Priority Axis 1 "Education, science and culture", the need to develop RDI infrastructure and human capital, as well as to promote different-level (international, interinstitutional and intersectoral) cooperation is emphasized. Similarly, Priority Axis 4 "High value-added, integral economy" foresees the development of strong system for supporting RDI (including public RDI infrastructure, such as science and technology parks, integrated science, studies and business centres (science valleys), and quality innovation services) and promotes cooperation between education and science institutions, centres of excellence and businesses in implementing joint RDI projects. In addition, the importance of creating the demand for innovation, by encouraging business to invest in R&D activities resulting in innovative products and services, is underlined.

Lithuania's innovation policy for 2014-2020 is further embedded in the sectoral strategic documents setting directions for strategic RDI development. In particular, the Lithuanian Innovation Development Programme 2014-2020[82] sets the ultimate goal of increasing Lithuania's competitiveness by creating effective innovation system and promoting the innovativeness of the economy. The programme defines an innovation as an introduction of new or substantially improved products (goods or services) or processes, new marketing or organisational methods in business practice or organization. Hence, it reflects quite broad understanding of innovation, including different kinds of possible innovations - both technological (innovative devices, tools, materials, techniques, etc.) and social/organizational (innovative solutions for managing processes, human resources, etc.).

Corresponding to the directions for strategic development indicated in the National Progress Programme, the Lithuanian Innovation Development Programme sets the objectives of improving RDI infrastructure (integrated science, studies and business centres (science valleys), science and technology parks, etc.), promoting international and intersectoral (especially between business and science) cooperation in developing high technologies and innovations, as well as promoting demand for innovations (especially those tackling social, economic and environmental challenges). In addition, in the context of promoting business' innovative potential, the programme stresses the importance of attracting private investment in activities generating high added value, especially in the priority areas of RDI (also known as areas of smart specialization).

[80] DG Research & Innovation (2019), Research and Innovation analysis in the European Semester 2019 Country Reports, 104-105.
[81] Approved by the Resolution No. 1482 of the Government of the Republic of Lithuania of 28 November 2012.
[82] Approved by the Resolution No. 1281 of the Government of the Republic of Lithuania of 18 December 2013.

The concept of smart specialization is further developed in the Programme on the Implementation of the Priority Areas of Research and (Socio-Cultural) Development and Innovation Development (Smart Specialization)[83]. The programme aims at developing innovative technologies, products, processes and (or) methods and using the results for responding to long-term national challenges, as well as increasing the competitiveness of Lithuania's economic entities and their abilities to establish in the global markets. On the basis of the existing RDI potential and trends of potential RDI development in the future, 6 priority areas (encompassing 20 priorities) of RDI development were selected.

The latter included economy sectors or their segments characterized by relatively strong scientific potential (ability to adapt new scientific knowledge for development of new technologies), capable economic entities (aware of the benefits of new technologies and able to apply them for increasing their competitiveness) and cooperation between science and business in developing new technologies. It is recognized that funds from foreign financing sources play an important role in funding R&D activities, however, the importance of attracting private sector's investments in RDI is repeatedly emphasized.

According to the 2019 European Semester Country Report on Lithuania, the smart specialisation strategy of Lithuania was rather broad and covered most economic sectors, thus contributing to a thin spread of limited funding[84]. Taking this into account, in 2019, the Programme on the Implementation of the Priority Areas of Research and (Socio-Cultural) Development and Innovation Development (Smart Specialization) was amended[85], regrouping 6 RDI priority areas and 20 priorities into key 7 priorities.

3.2.3. Innovation in the Health Sector

One of the key priorities of smart specialization indicated in the Programme on the Implementation of the Priority Areas of Research and (Socio-Cultural) Development and Innovation Development (Smart Specialization) is health technologies and biotechnologies. It was selected taking into account the most pressing health-related issues: relatively shorter healthy life years, increasing pandemic threats, rapid geographic spread of infectious diseases, environmental pollution by toxic substances, growing competition for highly qualified medical staff, as well as growing expenditure on health care and medicine, especially treatment and long-term care of elderly people. The evaluation of the implementation progress of smart specialization[86], carried out in 2018, revealed that advanced applied technologies for personal and public health was among the most relevant and effective smart specialization priorities, characterized by substantial public and private investment, abundant infrastructure and human resources, relatively higher number of RDI projects jointly implemented by private enterprises and science and education institutions and number of new researchers employed as a result of the projects, as well as relatively higher investment return of the projects. Taking into account the current and future potential of health technologies and biotechnologies (especially in the areas of genetic engineering, microfluidics technologies, epigenetics and biosensors), it remained one of the priorities of smart specialization in the upcoming programming period. In the Programme on the Implementation of the Priority Areas of Research and (Socio-Cultural) Development and Innovation Development (Smart Specialization), broadening the use of fundamental and applied research is suggested as a way of improving treatment, early diagnostics and prevention of diseases, while technological (in particular, e-technologies based) solutions are suggested for increasing the effectiveness of health care system. This echoes the discourse of the National Progress Programme indicating lack of innovation and national scientific research as pivotal challenges in the health sector and

[83] Approved by the Resolution No. 411 of the Government of the Republic of Lithuania of 30 April 2014.
[84] European Commission (2019), Country Report Lithuania 2019 (SWD(2019) 1014 final).
[85] Amended by the Resolution No. 760 of the Government of Lithuania of 24 July 2019.
[86] Research and Higher Education Monitoring and Analysis Centre (MOSTA) (2018), Evaluation of the Progress of Smart Specialization Implementation, 41.

stressing the role of RDI in assessing the impact of various health risk factors, identifying the most effective health interventions and, thus reducing morbidity and mortality from major diseases or health risk factors. Furthermore, under Priority Axis 8 "Health for all" of this programme, the importance of establishing and developing infrastructure for health-related RDI, and promoting cooperation between higher education institutions and scientific research centres, is emphasized.

Health-related RDI is specifically mentioned in the sole health policy strategic document, namely National Cancer Prevention and Control Programme 2014-2025[87]. The latter foresees the development of RDI infrastructure used for conducting cancer research (renovation, furnishing and equipping of science labs), improving human capital (cancer researchers), enabling international cooperation in RDI (integration in the common European research area), as well as indicates cancer-related R&D priority areas.

3.3. The System of Financing Innovation in Lithuania

This section provides an overview of the main funding streams for innovation in the health sector in Lithuania in the period of 2014-2020. The available funding sources are described in terms of size (total RDI funding and proportion of this funding dedicated for supporting innovation in the health sector), eligible beneficiaries and actions to be supported, project selection methods and criteria, project size and results.

3.3.1. European Structural and Investment Funds

In the period of 2014-2020, investment in RDI in Lithuania is highly dependent on European Structural and Investment (ESI) funds provided under the Lithuania's Operational Programme for the European Union Funds' Investments in 2014-2020 (OP). So far, approximately €103 300 000 of ESI funds has been contracted for the projects contributing to innovation in the health sector implemented under the OP's Priority Axis 1 "Strengthening RDI", Priority Axis 8 "Promoting social inclusion and combating poverty" and Priority Axis 9 "Educating the Society and Strengthening the Potential of Human Resources".

Table 17: RDI-related ESI and national budget funding provided under the OP

The type of the measures (number of measures)	The total funding envisaged for the measures	The total funding contracted for the projects	Funding contracted for the projects related to health innovation (share of the total funding contracted)
Creating favourable conditions for conducting R&D activities (4)	€225 615 749	€146 685 648	€34 488 524 (24%)
Funding the actual R&D (11)	€365 277 334	€249 187 166	€60 748 468 (24%)
Funding the introduction of the previously developed innovations (1)	€34 611 543	€22 637 654	€8 065 240 (36%)
Total	€625 504 626	€418 510 468	€103 302 232 (25%)

[87] Approved by the Order No. V-814 of the Minister of Health of the Republic of Lithuania of 16 July 2014.

Currently, 18 measures are being or have been implemented under OP's Priority Axis 1 "Strengthening RDI". 4 measures ("TechnoInvest" (No. 01.2.1-FM-F-816), "SmartInvest LT" (No. 01.2.1-LVPA-V-822), "Inogeb LT" (No. 01.2.1-LVPA-V-842) and "SmartPark LT" (No. 01.2.1-LVPA-V-830) are aimed at facilitating the implementation of RDI policy, in particular increasing private sector's involvement in RDI: developing financial instruments for funding enterprises engaged in R&D in the areas of smart specialization, attracting foreign direct investments in R&D activities implemented in the areas of smart specialization, developing innovation support services, industrial parks and free economic zones. €230 200 000 was contracted for the projects implemented under these measures. However, these projects are of a horizontal nature (benefiting RDI system in general), thus funding for health-related RDI cannot be specified.

Another 4 measures ("Development of RDI infrastructure and its integration into European infrastructure" (No. 01.1.1-CPVA-V-701), "InnoCluster LT" (No. 01.2.1-LVPA-K-833), "InnoConnect" (No. 01.2.1-LVPA-T-844) and "Intellect LT-2" (No. 01.2.1-LVPA-K-855)) largely aim at creating favourable conditions for conducting R&D activities by supporting development of RDI infrastructure and measures facilitating cooperation in RDI. €225 600 000 was assigned for the implementation of these measures and €146 700 000 was contracted for their projects. Almost one fourth (24 percent) of this funding (€34 500 000) was contracted for the projects contributing to innovation in the health sector, which encompassed investments in RDI infrastructure of science and education institutions, private enterprises and clusters engaged in health-related R&D, as well as partner search activities.

10 measures of Priority Axis 1 "Strengthening RDI" and 1 measure of Priority Axis 9 "Educating the Society and Strengthening the Potential of Human Resources" provide funding for conducting actual R&D activities attributable to different stages of R&D process. The funding assigned for the implementation of these measures amounts to €365 300 000. €249 200 000 was contracted for their projects, out of which €60 700 000 (constituting 25 %) was contracted for the projects related to innovation in the health sector. 1 measure of Priority Axis 8 "Promoting social inclusion and combating poverty" provides funding for introducing previously developed innovations. The total funding of this measure amounts to €34 600 000. €22 600 000 was contracted for its projects, out of which over €8 000 000 (constituting 36%) was contracted for the projects introducing health-related innovations.

3.3.1.1. Support for private sector

With an aim of strengthening private sector's RDI potential, 4 measures of the OP's Priority Axis 1 "Strengthening RDI" are exclusively directed towards providing funding for private entities, as project promoters, in conducting activities at different stages of R&D process.

Measure "Innovation Vouchers" (No. 01.2.1-MITA-K-824), aimed at initiating and strengthening cooperation in R&D between business entities and science and education institutions, provides fixed amount of funding (the so-called "innovation vouchers") for private legal entities for purchasing R&D services from science and education institutions, carrying out activities at early stages of R&D process. Projects of this measure were selected on the basis of competitive calls for proposals. Over €1 000 000 was assigned and contracted for the projects of this measure, out of which only a little over €50 000 (constituting 5%) was contracted for the projects related to health innovation (€1 000-4 000 per project), encompassing technical feasibility studies, fundamental research, concept validation and prototyping of innovative products for diagnostics and treatment of diseases.

Measure "InnoStart" (No. 01.2.1-MITA-T-852) provides support for small and medium-sized enterprises (SMEs) in conducting 2-9 stage R&D activities (from concept development to batch testing), as defined in the description of recommended classification of R&D stages[88]. The financing under this measure is available for both newly established SMEs (operating for up to 1-year prior application) and relatively

[88] Approved by the Resolution No. 650 of the Government of the Republic of Lithuania of 6 June 2012.

young SMEs (operating for 1-3 years), as well as for knowledge-intensive SMEs operating for more than 1 year. The projects of this measure are selected on the basis of the continuous project selection procedure (the timeframe for submitting project applications is longer than 1 year), providing a broader window of opportunity for SMEs to apply for funding. In addition, in order to ensure wider geographical coverage of support, two calls for proposals are open, one available for SMEs operating in the largest cities (Vilnius, Kaunas and Klaipėda) and their surrounding regions and another one inviting to participate SMEs operating in the rest of the country's territory. The total funding assigned for the implementation of this measure amounts to €9 400 000. €800 000 was contracted for its projects, out of which €200 000 (constituting 18%) was contracted for the projects related to health innovations (€3 000-30 000 per project), encompassing development of prototypes and innovative products for prevention, diagnostics and treatment of diseases.

Measures "SmartInvest LT+" (No. 01.2.1-LVPA-K-823) and "Smart FDI" (No. 01.2.1-LVPA-T-848) are aimed at attracting foreign direct investment in R&D by supporting foreign investors or local private enterprises whose operation is heavily influenced by foreign investors. The support under these measures might be used for financing R&D activities in the areas of smart specialization, as well as for developing private RDI infrastructure. Furthermore, these measures provide their beneficiaries an opportunity to cooperate in implementing R&D activities with other private entities or science and education institutions acting as project partners. Measures "SmartInvest LT+" and "Smart FDI" slightly differ in terms of project selection methods and requirements for potential applicants. Projects implemented under "SmartInvest LT+" are selected on the basis of competitive calls for proposals. Foreign investors supported under this measure are required to be engaged in R&D for at least 1-year prior application. In addition, either their average annual income of the last 3 years prior application has to amount to at least €1 000 000 and at least one year during this 3-year period their RDI investment has to constitute no less than 1% of the average annual income, or their assets in the last year prior application have to be worth at least €1 000 000. Projects implemented under "Smart FDI" are selected on the basis of the continuous project selection procedure (the timeframe for submitting project applications is longer than 1 year). This measure provides support for foreign investors that either have invested in Lithuania's production or service sectors in the last 10 years, or previously have not operated in Lithuania. The total funding of these two measures amounts to €31 100 000. €15 800 000 was contracted for their projects, out of which €1 500 000 (constituting 10%) was contracted for health-related projects (€300 000 -1 000 000 per project), encompassing development and testing of models used for drug development and development of prototypes of software used for health monitoring.

3.3.1.2. Support for both public and private sectors

3 measures of the OP's Priority Axis 1 "Strengthening RDI" ("InnoVouchers" (No. 01.2.1-MITA-T-851), "Intellect. Joint Science-Business Projects" (No. J05-LVPA-K) and ''InnoPatent" (No. 01.2.1-MITA-T-845)) provide equal financing opportunities for both private and public entities (acting as project promoters). Measure "InnoVouchers" (No. 01.2.1-MITA-T-851), aimed at initiating and strengthening cooperation in R&D between business entities and science and education institutions, provide fixed amount of funding (the so-called "innovation vouchers") for private and public entities (except for science and education institutions) for purchasing R&D services from science and education institutions, carrying out R&D activities at early stages of R&D process. This measure is very similar to the measure "Innovation Vouchers" but differs from the latter in terms of project selection method (applies continuous project selection procedure) and potential beneficiaries (also provides financing opportunities for public organizations that are not science and education institutions). Furthermore, it is worth drawing attention at the possible synergy between this measure and measure "SME Instrument" of the programme "Horizon 2020". Actions to be supported under "InnoVouchers" encompass provision of innovation vouchers for conducting stage 1 R&D activities in the projects implemented under "SME Instrument" of the "Horizon 2020" and awarded label "Seal of Excellence" that were not granted funding for such activities under "Horizon 2020". The total of €5 000 000 is foreseen for the implementation of this measure. Over €2 300 000 was contracted for its projects, out of which

0.2 (constituting 10%) was contracted for health-related projects (€5 000-36 000 per project) including feasibility studies, fundamental research, concept validation and prototyping of innovative products for diagnostics and treatment of diseases.

The largest, in terms of financial volume, measure "Intellect. Joint Science-Business Projects" (No. J05-LVPA-K) is aimed at supporting private entities and public institutions (except for science and education institutions) in conducting R&D activities at different stages of R&D process in cooperation with science and education institutions (acting as project partners). Actions to be supported under this measure also include certification of new products and technologies, thus its outcomes are actual innovations resulting from R&D activities. In addition, the measure provides funding for the development of private RDI infrastructure. The total funding assigned for the implementation of this measure amounts to €150 600 000. €147 800 000 was contracted for their projects, out of which almost €41 300 000 (constituting 28%) was contracted for the projects contributing to the development of health-related innovations (€500 000 -4 000 000 per project). Activities implemented under this measure encompassed the development of prototypes and innovative products (technologies, tools, equipment, etc.) for diagnostics and treatment of diseases, as well as health monitoring.

Measure "InnoPatent" (No. 01.2.1-MITA-T-845) supports activities beyond R&D process, in particular international patenting of inventions or registration of designs with sufficient potential for commercialization. Its projects are selected on the basis on the continuous project selection procedure, providing longer timeframe for submitting applications for support. The total funding of this measure amounts to over €3 000 000. So far, only around €500 000 was contracted for its projects, out of which €100 000 (constituting 22%) was contracted for patenting innovative health-related products (techniques, materials, tools, methods, etc.) to be used for diagnostics and treatment of diseases. These projects are characterized by relatively small size, varying from €4 000 to €18 000, since their actions largely encompass handling of documents required for patenting of inventions or registration of designs.

3.3.1.3. Support for public sector

3 measures of the OP's Priority Axis 1 "Strengthening RDI" ("Targeted research in smart specialization areas" (No. 01.2.2-LMT-K-718), "Promotion of activities implemented by competence centres and innovation and technology transfer centres" (No. 01.2.2-CPVA-K-703) and "Pre-commercial Procurement LT" (No. 01.2.1-LVPA-V-835)), as well as 1 measure of the OP's Priority Axis 8 "Promoting social inclusion and combating poverty" ("Improving infrastructure for cancer prevention, early diagnostics and treatment" (No. 08.1.3-CPVA-V-606)) are directed towards supporting exclusively public sector academic organizations, mostly the country's key RDI players represented by the science and education institutions and university hospitals.

Measure "Targeted research in smart specialization areas" (No. 01.2.2-LMT-K-718) supports R&D activities in the areas of smart specialization implemented by science and education institutions or university hospitals. The total of €53 700 000 was assigned for the implementation of this measure, out of which €27 800 000 was contracted for its projects. €5 600 000 (constituting 20%) was contracted for the projects (€100 000 - 700 000 per project) implemented in the health-related area of smart specialization, namely health technologies and biotechnologies. The absolute majority of these projects were implemented by the top science and education institutions engaged in health-related R&D, namely Lithuanian University of Health Sciences and Vilnius University.

Science and education institutions and university hospitals are also funded under the measure "Promotion of activities implemented by competence centres and innovation and technology transfer centres" (No. 01.2.2-CPVA-K-703). The latter provides funding for smooth operation of competence, innovation and technology transfer centres established within science and education institutions and university hospitals,

including their involvement in R&D activities resulting in patenting of new inventions. The projects of this measure are selected on the basis of competitive calls for proposals. The third call for proposals is currently open. Almost €26 000 000 was assigned for the implementation of this measure. €12 900 000 was contracted for its projects. Out of which €3 700 000 (constituting 29%) was contracted for the projects implemented by the universities and research institutes engaged in health-related R&D (€600 000 - 900 000 per project), indicating that science and education institutions largely assume the role of competence and technology transfer centres in Lithuania. The majority of the projects were again implemented by the key health-related RDI players, namely Lithuanian University of Health Sciences and Vilnius University.

Measure "Pre-commercial Procurement LT" (No. 01.2.1-LVPA-V-835) is aimed at promotion of demand for innovations by supporting contracting authorities in conducting pre-commercial procurement. This measure is of a different, the so-called state planning, type. The total funding assigned for this measure amounts to €15 600 000. Almost €7 000 000 was contracted for its projects, out of which around €1 000 000 (constituting 14%) was contracted for university hospitals (€200 000 - 800 000 per project) purchasing R&D services aimed at developing innovative technologies for tackling health-related challenges.

One of the actions to be supported under the measure "Strengthening scientific capacities of scientists, researchers and students through scientific practice" (No. 09.3.3-LMT-K-712) of the OP's Priority Axis 9 "Educating the Society and Strengthening the Potential of Human Resources" is aimed at funding top-level R&D projects contributing to strengthening of the scientists' capacities. In this case, financing is provided specifically for top-level R&D activities, whose results are expected to be recognized, published and cited in international peer-reviewed scientific journals. Eligible beneficiaries under this action to be supported are universities and public research institutes implementing doctoral programmes and / or cooperating with universities in training scientists. The total funding assigned for the implementation of this measure amounts to €69 800 000. €33 300 000 was contracted for the projects implemented in the above-mentioned area of actions to be supported, out of which €7 200 000 (constituting 21%) was contracted for the projects (up to €600 000 per project) contributing to the development of health-related innovations.

Measure "Improving infrastructure for providing cancer prevention, early diagnostics and treatment services" (No. Nr. 08.1.3-CPVA-V-606) of the OP's Priority Axis 8 "Promoting social inclusion and combating poverty" provides support for introduction of innovative technologies in health care institutions providing specialized oncology services. The total funding assigned for the implementation of this measure amounts to €34 600 000, out of which €22 600 000 was contracted for its projects. Over €8 000 000 (constituting 36%) was invested in the National Cancer Institute and the Hospital of Lithuanian University of Health Sciences purchasing innovative technologies to be used in surgical procedures.

3.3.2. National Research Programmes

Besides co-financing of the projects implemented under the OP, national budget financing is also provided for RDI in the health sector supported under two national research programmes, namely "Healthy Aging" and "Welfare Society". The total of €7 600 000 of national budget funds was contracted for the projects implemented under these programmes. €5 300 000 (constituting 70%) was contracted for health-related projects.

Table 18: RDI-related national budget funding provided under national research programmes

The name of the national research programme	The total funding contracted for the projects	Funding contracted for the projects related to health innovation (share of the total funding contracted)
"Healthy Aging"	€5 205 490	€5 205 490 (100%)
"Welfare Society"	€2 355 025	€89 302 (4%)
Total	€7 560 515	€5 294 792 (70%)

The programme "Healthy Aging"[89] constitutes the main national funding source of health-related R&D activities. It is aimed at production of new scientific knowledge to be used for extending the duration of healthy and quality life of Lithuanian population. In the period of 2015-2021, funds from the national budget can be provided for it projects implementing the following research tasks: (1) developing new methods and technologies for assessing risk factors and preventing aging-associated diseases, (2) developing new methods for early diagnostics and forecasting of the progress of aging-associated diseases by employing biotechnologies, nanotechnologies, information and communications technologies, (3) developing new

methods for treatment, rehabilitation and long-term monitoring of aging-associated health conditions, as well as new technologies reducing social exclusion of elderly people.

The eligible beneficiaries of the programme are limited to Lithuanian science and education institutions defined as legal entities whose principal activity is provision of higher education and / or R&D. In theory, they might encompass both public and private entities, however, in practice, Lithuanian science and education institutions are largely public sector organizations. Private entities might participate in the programme's projects as partners; however, it is rare practice. It is required for the project team to be led by a scientist. The project applications are submitted during competitive calls for proposals. Following the latter, the projects are selected on the basis of expert assessment.

The total of €5 200 000 was contracted for the programme's "Healthy Aging" projects selected during two calls for proposals. Almost €4 000 000 was assigned to 21 projects selected during the first call for proposals (€110 000 -200 000 per project), while another €1 200 000 was assigned to 9 projects selected during the second call for proposals (€13 000-14 000 per project). 80% of these projects were implemented by the two leading public science and education institutions engaged in health-related R&D, namely Lithuanian University of Health Sciences and Vilnius University. These projects encompassed R&D activities at different stages of R&D process: from fundamental research to development of innovative methods, technologies, tools, etc. for promoting healthy aging and preventing, detecting and treating aging-associated diseases. The third calls for proposals, foreseeing to distribute €2 400 000 for the projects (up to €140 000 per project), is currently open. The demand for this programme's funding is high. Only 22% of the total number of applications submitted during the first call for proposals was approved for funding, while in the second call for proposals it only constituted 11%. However, at least 70% of applications fulfilling administrative requirements submitted during both calls for proposals was considered eligible for financing following the expert assessment. Additional €15 000 000 would be required in order to fund all the projects eligible for financing for the 7-year programming period.

[89] Approved by the Order No. V-82 of the Minister of Education and Science of the Republic of Lithuania of 5 February 2015.

The national research programme "Welfare Society" is aimed at producing a comprehensive analysis of the preconditions, factors and trends for the development of a welfare society in Lithuania. Its research tasks include providing a scientific basis for the development of a safe, healthy and inclusive society by analysing social investment for improving healthcare and the health services system. Only 1 out of 24 projects selected during two calls for proposals was related to innovation in the health sector. In particular, over €89 000 was assigned for the National Cancer Institute conducting fundamental research on the application of radiation therapy infrastructure for treating cancer.

3.3.3. Horizon 2020

The main programme sections of Horizon 2020 providing funding opportunities for health-related RDI in Lithuania are "Health, demographic and wellbeing" and EIC Accelerator (SME instrument).

The total of €7 400 000 000 was foreseen for the implementation of "Health, demographic and wellbeing" under Horizon 2020. This programme section, among other things, aims at exploring the digital potential for health innovation and healthcare, as well as stimulating innovation in the European healthcare domain and industry by exploring the application of advanced technologies. The success rate of Lithuanian subjects applying for funding under this programme section is only 5%. Lithuanian subjects submitted 181 project applications, out of which 147 was deemed eligible and only 8 were approved for funding. The total of €800 000 was allocated to Lithuanian beneficiaries, acting as project partners. Half of these projects were implemented by the two leading public science and education institutions engaged in health-related R&D, namely Lithuanian University of Health Sciences and Vilnius University, while the rest were implemented by various public sector institutions. However, since the scope of this programme section is rather wide, it is not possible to identify the exact funding allocated for health-related RDI in Lithuania.

EIC Accelerator (SME Instrument) supports top class innovators, entrepreneurs and small companies, offering them both funding opportunities and acceleration services. The main focus of this programme section is on ground-breaking innovations that shape new markets and generate jobs. EIC Accelerator allows to gradually develop and realize innovative ideas. Phase 1 provides an opportunity to test the technical feasibility and commercial potential of an innovative idea and develop it into a credible business plan. Under this phase, 6 projects (€50 000 per project) were coordinated by Lithuanian subjects. These projects encompass different aspects of health, e.g. e-Health, health methods, tools, monitoring systems, etc. Phase 2 provides an opportunity to develop the business concept further and receive business acceleration services. The call for proposals under this phase is currently open.

3.3.4. Other sources

There are a few other sources providing funding opportunities for health-related projects of different kind (such as Third Health Programme) or research projects on different topics (such as Baltic Research Programme and Swiss-Lithuanian Research Programme) in Lithuania. However, the information on the exact funding allocated specifically for health-related RDI projects implemented by Lithuanian subjects is not available.

3.4. Key Challenges of Accessing Finance

This section provides an overview of the key obstacles to accessing financing for R&D and innovation in the health sector of Lithuania. The main difficulties on the different - strategic, operational and capacity - levels were identified on the basis of empirical research. It encompassed analysis of primary and secondary sources (documents and other publicly available information on the selection and implementation of RDI projects funded under various funding sources), interviews (with the representatives of the Research Council of Lithuania, responsible for managing different funding sources in Lithuania, and the Lithuanian University of Health Sciences, one of the key RDI players in Lithuania, also acting as an EIT Health Hub), a survey of private enterprises having received ESI funding under the OP for conducting health-related RDI and a workshop involving representatives from the Agency of Science, Innovation and Technology, the Hospital of Lithuanian University of Health Sciences Kaunas Clinics, Kaunas Technology University, Lithuanian University of Health Sciences, National Cancer Institute and innovative enterprises[90].

[90] In total, 17 out of 83 private enterprises having implemented projects under the measures of the 2014-2020 OP's Priority Axis 1 "Strengthening RDI" ("Innovation Vouchers" (No. 01.2.1-MITA-K-824), "InnoVouchers" (No. 01.2.1-MITA-T-851), "InnoStart" (No. 01.2.1-MITA-T-852), "Intellect. Joint Science-Business Projects" (No. J05-LVPA-K) and ''InnoPatent" (No. 01.2.1-MITA-T-845)) were surveyed. Due to low response rate of only 20%, the results of this survey are not representative of the views of the whole population. However, they allow to identify some trends regarding the participation of private subjects in the RDI projects funded under the OP.

3.4.1. Strategic-Level Challenges

On the strategic level, the main difficulties hindering the access to health innovation funding in Lithuania are inconsistencies in the planning of RDI investments, absence of coordination among various funding sources, absence of effective incentive system for researchers, lack of effort to promote the country's competitive advantage and insufficient attention from the political authorities to RDI results.

3.4.1.1. Inconsistencies in the Planning of RDI Investments

The first group of strategic-level challenges is related to insufficiently professional planning of RDI investments. This partly stems from the general immaturity of the innovation system and culture in Lithuania, however efforts to develop robust national innovation policy were made in the last decade. Lack of clear innovation priorities in terms of thematic areas and eligible beneficiaries are the key issues to be tackled further.

First of all, in spite of the commitment to smart specialization set in the main national strategic documents and referred to in the documents outlining financing requirements under the OP, the available funding for health-related innovations is still dispersed among thematic areas. It is partly due to the fact that health-related priority RDI areas, namely health technologies and biotechnologies, are still considered relatively broad, resulting in random health-related R&D projects funded under the OP. In contrast, RDI investments under the main health-related national research programme "Healthy Aging" are focused thematically - directed towards prevention and treatment of aging-associated diseases. Even though smart specialization is not explicitly mentioned in this programme, one of the health-related RDI priority areas, biotechnologies, is distinguished as a promising area for future R&D.

Furthermore, due to differing political interests and institutional culture, there is a lack of consensus on eligible beneficiaries between the national authorities in charge of planning innovation financing. Even though the main national strategic documents call for more active private sector's involvement in RDI, it does not automatically translate into clear prioritization of private entities in distributing funding. National authorities have differing stance towards the eligibility of private sector. The Ministry of Education, Science and Sport of the Republic of Lithuania predominantly prioritizes public sector entities - mostly science and education institutions which constitute the key academic RDI players in Lithuania. In contrast, the measures of the OP under the responsibility of the Ministry of Economy and Innovation of the Republic of Lithuania actively support R&D activities conducted by private subjects. However, the distribution of the available funds for private sector also lacks clear focus, as different size of support is provided for wide variety of private entities.

3.4.1.2. Absence of Coordination among Various Funding Sources

The aforementioned lack of consensus between the national authorities on the thematic focus and eligible beneficiaries leads to, on the one hand, absence of coordination among different funding sources and, on the other hand, inconsistencies among different measures within the same funding source.

The Ministry of Economy and Innovation tends to prioritize later phases of R&D process, such as experimental development and introduction of innovations, while the Ministry of Education, Science and Sport attaches greater importance to earlier phases of R&D process, namely fundamental and applied research. As the majority of the measures aimed at RDI under the OP are under the responsibility of the Ministry of Economy and Innovation, ESI funding under this programme is mostly focused on implementing R&D activities at later phases, preferably resulting in innovative products with a clear commercialization potential, while relatively modest funding within the OP is provided for fundamental research. Conversely, the national research programme "Healthy Aging" which is under the responsibility of the Ministry of Education, Science and Sport is mostly directed towards funding the early phases of R&D process.

Due to such inconsistencies, RDI investments under the programmes run at national level are rather fragmented and lack clear strategic orientation based on the competitive advantages of the country. In addition, there are no strategic-level mechanisms to coordinate RDI investments under the programmes run at national level (the OP and the national research programme) and those run at the EU level (primarily, Horizon 2020). Having access to the abundant ESI funds of 2014-2020, Lithuanian subjects engaged in RDI have a decreased interest in the opportunities offered by other funding sources, especially taking into account that the competition for RDI funding is much fiercer on the international level.

3.4.1.3. Absence of Effective Incentive System for Researchers

Another challenge with regards to accessing health innovation funding in Lithuania arises from the long-established remuneration system of researchers working in the public sector. Researchers in Lithuania are usually employed in the permanent positions in the science and education institutions or research centres and are remunerated according to the certain standard assigned to specific positions. Salaries of Lithuania's researchers are widely criticized as unreasonably low and contributing to decreasing occupational prestige and motivation of the researchers. Worse still, various programmes funding RDI do not offer additional financial or other incentives for Lithuania's researchers.

The external grant project occasionally leads to a deadweight effect where basic funding allocated for wage compensation is replaced by the project funding, offering no additional financial benefits for the researchers participating in the RDI projects. This issue stemming from the national legislation and practice is accompanied by the lack of incentive mechanisms at institutional level. Due to the lack of attention to the science internationalization on the strategic and, most importantly, institutional level, many science and education institutions do not have strategies for promoting science internationalisation through incentivising their researchers to participate in the international RDI projects. Science and education institutions are generally more focused towards promoting the internationalization of studies rather than research.

3.4.1.4. Lack of Effort to Promote the Country's Competitive Advantage

Top-level national RDI infrastructure, developed within 5 integrated science, studies and business centres (the so-called valleys) in the previous 2007-2013 programming period, is considered an important competitive advantage of the country. In the period of 2012-2015, the total of €298 700 000 was invested in these valleys providing opportunities to use open access infrastructure for external subjects, including private enterprises engaged in RDI. However, due to scarce human resources in science and limited scientific capacity, the potential of this infrastructure is rather untapped. For example, in the period 2012-2015, the average workload of the open access infrastructure was only 44%, some open access centres did not attract any external users[91]. Taking into account relatively weak networking culture in the country, national RDI infrastructure could be used to attract foreign researchers to conduct R&D activities in Lithuania. Entry of new RDI players from public or private sector could positively contribute to increasing competition in RDI on the national level and, thus, strengthening national scientific capacity. However, the international visibility of Lithuania's RDI infrastructural potential is poor, as not enough effort is made to promote it on the strategic level.

[91] National Audit Office of Lithuania, Public Investment in R&D towards Growth of Innovation. Audit Report (No. VA-P-50-1-7), 10 April 2017.

3.4.1.5. Insufficient Political Attention to RDI Results

The last strategic-level challenge is insufficient attention to the outcomes of R&D activities in the health sector. It is especially relevant for health-related RDI funded from the national budget. In spite of the fact that the national research programme "Healthy Aging" aims at using the results of fundamental and applied research for solving the most pressing health-related issues and the body supervising its implementation includes representatives from the Ministry of Health of the Republic of Lithuania, political authorities seem to have limited interest in the dissemination and application of scientific knowledge acquired as a result of this programme.

3.4.2. Operational-Level Challenges

On the operational level, the main difficulties in accessing health innovation funding in Lithuania are ambitious requirements for RDI projects, lack of mechanisms facilitating the involvement of new innovators, delayed implementation of RDI funding and absence of coordination of various funding sources at project level.

3.4.2.1. Strict Requirements for RDI Projects

RDI measures implemented under the OP, especially those under the responsibility of the Ministry of the Economy and Innovation, can be characterized by overly ambitious requirements for the outcomes of their projects. In particular, project beneficiaries are expected to demonstrate a quick return on the investments by creating market-ready products in a short period of a few years. Accordingly, project applications foreseeing to generate more patents as a result of R&D activities are given priority during the project selection. Taking into account that the development of health innovation requires considerable resources, including financial and time, such financing conditions of the projects create pressure on the beneficiaries, forcing them to patent results that are not of a sufficient level of maturity and quality, only in order to achieve the project indicators. In addition, the managing institutions of the RDI measures implemented under the OP do not tolerate possible failure in conducting R&D activities. R&D activities are inevitably risky and thus some margin of failure should be allowed, as it is already a case in the projects funded under Horizon 2020.

3.4.2.2. Lack of Mechanisms Facilitating the Involvement of New Innovators

Health-related RDI in Lithuania is largely dominated by the 2 strongest science and education institutions, namely Lithuanian University of Health Sciences and Vilnius University. There are very few private enterprises operating in the life sciences sector (pharmaceutics, health technologies and biotechnologies) of Lithuania that conduct actual R&D activities. Some of them are promising but small private enterprises lacking necessary resources for conducting extensive R&D activities. General lack of strong private RDI players in Lithuania considerably limits the opportunities of the country's researchers to access the financing of international funding sources. For example, significant share of funding for health-related RDI provided under Horizon 2020 is absorbed by large pharmaceutical companies. In addition, in some cases Lithuanian subjects, especially from the private sector, lack sufficient motivation to participate in the international research projects implemented by large consortiums due to difficult coordination of activities and responsibilities among multiple partners from different countries, the need to share intellectual property, lengthy processes and disproportional added value in terms of financial return and scientific capacities. Even though measures of the OP provide RDI funding for private entities of different size (distinguishing SMEs), level of maturity (both new and more mature) and origin (both national and subsidiaries of foreign companies), the aforementioned ambitious requirements for the projects limit the actual funding

opportunities of less established RDI players. It was confirmed by the surveyed private enterprises of the health sector having received 2014-2020 ESI funding. The predominant type of private enterprises having participated in the projects of the OP is SMEs engaged in R&D activities for 3-5 years and cooperating in R&D activities with the national science and education institutions. It confirms that RDI measures financed under the OP mostly provide funding opportunities for relatively mature innovators, since their conditions for financing projects require sufficient financial and human resources of the beneficiaries.

Even though private enterprises having received 2014-2020 ESI funding for RDI tend to assess this funding source as having a substantial added value for their engagement in RDI, ESI funding provided under the OP is largely focused on the later phases of R&D process, thus, it is virtually not accessible for new innovators having only an innovative idea but lacking the required capacities and resources to develop it until the later phases of R&D process that are eligible for financing under the OP. New innovators, such as start-ups, especially struggle in finding the required funds for co-financing, as they often lack sufficient financial resources and are ineligible for borrowing from financial institutions. In some cases, less mature innovators are forced to divert their limited human resources for conducting commercial activities in order to raise capital for engaging in R&D activities. This issue was partly addressed by establishing specific funding schemes on the institutional level for financing early phases of R&D process. The Lithuanian University of Health Sciences, acting as an EIT Health Hub, as well as the association managing one of the valleys, have set up funds for financing the development of innovative ideas at early phases of R&D.

3.4.2.3. Delayed Implementation of RDI Funding

Another operational-level challenge is inconsistent implementation of RDI measures under the OP. Calls for proposals do not follow a clear timetable and are often delayed. It results in unreasonably short periods for project application and fragmented distribution of the funding in an attempt to absorb the remaining ESI funds. Since preparation of application for research project requires considerable time and effort for developing research idea, finding partners, acquiring funds for co-financing, making required preparations for R&D activities etc., inconsistency in implementing RDI measures limits the opportunities to apply for funding.

3.4.2.4. Absence of Coordination of Various Funding Sources at Project Level

In line with the absence of coordination among various funding sources on the strategic level, there are no mechanisms used to coordinate the selection of the projects implemented under different funding sources. The Research Council of Lithuania managing the implementation of the funding provided under Horizon 2020, the national research programme “Healthy Aging” and some measures of the OP is aware of this challenge. However, lack of coordination among different funding sources partly stems from rigid national financing rules. According to them, funding of the national research programme “Healthy Aging” is implemented on the annual basis and annual programme budget has to be used by the end of each year. Thus, there are limited possibilities of postponing calls for proposals of the programme in order to allow potential beneficiaries to use the financing opportunities provided by other funding sources.

3.4.3. Capacity-Level Challenges

On the capacity level, the main difficulties faced by the potential applicants of health-related RDI projects are insufficient language, entrepreneurship, management and networking skills, as well as lack of effective technical assistance during the project application process.

3.4.3.1. Insufficient Language Skills

One of the factors hindering Lithuania's success in accessing funding under Horizon 2020 is insufficient English language skills for preparing quality project applications. It is partly due to the fact that significant share of the top-level scientists in the life sciences sector belongs to the older generation. Insufficient language skills also impede researchers' possibilities to smoothly communicate with international project partners. Promising initiative, in terms of strengthening the necessary language skills in the future, has been introduced by the Research Council of Lithuania. Potential beneficiaries of the national research programme "Healthy Aging" are now required to prepare project applications only in English language, in order to facilitate the assessment of the applications by the international experts. Identical requirement has been in place for a long time in Estonia whose researchers are much more successful in applying for the funding under Horizon 2020.

3.4.3.2. Insufficient Entrepreneurship Skills

Another relevant challenge on the capacity level is insufficient entrepreneurship skills of Lithuania's scientists. It is especially relevant in preparing project applications under the OP and Horizon 2020, as, in order to receive funding, applicants are required to demonstrate clear innovative potential of R&D activities to be implemented and commercial potential of innovative products to be developed. As a result of weak entrepreneurial culture in the public sector organizations of Lithuania, researchers working in the public science and education institutions and research centres tend to lack the necessary knowledge and understanding of business processes, hindering their capacities to properly present their project ideas in the project application and capture the commercialisation aspect of their innovations. Lithuania University of Health Sciences, acting as an EIT Health Hub, engages in various activities aimed at educating the community (from the younger generation to potential innovators) on the importance of and opportunities provided by health-related RDI. However, instead of strengthening entrepreneurship skills of researchers, it would be more reasonable to increase the capacities and role of technology transfer centres in the research institutions for providing assistance for researchers in the applications process.

3.4.3.3. Insufficient Management Skills

Unlike lack of sufficient language and entrepreneurship skills, which is more relevant in applying for funding under Horizon 2020 and the OP, insufficient management skills hinder the access to RDI funding under all the available funding sources. Experience from the project application process under the national research programme "Healthy Aging" reveals that applicants often fail in clearly presenting certain aspects of the project management (timetable, distribution of functions, risk assessment, etc.) in the application. It shows that, on the one hand, researchers are short of the necessary management skills and, on the other hand, science and education institutions lack effective research management systems, even though some measures are in place. For example, representatives from the Development Department of the Lithuanian University of Health Sciences might provide assistance for researchers in drafting administrative parts of project applications, when needed. The above-mentioned deficiency presents a significant obstacle for Lithuania's researchers to participate in the projects of Horizon 2020, let alone coordinate them, as coordination of such projects entails managing heavy workload and multiple partners of large consortiums. Hence, Lithuania's researchers participate as partners even in the RDI projects under Horizon 2020 implemented in the life science sector where Lithuania has competitive advantage.

3.4.3.4. Insufficient Networking Skills

Lack of success in absorbing the funding provided under Horizon 2020 and other international programmes also stems from insufficient networking skills of Lithuania's scientists. Due to immaturity of the partnership culture in the country, durable partnerships in research on the institutional level are generally lacking. International partnerships, especially crucial for accessing the funding under the international funding sources, are largely based on individual contacts. Deficiency in this area hinders the opportunities of Lithuania's researchers to participate in the international consortiums consisting of relatively stronger RDI

players. Networking and related activities funded by the COST programme are considered a springboard for developing international partnerships in research. However, actions supported under this programme are more popular among subjects less established in RDI and, thus, are mostly used for introducing new RDI players to the international research community. In addition, while private subjects have plenty of opportunities to receive funding for engaging in the international networking and partner search activities under measures implemented by the Agency for Science, Innovation and Technology, similar opportunities for researchers working in the science and education institutions are rather limited due to insufficient national budget funding and administrative burden of measures implemented by the Research Council of Lithuania.

Despite the emphasis in the strategic discourse placed on promoting different-level cooperation in RDI, partnerships are not strongly endorsed in the projects of the programmes run at the national level. For example, involvement of partners (including private entities) in the projects implemented under the national research programme "Healthy Aging" is optional. As a result, the share of the RDI projects implemented with partners, either national or international, is very modest. On the one hand, mandatory involvement of partners in the projects would pose a burden for potential applicants, since, for example, the number of potential national partners is very limited due to generally small pool of health-related RDI players. On the other hand, it would have added value on the quality of the project (increased scientific capacities) and development of durable partnership networks.

3.4.3.5. Lack of Effective Technical Assistance Mechanisms during Application Process

The last difficulty faced by the potential applicants of health-related RDI projects is lack of effective technical assistance mechanisms during the project application process. Although national bodies managing different RDI funding sources in Lithuania are making effort to ensure smooth application for funding, it is not always effective and sufficient. For example, the Research Council of the Lithuania has considerably reduced the administrative burden on the applicants under the national research programme "Healthy Aging" by simplifying project application form and providing an opportunity to electronically submit all documents required during the project application. Nevertheless, some excessive requirements in the selection and implementation of the projects remain. For instance, some documents required for the project implementation (project contract, reports on the use of funds, etc.) still have to be submitted in paper form. The Research Council of Lithuania also organizes information events for the potential applicants of the projects under the national research programme. Participants of these events seem to be mostly interested in the advice on meeting the quality criteria of the applications. Similarly, representatives from the Research Council of Lithuania and the Agency for Science, Innovation and Technology, acting as the national contact points, provide ad-hoc consultations to the potential beneficiaries of Horizon 2020. However, taking into account the aforementioned lack of the necessary skills (language, entrepreneurship, management and networking) by the country's researchers, general consultations are insufficient, as applicants require hands-on assistance in dealing with the specific aspects in the application form. Lithuanian University of Health Sciences, acting as an EIT Health Hub, foresees the establishment of international consultants assisting Lithuania's researchers in preparing applications for funding under international programmes.
Alternative solution to the problem of insufficient assistance mechanisms is outsourcing the preparation of project application to external private suppliers. Surely, use of such services might require additional financial resources, as expenses borne during the project application process are not eligible. There are a few private consultancy companies providing such services in Lithuania. However, the added value of their services is not unequivocal, as there are some examples indicating that use of private consultancy services might at time be valueless. In some cases, different project applications prepared by the same external supplier are standardized, based on the same template and, thus, fail to reveal the unique quality of specific project idea.

3.5. Recommendations

Innovation in the health sector constitutes an integral part of Lithuania's innovation policy set in a number of strategic documents of 2014-2020. In the strategic discourse, innovations are mostly referred to as a desired outcome of R&D activities. In terms of strategic development of RDI in general, the needs to create favourable conditions for conducting R&D activities (RDI infrastructure, human capital, services and cooperation among different RDI stakeholders) and increase the involvement in RDI by the private sector are outlined. The importance of health-related RDI is reflected by including health technologies and biotechnologies among the smart specialization areas.

The main funding streams for innovation in the health sector in Lithuania in the period of 2014-2020 are funds distributed under the investment programmes run at the national level, namely European Structural and Investment funds provided under the Lithuania's Operational Programme for the European Union Funds' Investments in 2014-2020 (investing over €103 000 000 in health-related RDI) and national budget funds provided under the national research programme "Health Aging" (investing over €5 000 000 in health-related RDI) and Horizon 2020. Key obstacles to accessing financing for RDI in the health sector of Lithuania might be distinguished on the different levels. On the strategic level, the main difficulties hindering the access to health innovation funding are inconsistencies in the planning of RDI investments, absence of coordination among various funding sources, absence of effective incentive system for researchers, lack of effort to promote the country's competitive advantage and insufficient attention from the political authorities to RDI results. On the operational level, key obstacles include ambitious requirements for RDI projects, lack of mechanisms facilitating the involvement of new innovators, delayed implementation of RDI funding and absence of coordination of various funding sources at project level. On the capacity level, Lithuanian subjects seeking for funding for health-related RDI lack sufficient language, entrepreneurship, management and networking skills. On top of this, effective mechanisms for providing assistance during the project application process seem to be lacking.

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4. Poland

4.1. Health situation[92]

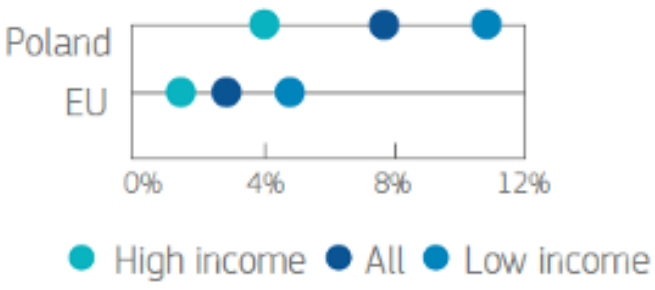
Life expectancy at birth in Poland is higher than in most neighbouring countries, but lower than the EU average. Disparities in life expectancy are observed between different population groups. Eight years separate Polish men and women, while the gap between those with the lowest and highest education levels is 10 years. Polish men and women aged 65 can expect to live another 16 and 20 years, respectively, but less than half these years will be free from disability.

The proportion of Polish residents who report being in good health is low compared to other EU countries. Many more high earners report good health than those on lower incomes. About a third of the total burden of disease can be attributed to behavioural risk factors, especially alcohol consumption (which is increasing among adults), obesity and physical inactivity. Polish people are 65% more likely to die from a circulatory disease than the average EU resident and the reduction in cardiovascular mortality has been slower than in most other EU countries.

Acute care in Polish hospitals is relatively effective and of high quality, especially for cardiac patients. Poland has one of the lowest case-fatality rates for heart attack patients in EU countries that report these data. On the other hand, outcomes for cancer care in Poland are less favourable. Survival rates for breast, cervical and colorectal cancers are low compared to other EU countries and the cancer mortality rate is higher than the EU average. Programmes to improve screening and prevention are currently being implemented. Poland also has high hospitalisation rates for chronic conditions such as asthma, COPD and congestive heart failure, suggesting room for improvement in non-acute sectors.

Affordability and unmet medical needs are key concerns in Poland. Due in part to workforce and allocative imbalances, Poland has high levels of unmet need for medical care and the longest waiting lists for elective procedures in the EU. Compulsory health insurance covers only 91% of the population. While entitlement covers a broad range of services, public underfunding means that the supply of services is limited. An undeveloped private health insurance market and limited public coverage of pharmaceuticals have resulted in high levels of out-of-pocket payments. As a result, a large number of lower-income Polish households face catastrophic health care costs.

Figure 33: Unmet medical need (2015)



Source: State of Health in the EU: Companion Report 2017

[92] State of Health in the EU: Companion Report 2017

Long-term care in Poland is in need of reform. The sector is fragmented and governed by numerous laws. Some long-term care is often provided in hospitals, but the principal source of provision is informal care by family members. This is unsustainable given changing demographics and women's growing participation in the workforce. Increased funding, infrastructure investment, and better planning and management could improve this situation.

The government is in the process of implementing far-reaching structural reforms of the health system, aimed at improving access and coordination and improving allocative and technical efficiency. The reforms include a fundamental restructuring of health care financing, priority setting and strategic planning. Sound governance, accountability and oversight are needed to ensure these reforms do indeed result in better outcomes for the Polish people.

4.2. National strategies and funds

4.2.1. Poland - Central level

The Strategy for Responsible Development for the period up to 2020 (including the perspective up to 2030[93]) is an applicable and key document of the Polish government in the field of the medium- and long-term economic policy. The Strategy includes recommendations for public policies. It is also a basis for changes to the development management system, including the valid strategic documents (strategies, policies, programmes).

The main objective of the Strategy is: to create conditions for increasing incomes of the Polish citizens along with increasing cohesion in the social, economic, environmental and territorial dimension. Within the Strategy there are three sub-objectives specified from which the most important role (as far as innovation in health sector is concerned) plays: specific objective I - Sustainable economic growth increasingly driven by knowledge, data and organizational excellence[94].

According to Strategy, in order to: 1) successfully implement specific objective and 2) to build lasting competitive advantages of the economy, it is important to concentrate on those sectors which have a significant potential to become successful on a global scale. The state will have to make strategic choices as to which areas may generate the highest results for the whole economy. The Strategy is thus based on the assumption that the former support to all sectors/branches will be abandoned and replaced by individualized packages for different strategic sectors which may become motors for the Polish economy in future. Those sectors are as follows:

1. the sector of transport means production (e.g. e-buses, rail vehicles or specialist vessels)
2. the sector of professional electronics (e.g. smart energy meters, inverters, vehicle chargers or sensors)
3. the sector of specialist telecommunication and information technologies (e.g. fintech, machine and building automation, cybersecurity, computer games or bioinformatics)
4. the aviation and space sector (e.g. drones or satellite components)
5. the sector of drugs production, medicinal products and modern medical services (e.g. e-medicine, medicinal products / therapies / biosimilar drugs)

[93] The Strategy for Responsible Development for the period up to 2020 (including the perspective up to 2030), adopted by the Council of Ministers on 14th February 2017.

[94] Ibidem

6. the sector of mining systems (e.g. smart mine)
7. the sector of raw material recovery
8. the sector of eco-buildings (e.g. passive buildings, pico-energy or timber construction)
9. the sector of high-quality foods
10. the sector of military systems[95].

This is important to acknowledge that "the sector of drugs production, medicinal products and modern medical services (e.g. e-medicine, medicinal products / therapies / biosimilar drugs)" has been selected as one of potential driving forces of the future Polish economy. This provides much better chances for current and future possibilities of getting public support for this kind of projects and activities.

Within the strategy even some examples of flagship projects have been specified in the field of innovations in health sector:

- **the Telemedicine project** - stimulating the development of modern services and medicinal products on the basis of innovative communication technologies; innovative products (services and technologies) will be prepared to improve the accessibility of specialist medical services.
- **the Biotechnology Development Centre** - building the position of Poland as an European hub of advanced generics and biosimilars. It will provide support to Polish companies in the production of modern drugs and their expansion into global markets.
- **the project of Polish Medicinal Products** - providing R&D support and the commercialisation of medicinal products under strategic groups (inter alia the Polish medicinal robot, artificial organs, networked solutions in the field of software – software + devices, systems of supporting or substituting senses), aimed at stimulating the development of a modern medicinal apparatus for the domestic and foreign markets.

It is worth noticing that 3 out of 12 examples of flagship projects listed in the main part of the strategy are in the field of innovations in health sector. This shows how important and how high in hierarchy is this sector.

According to Strategy the implementation of the objectives of the SRD requires the involvement of more than PLN 1.5 trillion from public funds by 2020 year. Funds will come from the state budget, budgets of the territorial government units, national earmarked funds (the Labour Fund and the National Fund for Rehabilitation of Disabled Persons (PFRON), resources of executive agencies and funds managed within the Polish Development Fund. Another source of funding of the development includes EU financing, i.e. EU funds, programmes and initiatives EEC Financial Mechanisms, external funds (e.g. Norway Grants). The third funding stream will come from other foreign sources - from credit, surety and guarantee programmes[96].

[95] Ibidem
[96] Ibidem

Institutional setup. Overall responsibility for implementation of the Strategy lies on Council of Ministers. However real day to day coordination is on Ministry for Investment and Development. What is more Ministry for Investment and Development is also responsible for overall coordination of EU funds which is one of the main drivers of public capital in the field of innovations in health sector. As far as innovations in health sectors are concerned important role also play:

Ministry of Health - as a body which supports setting of specific objectives in the area of health),

- National Centre of Research and Development - which is the most important institution for implementation of innovative projects (among others in health and medicine sector),
- Polish Agency for Entrepreneurship Development which is the most important institution for supporting start-ups and SMEs (among others in health and medicine sector).

4.2.2. Regional level - Pomorskie Voivodship

Pomorskie has a population of approximately 2.3 million inhabitants, much of it concentrated in the metropolitan Tri-City area (Gdansk, Gdynia and Sopot). It has experienced relatively strong economic growth in recent years, associated with population growth and low unemployment. Its rate of new business creations and share of high-growth enterprises are above the Polish average, although the European Regional Innovation Scoreboard indicates that its innovation performance is still only "moderate" in comparison with all European Union regions[97].

Map 1. Pomorskie region on a map of Poland

Source: Wikipedia

97 "Local entrepreneurship ecosystems and emerging industries: Case study of Pomorskie, Poland", OECD 2019

Strategy

The Pomorskie Voivodeship Development Strategy till 2020 was adopted by Regional Parliament of Pomorskie Voivodeship of 18th July 2005[98]. The strategy specified 3 strategic objectives being of a general nature and determining the desired target states in problematic terms:

- modern economy,
- active residents,
- attractive space.

They are implemented by 10 operational objectives from which the most relevant (in the context of innovations in health sector) is Operational objective 1.1. High efficiency of enterprises. According to regional strategy public support should be targeted at:

- Dissemination of innovation in enterprises and the transfer of knowledge to the economy,
- Support for cluster initiatives and projects implemented by clusters,
- Support for foreign expansion of enterprises,
- Acquisition of external investment[99].

It is important to indicate that currently new Strategy is being prepared: The Pomorskie Voivodeship Development Strategy till 2030. On 28th of January 2019 the legal act was adopted by regional parliament which specifies how and when the new strategy will be prepared. One of the assumptions for future strategy objectives is concentration on smart specialisation sectors for Pomorskie Region.

The Board of the Pomeranian Voivodeship has identified the following areas of smart specialisations:

- Offshore and port-logistics technologies;
- Interactive technologies in an information saturated environment;
- Eco-efficient technologies in the production, transmission, distribution and consumption of energy and fuels, as well as in construction;
- **Medical technologies in the field of lifestyle and aging diseases[100].**

As far as potential for receiving public support for innovative projects in health sector is concerned especially the last area of smart specialisations is important. This significantly increases possibilities of getting public support for this kind of projects and activities in Pomorskie Voivodship.

Interlocutors from Marshal Office also emphasised that choice of regional smart specialisations was collective process with grate involvement of many regional partners. Recently the process was updated so (especially smart specialisation of Medical technologies in the field of lifestyle and aging diseases) is equally important both for current as well as for the next programming perspective.

98 The Pomorskie Voivodeship Development Strategy was adopted by Resolution No. 587/XXXV/05 of the Sejmik of Pomorskie Voivodeship of 18th July 2005.

99 Ibidem

100 Official website of Pomorskei Regional http://www.rpo.pomorskie.eu/inteligentne-specjalizacje

4.3. The System of Financing Innovation in Poland (Pomorskie Voivodship)

4.3.1. EU funds

As far as direct financing of innovative projects (both in form of grans as well as loans) EU funds play main role in Poland. Within the European Funds, in Poland innovation activities are financed mainly within thematic objectives (TO) 1 and 3. There are the following operational programmes, which are the source of financing:

- TO1: Operational Programme Smart Growth and 16 Regional Operational Programmes;
- TO3: Operational Programme Smart Growth, 16 Regional Operational Programmes and Operational Programme Eastern Poland.

Moreover, there are some activities regarding health sector that could be recognised as innovative which could be financed within Operational Programme Knowledge, Education, Development. All the programmes are described below.

4.3.1.1. Operational Programme Smart Growth 2014-2020

Objectives: The Programme aims to boost the innovativeness and competitiveness of the Polish economy by increasing business expenditure on Research & Development (R&D) and by improving the level of co-operation between all participants in the innovation lifecycle. The funding is used nationwide to strengthen research activities and improve the links between science and business in the sixteen Polish regions. The funding should allow for the development of innovative ideas into concrete, marketable new products and technologies, thus increasing the position of Polish enterprises in the global value chain.

In order to address problems with innovations in Poland OP SG has the following specific objectives:

- Increased R&D activity of enterprises
- Increased enterprise capacity for R&D&I activity
- Increased funding of the SME innovative activity using venture capital (VC)
- Increased activity of the enterprises in innovative activity
- Improved level of the internationalisation of enterprises activity
- Increased level of research results application on the market

Budget: Interventions of the TO1 implemented in the Operational Programme Smart Growth amount to €6 100 000 000, while interventions of TO3 in the Programme amount to €2 200 000 000
System of implementation: The programme is implemented by the following institutions:

- **Managing Authority** – which is responsible for general management of the Programme: Ministry of Infrastructure and Development, Managing Department for Competitiveness and Innovation Programmes;

- **Intermediate Bodies** – which are responsible among others for management of particular axes application and selection procedures, monitoring of the projects implementation:
  - Axis I.: National Centre for Research and Development
  - Axis II.: Polish Agency for Enterprise Development

- Axis III.: Polish Agency for Enterprise Development (and Bank Gospodarstwa Krajowego for measure 3.2.2)
- Axis IV.: National Centre for Research and Development

Who can apply for support: depending on the measure, the Programme is addressed to the following types of beneficiaries:

- enterprises/consortia of enterprises,
- financial instrument implementing body,
- Coordinators of Key National Clusters/Members of Key National Clusters,
- Ministry of Economic Development in a partnership with the Polish Agency for Enterprise Development,
- consortium of research units or consortium whose members include enterprises and research units.

Table 19. Priority axes and measures within the Operational Programme Smart Growth

Priority axes	Measures	Link to proper Intermediate Body
Priority 1. Support for R&D activity of enterprises	Measure 1.1 R&D projects of enterprises ▪ Sub-measure 1.1.1 Industrial research and development work implemented by enterprises ▪ Sub-measure 1.1.2 R&D work related to manufacturing a pilot/demonstration installation Measure Measure 1.2 Sectoral R&D programmes Measure 1.3 R&D activity financed with capital funds participation ▪ Sub-measure 1.3.1 Support for R&D projects at the 'pre-seed' stage by proof of concept funds – BRIdge Alfa ▪ Sub-measure 1.3.2 Public-private support for R&D work with capital fund participation – BRIdge VC	https://www.ncbr.gov.pl/index.php?id=19711&L=716

Priority 2. Support for the environment and capacity of enterprise for R&D&I activity	Measure 2.1 Support for investments in R&D infrastructure of enterprises Measure 2.2 Open innovation – support for technology transfer Measure 2.3 Pro-innovation services for enterprises ▪ Sub-measure 2.3.1 Pro-innovation BEI services for SMEs ▪ Sub-measure 2.3.2 Innovation vouchers for SMEs ▪ Sub-measure 2.3.3 Internationalisation of Key National Clusters ▪ Sub-measure 2.3.4 Protection of industrial property Measure 2.4 Cooperation within the framework of the national innovation system ▪ Sub-measure 2.4.1 Centre for analysis and pilot implementation of new instruments inno_LAB ▪ Sub-measure 2.4.2 Monitoring of the National Smart Specialisation	https://www.parp.gov.pl/harmonogram-naborow?programs=poir
Priority 3. Support for innovation in enterprise	Measure 3.1 Increased funding of the SME innovative activity using venture capital (VC) ▪ Sub-measure 3.1.1 Investments in innovative start-ups – Starter ▪ Sub-measure 3.1.2 Business angels' group investments in SMEs – BizNest ▪ Sub-measure 3.1.3 Innovation Loan Fund ▪ Sub-measure 3.1.4 Competitive Nationwide Fund of Innovative Funds (KOFFI) ▪ Sub-measure 3.1.5 Support for SMEs to access the capital market – 4 Stock Measure 3.2 Support for R&D results implementation ▪ Sub-measure 3.2.1 Research for the market ▪ Sub-measure 3.2.2 Loan for technological innovation ▪ Sub-measure 3.2.3 Guarantee fund for innovative enterprises Measure 3.3 Support for promotion and internationalisation of innovative enterprises ▪ Sub-measure 3.3.1 Polish tech-bridges ▪ Sub-measure 3.3.2 Promotion of the economy on the basis of Polish product brands – Brand of the Polish Economy ▪ Sub-measure 3.3.3 Support for SMEs in the promotion of Polish product brands – Go to Brand	https://www.parp.gov.pl/harmonogram-naborow?programs=poir

Priority 4. Increasing the research potential	Measure 4.1 Research and development ▪ Sub-measure 4.1.1 Research programmes of strategic importance for the economy ▪ Sub-measure 4.1.2 Regional research agendas ▪ Sub-measure 4.1.3 Innovative methods of research management ▪ Sub-measure 4.1.4 Application projects Measure 4.2 Development of modern research infrastructure of the science sector Measure 4.3 International Research Agendas Measure 4.4. Increasing the human potential in R&D sector	https://www.ncbr.gov.pl/index.php?id=19711&L=716

Source: own elaboration

4.3.1.2. Regional Operation Programme for Pomorskie Voivodship for 2014-2020

Objectives: The objective of the Programme is to increase the competitiveness of the Pomorskie region, ensuring in parallel the improvement of living conditions of its inhabitants through the principles of sustainable development. It aims to undertake the development challenges facing the region in the economy, education, vocational and social activities, potential of individual territories, the transport system, energy and the environment.

Specific objectives focused on innovations (and health sector) are:

- Increased R+D activity of enterprises
- Increased marketization of R+D
- Increased ability of SMEs to developing products and services, also with the use of innovations
- Increased accessibility of health services
- Implemented interoperable IT systems operating all processes connected with activity of health system units

Budget: Total allocation for all OPs to TO1 is €2 200 000 000 and to TO3 -€3 700 000 000. In ROP for Pomorskie it is for TO1 – €139 900 000, for TO3 – €157 500 000. In this particular ROP innovation in health sector could be also financed within TO9 – €63 000 000 and TO2 – €42 000 000.

System of implementation: The programme is implemented by the following institutions:

- Managing Authority: responsible for efficient and proper implementation of the Programme: Pomorskie Voivodship Board, the operations are delivered by the Regional Programmes Department, European Social Fund Department as well as Regional and Spatial Development Department.
- Intermediate Bodies (which are among other responsible for application and selection procedure):
- Agencja Rozwoju Pomorza S.A for priority axis 1
- ITI Association (Stowarzyszenie Obszar Metropolitalny Gdańsk-Gdynia-Sopot) for action 7.1.1.

Who can apply for support: Depending on the priority, there are different group of beneficiaries who can apply for support:

- entrepreneurs in possible partnerships with other entrepreneurs, higher education institutions, business environment institutions, chambers of commerce and other business organisations, NGOs, other R+D institutions
- higher education and science system units in possible partnerships with entrepreneurs
- local government units and associations of local government units
- Bank Gospodarstwa Krajowego as Funds of Manager
- micro, small and medium enterprises
- public and private units delivering health services

4.3.2.3. Operational Programme Knowledge, Education, Development 2014-2020

Objectives: The operational programme Knowledge Education Development for the implementation of the European Social Fund and the Youth Employment Initiative (YEI) in Poland aims to contribute to addressing key challenges which Poland faces in the fields of employment, social inclusion, health, education and public administration.

The activities are focused on Investment Priority 8VI, 9IV, 10II, 10III

In order to address problems with innovations in Poland OP KED has the following specific objectives in the area of health innovation:

- implementation and development of preventive programmes for diseases having a negative impact on labour resources, dedicated to working age population
- implementing actions enhancing quality and organisational solutions in the healthcare system, facilitating access to affordable, sustainable and high-quality services
- mproving the quality of higher education at medical faculties
- developing professional competences and qualifications of medical staff, responding to the epidemiological and demographic needs of the country

Budget: Interventions in OP KED for health innovations will amount to €260 200 000 for less developed regions, €40 900 000 for more developed regions

System of implementation: The programme is implemented by the following institutions:

- **Managing Authority** – which is responsible for general management of the Programme: Ministry of Infrastructure and Development, Department for European Social Fund;
- **Intermediate Body** – which is responsible among others for management of the axis, application and selection procedures, monitoring of the projects implementation:
    - Ministry of Health

Who can apply for support: depending on the measure, the Programme is addressed to the following types of beneficiaries:

- medical universities;
- teaching hospitals;
- research institutes supervised by the Ministry of Health;
- National Health Fund;
- minister responsible for health.
- Centre for Quality Control in Healthcare;
- universities;
- non-governmental organisations active in the field of patients health protection;
- entities providing services for dependent persons;
- healthcare facilities;
- local government units and their organisational units
- institutions authorised to provide training for medical staff
- Medical Postgraduate Training Centre
- Centre for Postgraduate Training of Nurses and Midwives

For the two main EU programmes with the biggest financial possibilities(OP SG and ROP Pomorskie), we provide the tables with particular measures for innovations (in health sector where possible)

Table 20. Priority axes and measures focusing of innovation in health sector within the Regional Operational Programme for Pomorskie Voivodship 2014-2020

	Axis	Measure	Sub-measure	Name	Investment priority	EU Support in total	National contribution)
ERDF	1	1.0	1.0.0	Know-how commercialization		€139 860 877	€24 681 332
ERDF	1	1.1	1.1.0	Expansion by innovation	1b	€118 881 745	€20 979 132
ERDF	1	1.1	1.1.1	Expansion by innovation- grant support	1b	€83 217 222	€11 748 314
ERDF	1	1.1	1.1.2	Expansion by innovation – non-grant support	1b	€35 664 523	€9 230 818
ERDF	1	1.2	1.2.0	Know-how transfer to the economy	1a	€20 979 132	€3 702 200
ERDF	2	2.0	2.0.0	Enterprises		€157 479 140	€27 934 083
ERDF	2	2.1	2.1.0	Basic and profiled investments – non-grant support	3c	€48 464 734	€12 543 813
ERDF	2	2.2	2.2.0	Profiled investments – grant support	3c	€40 605 587	€5 732 554
ERDF	2	2.2	2.2.1	Profiled investments – grant support	3c	€40 605 587	€5 732 554
ERDF	7	7.0	7.0.0	Health		€104 975 500	€18 525 089
ERDF	7	7.1	7.1.0	Healthcare resources	9a	€62 985 300	€11 115 053
ERDF	7	7.1	7.1.1	Healthcare resources- ITI mechanism	9a	€6 928 383	€1 222 656
ERDF	7	7.1	7.1.2	Healthcare resources	9a	€56 056 917	€9 892 397
ERDF	7	7.2	7.2.0	Information and telemedicine systems	2c	€41 990 200	€7 410 036

Source: own elaboration

Coordination of the EU support at the central level

Coordination tasks are a responsibility of the Steering Committee for the coordination of ESI Fund interventions in the health sector. It has a status of a subcommittee within the Committee for Partnership Agreement[101]. It is the main tool for coordinating interventions from EU funds. It consists of representatives of the government, local government, non-governmental organizations and representatives of other entities that have an impact on the situation in health care. The goal of coordination is to ensure that interventions are targeted correctly, to prevent overlaps, to ensure cost-effectiveness, and to fine-tune interventions to the needs identified at national and regional level. One has to underline, that this coordination is only limited to EU funds. There's no such a body which would coordinate the intervention related to health as such. The reason for that is, that financial sources for health related measures can be found under different tools, which normally are not associated with health and therefore are not identified as relevant by the Ministry of Health nor its collective bodies.

4.3.2. National funds

4.3.2.1. STRATEGMED

Objectives: Main objective of the programme is:

- Achieving substantial progress in preventing and treating civilization diseases and in regenerative medicine based on the results of scientific research and development works carried out under the program

Specific objectives:

- A significant increase in Poland's international position in the field of scientific research and development works in the disciplines of science covered by the program.
- Creating dynamic, young research teams, in an international composition and with a strong, documented international position.
- Transfer of know-how and new technologies in the field of prevention, diagnostics, therapy and rehabilitation from Polish scientific institutions (public research organizations) to the economy.

Budget: €186 000 000

System of implementation: Program Operator: National Centre for Research and Development

Who can apply for support: Research consortia, which includes at least five organizational units (scientific units and enterprises)

[101] The main body supporting the Minister of Investments and Development in the process of coordinating the use of European Union funds in Poland.

4.3.2.2. Programmes: OPUS, SONATA, PRELUDIUM[102]

Objectives: Support for research projects, including financing the purchase or production of research equipment necessary for the implementation of these projects

Budget[103]: Budget for calls is announced on a regular basis (no dates for 2020 specified so far). For the 17th edition of OPUS the amount of €75 000 000 was allocated, for 14th edition of SONATA the amount reached €22 500 000 and for 17th edition of PRELUDIUM – €7 500 000.

System of implementation:
National Science Center. Applications in NSC calls are submitted via an electronic system on the website[104].

4.3.2.3. Programme INFOSTRATEG[105]

Objectives: Identifying and intensifying research on selected machine learning problems that have development potential on a larger scale.
Within that, there are three themes which are related to innovativeness in health:

T1) Intelligent speech processing system for doctors

T2) Recognition of medical images

T3) Diagnostics of congenital metabolic disorders in neonatal screening

Budget: The total INFOSTRATEG budget is approximately, of which on the above-mentioned themes the following amount will be allocated: T1 and T2 – €7 500 000, T3: €5 000 000.

System of implementation: The programme will be implemented by National Center for Research and Development. The detailed procedures regarding announced calls will be specified in the rules of the call.

There will be two types of calls:

- open calls for projects - covering the whole thematic scope of the programme;
- for so called „ordered projects" - covering the thematic scope defined, as a result of needs assessment of research subjects, which will be made among public administration entities.

Calls will be announced once a year and will cover more than one topic from the thematic scope of the programme.

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[102] Funding basic research is one of the statutory tasks of the National Science Center (NSC). The NSC announces calls for funding research projects in selected areas. Among them there is a "thematic calls" Drug sciences and public health which covers the subtopics of epidemiology, civilization diseases and social environmental threats to human and animal health, medical and veterinary protection of public health, occupational medicine and medicine sciences. OPUS, PRELUDIUM and SONATA were the most popular programs in the NCN offer at the end of 2018. Each year, the amount of submitted applications is getting higher and it happens that it exceeds the total budget allocated.

[103] In practice usually only part of the budget is dedicated to researches in health sector

[104] The application is subject to formal and substantive assessment. Formal assessment is carried out by the so called "theme coordinator". Only complete applications that meet all the requirements specified in the announcement are eligible for substantive evaluation. The substantive evaluation procedure has two stages. At the first stage, the application is subject to a qualifying assessment, based on the data from the application and annexes to the application (excluding the detailed description of the research project). Qualifying assessment is first carried within individual assessment of two members of the team of experts and then application is subject to the assessment of a team of experts, made during the first meeting and based on discussion on individual assessments. After that, a list of applications submitted for stage II is created. At the second stage, the application is subject to specialist assessment, based on the data contained in the application and annexes to the application (excluding the short description of the research project). Here again we have a two-step procedure - individual assessment by at least two external experts and group assessment based on discussion. After that a list of applications recommended for funding is created.

[105] The previous INFOSTRATEG programme has ended and now a new programme is being prepared. It's expected to be ready in 4Q of 2019

Who can apply for support: The programme will be open to scientific units, entrepreneurs and consortia consisting of scientific units, entrepreneurs and other entities. The catalogue of potential applicants will be specified in rules of the call.

4.3.3. Other sources

4.3.3.1. Programme: „Health" under the EEA and Norway Grants (2014-2021)

Objectives: Reinforced prevention and reduction of social inequalities in health[106]

The programme will focus on reducing social inequalities in health. It will include measures related to telemedicine, e-health policy, healthy lifestyle of children and youth, as well as community based care for mental health . Financing infrastructure will be possible - no more than 50% of the total eligible expenditure of the programme will be available for such „hard measures".

Budget: €20 000 000

System of implementation: The program will be implemented by the Polish Ministry of Health

Who can apply for support: to be announced

4.3.3.2. Actions of Medical Research Agency

The Medical Research Agency (MRA) was established in 2019. It is a state institution responsible for the development of scientific research in the field of medical sciences and health sciences. The analyses of MRA will allow to present specific solutions thanks to which the healthcare system will be able to function in a more efficient way. The functioning of Agency will allow to assess what new medical technologies and therapeutic methods should be used to meet the needs of society.

Recently, during the Economic Forum in Krynica a letter of intent was signed declaring cooperation between the Medical Research Agency and representatives of twelve pharmaceutical companies. These are companies that belong to the Pharmaceutical Committee of the American Chamber of Commerce, including Amgen, AstraZeneca, BMS, Janssen, Medtronic, MSD, Mylan, Novartis, Pfizer, Roche and Takeda. Signing the letter is one of the initiatives supporting the creation of an ecosystem in Poland which would facilitate the development of innovation[107].

4.3.3.3. Repayable instruments in Pomorskie

Access to credit for entrepreneurs is supported by various public initiatives in Pomorskie, including the Pomorskie Loan Fund, the Pomorskie Regional Loan Guarantee Fund, and the Pomorskie Development Fund. However, there is a shortage of private equity funding, despite instruments such as the national Bridge Alfa Investment programme. There are emerging inter-regional business networks in the Baltic Sea Region (BSR) and Central and Eastern Europe (CEE) that could help connect entrepreneurs with potential equity investors, but they are not yet promoted sufficiently to local start-ups and scale-ups[108].

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[106] Source: Norway Grants webpage (http://www.eog.gov.pl/en/site/learn-more-about-the-grants/programmes-overview/health/)

[107] Source: Read article (in Polish) https://www.termedia.pl/mz/Sierpinski-podpisal-list-intencyjny-wspierajacy-rozwoj-innowacji,35340.html

[108] "Local entrepreneurship ecosystems and emerging industries: Case study of Pomorskie, Poland", OECD 2019

4.4. Key Challenges of Accessing Finance

4.4.1. General challenges and obstacles to getting access and implementing innovation finance in the health sector

Innovative medical projects financed from public resources in Poland are mainly implemented within programmes co-funded by the EU. Most of the programmes are not aimed thematically at implementing medical ventures, however they provide an opportunity of developing innovative projects in the field of medicine and public health in a broader sense. The table below presents the four main sources of funding for medical projects in Poland.

Table 21. Programmes with the highest value of contracts signed under which it was possible to implement medical projects (2019)

Programme	Value of medical projects	Value share of medical projects in the competition (%)	Number of medical projects	Share of medical projects in the total number of projects in the competition (%)
OPSG Measure 1.1.1	€282 674 965	24%	81	15%
STRATEGMED (I, II, III)	€207 567 992	100%	43	100%
INNOMED (OPSG Measure 1.2)	€66 186 350	100%	27	100%
InnoNeuroPharm (OPSG Measure 1.2)	€61 080 079	100%	16	100%

Source: Ewaluacja Strategicznego Programu Badań Naukowych i Prac Rozwojowych Profilaktyka i Leczenie Chorób Cywilizacyjnych – STRATEGMED, IDEA, 2018

The data presented above confirm that in terms of value the biggest share of supporting projects within the area of medical science is held by programmes co-funded by the EU whose implementation is not targeted in a specific way (Measure 1.1.1. within the Operational Programme Smart Growth (OPSG) 2014-2020). Additionally, an important source of funding is the STRATEGMEG Programme[109].

It is also confirmed by the results of evaluation studies in which beneficiaries point out that the most important medical programmes are those funded by the EU, most frequently including: the INNOMED Programme, as well as OPSG Sub-measure 1.1.1. and OPSG Sub-measure 4.1.4. Following the respondents' opinions, the key motivator for making use of EU financial support which is not targeted at medical purposes was a high allocation within particular measures along with a high level of freedom in defining the thematic scope of the projects. It is also confirmed by the results of analyses of programme documents, including provisions of the regulations of particular competitions (e.g. within OPSG Sub-measure 1.1.1. where - in accordance with the regulations - co-funding included projects involving industrial research and experimental development works or experimental development works with the possibility of doing pre-implementation works without pointing at the thematical scope of the support)[110].

As the data presented above show, the most important medical programmes targeted thematically (100% of medical projects) are the STRATEGMED Programme, the INNOMED Sector Programme and the InnoNeuroPharm Programme. These programmes could be regarded as complementary from the perspective of the addressees of the support provided. STRATEGMED is targeted at a wide range of consortia consisting of science units and enterprises which go along with the interdisciplinary nature of the programme. In order to trigger entrepreneurs' R&D investments and to strengthen cooperation between industry and research science units within competition I, INNOMED engaged academic partners or institutes (research consortia consisting of science units and enterprises, enterprises as such, as well as groups of enterprises). Competition II, by contrast, was targeted solely at enterprises (enterprises or consortia consisting of enterprises). Due to the defined specific objectives (support of sector development) the InnoNeuroPharm Sector Programme is targeted directly at enterprises (enterprises and consortia of enterprises)[111].

[109] Ewaluacja Strategicznego Programu Badań Naukowych i Prac Rozwojowych Profilaktyka i Leczenie Chorób Cywilizacyjnych – STRATEGMED, IDEA, 2018
[110] Ibidem
[111] Ibidem

The table below presents financial progress and the available allocation percentage for the most important sources of financing for medical projects[112].

Table 22. Financial progress and available allocation percentage for the most important sources of financing for medical projects (2019)

Measure	Number of companies	Areas of National Smart Specializations				
		Bioeconomy	Innovative technologies and processes	Natural resources and waste	Healthy Society	Sustainable energy
Beneficiaries						
1.1.1	981	13%	42%	9%	17%	19%
1.2	426	8%	36%	13%	8%	35%
4.1.4	144	10%	39%	15%	15%	21%
OPSG- Total	1 643	11%	40%	11%	14%	24%
Ineffective applicants						
1.1.1	3 941	10%	42%	11%	16%	21%
1.2	488	3%	45%	10%	4%	38%
4.1.4	617	13%	34%	15%	19%	18%
OPSG- Total	5 382	9%	42%	11%	15%	23%

Source: Badanie ewaluacyjne pomocy publicznej udzielanej w ramach Rozporządzenia Ministra Nauki i Szkolnictwa Wyższego w sprawie warunków i trybu udzielania pomocy publicznej i pomocy de minimis za pośrednictwem Narodowego Centrum Badań i Rozwoju (B+Radar). On-going report, 2019

The results of evaluation studies indicate that the support provided for innovative projects under EU programmes is of 'two-track' nature. The vast amount of the support is allocated to companies relatively bigger as compared to all, which have also been present in the market for a longer time and which possess greater capacity and experience in doing R&D works. The projects of that kind are characterized by a lower level of risk and higher probability of the ultimate success, which is the commercial implementation of the results of the works performed. It can be also assumed that in this case it is possible to expect innovations with a wider range of impact and a higher value added. Hence the support targeted at the entities of that kind to a greater extent contributes to achieving the objective by an overall increase in the innovation and productivity of the economy. The results of the analyses show that although the programme does not rule out the participation of smaller companies, which do not have R&D experience, the selection system favours in a way the companies of greater capacity and experience (in this respect the structure of applicants differs from the structure of beneficiaries, i.e. among applicants, companies with lower R&D capacity and experience outnumber beneficiaries)[113].

[112] Badanie ewaluacyjne pomocy publicznej udzielanej w ramach Rozporządzenia Ministra Nauki i Szkolnictwa Wyższego w sprawie warunków i trybu udzielania pomocy publicznej i pomocy de minimis za pośrednictwem Narodowego Centrum Badań i Rozwoju (B+Radar). On- going report, 2019

[113] Badanie ewaluacyjne pomocy publicznej udzielanej w ramach Rozporządzenia Ministra Nauki i Szkolnictwa Wyższego w sprawie warunków i trybu udzielania pomocy publicznej i pomocy de minimis za pośrednictwem Narodowego Centrum Badań i Rozwoju (B+Radar). On-going report, 2019

Due to a relatively small number of companies with high R&D capacity and a wide range of the support that has been already provided (according to the evaluation study 40% of all R&D companies in Poland have been supported). Implementation institutions are considering an increase in the support scope for companies which have either no or less R&D experience. In this respect a good example is the competition for small projects within Sub-measure 1.1.1. (the main source of financing innovative medical projects in Poland), which aroused relatively a lot of interest among applicants. The studies have recommended that a pilot programme/competition targeted strictly at companies previously not operating in R&D should be launched with adopting suitable selection criteria[114].

The results of the analyses indicate that the scope of the support offered to enterprises within various operational programmes facilitates implementing projects which are complementary in view of their development needs. The support complementarity is observed particularly in the case of early-stage companies. The nature of the support including aid within various programmes provided at different stages of the company growth favours the successiveness of implementing projects, which is strictly connected to the company lifecycle. With this regard it is possible to take account of the three main development sequences: (1) support provided with reference to developing a concept (start-up stage), (2) support provided to facilitate entering the market (early stage), (3) support for business expansion and diversification (expansion stage)[115].

The support complementarity is also observed as for ventures implemented by companies at later stages of development, by those which have not used incubation or acceleration support. In some cases such complementarity is not as strict as in the case of start-up companies (it refers to, e.g. different groups of products). However, complementarity referring to the scope of the company's business (e.g. launching new types of services in the given branch) and to the development strategy of the company is maintained. An example of the complementarity of that kind is the case study of a company specializing in medical services.

Box 7: Case study: SPECMED

Case study: SPECMED[116]

Specmed is a medical company which consists of several primary healthcare units (PHU) and specialist clinics. It launches innovative services on the medical market, such as personalized PHU e-services, services related to specialist counselling, occupational medicine as well as diagnostic services.

Within the support provided under the Operational Programme Eastern Poland (OPEP) a design audit has been carried out as for, among other things, the company's offer, its business model, marketing strategy and communication processes. Then a design strategy was created and implemented.
It included, among other things, initiatives referring to the improvement of visual identification, communication with the patient as well as the management of an information flow. As a result, design tools were worked out and they were later used to implement the Integrated System of Communication with the Patient. The implementation project included the following: starting up a system of e-patient service, as well as a system of access to data along with data exchanging and filing . In healthcare units the development of information technology included a queuing system, info-kiosks, e-labels, LED displays along with software for content management. The project also succeeded in providing specialist doctor's surgeries with extra diagnostic and diagnostic- treatment equipment.

[114] Ibidem

[115] Komplementarność i synergia wsparcia przedsiębiorstw makroregionu w ramach Programu Operacyjnego Polska Wschodnia 2014-2020, Programu Operacyjnego Inteligentny Rozwój 2014-2020 oraz 5 Regionalnych Programów Operacyjnych 2014-2020 województw lubelskiego, podkarpackiego, podlaskiego, świętokrzyskiego i warmińsko-mazurskiego, 2019

[116] Ibidem

The project implemented within OPSG Sub-measure 3.3.3. has made it possible for representatives of SPECMED to participate in international trade shows and fairs. So far they have taken part in four such events (in the USA, Dubai, Great Britain and Sweden). Among the services promoted in the presence of foreign participants during the events there were, among other things, services of 'one-day treatment centre', where commercial aesthetic medical treatments are performed. The promotion translated into signing a few agreements with clients.

Next, the project implemented within Sub-measure 1.4.1. under the Regional Operational Plan (ROP) for Podkarpackie voivodeship will include creating the system of care taking services combined with the system of behavior control of the elderly and with computer assisted activation of such people. The project assumes creating a modern centre of active care for the elderly, which now is under construction. Another element of the project initiatives will be smart systems of managing the building and of behavior control of the elderly and the activation of elderly people. They will be equipped with bands monitoring, among other things, their vital signs and registering their location.

These projects concern different aspects of the company's business, however they complement each other, taking account of SPECMED's strategy and the company's business area, which is health care.

However, it should be stated that the complementarity and synergy of ventures implemented by enterprises are conditioned mostly by entrepreneurs' economic rationality and they are partially independent of the level of support complementarity understood as a chance of obtaining a different kind of aid within different programmes. It can be assumed that even if the support should overlap as there are analogous offers within different measures, the entrepreneur will use only those which ensure complementarity and respond to their needs. Nevertheless, the diversified and complementary offer of operational programmes to much extent favours and facilitates implementing such ventures[117].

In the context of access to funding, the key elements of the systems of implementing EU programmes are the criteria and the system of selecting projects. The system of selecting projects within EU programmes in Poland was modified in 2017 with regard to the increased accessibility of the support offered to companies. As for the measures which, according to the above analysis, are the main source of financing for innovative medical projects in Poland, i.e. OPSG 1.1.1. and 1.2., some changes aimed at stronger favouring the most innovative projects have been introduced. A good example can be an amendment with reference to Sub-measure 1.1.1. and Measure 1,2 made at the beginning of 2017 in competition regulations. It involved adding to the criterion 'Market demand and implementation profitability' more details stating that projects of groundbreaking innovation for which it is impossible to define precisely market demand obtain 3 point minimum. This change facilitates selecting groundbreaking projects whose assessment and approval within this criterion was previously hindered. Potentially, adding this provision could result in the increased innovation of projects implemented under the Programme by an easier selection of projects introducing the so-called disruptive innovation. Obviously, this change was definitely justified, mainly because of the necessity of creating a mechanism which would not eliminate (or would not promote) the projects of that kind, even if they are rare[118].

[117] Ibidem

[118] Ewaluacja systemu wyboru projektów POIR 2014-2020-ocena wybranych zmian, 2019

The most significant systemic change in the process of selecting projects in competitions within Sub-measure 1.1.1., as well as Measure 1.2. was adding the content to what extent it is permissible to amend the information assessed within the given criterion and included in the application for financing. This change resulted from adopting a new implementation law in the second half of 2017. Defining precisely the scope of possible changes in the application for financing was aimed at increasing transparency of the whole process and avoiding controversy over to what extent the applicant can amend the application submitted. Potentially, the introduced possibility of amending the application as for particular criteria should result in the increased effectiveness of applying for support (including the increased success rate) by improving applications which are good substantially but not well-developed enough[119].

Within Sub-measure 1.1.1. as for the competition including SME projects apart from decreasing the minimum level of eligible costs, requirements included in some criteria have been eased. Particularly, the required innovation of projects was decreased – a novelty on scale of an enterprise will do, whereas in the case of 'the fast track' a novelty on the national scale minimum is demanded as a rule. The set of other criteria has been also modified, among other things, the criterion concerning managerial staff was deleted, conditions to be met by a research team were eased (lack of conditional contracts with key team members and sub-contractors at the moment of submitting applications was approved) and the evaluation of cost-effectiveness was simplified. All the changes were aimed at making it possible also for smaller entities, including entities inexperienced in research works, to apply for support and to start R&D works. Additionally, the changes improve access to support, but they should result in decreasing the innovation of the supported projects by definition[120]. It is a response to the problem described above, which is a limited access to financing for companies not experienced enough in research and innovation.

Apart from EU programmes an important source of financing for medical projects are national strategic programmes. Over 2012-2017 it was the function of the STRATEGMED Programme (accessible funds were allocated within three competitions (2013, 2014. 2015). Within STRATEGMED it was possible to obtain financial support for projects in the following four thematic areas (which were divided into several or more than a dozen specific subjects): cardiology and cardiac surgery, oncology, neurology and senses, as well as regenerative medicine. The results of the evaluation studies indicate that the key conditions of the effectiveness of the research projects implemented within the STRATEGMED Programme are those factors which are connected directly or indirectly to the project cycle and research risks in a broader sense (time assumed for project implementation and a possibility of making changes in the course of project implementation), as well as factors related to the organization and management of a large interdisciplinary and multisectoral research consortium (different objectives of business and of academic sector, as well as difficulty managing and coordinating the work of the consortium). The major hindrances pointed out by beneficiaries are also formal and legal requirements (including procurement law) and problems with the commercialization and implementation of research results[121].

According to the evaluation study results, issues related to the organization and coordination of the works within the consortium are one of the most important factors determining the ultimate project success. It results directly from the assumptions of the programme within which big projects are implemented by multi-entity (5 consortium members minimum) and multisectoral research consortia including science units and enterprises. The projects are interdisciplinary, which additionally increases the significance of the way they are organized and managed and of internal communication for the ultimate effectiveness and efficiency of the implemented ventures.

[119] Ibidem
[120] Ibidem
[121] Ewaluacja Strategicznego Programu Badań Naukowych i Prac Rozwojowych Profilaktyka i Leczenie Chorób Cywilizacyjnych - STRATEGMED, IDEA, 2018

A key element of cooperation is effective communication between projects participants. The effective communication and up-to-date direct contacts between members of the consortia and research teams were pointed out by many respondents as the most important factor of the project success. The ineffective coordination of the know-how and information flow within some projects translates into substantive quality of research works of particular teams that are part of the consortium, as well as into organizational problems causing delays in implementation[122]. The case study below illustrates the types of projects which could be implemented within the STRATEGMED Programme.

Box 8: Case study: New technologies for pharmacological stimulation of regeneration - REGENNOVA

Case study: New technologies for pharmacological stimulation of regeneration - REGENNOVA[123]
Project leader: University of Gdańsk

The aim of the project is to work out methods and technologies for pharmacological stimulation of the regeneration of damaged tissues and organs, which would be an alternative to methods involving transplantation of tissues or cells into the patient's body. The long-term strategic objective is to increase the effectiveness of therapy by accelerating the process of wound healing, treating chronic wounds and treating the effects of nervous system damage. The objectives and expected effects of the projects are of particular significance to people waiting for organ transplantations, victims of serious accidents (a.o. spinal cord injuries), people suffering from civilization diseases (diabetes in particular), from chronic wounds, cardiovascular diseases, bedsores and stroke effects. The project is interdisciplinary and it involves carrying out research concerning a possibility of activating stem cells (progenitors), which participate in the processes of regenerating damaged tissues and organs.

As a result of the research carried out within the projects, about 120 new compounds of prospective pro-regeneration significance have been obtained. The compounds have been or will be tested. The tests conducted so far have confirmed that some of them have pro-regeneration properties. It was observed that one substance is of great importance in particular, which was confirmed in ten independent experiments. In this respect the results will be the basis for preparing a worldwide patent application and for a publication in a prestigious, JCR – listed science journal. The research results have been also widely popularized (at almost 100 conferences and science meetings, they have been also presented and commented on in local and national media) and printed in science publications (ultimately in 7 publications).

One of the main factors determining the successful implementation and effectiveness of the project (including its great implementation capacity) was the mode of organization and management of research teams and the consortium as a whole (rules of cooperation defined in writing as procedures of managing the project). The consortium content was characterized by a high level of complementarity due to the specialization and capacity of particular entities – it referred not only to science units (research specialization), but also to commercial entities (a company specializing in the processes of commercializing the research results, as well as a company that supported the research substantively). The cooperation within the consortium assumed tight coordination and intensive communication (a.o. regular meetings of all consortium members). An effective and free (also informal) flow of know-how and information within the consortium was one of the basic condition of the effective implementation of such a large interdisciplinary project.

[122] Ibidem
[123] Ibidem

An important advantage of the project was an 'inclusive' way of managing it: not only did members of research teams and consortium representatives participate in project meetings, but also representatives of a wide range of stakeholders, a.o. doctors. Their participation and substantive contribution made it possible to introduce a number of improvements, particularly as for practical use of the research results (e.g. ways of applying active compounds in the operation theatre). The biggest visible barrier for implementing the project was terms of reference for public procurement. Burdensome and maladjusted to science and research works, formal procedures of public procurement translated into problems with coordination of works within the whole consortium (prolonging procedures in one consortium member caused problems to other entities). However, as a result of adopting the participatory model of project management which has been described above the problems did not translate into the effectiveness and efficiency of the whole venture.

STRATEGMED

Name of the programmee:
STRATEGMED

Objectives:
Main objective:

- Achieving substantial progress in preventing and treating civilization diseases and in regenerative medicine based on the results of scientific research and development works carried out under the programme

Specific objectives:

- A significant increase in Poland's international position in the field of scientific research and development works in the disciplines of science covered by the programme.
- Creating dynamic, young research teams, in an international composition and with a strong, documented international position.
- Transfer of know-how and new technologies in the field of prevention, diagnostics, therapy and rehabilitation from Polish science institutions (public research organizations) to the economy.

Budget: €186 000 000

System of implementation: Programme Operator: National Centre for Research and Development

Who can apply for the support:
Research consortia, which includes at least five organizational units (science units and enterprises)

EU funds project application and further implementation is connected with significant administrative burden. The evaluation studies results indicate the following main sources of burden for applicants of EU programs: accessing information on the financing principles; preparation of application together with all required attachments, application of Public Procurement Law and/or competitiveness principle, usage of SL database and other IT bases, preparation of payment application together with documents for control.

At the application stage, preparation of the application was considered the most time-consuming activity (with average costs: 0.6% of the value of the project in the case of outsourcing and 0.2% in the case of its own preparation). The most time-consuming activities at the implementation stage are: application of Public Procurement Law and/or competitiveness principle, usage of SL database and other IT bases, preparation of payment application together with documents for control. According to the evaluation results, the total administrative costs are on average 3,5% of the project value and this amount is independent of the project size. These data indicate a space for supporting activities aimed at reducing administrative costs (consultancy, legal services, etc.), both at the application submission and project implementation stages[124].

4.4.2. Specific challenges for Pomorskie Region

Some interesting findings about local entrepreneurship ecosystems and emerging industries in Pomorskie, especially in the field of innovations in health sector are provided by recent OECD report[125]. According to this report:

- The medical technologies (medical technologies in the area of civilisation- and ageingassociated diseases) smart specialisation in Pomorskie can be seen as largely following a path of 'industry upgrading' through 'renewal' of existing activities, i.e. shifting into a new direction based on importing new technologies, organisational innovations or new business models through external knowledge exchange connections.
- There are also opportunities for related and unrelated industrial diversification in the smart specialisation.
- There is a variety of organisations of different scale in the smart specialisation, including the leading domestic large firm, Polpharma, the Medical University of Gdansk (MUG), and some spin-off enterprises from the MUG
- Compared with leading biotechnology regions, there are relatively few innovative start-ups in the smart specialization[126]

4.4.3. Financial perspective 2021-2027

Support for innovation within the new financial perspective will most probably be carried out under Policy Objective 1 – Smarter Europe. In this regard Poland has some draft ideas on directions of support for 2021-2027, which were highlighted in draft Assumptions of the Partnership Agreement[127]. They may however be still changed, depending on the outcomes of negotiations. According to this document, the main goal of intervention in the PO1 area will be: an increase in the productivity of the Polish economy, which is to be achieved thanks to the increase of its innovativeness, as well as through restructuring and modernization of the SME sector. To achieve the goal of increasing the innovativeness of the economy, Poland envisages, among others:

- support for the development of R&D activities of enterprises and their consortias;
- support for the implementation of R&D results;
- support for the development of cooperation between enterprises, enterprises and the science sector and enterprises, the science sector and public sector entities;
- development and implementation of innovation;
- support for increasing the supply of innovation from the science sector - staff development, cooperation between institutions and technical resources necessary for industrial research and development, focus of public R&D works on selected key areas for the modern economy;

[124] Assessment of administrative burden within project implementation lifecycle within national and regional operational programs 2014-2020 programming perspective, Foundation IDEA for Development for Ministry of Investment and Development, 2018
[125] Local entrepreneurship ecosystems and emerging industries: Case study of Pomorskie, Poland", OECD 2019
[126] Ibidem
[127] Link to the document (in Polish)

- support for the development of the intellectual property protection system;
- support for the development of knowledge diffusion mechanisms in the economy (technology transfer);
- R&D infrastructure support (in particular in enterprises).

To achieve the goal of restructuring and modernization of SME sector, Poland wants to support the following activities:

- Support for productive investments in SMEs, in particular those increasing their technological advancement;
- Stimulating the demand for innovation from enterprises, especially from the SME sector;
- Increasing the ability of enterprises to create products and services with export potential
- (searching for new markets, product development, changes in the business model);
- Digital transformation of the economy, consisting of transformation of business models towards

Industry 4.0 and the data-driven economy, in particular automation, robotization and digitization of enterprises, increasing the use of process systems, supporting the transition of companies to the digital chain of supply and introduction of ICT to everyday activities. It is also planned to support projects in the field of e-administration, including in the field of digitization and increasing the availability of public data

- Support for the development of innovative services for SMEs, including increasing the capacity of the national ecosystem for networking of business and scientific entities
- Dissemination of quality systems and standards among enterprises, supporting the demand for pro-quality services provided by business environment institutions (including mentoring, networking, changing business models, internationalization);
- Development of competences and skills of entrepreneurs, managers and employees necessary for the modern economy, in particular in the area of digital skills and management of new business models.

A cross-sectional principle accompanying actions taken under PO1 will be to support measures for transformation towards circular economy. Therefore, all activities aimed at reducing the resource and material intensity of production and logistics processes will be supported, as well as development in implementation of eco-innovation. Support for various types of projects will be implemented in various forms, so grant financing will be provided for the most innovative projects and the most risky ones (e.g. support for start-ups, green technologies). Financial instruments will be available for projects with a lower level of risk.

As for the financial aspects there are no final decisions regarding the allocations for supporting innovative actions. According to the proposed regulations, Poland has to allocate at least 35% of ERDF (so more than €14 000 000 000) on Policy Objective 1. No decision has been made yet as for the exact thematic scope of future operational program(s) supporting innovations. The answer to the question about the future of support in the area of health can be sought in the Strategy of Responsible Development, which was discussed in chapter one. Since it is a basic medium-term strategic document, the Strategy can be perceived as a basis for planning the intervention of European Funds in all areas.

4.5. Conclusions and recommendations

Main conclusions coming from conducted analysis are as follows:

- Innovations in health and medicine are high in Polish development agenda which is expressed in Polish most important strategic document The Strategy for Responsible Development for the period up to 2020 (including the perspective up to 2030), adopted by the Council of Ministers.
- Innovations in health and medicine are as well important in strategic objectives of development in Pomorskie Self Government. Medical technologies in the field of lifestyle and aging diseases are specified as one out of four smart specializations in this region.
- The choice of regional smart specializations was collective process with grate involvement of many regional partners. Recently the process was updated so (especially smart specialization of Medical technologies in the field of lifestyle and aging diseases) is equally important both for current as well as for the next programming perspective.
- There are numerous sources of financing innovations in health and medicine sector. Currently the most important sources are: Operational Programme Smart Growth 2014-2020, Regional Operation Programme for Pomorskie Voivodship for 2014-2020 and national strategic programe STRATEGMED.
- Additional sources where innovative projects from the sector of health and medicine can find its financing are: Operational Programme Knowledge, Education, Development 2014-2020, Research programs: OPUS, SONATA, PRELUDIUM, Programme INFOSTRATEG, Programme: „Health" under the EEA and Norway Grants (2014-2021). There are also some regional repayable instruments: Pomorskie Loan Fund, the Pomorskie Regional Loan Guarantee Fund, and the Pomorskie Development Fund.
- It is important to take into consideration that usually support from above mentioned programs is available for the sector medicine&health. However, projects from this sector have to usually compete with any other innovative applications.
- Results of conducted evaluations show that quite often this competition is in favor for innovative projects from health & medicine sector. For example, around 15% of total allocation of grant schemes in biggest Polish Operational Programme Smart Growth 2014-2020 are implemented within national smart specialization "Healthy society". Projects concerning smart specialization of medical technologies in the field of lifestyle and aging diseases received also a biggest financial allocation (within measure 1.1.1 dedicated to innovative projects in Regional Operational Program for Pomorskie Voivodship 2014-2020) from all 4 regional smart specializations in this region
- Evaluation results show also that in fact there is very little day-to-day coordination between different funds (for instance as far as scope and timing for calls for proposals is concerned). However active companies and other entities can quite successfully find ways to get financing from different programs and measures (but coordination of various funding sources at project level - due to earlier mentioned factors- is almost impossible).
- Evaluation results also indicate that especially difficult is receiving support and further successful implementing projects financed under EU-funds. Administrative burden is very challenging for companies and other entities from outside of public sector like: NGOs, research institutes. To "get the money" and successfully implement project significant experience and potential is needed for all parties involved in project.
- Although there is still little to know about public support for innovations in health and medicine sector in programming perspective 2021-2027 one can expect that this sector will be equally important as in current programmes.

Main strategic recommendation which is coming from this research is as follows:

There is a great potential for regional partner institutions for EIT Health to become main broker of knowledge as well as provider of support for different entities in application and further implementation of innovative projects in the area of health&medicine. They tasks could be:

- Preparation every moth overview of upcoming calls for proposals from different funds where innovative projects in the area of health&medicine.
- Dissemination of this knowledge to all interested parties
- Provide support to applicants in preparation of application form
- Providing a support for beneficiaries in smooth implementation of projects (helpdesk)
- Managing small grant schemes for preparation of complete project proposals
- Day-to-day cooperation with main government and self-government actors in the field of innovations (Ministries, Marshal Offices, public agencies)

It should be taken into account that all of this activities are time and cost consuming and should be financed from EIT Health programme within Regional Innovation Scheme (RIS) (or maybe also from other sources). It is also essential to take into account that such activities should be connected with main objectives of regional partners (for example Center of Transfer of Technologies is first of all a part of Medical University in Gdansk and should serve the interest of the University not necessarily external actors).

Nevertheless regional partners in EIT Health network may become important partners for government/ self-government institutions in defining scope of support for innovative projects in the upcoming programming perspective.

Except above mentioned main recommendation some interesting policy recommendations concerning medical technologies in the area of civilization - and ageing-associated diseases in Pomorskie voivodship are provided by recent OECD report. They are also coherent with findings of the current research:

- Stimulate greater connections between basic and applied research in the smart specialization by supporting research projects and PhDs undertaken in companies, and supporting collective actions and networks around existing 'first mover' spinoffs in this specialization in region.
- Supporting the development of university spin-off enterprises with finance, advice, mentoring and other relevant support.
- Increase incentives for academics to commercialize their research both at the level of the national higher education system and at the level of individual HEIs[128].

[128] Local entrepreneurship ecosystems and emerging industries: Case study of Pomorskie, Poland", OECD 2019

5. Slovak Republic

5.1. Health situation[129]

The health status of the Slovak population has improved since 2000, but life expectancy at birth is still almost four years below the EU average. Life expectancy for men is more than seven years lower than for women, and a large gap also exists by socioeconomic status: Slovak people who have not completed their secondary education can expect to live 10 years less than those with a university education.

The lower life expectancy in the Slovak Republic is to a large extent due to higher mortality rates from cardiovascular diseases. Mortality rates from ischaemic heart diseases are the fourth highest among EU countries, and death rates from stroke are also well above the EU average. The implementation of a more comprehensive tobacco control policy may help achieve further reductions in tobacco smoking among adolescents and adults, the largest avoidable risk factor for cardiovascular diseases.

Progress was achieved over the past decade in reducing mortality rates for people admitted to hospital for a heart attack or stroke. On the other hand, cancer survival did not improve significantly over the past decade, and the gap widened with many other EU countries in survival following a diagnosis of breast, cervical or colon cancer. This lack of progress is partly due to low screening rates. The Slovak Republic has not yet developed any national cancer plan, a tool used in other countries to achieve progress in prevention, early detection and treatment for people with cancer.

The statutory health insurance system is designed to provide the whole population with the same benefit package, regardless of health status, ability to pay and place of residence. Insurance companies are mandated to maintain contracts with a minimum set of providers by type of service and speciality in each region. In practice, however, coverage still varies across the country, mainly because the supply of health professionals is uneven across regions and districts. The capital region has the highest number of doctors per population and providers tend to cluster in regional capitals, limiting access for the rural population.

The Slovak Republic has successfully downsized hospitals and allocated resources to outpatient services. The hospital sector reduced substantially over the last two decades, as illustrated by the reduction in hospital beds and average length of stay. Nonetheless, the overall consumption of hospital services remains high, with hospital discharge rates above the EU average and rising in recent years. Further efficiency gains may be achieved by reducing avoidable hospitalisations through better self-care and primary care.

The Slovak Republic has a general lack of GPs, with few medical graduates choosing to specialise in general medicine. The lack of effective primary care is particularly felt in deprived areas, especially those with a large Roma population, a group that suffers from poorer health status and service access. A large proportion of GP consultations also result in referral to a hospital specialist. Expanding the role of GPs and other health professionals (such as nurses and community pharmacists) can make primary care more accessible and effective, and increase the overall efficiency of the system.

[129] State of Health in the EU: Companion Report 2017

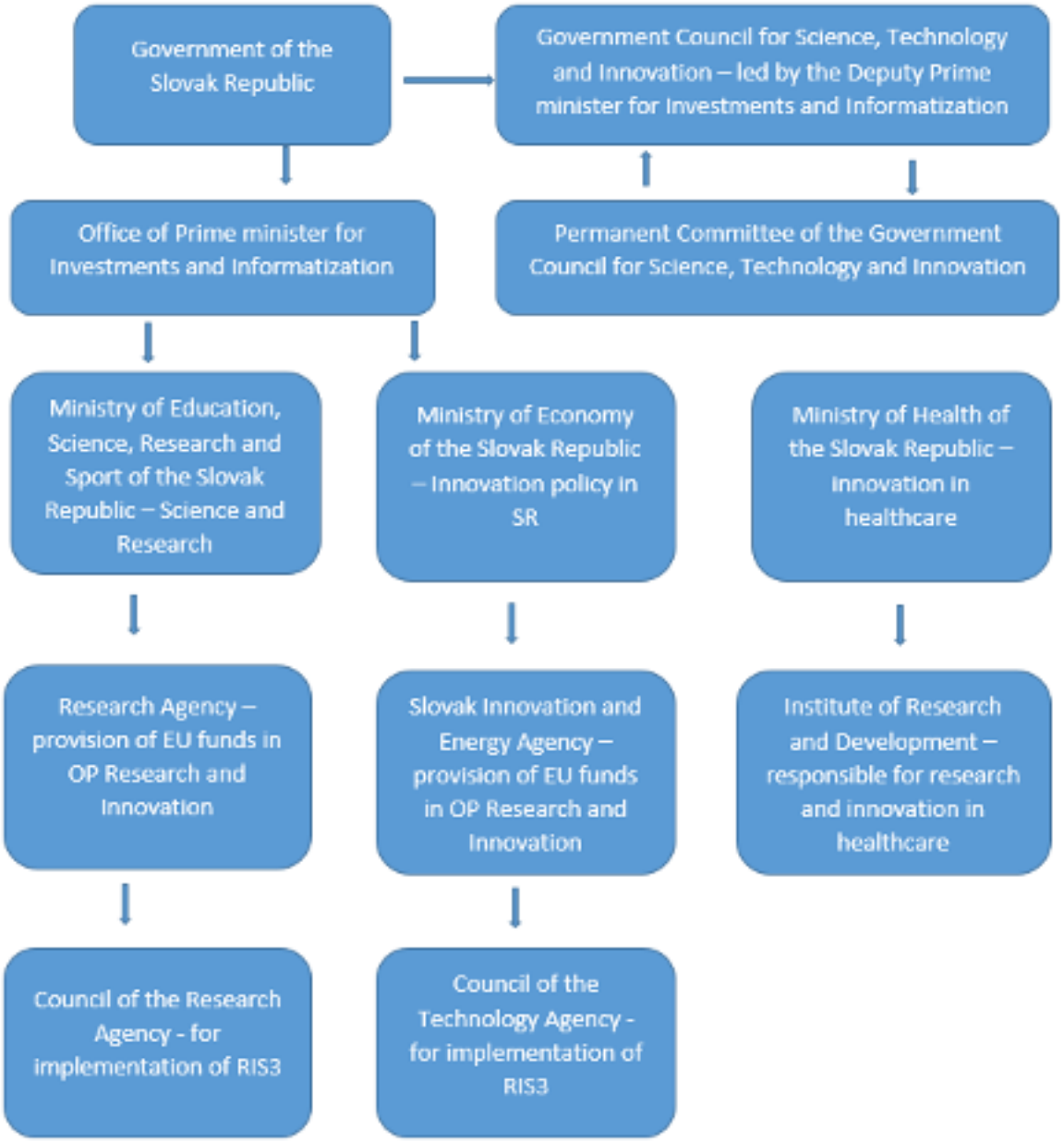
5.2. Institutional set up of innovation sector in Slovakia

The central body of the state administration for science, research and technology is the Ministry of Education, Science, Research and Sport of the Slovak Republic. The Ministry creates conditions for the development of science and technology and co-ordinates the activities of central bodies, the Slovak Academy of Sciences and universities in the preparation and implementation of state science and technology policy, and in addition to research and development. At the same, the Ministry is responsible for effective use of state budget funds on science and technology. The Ministry of Education, Science, Research and Sport of the Slovak Republic closely cooperates with Ministry of Economy responsible for innovation policy in Slovak Republic. In order to establish a functional body for support of operational activities the Slovak government has created a Government Council for Science, Technology and Innovation. This council is a permanent expert, advisory, initiative and coordinating body for science, technology and innovation in the Slovak Republic. Its task is to coordinate cooperation of public and private sector organizations in achieving the objectives of state science, technology and innovation policy and to comprehensively assess relevant documents submitted to the Slovak Government or European Union and international organizations.
The Chairman of the Council is the Deputy Prime Minister of the Slovak Republic for Investment and Informatization. The Council Presidency consists of the Chairman and Vice-Presidents. The Vice-Presidents of the Council are the Minister of Education, Science, Research and Sport of the Slovak Republic, the Minister of Economy of the Slovak Republic, the Minister of Finance of the Slovak Republic, the President of the Slovak Academy of Sciences and other vice president authorized by the chairman. The Council is also responsible for implementation of the Strategy for Smart Specialisation (RIS3) in Slovakia. For monitoring and evaluation, permanent committee of Government Council for Science, Technology and Innovation has been established.

In order to eliminate the existing fragmentation and to achieve synergies, the existing network of implementing institutions was transformed into two separate agencies: Research Agency under Ministry of Education, Science, Research and Sport of the Slovak Republic and Slovak innovation and energetic agency (SIAE) under the Ministry of Economy of Slovak Republic which acts as technology agency. Both agencies are responsible for EU support for innovation in Slovak Republic.

For the sake of RIS 3 implementation in Slovakia two councils have been created. The Council of the Technology agency for implementation of RIS3 acts as advisory body of the SIAE and is formed on the basis of the 50:50 principle of public-private partnership, while part of the members are also members of the Research Agency established under the Ministry of Education, Science, Research and Sport of the Slovak Republic. The Council consists of a Chairperson, a Vice-Chairperson and 16 members, including representatives of major employers' associations, professional associations and other professional organizations, representatives of research institutions and universities. Similar body - Council of the Research Agency has been established by the Ministry of Education, Science, Research and Sport of SR which serves as an advisory board for implementation of RIS3. The Board is chaired by the Chairman and one Vice-Chairman. The Chairman of the Council is the Minister of Education, Science, Research and Sport of the Slovak Republic. The Vice-Chairman of the Council is the Minister of Economy of the Slovak Republic.

Figure 34: Institutional set up for research, development and innovation policy



5.2.1. General context of innovation finance in the health sector

The responsible institution for overall coordination and financing of innovation in the health sector is the Ministry of Health of the Slovak republic. Within the Ministry an Institute of Research and Development has been established. The main goal of the Institute, which has been transformed since 1 January 2019 from the department for Research and Development, is to improve the health of the Slovak population as well as support generating and exploiting the innovative outcomes of excellence in health science. These include in particular innovative products and methods in the field of prevention, diagnosis and treatment, new or innovated medical technologies, intelligent equipment and equipment, effective approaches in

clinical practice. On the other hand, it is able to effectively monitor the results of research and development activities in this field, in cooperation with users of these results - healthcare providers, healthcare and academia, patient organizations, managers of public and private organizations that are involved in biomedical research.

National Reference Centres (hereinafter referred to as "NRC") are methodological and professional guarantors for coordination the workplaces of regional offices of public healthcare (altogether 26) in fulfilling national and international programs in health protection and promotion. Their main activity is specialized post-diagnosis in the given area, providing external control for subnational and cooperating laboratories, providing expert information, consultations and professional roofing of training events and education. The mission of the NRC includes also research, development, implementation and applying of new progressive methods to laboratory practice in accordance with diagnostic standards recommended by the Organization for Economic Cooperation and Development (OECD), the World Health Organization (WHO), the European Food Safety Authority (EFSA) and the Superior European Reference Centres.

In terms of innovation in healthcare it can be stated that such innovations have potential to reduce costs and improve quality of healthcare. The high importance of threats to innovation activities is qualification of employees, as well as the lack of standards, norms and rules. As the most significant barriers for adopting technological innovations in hospitals and other healthcare institutions, hospitals declared the lack of financial and personal resources. Any introduction of new technology whether it is the implementation of new IT solution or upgrading hospital operation, reconstruction and other, requires interventions into individual organizational units and requires complementary knowledge of employees, which is expensive[130].

Despite strong economic growth, Slovakia still lags behind in science, research and innovation compared to other developed EU countries. For this reason, the development of biomedicine is becoming one of the main priorities of the government of the Slovak Republic, which is essential for a healthy population and diversification of knowledge economy. Strategic support for excellent biomedical research and development is essential in the fight against civilization diseases and is also very important if we want top scientists to work in Slovakia. One of the fundamental goals is that hospitals respectively health care providers have worked more closely and more effectively with universities and research institutes. Strategically, it is crucial to systematically strengthen the position of excellent biomedicine as an emerging economic specialization, which is a prerequisite not only for improving the quality of health care, but also for increasing the competitiveness and sustainability of economic growth. This area is able to attract significant investments, support the creation and establishment of start-ups or spin-offs with this focus, which have a high potential for generating innovation, including exclusive intellectual property rights linked to high value-added products.

In order to overcome these barriers the responsible institutions for innovation in Slovak Republic have elaborated the main strategic documents.

5.2.1.1. Research and Innovation Strategy for Smart Specialization (RIS3 in Slovakia)

Research and Innovation Strategy for Smart Specialization of the Slovak Republic (RIS3) is the basic framework strategy document for supporting research and innovation in the current 2014-2020 programming period. The elaboration of smart specialization strategy has become an ex ante conditionality for use of ESI Funds.

[130] Based on the questionnaire conducted by the Faculty of Economics of Technical University in Košice during personal visits in 20 hospitals in Eastern Slovakia in the period December 2011-March 2012. The main objective of research was to map an existing management information systems and information technologies in the hospitals of the region and to obtain information about the current status of innovation development.

At the same time, it is a key document aimed at sustainable economic growth and increasing employment in Slovakia through targeted support for research and innovation and reaching a critical mass in individual strategic priorities, while taking into account regional specificities. RIS3 has been drafted by the Ministry of Education, Science, Research and Sport of the Slovak Republic in close cooperation with the Ministry of Economy of the Slovak Republic. The Office of the Government of the Slovak Republic together with representatives of the business, academia also participated in the creation of RIS3. The Strategy has been approved by the Slovak Government in November 2013.

The role of RIS3 is to define the vision, objectives and measures on the basis of a comprehensive analytical part and set priorities of economic specialization and research and development in the SR, while taking into account the principles of smart, sustainable and inclusive growth to strengthen the competitiveness of the SR. The main objectives of RIS3 are:

- deepen the integration and anchoring of key industries that increase local added value through cooperation of local supply chains and by promoting their networking;
- increase the contribution of research to economic growth through global excellence and local relevance;
- creating a dynamic, open and inclusive innovative society as one of the prerequisites for improving the quality of life;
- improve the quality of human resources for innovation in Slovakia

Following the approval of RIS3, measures for implementation of the Strategy had to be taken in order to utilise the ESI Funds. Therefore, the Action plan for implementation of RIS3 was elaborated.

5.2.1.2. Action Plan of the Research and Innovation Strategy for the Smart Specialization of the Slovak Republic

Action Plan of Research and Innovation Strategy for Smart Specialization of Slovakia elaborates procedures and processes for meeting the missing criteria in relation to thematic ex ante conditionality 1.1 for thematic objective - Strengthening research, technological development and innovation and the implementation of relevant investment priorities funded in the 2014-2020 programming period. The Action Plan specifies the provisions of RIS3 so that they comply with the applicable ESIF legislation as well as other national legislation in order to fully support objectives contained in RIS3. The Action Plan was elaborated by the Ministry of Education, Science, Research and Sport of the Slovak Republic in close cooperation with the Ministry of Economy of the Slovak Republic, Office of Government of the Slovak Republic and Office of the Deputy Prime Minister of the Slovak Republic for Investments and Informatization. The document defines main sources of funding, available also for innovative projects in the health sector. As a matter of fact, the main source of the financing is EU Cohesion policy aid, especially from the OP Research and Innovation.

The document describes all five domains for smart specialization:

- Cars for the 21st century,
- Industry for the 21st century,
- Digital Slovakia and creative industry,
- Population health and health technology,
- Healthy food and environment.

Domain platforms are built on previous activities that were aimed at prioritizing smart specialization areas within the continuous Entrepreneurial Discovery Process (EDP). In the EDP process, the platforms provided identification of key activities and products for the economic and research specialization of the SR, taking into account the technological and research capacities of organizations, the existing research infrastructure

in the public and private sectors and the research potential of top Slovak scientific teams. The domains were created on the basis of the intersection of economic and research specialization of Slovakia according to pre-defined criteria. The proposed domains contain both the main relevant SK NACE sectors and functional links to the main supply and customer sectors.

5.2.1.3. Population Health and Health Technology Domain

The Population Health and Health Technology domain must be viewed differently from other domains. It is a cross-sectorial domain that strengthens interconnections and cooperation with other domains of the Research and Innovation Strategy for the Smart Specialization of the Slovak Republic. The domain is closely connected to all four priorities of the RIS3.

The Slovak Republic is lagging behind the developed part of Europe in the trends of preventive and personalized medicine, early disease screening and in the quality of health of the senior population. Therefore, an environment is currently being created in the Slovak Republic that supports mainly biomedical research, development and education aimed at a comprehensive improvement of the health status of the Slovak population with a consequent positive impact on the economic, economic and social area. Research and development in medicine and its related disciplines enables the use and development of cutting-edge biomedical, laboratory and medical procedures and technologies, biotechnology and information/communication technologies/applications. The results of these activities and their implementation increase the competitiveness of health care facilities, scientific research (academic) institutions and enable the development of the business environment, including the emergence of new spin-off and start-up companies.

Targeted healthcare investments and related innovation in prevention, early diagnosis and adequate treatment (especially to increase the potential of personalized medicine) lead to reduced morbidity, mortality, both temporary and lasting effects of diseases, which are major socio-economic factors affecting the labour market and economic result of the country. The long-term vision of this domain is the fulfilment of tasks and obligations resulting from the program declaration of the Government of the Slovak Republic for 2016 - 2020, the National Reform Program 2017 and the strategic documents in the area of health. In accordance with the methodology established by the Office of the Deputy Prime Minister, the Working Group of the Ministry of Health of SR consisting of various experts from academic sector, hospitals and from business sector carried out the collection and evaluation of data prepared by experts with experience in the domain creation process and their functional links in order to determine the definitive list of product lines.

During this procedure following steps have been identified:

- Determination of development trends - in the framework of continuous EDP, the development trends (themes) for the domain of Population Health and Health Technologies were established by the platform, which subsequently created an input for the questionnaire survey. Overall, for the domain five basic development trends have been identified, which took into account the links of the smart specialization domain to relevant topics of long-term strategic programs as well as their sub-themes.
- Questionnaire survey - within the analysis, definition of links between health and biomedical research actors and the structure of the questionnaire that was set as data collection tool was provided. All activities were carried out in close cooperation with stakeholders in the form of meetings of the working group of the Ministry of Health and the analytical working group created at the Slovak Innovation and Energy Agency.
- Synthesis of knowledge and analysis - the result of the work of the platform was the analysis of the questionnaire survey and structured interviews, which were carried out by selected stakeholders in the healthcare sector. The working group of the Ministry of Health of the SR dealt mainly with the identification of development trends, key activities and product lines for the economic and research

specialization of the SR. The experts have adequately entered into the analysis, pointing out the importance of individual development trends and the product lines resulting therefrom. Subsequently, the working group synthesized this knowledge and discussed the most appropriate determination of the product lines.

- Determination of product lines - the final result of the work of the platform was a precise definition of product lines, which will subsequently be transferred to the setting of calls for proposals within the Operational Program Research and Innovation and other relevant schemes for funding research, development and innovation from national sources. The product lines are linked to established development trends for the relevant main NACE sectors of the domain and their functional links.

5.2.1.4. Strategic Framework for Health for 2014-2030

This document defines medium and long term direction of health policy in Slovak Republic. The main incentive for its creation is implementation of measures for improving the quality, sustainability and efficiency of the healthcare system and the health status of the population.

The Health 2020 policy is based on the following four priority areas:

- investing in health through the lifecycle and empowering people,
- tackling region's major health challenges: no communicable and communicable diseases,
- strengthening the health systems, public health capacity and emergency preparedness, surveillance and response,
- creating resilient communities and supportive environment for health of population.

Full use of tools and innovations as communication technologies (digital records, telemedicine and e-Health) and social media may contribute to better and more cost-effective healthcare. Further strategic documents have been identified at the central level, which are linked to innovation topic however they are not directly connected to innovation in health. They are listed below for getting a picture on strategic documents for innovation in Slovak republic.

5.2.1.5. Concept of Intelligent Industry for the Slovak Republic

The main aim of the Concept of Intelligent Industry is to convince the public for concrete action through recommendations that will maintain the position of Slovak businesses on Europe's industrial map and in global structures to contribute to the strength and impact in the economy and the functioning of society as a whole. The main recipients of the changes brought by the Concept are industrial companies, which will increase their competitiveness thanks to the possibility of more efficient production and sale of products. The changes also bring benefits to small and medium-sized enterprises, especially to suppliers of equipment, technology and services through interconnected industrial production. The document has been elaborated by the Ministry of Economy of Slovak Republic.

5.2.1.6. Action Plan for Intelligent Industry of the Slovak Republic

The Action Plan aims to support industrial, service and commercial enterprises, regardless of their size, to create better conditions for implementing digitization, innovative solutions and increasing competitiveness by reducing bureaucratic burdens, amending legislation, defining standards, changing education programs and the labour market, co-financing research and the like. The Action Plan provides a set of 35 measures to be implemented by the end of 2020. The Action Plan has been prepared in cooperation with the representatives of the sectors, industry, associations and universities.

Fulfilment of the Action Plan for Intelligent Industry by 2020 will create the basic prerequisite for the successful transformation of the Slovak economy in response to the digitalization of most of the companies in Slovakia. In order to achieve these strategic objectives, the following priority areas have been identified:

- Research, development and innovation,
- Basic principles of IT security implementation of intelligent industry,
- Labour market and education,
- Reference architecture, standardization and development of technical standards, European and national legal framework,
- Information and promotion.

5.2.1.7. Concept for Support of Start-ups and Development of Start-up Ecosystem in Slovak Republic

The concept for support of start-ups and the development of the start-up ecosystem is set in the broader concept of gradual growth oriented measures to support the Slovak economy and innovation policy of the Slovak Republic. It reflects on strategic documents adopted at both national and European level. The document provides information on the current state of the start-up environment in the Slovak Republic analyses the phases of the start-up life cycle, where assistance is necessary for these companies (including companies in health sector) and proposes concrete measures to support them. The document has been elaborated by the Ministry of Economy of Slovak Republic.

5.2.2. Strategic documents for Innovation at the regional level

NUTS II region East Slovakia consists of two self-governing region, Košice and Prešov (NUTS III level). The main task of the self-governing regions in terms of healthcare is mainly to coordinate and fulfil the priorities of regional health policy and to ensure the availability of health and medical care in the self-governing region. The self-governing region issues permits for the operation of medical facilities within the scope of delegated state administration and supervise health care providers and medical care providers. They deal with citizens' complaints and may impose sanctions if inconsistencies are found. Below the main development document of self-governing regions can be found.

5.2.2.1. Program of Economic and Social Development of the Košice Self - Governing Region

The Program is key document for social and economic development of Košice self–governing region. The document has been prepared for a period 2016 - 2022. It can be stated that the Košice region has an evident potential for innovation, which is represented in particular by the number of universities of transnational importance, Slovak Academy of Sciences workplaces and private research and development institutes. In addition to this document a Regional Innovation Strategy for the period 2013-2020 has been elaborated. The strategy describes the potential, challenges and possibilities for innovation in Košice self-governing region. There are relatively strong elements of the research and innovation ecosystem in the Košice region that need to be further developed and consolidated so that it can be integrated into European research and innovation structures and global networks. The Technical University of Košice should play a central role in further acceleration of research and development, especially in the field of knowledge technologies, production systems and material research, in the field of sustainable use of raw materials and the university of Pavel Jozef Šafárik in Košice for bio-medical research.

5.2.2.2. Program of Economic and Social Development of the Prešov Self - Governing Region

The document provides the basis for social and economic development of the Prešov self-governing region. Similarly, to the Košice self-governing region, the Program has been is valid for the period 2014-2020. It

can be summarized that the Prešov self-governing region as one of the most underdeveloped regions in Slovakia has on one hand innovation potential, which can be transferred in to real actions, however at the same time, it is necessary to perceive the negatives of the present position. The economic differences are due to a variety of factors and reflect the fact that there are regions in the structure of the economy that are characterized by different economic, environmental and social conditions. This obstacle needs to be taken into account while sharing practice at the Regional innovation forum. This platform has been created in order to serve the exchange of information of stakeholders on the development of innovation and increase the competitiveness of the region. It regularly monitors and evaluates the fulfilment of the Regional Innovation Strategy of PSK. This Strategy complements the Program of Economic and Social Development. It describes that the structure of economic activities in the Prešov region is considerably diversified, which decreases dependence of Prešov region on dominant sectors in the region. At the same time, there is a lack of industry sector that would be leader and pull the region forward. Level of innovation compared to neighbouring regions is therefore lagging behind, despite considerable innovation potential in the region.

5.2.3. Innovation in EU funded programmes

The main source of financing of innovation activities in Slovakia is the ESI Funds mainly the OP Research and Innovation. The program has a budget of more than €2 200 000 000 (ERDF source), which will be spent for research, technological development and innovation, as well as increasing competitiveness and supporting the growth of small and medium-sized enterprises in Slovakia. The strategic orientation of the innovation sector for the ESI Funds in Slovakia is described in the document below.

5.2.3.1. Partnership Agreement of the Slovak Republic for the programming period 2014-2020

Partnership Agreement between the European Commission and Slovakia set out the national plan for use of funding from the European structural and investment funds between 2014 and 2020. This document states that the innovation environment needs to be improved through coordinated structural policies.
Slovakia needs to significantly increase the rate of its internationalization with particular emphasis on participation in the European Research Area, interlink the education, Research, Development and Innovation and enhanced cooperation with the business sector, consolidate, intertwine the existing research infrastructure (e.g. research centres, scientific parks at universities, and the like) established in the 2007 – 2013 programming period, and support the activities of interdisciplinary and multi-sectorial research teams of excellence in order to maximise the value added for society and economy. It is equally necessary to ensure sufficient number of scientists, young researchers and innovators, enhance cooperation between the educational and research institutions and the business sector, and support RD&I capacities in companies and networks, including clusters and technological platforms. At the same time it is necessary to improve the integration of health services through innovated health infrastructure. This should be financed out mainly through OP Research and Innovation.

5.2.3.2. Operational Programme Research and Innovation

The Operational Programme Research and Innovation (R&I) is a joint programme of the Ministry of Education, Science, Research and Sport of the Slovak Republic acting as Managing authority and the Ministry of Economy of the Slovak Republic acting as Intermediate body financed from the ERDF in the programming period 2014 – 2020. The programme focuses on creating a stable environment favourable to innovation for all relevant actors and to help increasing the efficiency and performance of research, development and innovation system as an essential pillar to boost competitiveness, sustainable economic growth and employment. The proposed OP R&I actions aim to improve the situation in the knowledge triangle – education, research and innovation, which directly corresponds to the Council´s country-specific recommendations under which it is necessary to elaborate plans to support effective knowledge transfer

and cooperation between academia, research and business and to improve the quality and relevance of the science base.

OP R&I is the key implementation tool for the Research and Innovation Strategy for Smart Specialization of the Slovak Republic. OP R&I is based on the strengths identified, and reflects not only the existing situation, but also the potential of the Slovak Republic. OP R&I will contribute to objectives of the RIS3 by supporting quality/excellent research as the principal condition for future high-tech innovation within a longer time horizon, experimental development with actual chances for the transfer of acquired knowledge to the building of a competitive business sector (especially SMEs) by supporting the introduction of innovation and active cooperation between enterprises, research and development centres and education.
In terms of health innovation, the document generally provides the possibility to finance research activities in healthcare particularly in support of R&D capacities in the field of Population Health and Health Technologies. Potential activities can be financed under correspondent priority axis Supporting Research, Development and Innovation.

5.3. Main funding schemes

In Slovakia, there are two main streams of public funding available for research, development and innovation in the health sector:

- national (state budget) funding,
- EU Cohesion policy funds.

National policies for research, development and innovations are designed and implemented in the framework EU strategic priorities in order to be able to fully utilise available support from ESI Funds in the programme period 2014-2020. Consequently, the national policies and priorities are into considerable extent financed from the EU Cohesion policy funds, including health innovations. As a matter of fact, EU financial resources have become the main source of public support of innovations in the country.

5.3.1. National funding

5.3.1.1. Grant scheme of the Ministry of Health of the Slovak Republic

As stated above, the Ministry of Health of Slovak Republic (MoH) is responsible for setting-up and implementation of sector priorities for research, development and innovations. The Act no. 525/2010 forms legal basis for provision of grants by the Ministry in order to achieve priorities stated in the strategic documents approved by the government. According to this law, the MoH can finance research and development activities; however, there is no specific notion of support to innovations in the health sector. Eligible for funding from national resources are: stand-alone research and development projects and research and development projects implemented under international agreements, programmes and initiatives in the field of health.

The support from national state budget has not been systematic so far. The calls for submission of applications under for national support scheme are not published regularly (e.g. annually). Since 2010, there were 6 calls launched, out of which one in 2018 and two 2019. Eligible applicants are public research institutions and legal entities entitled to perform research and development activities for at least 3 years. In practice, the scheme is primarily designed for public research institutions in health sector such as

universities, hospitals and relevant institutes of Slovak Academy of Sciences (SAV). There was only 1 private company, which submitted an application (and received financial support) among applicants in 2016 and 2018. Therefore, the scheme managed by the MoH has limited relevance to innovative actions in health domain initiated by private sector.
Calls for submission of applications launched in 2018 and 2019 clearly define the priority areas for funding. They reflect on the priorities set in the strategic documents (e.g. RIS3 and Implementation Plan), especially those formulated as a result of the Entrepreneurial Discovery Process for the domain "Health of population and health technologies". Compared to previous periods, the state budget support is concentrated to the priority areas for research and development in the health sector.

State budget resources available for the scheme in 2018 and 2019 has increased substantially compared to previous years. The overall budget for the call for submission of applications launched in 2018 was €3 000 000 and €1 100 000 in 2019. The approved grants should be spent within 3 years. The minimum contribution from the scheme is €17 000 per a financial year while maximum contribution cannot exceed €100 000 for single project. So far, the average number of applications received under the calls was around 50; therefore only part of the submitted projects could be supported.

5.3.1.2. National programmes for research and development

The Implementation Plan defines responsibilities, timeframes and allocations for activities under the Strategy for Smart Specialisation, which was adopted for 2014-2020 period. One of the key instruments for support of research and development at the national level is the national programme for research and development for 2019-2023. It aims at addressing the key challenges for development and needs of the Slovak society. This type of support formally existed before, but had no financial allocations from the state budget before 2018.

The state programme for research and development 2019-2023 consists of 5 main programmes/components. One of the programmes/components is dedicated to "Quality of health and nutrition of citizens, prevention, and development of biomedicine and biotechnologies and agriculture, protection and improvement of environment". The overall allocation for the programme from the state budget for 5 years is €151 000 000 (and additional €15 000 000 is foreseen from other sources). The programme contains two sub-programmes relevant to the health: (i) Innovations for prevention, diagnosing and therapy of civilisation diseases and (ii) Biotechnology. There is no evidence that the state programme (relevant sub-programmes) has launched calls for submission of proposals. However, this instrument is primarily designed for more strategic research and development tasks of national and international relevance, not smaller-scale innovations in the health sector.

5.3.1.3. Agency for research and development support

The Agency for Research and Development Support (ARDS) was established in 2005 as specialised agency of the Ministry of Education, Science, Research and Sports of the Slovak Republic. Its mission is to provide support in the form of grants to research and development organisations from private and public sector.

Grants are awarded as in other instruments on competitive basis. Basic research as well as applied research is eligible for funding. There are three categories of support:

- general calls – for support of wide range of research and development activities, including medicine/health (bottom-up activities),
- programmes – support to the state programmes of research and development (long-term priorities),
- nternational cooperation – support for participation in international and bilateral cooperation programmes.

The most of resources is dedicated to general calls for proposals. On the other hand, the call to support preparation of Slovak applicants for participation in HORIZON2020 published in 2019 was the first call after 8 years in the category of programmes. The average annual budget for support of research and development activities should be €45 000 000 in the period 2018 - 2020. Maximum financial support provided for a project is €250 000.

According to the official information of beneficiaries of the grants in the area medicine/health, the support is provided exclusively to the universities and institutes of the Slovak Academy of Science. In this domain, the number of supported projects during 2016-2018 was approximately 15. Out of these projects, there was only 1 implemented by non-profit company (MEDIREX GROUP ACADEMY). This indicates that support from the Agency for Research and Development Support is available to innovative projects in the health sector into very limited extent.

5.3.2. EU Cohesion policy funds

5.3.2.1. Operational Programme Research and Innovation 2014-2020

OP Research and Innovation is formally divided into two parts: support to research managed by the Ministry of Education, Science, Research and Sports and support to enterprises managed by the Ministry of Economy. Within the programme, there are two priority axes aimed at increasing the competitiveness and growth of SMEs. One is dedicated to SMEs in Bratislava NUTSII region (more developed) and the second to rest of the country (3 less developed regions). The contribution from ERDF for the programming period 2014-2020 is €400 000 000. By the end of September 2019, the absorption under these priority axes was €75 000 000, which represents 18.75% of the ERDF allocation. The absorption rate is significantly behind the expected progress in financial implementation in 2019 (44% of ERDF allocation). The support to SMEs is provided in various forms.

Box 9: Slovak health projects financed by EU funds

Solution for infusion - innovative measures in the production of solutions
Project applicant: IMUNA PHARM, a.s. Šarišské Michaľany
Operational programe Research and Innovation
Total costs of the project: €6 111 859,00
ERDF financing: €2 750 336,55

Short description of the project:
The content is product innovation, achieved by innovation of technical and technological equipment for the production of pharmaceutical products, including process innovation. The main goal of the project is to achieve product innovation, which is based on filling the chemical substance into a suitable primary flexible pharmaceutical quality material intended for the pharmaceutical purposes. The new packaging materials used in the newly procured technology will be especially diverse to connectors that are already standards in other countries. These special connectors will be used to connect to various medical sets that differ significantly in different regions of the world.

The main activity of the project will enable the applicant to purchase Technologies to fulfill chemical substances in to infusions. Innovation measures will take into account not only the purchase of the primary technological unit, which is the filling device for the chemical substances of the pharmacological equity as well as other necessary technological units related to the filling process, which represent automated control and packaging technology. Besides the primary technology of the product, as

part of the whole set the technology for its preparation, media distribution technology and clean room technology will be produced. A measurable indicator of this diversification of production will be an innovated product consisting of a chemical substance in another form of primary packaging, which includes fundamentally different connectors from the currently manufactured ones, which will undoubtedly meet the requirements of markets abroad. At the end of the project, the applicant will enable to present products that are new and innovative.

Development and production of large-volume irrigation solutions
Project applicant: IMUNA PHARM, a.s. Šarišské Michaľany
Operational programme Research and Innovation
Total costs of the project: €318 950
ERDF financing: €187 103,72

Short description of the project:
The content of the project is the purchase of new fixed assets for the production of irrigation solutions, i. manufacturing technology for filling bulk bags and applying new ports to innovate production processes, which will include the use of new filling and sealing technology. This technology will ensure the filling of large-volume PVC-free bags of various volumes (from 1000 ml upwards), with brand new application ports, which are characterized mainly by different applications in the industry. By successful implementation of this project IMUNA PHARM, a.s. will become an highly innovated enterprise which will be in the process of product research and development. Five new products for the company will be developed within this project. The project will contribute to employment growth by 2 newly created jobs in the less developed region. As part of the implementation of the project, production will be diversified in the existing establishment of the beneficiary IMUNA PHARM, a.s. in Šarišské Michaľany.

5.3.2.2. Non-refundable financial assistance (grants)

The most common and financially most significant form of support is the provision of grants to small and medium enterprises specialising in innovations in health sector. Following the announcement of call for proposals, eligible applicants can apply for the non-refundable financial support in compliance with the relevant aid scheme. The grants are awarded on the competitive basis – projects with the highest score have a priority. The Ministry have launched open calls for proposals in line with published time schedule, which have given applicants possibility to plan investments from the programme. Launched calls are closed under two conditions: financial allocation for a call was spent or there were not enough projects submitted. In 2016 and 2017, most of the open calls were not thematically/sector oriented. They were designed for support of: technology transfer in companies, development of new companies, innovation through industrial research and experimental development. In 2017, the approach to the calls for proposals has changed and the Ministry of Economy has started to announce specific calls for proposals, including the calls directly linked to key domains of RIS3. Support of innovation in health fall under RIS3 theme "Population Health and Health Technologies". Corresponding call was published in April 2018 with ERDF allocation of €12 000 000.

Companies could receive financial support for innovation of products and services. In general, the eligible activities were:

- Industrial research
- Experimental development
- Implementation of innovative measures.

Despite the fact that the call was open for small, medium as well as large companies, the Intermediate Body had to close the call by the end of November 2018. The reason was insufficient demand under the scheme as total amount of submitted projects did not exceed €7 000 000. Minimum contribution from the programme was €200 000 and maximum €1 000 000. Low demand for the support could be attributed to overall limited innovative capacity in the health sector in Slovakia (outside of Bratislava region) and/or inappropriate conditions for implementation of innovations.

Additionally, OP Research and Development is implemented in a form of so called "national projects". This type of project is of strategic importance and can be implemented only by public institution responsible for the agenda at the national level. Ministry of Economy and its organisations implement number of national projects in the programme period 2014-2020. The most relevant are project for establishment and functioning of National Entrepreneurial Centres located in each NUTS III region. The centres provide non-financial assistance to businesses regardless on their size. The only condition is that private entity does fall into category of firm in difficulty, which is verified ex-ante.

5.3.2.3. Refundable financial assistance

The Slovak Investment Holding established "National Fund II", through which financial instruments from ESI Funds are implemented in the programme period 2014-2020. Financial resources concentrated in the National Fund II amount to €623 000 000. Financial instruments implemented through the Fund have non-refundable form. There are 5 investment areas:

- Transport infrastructure
- Energy efficiency
- Waste management
- Social economy
- Small and Medium Enterprises.

For each investment area, there are specific financial instruments available in order to reflect on needs of final beneficiaries.

Support to SMEs from financial instruments is provided through contracted financial intermediaries[131]. The resources available for small and medium enterprises through financial instruments are almost €250 000 000. In principle there are 3 financial instruments available for SMEs, including those in the health sector:

- Portfolio Risk Sharing Loan (PRSL)
- First Loss Portfolio Guarantee (FLPG)
- Capital Investments (CI).

In general, there is significant delay in implementation of financial instruments in Slovakia. By the end of 2018, there was only one financial intermediary that actually provided financial products financed from ESI Funds (PRSL) to SMEs. Therefore, innovation companies in health sector have had limited access to non-refundable support from ESI Funds.

[131] In some cases, the National Fund II can provide direct capital investment to SMEs.

5.4. Key Challenges of Accessing Finance

5.4.1. Strategic level

One of the major obstacles of innovation policy in Slovakia was the undeveloped system of financial support of the innovation system. For many years, the coordination of funding research, development and innovation as not coordinated at the central level. Fragmentation of various financial sources has caused a low efficiency of the innovation system, characterized by insufficiently developed coordination and consultation mechanisms of the responsible institutions. The Long-term Plan of State Science and Technology Policy, main policy document, was in force until 2015. The document defined the priority areas of R&D. The priorities were broad and their scope and number did not allow the actual concentration of resources and their targeting in the areas in which Slovakia had the potential of using R&D results for the development of key economic areas.

Reflecting the current programming period 2014-2020 in order to achieve the objectives of RIS3 mentioned in the first chapter, the existing science and innovation management and support system has changed. For the implementation of RIS3, an institutional governance scheme was created that has significantly strengthened the strategic approach of science and innovation management (including those in healthcare) in Slovak Republic.

The Government Council for Science, Technology and Innovation has been established as key body for managing the implementation of RIS3. This body supervised the Ministry of Education, Science, Research and Sport of the Slovak Republic and the Ministry of Economy of the Slovak Republic while working out the Action Plan for RIS3. The Plan was prepared in order to meet the missing criteria in relation to thematic ex ante conditionality 1.1 for thematic objective - Strengthening research, technological development and innovation and the implementation of relevant investment priorities funded in the programming period 2014-2020. The Action Plan was developed just to launch the implementation of the OP Research and Innovation. All this measures and new institutional set up helped to make the system of subsidies for innovations in Slovakia more transparent.

RIS3 approved by the Slovak Government in November 2013, is the main strategic document of R&D&I in connection with economy and society in Slovakia. The document sets out the major investment and structural measures for the research, development and innovation policy in Slovak Republic. RIS3 is a strategy that, through innovation, science and technological development, creates the prerequisites for sustainable growth of the Slovak Republic's competitiveness.
The main objectives of the RIS3 are following:

- Enhance the integration and anchoring of key industries that increase local added value through the cooperation of local supply chains and promoting their cross-networking,
- Increase the contribution of research to economic growth through global excellence and local relevance,
- Create a dynamic, open and inclusive innovative society as one of the prerequisites for improving the quality of life,
- Improve the quality of human resources for innovative Slovakia.

The document has been elaborated for the programming period 2014-2020. The Operational Program Research and Innovation with €2 270 000 000 (ERDF source) together with €1 440 000 000 (national sources) is the most important tool to fulfil the objectives of RIS3. More than three-quarters of this allocation are intended to boost research, technological development and innovation and the remainder is allocated to support the increase in the competitiveness of SMEs.

The main sources of financing for innovation in the Slovak Republic are the EU funds. This has a significant impact on the whole support system, as in most EU countries Union resources are complementary to national resources. For this reason, the whole strategy of innovation support in Slovakia, including the implementation of RIS3, is heavily dependent on the efficient use of EU resources. In this connection, it is important to fully ensure the absorption capacity of these sources. Although there is formal coordination between the national level and implementation of strategic documents it has not manifested itself the ability of mutual coordination of financial support and possibilities of multi-source financing. This is due to the time-consuming process of obtaining financial support for innovation actors, as well as the non-systematic way of identifying sources of funding for research and innovation. Entities, respectively innovation companies (including health care) do not essentially create strategic but dedicated partnerships. In most cases, their goal is to get funds quickly without any focus on results or long term impacts. This was also the case of the first call for proposal for RIS 3 implementation within OP Research and Innovation in which various partnerships between companies that did not operate for a long time in research and innovation and public research institutions were established. Finally, this call has been cancelled due to the

non-transparent assessment process of the projects. For this reason, no projects have been approved under the OP Research and Innovation yet. The call published in 2018 is currently being assessed, suggesting that the first projects could be contracted by the end of the year 2019. Only one call for proposals for research activities focused on the domain Population Health and Health Technology has been published so far. The indicative amount of EU funding secured for the call is €31 100 000. The Intensity of ERDF contribution for applicants who must be research institutions is as follows:

The state organisation can get financing up to 100 % of the total project costs, whereas 85 % comes out of ERDF source and 15 % from the state budget.

Other public institutions can get financing up to 95 % of the total project costs whereas 85 % comes out of ERDF source and 10 % from the state budget. The remaining 5 % must be financed from own sources.
Main opportunity for companies in area of implementation of innovative technologies was to obtain support within the OP Research and Innovation coordinated by the Ministry of Economy of the Slovak Republic as intermediary body. The Ministry published an open call for proposals aimed at deploying smart solutions on existing technologies, as well as procuring the new technologies needed to implement smart solutions and creating intelligently managed, interconnected autonomous systems exclusively within existing business operations. The submitted projects must comply with the RIS3 SK. The indicative amount of EU funding allocated for the call is €30 000 000.

The intensity of ERDF contribution for private companies (large, medium and small enterprises) depends on the territory. The maximum intensity for companies from Košice self-governing region and Prešov self-governing region is as follows:

- Large enterprises: 35 % of the total costs
- Medium enterprises: 45 % of the total costs
- Micro and Small enterprises: 55 % of the total costs

Few companies performing their activities in the field of healthcare received support for introduction of new innovative technologies in to the daily work of the companies. The aim of the scheme is to increase the technological and production capacities of the productive sector through purchase of modern technologies. However, this support has only marginal relevance to innovative actions in the health sector.
One of the options for the innovative companies to receive public (national) sources for financing projects in health care is the grant mechanisms of the Ministry of Health of SR. This mechanism was introduced in 2006; to date several calls have been launched in the field of health research and development. For 2019, two calls for proposals were launched aimed at innovative diagnostic and therapeutic procedures and personalized/precision medicine products; medicines for innovative therapy, innovative biotechnologies in medical sciences and innovative medical devices.

The total budget of the call for proposals is €700 000.

The second call for proposals was oriented on selected topics for research and development purposes in the areas of translational and applied biomedical research for:

- testicular tumors, malignant lymphomas,
- pancreatic cancer, colorectal cancer,
- breast, lung and prostate cancer.
- The total budget of the call for proposals is €400 000.

Summing up, it can stated that in the 2014-2020 programming period, access to public support for entities operating in the field of innovation in health was quite limited. This situation should slightly change with potential contribution from the ongoing call for proposals aimed on implementation of RIS3 within OP Research and Innovation.

5.4.2. Operative level

Decision-making on project selection is an important step for each entity responsible for implementing a call for proposals. As mentioned in the chapter above, there have been few possibilities for potential project applicants to get financing for innovative projects in the programming period 2014-2020.

Ministry of Health of Slovak Republic – The purpose of the call for proposals published on a half year basis is to define priority areas of scientific and research issues of Slovak health care that are elaborated in accordance with current trends and knowledge in the field of health research and development, as well as with the strategies and intentions of the Ministry and recommendations of the European Commission. The last call for proposals published in May 2019 was prepared on the basis of the Summary Report of the Entrepreneurial Discovery Process for the product lines of the domain Population Health and Health Technology. The call has identified following priorities:

- Innovative diagnostic and therapeutic procedures and personalized/precision medicine products;
- Medicines for innovative therapy;
- Innovative biotechnologies in medical sciences;
- Innovative medical devices.

The deadline for submission of project applications is usually 2 months from date of launching the call. The maximum duration of the project is set for 3 budgetary years. Maximum 70% of the total project costs may be granted, the applicant is obliged to prove that it has at least 30% secured from own or other sources to finance the project. The successful projects should be selected based on the criteria for project selection in order to select the high quality projects that contribute to the achievement of health objectives for research and development.

The budget of the call for proposals is €2 100 000 for three years. In the first year, in 2019, it is €700 000, in the second year, in 2020, it is €700 000, in the third year, in 2021, again €700 000. The minimum amount for scientific-research project is €17 000 per year and the maximum possible funding is €100 000 within a single budgetary year. The project application cannot be longer than 15 pages.
Subsidy may not be granted to the applicant's commitments from previous budgetary years or reimbursement of expenditure paid in previous budgetary years. Applications are being assessed by the Scientific Council of the Ministry of Health of SR. The assessment criteria are determined by the Decree of the Ministry of Health of the Slovak Republic, laying down the criteria and procedure for the assessment of applications.

The assessment criteria are based on following areas:

- scientific and technological excellence,
- quality and effectiveness of project proposal,
- management of the project proposal,
- task of the project proposal in the education process,
- requested financial sources,

The application must receive at least 56 out of 87 points. Applications are being assessed without identifying the applicant.

On the basis of the above mentioned it can be stated that obtaining financial support for scientific projects focused on the field of innovation in health care is not administratively demanding. It is necessary to prepare a quality project application with clearly defined activities and budget. The application form is quite clear, only information for implementation of the project is needed. As the total number cannot exceed 15 pages the application form must be filled in very precisely. Applications are assessed independently without identifying the applicant. In this way, the aim is to ensure greater transparency of the process. As for 2018, out of 46 applications submitted, 18 have been approved by the Ministry of Health of SR. An interesting feature of the project applications assessment for 2018 was that two projects with a lower score were approved at the expense of projects with a higher score. Unfortunately the reasons are not stated in the ranking list.

Operational programme Research and Innovation - so far, only one call for proposals has been launched for the implementation of RIS3 within the programming period 2014-2020. The call has been launched in September 2018. There is possibility of continuous submission of applications based by the deadlines set on the individual assessment rounds. The applicant may submit the application any time from the date of launching the call for proposal. The first deadline was the 29 of March 2019. Minimum amount of subsidy is €100 000 (ERDF + national co-financing). There is no maximum threshold of the project. Eligible applicants are as follows:

- state sector, which consists of the Slovak Academy of Sciences and legal entities conducting research and development established by central state authorities
- sector of public research institutions sector
- higher education sector, which is made up of public higher education institutions and state universities,

In terms of project compliance with the RIS3 SK strategy, it must be proven that the project implementation under this call is closely connected to the domain Health population and Health technology. No other activities realized outside the specified domain will be eligible. The applicant shall add the activities of the project for research and development to the respective product line of the above mentioned domain.

The Research Agency verifies the fulfilment of assessment criteria within the following areas:

- Contribution of the proposed project to the objectives and results of the OP and the priority axis
- Proposed method of project implementation
- Administrative and operational capacity of the applicant
- Financial and economic aspects of the project

The applications will be ranked according to the score obtained in assessment. Based on the application of the selection criteria, applications are ranked in descending order of the number of applications starting with application with highest number of points and ending with the lowest number of points. Applications that are within the allocated range of funds in the certain call are recommended for approval.

As the above call for proposals has not yet been assessed, it is not possible to obtain a complete overview of the number and form of involvement of scientific institutions in the specific subject of the call. The protracted process of assessing project applications also causes significant delays in the use of funding for research and innovation. A similar call for proposals was cancelled in 2017 due to the lack of transparency of the evaluation process. Since then, the implementation of RIS 3 has not created adequate opportunities for financing innovative projects.

Second possibility to get grant within OP Research and Innovation for applicants aiming on innovative projects in health is the call for proposals published by the Ministry of Economy of the Slovak Republic as intermediary body. The Ministry launched in December 2017 an open call for proposals aimed at supporting innovation through industrial research and experimental development within the domain of Population Health and Health Technology. The call has been cancelled in November 2018. The reason for closing the call was the lack of demand from potential applicants although the deadline for call for proposals has been postponed originally.

At the same time the Ministry of Economy of SR launched in February 2018 an open call for proposals aimed at deploying smart solutions on existing technologies, as well as procuring the new technologies needed to implement smart solutions and creating intelligently managed, interconnected autonomous systems exclusively within existing business operations. The call has been closed by the end of July 2018 as the indicative allocation has been disbursed. The assessment criteria are set to take into account the innovation potential of the company, the contribution to the implementation of RIS3, the and form size of the enterprise (the smaller the more points, start-up means more points), the cooperation between the private and public sectors, especially with regard to scientific institutions. The minimum score required to meet the scoring criteria is 60% of points out of the total sum. The assessment criteria shall be performed to the same extent by at least two assessors. The eligible applicants were large, small and medium enterprises.

Minimum amount of subsidy was €100 000 and maximum €2 000 000 (ERDF source). Finally, out of successful companies few enterprises aiming on technology transfer for health have been supported. In the current programming period 2014-2020, support for projects with innovative potential in the health sector is limited to a number of sources. Main stream of funding of the research, development and innovation activities including health sector has been EU financial assistance through OP Research and Innovation. As a matter of fact, there is minimum absorption of the financial support for research and development in Slovakia in the programming period 2014-2020. Consequently, public and private research institutions have not been able to benefit from EU financial assistance and implement strategic activities within the framework of RIS3. The same applies for the health sector – due to significant delays in implementation of OP Research and Innovation there has not been opportunity for fostering links between research sector and private companies oriented on innovations. Ministry of Economy acting as the Intermediate Body for the OP Research and Innovation is responsible for support of SMEs (in some case large companies are eligible too). The Ministry provides the most relevant support for the innovative projects in the health is pro Calls for proposals published so far aimed at: technology transfer, innovation of products and services of new enterprises, industrial research and experimental development. Since December 2017, the calls for submission of projects were directly linked to key domains of RIS3. In April 2018, the call for projects to support innovations through industrial research and experimental development in the domain Population health and health technologies was published. However, the Intermediate Body decided to close the call due to insufficient demand. This indicates that there is limited capacity to generate innovative projects in this domain under existing conditions of funding.

The implementation of scientific projects aimed at engaging in innovation is not an easy matter, it is necessary to plan such projects in the long term. The real situation shows that this is not always the case. In view of the challenges described above, project planning and project generation is limited to a shorter time horizon. However, this process can also negatively affect the quality of projects. This may be one of the reasons for the low interest in projects under the call for the OP Research and Innovation.

Generally, it can be stated that the process of support of innovations in health care in Slovakia is not harmonized in terms of management. Despite of several possibilities of financial grants, the real support has practically narrowed to the scheme of the Ministry of Health of the Slovak Republic and possibly support from the EU Community programs. The main source of support for innovation in form of the OP Research

and Innovation has not yet produced the desired effect. While this may slightly improve in the years to come, however, given the considerable delay in the process of calls and the under-spending funding allocated for innovation projects, no radical change can be expected.

The above mentioned facts add to the difficulties in implementing EU projects. Here it can be mentioned the public procurement as one of the most common and important reason for delays in absorption of funding. Despite the simplification of public procurement procedures in Slovakia, the beneficiaries are faced with lengthy control of public procurement procedures by programme structures. Another significant problem is the relatively lengthy and demanding mechanism of verification of expenditure. This process results in to the situation that the beneficiaries get the funds with a long time delay. For projects with a large budget, this can be a significant obstacle in implementation.

5.4.3. Capacity level

There is still a significant need for innovation in heath sector in Slovakia, especially in the Eastern Slovakia. Limited innovation capacities in the health sector, asks for strategic project generation. Theoretically, there is a range of funding opportunities for potential applicants, but in reality very limited number of innovative operations in the health sector received public support. There are projects related to innovation in healthcare, which have been implemented in Košice self-governing region, however most of them have no link to companies, which might turn the results into practise. There are quite a lot of possibilities to get financing (sources of financing are mentioned in the chapter above) however lack of project ideas as well as turning ideas into concrete projects makes not an easy task for potential applicants. Main actors for innovation in healthcare are mainly universities (Technical university of Košice and University of Pavol Jozef Šafárik) together with few private companies (e.g. STEMI Global, EMPIRICA).

The main barrier is lack of transfer of know between research institutions and universities and business sector. It is undisputable that the financial side is the main motivating factor for cooperation between the academic sector and the business sector. If an academic institution is to undertake innovative, scientific, research and development activities, it is not unusual that its demanding costs will cause overpricing of the whole project to such an extent that its competitiveness will decrease significantly. A functioning transfer of knowledge and technology between academia and industry has number of benefits for both actors and the society as well. It is important to transfer the technology by academic institutions, which in their traditional mission as education and research, add another important element with the added value for business.
On the other hand, the company's task is to create motivational conditions for cooperation between the academic and business sectors, supporting corporate research. Favourable conditions in the academic environment would improve research results, which would be translated into business innovation sector.
One of the successful examples of the interconnection of the business sector with the academic sector is IT Valley Košice. The association was established in 2007 as a joint initiative of educational institutions, government and leading IT companies. In 2012 it was transformed into the cluster. IT Valley as the accelerator building regional innovation partnerships of IT companies, universities and self-governing institutions contributes to providing wider and more accessible European, national and regional innovation programs and strengthens the innovation potential not only in the IT area. This can be emphasized by the fact that out of a total of 55 members, several companies are active in the field of healthcare innovation.
The availability of financial resources is often a significant factor that can accelerate innovation initiatives by companies. Ensuring co-financing for individual projects by applicants, which are business entities, is in many cases a difficult process. The intensity of public support for such entities is around 50%, which is significantly lower than for scientific institutions, which in most cases are entitled to be supported up to 100% of the total costs. For this reason, efforts are being made to transfer most of the costs of innovation

projects from business sector to public organizations. In any case, there are several alternatives for entrepreneurs to secure their own co-financing. There is e.g. Venture capital funds, respectively Fund of Innovation and Technology that provide funding for innovative business plans of the companies. Another possibility of co-financing is business loans, in which the Slovak Guarantee and Development Bank (SZRB) plays an important role. SZRB's mission is to support and develop small and medium-sized enterprises in Slovakia. Generally, securing mandatory financing for innovative companies can be complicated, however depending on the company's size various funding opportunities might be provided.

EIT Health Hub in Košice has its own place in the system of health innovation support. T-Systems Company as provider of the Hub has been selected in an open call published by the EIT Health by the end of 2017. The Slovak company based in Košice provides outsourcing services for corporate customers in Germany, the European Union and at a global level. It is one of the leaders in IT segment in Slovakia. The collaboration with Technical University Košice (TUKE) will provide not only students, but also start-ups the opportunity to come up with innovative ideas that will contribute to improvements in health, healthy lifestyle and active ageing. The Hub has been operating since mid of 2018. The budget for the year 2019 is €100 000. This has been spent mainly for personal costs, external costs and equipment. The EIT Health Hub has currently 3 employees. T-Systems operates in the area of Košice self-governing region and provides the EIT Health Hub with following activities:

- focus on digital health
- possibility to validate and commercialise new applications in this field
- consulting of the applicants
- preparing the ecosystem for technology transfer, innovation and business support
- organization of thematic events
- education of students and other stakeholders

As the EIT Health Hub has been established quite lately, the work cannot be assessed in a broader way, however, it seems that the institution might have its place in support of innovation companies in Eastern Slovakia.

5.5. Recommendations

Strategic objectives for research, development and innovations in the country are financed by national public and ESI Funds. As a matter of fact, the EU funds are the main source of public assistance provided to public and private organisations. In response to low innovation capacities of Slovakia, the Commission allocated €2 122 000 000. for OP Research and Innovation. Together with national public funds, the investments earmarked for support to research and innovation during 2014-2020 were expected to substantially enhance competitiveness of Slovakia and its regions. In other words, the generated resources allow for systematic and effective support of innovations, including innovation in health sector.

In reality, entities focused on innovations in health sector had very limited opportunities to access public funds. Ministry of Economy acting as Intermediate Body for OP Research and Innovation is responsible for SMEs support. In 2016-2017, the target group could apply for general calls for proposals to provide refundable financial assistance to industrial research and experimental development. In 2018, the Intermediate Body launched thematic call for domain "Population Health and Health Technologies"; however, it was cancelled due to lack of interest from eligible applicants. This indicates limited capacity of

the sector to generate innovate products/services and at the same time conditions for utilisation of grants to innovation. So far, Ministry of Economy was able to spent approximately 20% of total ERDF allocation for innovation (€400 000 000). Another opportunity for SMEs to finance innovations in health sector is financial instruments from ESI Funds. The access to non-refundable funds in Slovakia has been so far very limited. By the end of 2018, only one financial intermediary was contracted to provide portfolio risk sharing loans. Ministry of Health of the Slovak Republic is responsible for implementation of research, development and innovation policy in the sector of health. To fulfil its mission, it has introduced its own grant scheme in 2010. The allocations for the grant scheme increased significantly in 2018 and 2019. On the other hand, the scheme almost exclusively supports public research institutions. By now, only one private applicant received funding from the grant scheme of the Ministry of Health. National research and development programmes for 2019-2023 have been approved, but no evidence on support to innovative actions in health sector is available.

At the level of Partnership Agreement, the Commission for Coordination and Synergies was established to actively seek links between various EU and national programme. However, the first opportunities to connect various sources of funding occurred only recently (funding for projects that received “seal of excellence”).