**Research, Innovation and Digitisation Window**

**Policy Note**

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# Introduction

This policy notes describes policy objectives and rational for different financial product supported by Research, Innovation and Digitisation (RID) Window.

[This policy note will need to be updated to align with further policy developments in the context of final decisions under the MFF and the implementation of the Green Deal.]

# InvestEU for Research, Innovation & Digitisation Projects

Research and Innovation (R&I) investment is a key driver of productivity and economic growth. However, private companies do not sufficiently invest in R&I, one of the reason being that they do not realise the positive externalities from knowledge spill-overs, from which the whole economy could benefit. Indeed, the social returns from R&D investment are estimated to be two to three times higher than the private returns. The IMF (2016) shows that fully internalising the externalities of R&D would lead to 40% higher investments compared to the status quo. Such an increase could lift GDP in individual economies by 5% in the long term – and globally by as much as 8% due to international spill-overs. Moreover, innovation, and the diffusion of innovation, is one of the main drivers of productivity growth and job creation. For example, because of investments in R&I-enabled new technologies such as ICT, robotisation or Artificial Intelligence, 400.000 net jobs were created in technology and knowledge intensive sectors in Europe during 2008-2013.[[1]](#footnote-1) Yet, the R&D investment gap to reach the 3% of the Union’s GDP amounted to EUR 144 billion for the year 2016.[[2]](#footnote-2)

R&I projects are more difficult to finance because they are risky and their returns are highly skewed. This leads to lower investment both in terms of equity – as investors discount this uncertainty on financial markets – and in terms of debt financing – because of the intangible nature of investment or high risks related to innovative technologies, which makes collateralisation difficult, if not impossible. Financing constraints thus hamper profitable R&I investment opportunities, reduce firms’ innovative performance and growth prospects of economies, as opposed to the case of frictionless capital markets.

Digitisation, particularly investment in ICT has a strong impact on innovation, job creation, productivity and economic growth. Certain technologies have in particular the potential to transform radically the way the business is conducted and the way services are provided. These technologies include high performance (including quantum) computing, cloud services, smart networks and the Internet of Things (IoT), big data, artificial intelligence, blockchain and cybersecurity. High volumes of investment in these digital technologies are essential for the competitiveness of key sectors of the economy and for technological sovereignty. Overall, investment in both the innovation and the rollout of these technologies will boost the competitiveness of European economy and industry. Due to the disruptive nature of these technologies, it is important to ensure that the digital transition is widespread across individuals and firms thereby closing the digital divide. This is particularly pertinent in view of the decreasing R&D investment in the ICT sector and the low R&D intensity of European ICT companies compared to those in the US, Japan or South Korea (SRIP, pp.102-105, 2018).

The overall objectives under the RID window are:

* Investment in research, innovation and digitisation activities that entail **higher risk** and address EU policy priorities as set out in Horizon Europe, Digital Europe, and other programmes, including in synergies with the Innovation Fund activities, with the objective of contributing to Europe’s innovative, sustainable and carbon-neutral economy of the future, while ensuring its **industrial leadership**.
* Investment in **highly innovative, breakthrough, and market creating products**, processes or services in the areas of health, digital, industry, climate, energy, mobility, food and natural resources, security, space, space-enabled solutions/applications, and others.
* Allow financially constrained firms to maintain a smooth flow of R&D expenditure via access to risk finance at better terms and conditions.
* Increase the supply of loans and other financing to R&I-driven enterprises, R&I Infrastructures, innovation-enabling infrastructures and other entities in Countries that are classified as **Modest or Moderate Innovators** in the latest or in the previous European Innovation Scoreboard.
* Support R&I investments by **R&I infrastructures**, including innovation-enabling infrastructures, **universities** and **research and technology organisations** (RTOs) as well as networks of open access pilots and demonstration infrastructures. It will finance facilities, resources and services used by the research community to undertake research, test their products and foster innovation.
* Contribution to the **societal challenges** and **missions** identified under Horizon Europe, ensuring the prioritisation of investments with the highest overall impact and added value for Europe.
* Support the rollout and adoption of **strategic digital technologies** identified as having a strong transformative impact on key sectors of the European economy, strongly linked to competitiveness and technological sovereignty.

## Mid-Caps

Innovative European mid-caps contribute to Europe’s future growth, prosperity and competitiveness through their ability to develop and market higher value-added products and services. Their continued investment in research, development and innovation (RDI) is therefore crucial to sustain their competitive advantage over time. Yet, when expanding beyond the Venture Capital funding stage, mid-cap companies lack the cash flow stability and asset quality to have access to sufficient equity and/or stable debt financing.

The 2012 PwC Growth Capital Instrument Study on the access to finance for European mid-cap companies analysed 300 companies out of which two-thirds indicated a lack of appropriate debt financing, while one-third indicated interest in, but no access to, hybrid and equity-type financing. The study estimated the total gap in equity-risk financing for the target mid-caps across Europe to be EUR 32-34 billion over the next three years.In 2017, EIB estimated that the market gap for innovative mid-caps affects about 2.500 European companies, where the financing need is between EUR 10-17 million (Rees, 2017).[[3]](#footnote-3)

Finding available risk capital is one of the key problems faced by innovative mid-caps. In most cases, the balance sheets of innovative mid-caps reflect their efforts to develop and/or acquire skills and intellectual property while experiencing above-market growth, and as a result are dominated by long-term intangible assets and/or short-term working capital assets and liabilities. Such situation limits their borrowing capacity, and as such, many European mid-cap companies find themselves unable to sustain growth as well as the development of their innovations from technical and economic feasibility to commercial production.

The objective of the support to Mid-Caps is to ensure that innovative European mid-caps can sustain or even increase their R&I investments, particularly in the priority areas of Horizon Europe and Digital Europe Programmes, by providing them with the necessary level of financing.

## Large Projects

Large size R&I projects require significant investments and capital outlays are key for competitive advantage of EU companies. R&I driven entities and innovative companies tend to have higher risk profiles, in terms of the industry in which they operate and their business models, compared to less innovative firms. Furthermore, the value of R&I‑driven entities and innovative companies is harder for banks to assess as they are often more reliant on intangible assets, which is rarely accepted as collateral. Cost and market barriers for innovation are also present for non-innovative firms that want to embark on innovative projects as well as for highly innovative firms.

For financing and investment operations benefiting final recipients that are large corporates, public sector and public-sector type entities, which benefit from easier access to capital markets or display lower levels of risk, the implementing partner shall demonstrate high policy value added. In particular, large Research, Innovation and Digitisation projects shall encompass high-risk innovation and shall contribute to sustainable transformation, including investment in sustainable ICT and employing digital technologies to decarbonise other sectors of the economy, particularly energy intensive industries. The projects shall be in line with the objectives of the Paris Agreement and contribute to carbon-neutral economy by 2050.

## Research Infrastructures

Public investment in science often undertakes the longer-term, higher-risk research and complements the activities of the private sector. Besides, it creates highly skilled human resources, knowhow and experience, new scientific instruments and methodologies, as well as the networks that transmit the latest knowledge.

The excellence of the European science base should not be taken for granted as it is being challenged constantly by traditional competitors such as the US, as well as emerging actors such as China and India.

In the case of universities, governments have increased funding for European higher education over the past decade but this recovery is not happening fast enough. Moreover, research and technology organisations (RTOs) face an exogenous funding gap due to their focus on highly innovative technologies, as well as certain features of their projects (long cycle, diversity of project portfolio, etc.). As such, RTOs face increased credit requirements, high interest rates, short repayment periods, complex and stringent due diligence frameworks and guarantees from financial market participants, due to their revenue and liquidity risk. [[4]](#footnote-4)

Consequently, under the RID window, support will be provided to universities, research institutes, research organisations and RTOs for embracing the tech-driven economy and the role of driving innovation, fostering entrepreneurship and catalysing economic development. Moreover, support will be provided to investments in intangible research activities, capital investments in infrastructure and RDI activities as well as operational costs, covering the funding needs along the entire life cycle of R&I projects and also for long-term operational programme (e.g. Copernicus). Involvement of RTOs in particularly relevant policy-related R&D activities, for example the development of actual product/solutions/applications linked to EU policies (e.g. regulated use of space-based technologies, in transport, security, climate-change, etc.) should be a catalyst for mobilizing research, development and innovation support under the RID window.

## Emerging Innovators

The latest European Innovation Scoreboard[[5]](#footnote-5) shows that wide disparities exist across the EU Member States in terms R&I performance. While the innovation performance for Moderate Innovators has been increasing since 2014, for Modest Innovators, the performance declined between 2011 and 2018. This has led to a widening of the performance gap even between the Moderate and Modest Innovators. In addition, in terms of finance and support, Moderate and Modest Innovators perform below the EU average level.

Consequently, the RID window will aim at closing the innovation and digital divide by targeting transactions in countries defined as Modest and Moderate Innovators.

# InvestEU for the European Green Deal

The objective of the focus on the European Green Deal is to unlock a significant part of the targeted EUR 1 trillion investment over the next decade under the Sustainable Europe Investment Plan and achieve a full economic and societal decarbonisation by 2050. This shall be attained while making Europe a world leader in clean technologies and strengthening Europe’s competitiveness and socio-economic cohesion. Private investment will be crowded-in by de-risking Green Deal projects and closing financial gaps that still hamper the development of high-potential companies and innovations.

## Tackling Climate Change and Transitioning to a Sustainable Planet

According to the UN’s Intergovernmental Panel on Climate Change (IPCC) "Special Report on the impacts of global warming of 1.5 °C above pre-industrial levels and related global greenhouse gas emission pathways" (2018), the world has just over a decade to get climate change under control. The "Global Assessment Report on Biodiversity and Ecosystem Services" (2019) by the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES) warns that nature is declining globally at rates unprecedented in human history and the rate of species extinctions is accelerating. The report warns that the destruction of nature threatens humanity at least as much as human-induced climate change and declares a global social and ecological emergency.

This situation forces us to transition quickly towards a post-fossil fuel economy, as well as to seek new ways of producing and consuming our resources that respect the ecological boundaries of the planet and ensure the sustainability in the long term. A sustainable and circular **Bioeconomy**[[6]](#footnote-6), **Circular Economy**, **green infrastructure**[[7]](#footnote-7), **climate services**[[8]](#footnote-8), **Natural Capital**[[9]](#footnote-9) and **Nature based solutions**[[10]](#footnote-10) are among the key solutions to transition to a climate-neutral economy and sustainable development, reduce the dependence and manage natural resources in a sustainable way, ensure food security, enhance climate resilience, promote energy diversification, and transform infrastructure and manufacturing.

Yet, substantial funding needs have been identified in these sectors, which remain unmet by private investors who are often reluctant to invest because of uncertainties and risks in terms of regulation and policy, technology, market demand as well as feedstock supply issues amongst others.

* It is estimated that EUR 320 billion will be needed between 2019 and 2025 to implement projects that put the EU economy on the path to circular economy transition[[11]](#footnote-11);
* In the area of agrifood, over EUR 20 billion of additional financial investments per year would be needed in Europe to match US agrifood investments[[12]](#footnote-12);
* Total economic losses caused by weather and other climate-related extremes in Europe (1980-2016) amounted to €436 billion[[13]](#footnote-13). Due to climate change alone, annual damage due to Europe’s infrastructure could increase ten-fold by 2100.

While funding is available to support the research and development stages of projects in these areas, insufficient funding is available for demonstration, upscaling and commercialisation of such projects and solutions.

In the case of **bio-based industries,** operational risks coupled with information asymmetry and insufficient understanding of the sectors represent the major investment hurdles.[[14]](#footnote-14) In **primary production and food**, obtaining finance for growth is a key challenge with companies looking for “intelligent capital” that would be combined with industry knowledge and relevant networks.[[15]](#footnote-15) In the area of **circular economy**, the mostly affected groups are mid-caps and SMEs[[16]](#footnote-16). In the case of Nature-based solutions (NBS) and Natural Capital, innovations, the non-monetary nature of some of their benefits[[17]](#footnote-17), and the lack of maturity of the NBS market (supply and demand) increases the operational risks of investing in these solutions, which stagnates their development and commercialisation. Regarding **climate adaptation**, the innovative character of solutions for urban and rural areas to transform the way they are built and organised to adapt to the impacts of climate change, high upfront costs of technologies and related uncertainties linked to climate change render finding financial resources difficult[[18]](#footnote-18). Many of these solutions (bio-based, circular economy, natural capital, NBS, and climate adaptation) require as a first step the provision of readily available and open data coming from environmental observations[[19]](#footnote-19) (whether atmospheric, oceanic or terrestrial) through remote, space-based or in-situ monitoring combined with analysing and forecasting models. Hence, the need for financing **environmental observations activities**, prior or in parallel to financing such solutions.

The transition to a **Bioeconomy** has the potential to contribute significantly to reducing greenhouse gas emissions, improving food and nutrition security and generating growth and employment, in particular in rural, urban and coastal areas. Innovations in this field contribute significantly to the creation of new markets for a broad range of sectors – such as the expansion of new non-food markets for agriculture in the area of biobased chemicals, bio-materials and bio-plastics and creation of new marine value chains. A sustainable circular **bio-based sector** can contribute systematically to turn low value by-products and organic waste streams into valuable bio-based products, thus achieving circularity and economic and environmental gains.

Our current **food system** is not fit for the future. Scientists and EU citizens urge us to transform our food system towards sustainability and guarantee food security and health for the next generations, to remain competitive, and to sustain Europe’s rich and diverse food culture. Research and innovation are key drivers of the transition to a future-proof, sustainable, healthy, resilient, climate-neutral, and inclusive food system, as promoted through the European Commission’s FOOD 2030 initiative. Thus it is important to improve access-to-finance and mobilise private capital for innovators wishing to scale-up their business across Europe's food systems, and make sure that research, innovation and potential solutions reach the market, realise the social and ecological innovations in practice, and that the possibilities and the capacities of farmers and SMEs to innovate and take risks are enhanced.

Rapid transformation towards **circular economy** and behavioural changes, are among the changes that could have the potential to reduce the need for additional investments in the European energy system and infrastructure needed to decarbonise the economy. By moving from a linear to a circular economy, the value of products and materials are maintained for as long as possible; resources are kept within the economy when a product has reached the end of its life, to be reused to create further value. It is a strong tool in the fight against climate change, it contributes to reducing pressure on the environment and it improves the security of the supply of raw materials. It increases competitiveness, stimulates innovation and boosts economic growth.

Global and EU Experience and research show that **nature-based approaches** are sustainable, cost-effective, multi-purpose and flexible. If holistically designed such approaches will not only provide climate change adaptation, mitigation and disaster risk reduction benefits at the same time[[20]](#footnote-20), they will also deliver additional benefits like nature and biodiversity conservation, better public health, greater food security, or new economic and job opportunities.

Climate impacts will be widespread in Europe’s future. It has been shown that well planned, early adaptation action saves money and lives later. The economic, environmental and social costs of inaction for the EU, for a number of sectors of the economy, have been estimated at EUR 100 billion a year in 2020 and at EUR 250 billion a year in 2050.[[21]](#footnote-21) Current estimates indicate that the cost of inaction could increase exponentially by the 2080s[[22]](#footnote-22). Adaptation is required to make action at all governance levels transformative enough to cope with systemic changes in our climate, environment and society.

Improved multidisciplinary cooperation and information on monitoring, reporting, validation and compliance assurance should lead to the improvement of, among others, forecasting and modelling capabilities for decision-making by governments and to more efficient implementation of environmental objectives of Member States and the EU.

## Sustainable Blue Economy (SBE)

With 23 out of its 28 Member States possessing a coast[[23]](#footnote-23), and two-thirds of European frontiers being sea-bound, oceans and seas are important drivers for the European economy. According to OECD projections, by 2030, the SBE could outperform the growth of the global economy as a whole, both in terms of value added and employment.

At global level, the European Union is an active player in protecting oceans and shaping ocean governance. It has made progress by taking measures in a series of areas: maritime security, marine pollution, blue economy, climate change, marine protection, and sustainable fisheries.

At European level, the European Union aims to improve and scale up the sustainable use of renewable resources (including aquatic) to address global and local challenges (New Bioeconomy Strategy for a sustainable Europe[[24]](#footnote-24)). As part of the Integrated Maritime Policy[[25]](#footnote-25), Blue Growth is the long-term strategy to support sustainable growth in the marine and maritime sectors, taking duly into account the environmental pillars embedded in the IMP[[26]](#footnote-26). On food and nutrition security (FNS), the FOOD 2030[[27]](#footnote-27) research and innovation (R&I) policy framework aims to ‘future-proofing’ our food systems to become more sustainable, resilient, responsible, inclusive, diverse and competitive and with Horizon Europe, Healthy Seas, Oceans and Natural Waters as one of the five missions to maximise the impact of intervention and investment in this area.

Nevertheless, the pace of innovation in the SBE is lower than anticipated, in particular as concerns commercialisation and upscaling of successful innovations and attracting funding for these stages remains a challenge due to the lack of understanding of the SBE technology risks, market potential or potential upside.

Despite concerted efforts by the European Union to increase funding for SBE actors, access to funding with acceptable terms remains a key obstacle for innovative businesses. SMEs in the SBE face limited access to private funding, with a funding gap identified of about EUR 60 to 70 billion. [[28]](#footnote-28) A particular funding gap has been identified for amounts between EUR 3-15 million.[[29]](#footnote-29)

The objective under the RID window is to support investments into innovative and digitisation activities and projects seeking to monitor and forecast, restore, protect, decarbonise or maintain the diversity, productivity, resilience, core functions, value and the overall health of marine ecosystems, as well as the livelihoods and communities dependent upon them. The investments will target areas such as:

* Sustainable Blue-Bioeconomy: the cultivation and harvesting, husbandry or capture of living resources from fresh or saltwater and activities based on the use or processing of this material (for food, feed and marine biotechnology purposes), including blue-biotechnologies;
* Enabling technologies for environmental and ocean observation and monitoring (such as underwater laboratories, monitoring systems, new generation sensors, robots, AI, digitisation, space-based data & services, platforms for observation, etc.);
* Innovative multipurpose offshore platforms combining several SBE activities, e.g. sustainable aquaculture, biodiversity and ecosystem proof marine renewables;
* Circular economy: New products from living or non-living marine waste resources, offshore aquaculture of shellfish or algae;
* Water and seabed pollution prevention, reduction, monitoring and management technologies (e.g. water treatment plants for nano, nutrients, antibiotics and chemical pollutants, technologies collecting marine debris and litter, etc.), including solutions for alternative products; where relevant, investments in river catchment areas and coastal cities to effectively prevent pollution from reaching the coastal waters;
* Innovative solutions that contribute to the conservation and restauration of the biosphere integrity and that combat plastics pollution and marine litter in the oceans;
* New ecosystem proof facilities that support the sustainability, diversification or energy efficiency of ports and coastal areas.
* New ecotourism facilities that contribute to the protection, preservation and restauration of the natural capital and potentially linked with development of small-scale SBE.

## Sustainable ICT

Information and communication technologies (ICTs) are at the same time a potential response to and an increasingly significant contributor to climate change.

[The Paris Agreement](https://unfccc.int/sites/default/files/english_paris_agreement.pdf) (2016) is explicit in highlighting the importance of digital climate technologies for a sustainable future, stating in Article 10, that “Parties share a long-term vision on the importance of fully realizing technology development and transfer in order to improve resilience to climate change and to reduce greenhouse gas emissions.” Digital technologies offer strong, untapped potential to help address the world’s most pressing climate concerns through e.g. supercomputing for improved earth observation and climate change modelling, real time data gathering and analysis on carbon emissions with blockchain innovations, sustainable agriculture and precision farming, energy efficiency solutions such as smart energy grids, better management through intelligent transport systems and smart cities.

At the same time, ICT is the fastest growing sector in terms of greenhouse gas emissions. According to estimates, ICTs alone are directly responsible for 1.4 per cent of global greenhouse gas emissions and 3.6 per cent of electricity consumption. In 2015 the wider ICT ecosystem used about 8 per cent of the global electricity consumption. If the current trends in consumption of data and growth of connected devices continue, by 2025 ICTs could be using 20% of global energy and producing 14% of CO2 emissions, which would surpass emissions from aviation and shipping sectors. The use of hazardous substances and scarce and non-renewable resources in production and the generation of e-waste are also part of the environmental load of ICTs.

The financing of innovative digital climate technologies companies however remains a critical challenge, due to their high-risk profile, their capital-intensive nature and/or the lack of collateral and to the high opportunity cost due to high profitability and shorter returns of competing technological investments. Market operators are often not able to internalise positive externalities of the investments into sustainable ICT, leading to substantial underinvestment in digital climate technologies both in the areas of (i) digital for sustainability and (ii) sustainable ICTs.

The objective under the RID window is to facilitate and accelerate access to finance in the area of digital climate technologies, including green ICTs. It will specifically target research, innovation and deployment projects that either demonstrate a potential to achieve a significant reduction or avoidance of GHG emissions as compared to currently used technologies/business models or systematically use technologies leading to a significant GHG emission reduction. Examples of green ICT projects include sustainable computing, low-power microprocessors, low energy AI algorithms, sustainable solutions for blockchain technologies, reduction of energy consumption of data transmission, sustainable ICT equipment.

## Energy demonstration projects for decarbonisation

The InvestEU EDP-FM will aim at accelerating:

* The low-carbon energy and transport innovation, including demonstration of technologies and solutions with potential for material avoidance of GHG emissions in energy intensive industries, renewable energy production and use, energy storage and CCS;
* The deployment of future mobility solutions;
* The path towards digitalisation of energy and transport

Targeting high EU added-value areas of policy focus where the final recipients bear a higher risk (e.g. early demonstration, technology risks, insufficient track records, lack of collateral or untested business cases) than operations otherwise supported by other InvestEU products.

The InvestEU EDP-FM will focus on early demonstration of the commercial viability and deployment of innovative transport and energy technologies and business cases. It should include projects that are at pre-commercial level or early commercialisation stage, or have not yet reached at commercial scale at a sustained pace, including digitalisation aspects.

In relation to demonstration, innovation may relate to a specific technology or processes, products or services. Such projects will aim to have the potential to be replicated and not be conceived for the sole purpose of demonstration, while delivering significant avoidance of GHG emissions. Regarding transport projects, the TEN-T regulation Article 33 further elaborates on the aspects of innovation and new technologies eligible for support.

The objective is to fill a critical gap in access to risk finance for projects attempting to cross the 'valley-of-death' from 'technology demonstration' to the 'demonstration of commercial viability of the technologies' (at the appropriate scale of commercial applications).

Access to finance is hampered at these stages, as financial investors still need reassurance and visibility on the commercial viability of the technologies in question, and demand risks during deployment. Such technologies are indeed still unproven for the period of time and/or were only implement in a limited number of projects (considering for example different geographical or geological conditions). Many innovative low-carbon products (e.g. fuels or chemicals) for instance do not yet have established markets that would remunerate the increased costs of the innovations involved in their manufacturing.

Therefore, support should be given to companies facing higher risks for innovative early demonstration projects and deployment of innovative technologies and new business cases in the areas of energy and future mobility.

The InnovFin Energy Demonstration Projects instrument was underpinned by a market study[[30]](#footnote-30) in 2016 concluding that the supply of equity and debt is at much lower levels for first-of-a-kind projects compared to financing of proven low carbon technologies. The study highlighted that market participants have very different appetites for risk. It leads to complex financial structures being required to enable such projects to achieve financial close, and to a high demand public sector funding mechanisms to fill the ‘valley of death’ financing gap.

The study identified two needed financial support: equity provision and loans, blended in some cases with grants and equity. Both types of support were deemed to be of strategic importance to be developed in parallel, as complementary interventions.

Innovation Fund Market testing Study[[31]](#footnote-31)  also underpins the need for complementary financing in the form of debt or equity on top of grants enabling industrial decarbonisation investments (also) by large corporates, innovative renewables, energy storage and CCS, or their combinations in the industrial symbiosis.

The study implemented by InnovFin Advisory on innovative transport technologies[[32]](#footnote-32) highlighted that easier access to finance could benefit the sector in the emerging areas of: urban green mobility solutions and services; low carbon highly energy efficient road vehicles; and automated and connected road transports. These areas represent the scope of this work and have a high potential to contribute to the Commission's objectives.

As a result of the analysis and market consultation carried out as part of this study, a set of nine recommendations was developed to address the financing gap and further barriers to innovation and access to finance in European Innovative Transport. These recommendations notably included: the development of tailored flexible grants (i.e. blending) for fast growing service companies; the push to the build-up of charging infrastructure through blending grants with flexible debt; and the support to dedicated innovative transport or multi-corporate funds to address the growth-phase financing gap.

The market study on CEF Transport blending facility[[33]](#footnote-33) further assessed potential for blending in the areas of decarbonisation of transport and deployment of alternative fuels and digital and telematics applications.

# InvestEU for Health

## Health innovation – Clinical development, validation & market entry

The EU health sector accounts for 10% of GDP, 15% of public expenditure and 8% of the EU’s workforce and has a high potential for innovation and growth. Yet, a lack of funding is limiting the growth of the European life sciences R&D. According to the InnovFin Advisory study on life sciences[[34]](#footnote-34), it is estimated that organisations developing innovative medicines across the South East of England, Bavaria, Catalonia and Poland will face a collective funding shortfall of approximately EUR 30-40 billion over the period 2017-2021.

The policy focus concentrates areas of **unmet public health needs** (includingfunding gaps, and market failures), putting emphasis on the prevention (including identification/diagnostic) and therapies of Communicable Diseases and Non Communicable Diseases. This product specifically targets **late stage clinical development, validation and market entry.**

Market analysis shows a severe deficiency in capital availability for mid- to late stage clinical development, validation, and market entry. European companies advancing their products to this stage require large volumes of investment and while the risk of trial failure decreases towards commercialisation, the opportunity cost of capital increases with larger ticket sizes. Few investors in Europe have the capacity to follow on to such a late stage, therefore, the options left to the companies are limited. [[35]](#footnote-35)

Late stage clinical development, validation and market entry investments in health innovation are very expensive but also risky, marked by arguably the strictest regulatory system in any sector. Very expensive and time-consuming clinical trials (with in turn strict requirements for patient safety, robustness of data collected etc.) are required as a basis for stringent regulatory approval in different markets. Personalised medicine increasingly replaces blockbusters and generally requires complex multinational trials in order to reach required patient numbers. Health technology assessment is increasingly a requirement for market entry and comes with its own set of requirements, sometimes in the form of additional clinical trials.

According to the Capstone Partners study 'European Private Equity Market Overview Q1 2019’, the size of most of the VC in the EU is simply too limited (< EUR 250 million) to finance single company loans in excess of EUR 25 million. This financing limit, however, is too limited to conduct late stage clinical trials for many promising therapeutics.

The market of diagnostics and medical devices (medical technologies) grows fast, with many SMEs involved. Biomarkers play a crucial role in this evolution, and in health innovations in general, while new EU regulations require expensive clinical validations for which funding is lacking. Since the European MedTech sector consists to 95% of SMEs, clinical validation very often is the crucial step, both, in terms of value of the technology and in financial terms.

The objective under the RID window, is to fund **high-risk and/or large-scale projects** in the below areas, accelerating product development and providing long lasting solutions for EU patients and vulnerable groups within and outside the EU. The following areas of intervention should be considered:

1. **Communicable Diseases** – focusing onprevention (including identification/diagnostic) and therapies, and addressing at least one of the following**:**
	1. Diseaseswhich are prevalent in populations/markets that do not have the purchasing power to sustain high product prices, but in some cases present a great threat of (re-) emerging epidemics.
	2. Aspects of antimicrobial resistance[[36]](#footnote-36) which can lead to economies of scale;
	3. Other areas of unmet public health needs – areas relevant from the public health perspective for which there are few or no solutions in the market.
2. **Non Communicable Diseases** – focusingon prevention (including identification/diagnostic) and therapies, and addressing at least one of the following**:**
	1. Interventions of public health interest in the fields of Rare Diseases and Neurodegenerative Diseases;
	2. Other areas of unmet public health needs – areas relevant from the public health perspective for which there are few or no solutions in the market.

## Health and Care Systems

Health systems in the EU are in need of reforms and cost-effective innovations to adapt to the challenges they face, such as the increasing demand for healthcare, population ageing, rising burden of chronic conditions and multi-morbidity, as well as risks to their sustainability due to expensive innovative products. The direction of travel is towards new care models that support a shift from the traditional hospital-centred approach to more community-based and integrated care structures, putting the focus on health promotion, disease prevention and person-centred care. The reforms can be facilitated by the digitisation of health systems and by strengthening the research, development and testing of innovative cost-effective solutions, including technological, organisational and service innovations.

The reforms and modernisation of health systems require **sustained** financing - both for up-front investments and during a transitional period until the reforms are implemented and bring the anticipated benefits and returns. In this context, investments are needed **not only** in the traditional areas of hospital infrastructure and medical equipment, but also on several **additional** fronts: new facilities such as primary care and community care centres; digital systems such as eHealth and mHealth tools and services; system re-organisation into new service models; novel financing/reimbursement methodologies; integration of new innovative products/technologies; and education and up-skilling of health workforce in new roles and skills.

The lack of investments in health has been documented by the High-Level Task Force (HLTF) on investing in social infrastructure in Europe, which indicates an **annual investment gap of EUR 70 billion in social infrastructure for health and long-term care** across the EU Member States. Furthermore, a market study commissioned by the EIB and DG SANTE has identified a combined **deficit in healthcare capital stock (assets) of EUR 262 billion in 18 Member States**[[37]](#footnote-37). The same study revealed that even if EU Member State strategies prioritise investments in areas such as primary care and disease prevention, in practice, little is invested in these. **Limited available budget** and **insufficient access to financing** are among the reasons for this failure.

Other market failures relate to:

1. The fact that it can take several years to realise the benefits of reformed health services, hence the return on investment may come in the medium to long term and at high risk
2. Risk due to regulatory uncertainties
3. Risk caused by the uncertainty of whether an innovative solution will actually deliver benefits when integrated in a health system or whether it is of limited value or poses risks to patients (in essence, lack of sufficient evidence for many innovative solutions)
4. The fact that investments in services are "intangible" and of rather small size, thereby less attractive to many investors
5. The financing for combinations of technological, service and organisational innovations is complex and risky

A debt product with a guarantee against first losses can play an important role in accelerating the integration of innovative solutions in reformed health systems, by offering an opportunity for the public and private sectors to join together in high-risk health investments and in filling investment gaps that cannot be covered by resources from national, regional, or local budgets.

Support will be provided to EU health related policies, in particular:

1. The Commission’s Communication on "effective, accessible and resilient health systems"
2. The Commission’s Communication on “enabling the digital transformation of health and care in the Digital Single Market”
3. The Commission’s Communnication on Artificial Intelligence for Europe
4. The Recommendation on a European Electronic Health Record exchange format.
5. The European Pillar of Social Rights
6. The UN Sustainable Development Goal 3: “Ensure healthy lives and promote well-being for all at all ages”

In the area of Research, Innovation and Digitisation, support will be provided to the following areas:

* Strengthening research, technological development and testing of innovative solutions in health systems: organisational and service innovations (including technological innovations that support these), from novel health interventions that address unmet public health needs and targeted health outcomes, to new financing, reimbursement and service delivery models.
* Digitalisation of health systems, including the research, development, testing and small-scale implementation of novel digital solutions (Artificial Intelligence, Blockchain technology, data analytics, etc.) that improve the delivery of health services and the performance of health systems.

# InvestEU for strategic technologies

## Strategic Digital Technologies

Specific digital technologies, such as high performance and quantum computing, cybersecurity, 5G and the Internet of Things, Artificial Intelligence and Blockchain have been identified as being essential for the competitiveness of the European economy and for technological sovereignty. The InnovFin advisory studies on Financing the Deep Tech Revolution (2018)[[38]](#footnote-38); Financing the Future of Supercomputing (2018)[[39]](#footnote-39) and the forthcoming study on Financing of Digitalisation and Digital Innovation Hubs (2019) have emphasized that strategic digital technologies are a critical enabler for Europe’s economic growth and social development.

Despite the proactive measures by the EU to boost funding for these strategic digital technologies, access to finance remains a critical obstacle for innovative, R&D intensive companies and project promoters, in both upstream and downstream research as well as and in deployment. There is a substantial funding gap for the scale-up and commercialisation phases of strategic digital technologies due to the associated market information asymmetries, high technology risk, lack of collateral and long development periods.

The investment gap for large-scale deployment of such technologies, in addition to R&I, is evident from the mismatch between the growing demand for latest technology and the supply. In High Performance Computing, insufficient supply is pushing EU scientists and engineers to turn massively to computing resources outside Europe notably the US where governments' programmes maintain supply for high end computing at the frontier of performance. Europe is also home to a world-leading Artificial Intelligence (AI) research community as well as a host of small companies providing AI expertise, but its AI market is underdeveloped compared to the US, where the capacities available, notably in data, provide supportive conditions for innovation at scale. The fragmentation and relatively low public investment in cybersecurity is putting our society and economy at risk while the European cyber industry remains highly dispersed, with no major market players.

While this issue applies to all EU countries, the financing gap is particularly pronounced in Central and Eastern Europe and EU-13 countries. The lack of investments in digital technologies in this region represents a significant threat to ensuring improved regional and social cohesion across all EU regions. Therefore, it is critical to address the investment gap for strategic digital technologies within Europe by enhancing investments across all of its regions.

The objective of the intervention is to strengthen the EU’s technological sovereignty regarding strategic digital technologies, to support research, innovation and in particular the roll out and deployment of strategic digital technologies to the market, including high performance and quantum computing, cloud, artificial intelligence and blockchain, cybersecurity, smart networks (5G and beyond) and the Internet of Things.

## Key enabling technologies

InnovFin Advisory study on the Access-to-finance conditions for KETs (2016)[[40]](#footnote-40) showed that KETs companies, particularly SMEs and midcaps struggle to obtain adequate debt financing for growth and innovation. This issue is pronounced particularly for higher risk KETs companies lacking adequate assets and guarantees, and is a result of risk aversion on the side of the European financing ecosystem.

In particular, KETs projects/companies require particularly high capital expenditure due to high R&D and component costs, while at the same time the funding institutions and lenders lack adequate financing instruments for such high-risk investments or require a very high interest rate. Consequently, KETs companies of various sizes that are looking for large scale-up and require large amounts of debt as well as established KETs companies with stable market positions and a solid revenue base find it difficult to access adequate funding.

In particular, support will go to investments in the area of:

* Industrial biotechnology;
* Advanced materials: support to the development of advanced materials and nano-enabled products from laboratory validation to prototypes in industrially-relevant environments;
* Additive manufacturing (3D printing, emerging “4D printing”), including investing in R&I of processes and materials and in the industrialisation of the technology.

## Defence

The EU has of recently increased efforts to strengthen its defence capabilities (relevant initiatives/frameworks include notably CDP, PESCO, EDF/EDIDP). These capabilities are increasingly dependent on the development of new technologies in fields such as artificial intelligence, cyber-security or innovative materials, which are initiated outside of the defence sector. Several jurisdictions (particularly the US and China) have equipped themselves with tools (notably investment funds) to actively identify and invest in the development of such promising technologies, including within the EU with the associated risks of ‘technology drain’. In the EU, only France has adopted a similar approach at national level, which could potentially be up-scaled at the EU level in line with the EU objectives in the area of security and defence.

In that context, the objective will be also to reap the benefits of the single market for defence by fostering cross-Member State cooperation.

Despite a certain degree of consolidation at the level of large players, the EU defence industry is fragmented. This also affects cross-border access to the defence industry supply chains: access for new suppliers, especially for those located in other Member States, remains limited, leading to low levels of cross-border engagement in the defence industry’s supply chains. Barriers to the cross-border participation in the supply chains have particularly negative effects on SMEs’ participation in the defence market.

A wide-ranging consultation of relevant actors[[41]](#footnote-41) allowed identifying the following risks and access to finance constraints that affect companies active in defence, especially those that focus on the development of disruptive technologies:

* Concentrated demand side of defence industry as companies need to ensure purchase of the materials by the government prior to investing in R&D;
* Restrictions on exploitation of intellectual property or exports of related outputs where applications are considered sensitive/important;
* Significant up-front investment costs arising from participation in public tenders (especially for initial stage development);
* Long duration of programmes and uncertainties about the timing/margin for commercialisation (product research, development and commercialisation spans can stretch for up to 15 years and beyond);
* Continuing fragmentation along national borders and limited cross-border access to the supply chains of the large system integrators reduces the scope of the market that can be served;
* Technology risk (reluctance of banks to finance companies, particularly SMEs, involved in ambitious projects, new specifications that could generate non-anticipated costs);
* Limitations in the lending policies of financial institutions, which in some cases exclude the funding of defence activities. This may also affect the willingness of investors to get involved;
* A lack of track-record for defence sector start-ups which, coupled with unfamiliar technology/demand-side potential, excludes them from the lending of commercial banks, while there is a limited number of alternative finance providers that would have the capacity and strategy of investing in defence companies;
* Constrained exit opportunities for investors;
* The risk of technology-drain from the EU due to insufficient late-stage capital and the absence of strategic intent to safeguard critical European technologies;
* Focus of procurement on the traditional value chain: upstream industry is used to a large institutional market of traditional public procurement and R&D grant programmes. Industry associations and entrepreneurs in both the up- and downstream sectors indicate a lack of public anchor tenants to stimulate the sector; and
* Defence-related businesses may have particular difficulty gaining access to capital market based finance (bonds or equity) – particularly in Member States with less developed or efficient financial markets.

The above factors specific to the defence sector amplify access the finance barriers typical for companies focused on new technology development in other sectors and call for tailor-made investment support.

## Space

Space technologies, data and services can support numerous EU policies and key political priorities, including the competitiveness of our mobility, transports & economy, control of migration, control of climate change, the Digital Single Market and sustainable management of natural resources. Space is also of strategic importance for Europe. It reinforces Europe’s role as a stronger global player and is an asset for its security and defence. Space policy can help boost jobs, growth and investments in Europe, for its spill-over positive externality effect into the wider economy. Investing in space also pushes the boundaries of science and research in relevant sectors outside the space domain.

Europe has a world-class space sector, with launching capabilities and a strong satellite manufacturing industry, which captures around 33% of the open world markets, and a dynamic downstream services sector with a large number of SMEs. The European space economy, including manufacturing and services, employs over 230 000 professionals and its value was estimated at EUR 46-54 billion in 2014, representing around 21% of the value of the global space sector.

Given the importance of space for the European economy and society, a EUR 16 billion Space Programme has been proposed for the Multiannual Financial Framework 2021-2027.

The space industry is at the higher end of an important value-added stream of commercial and public-private services that generate socio-economic benefits and support the sustainable development of Europe.

A recent study on access to finance conditions for the European space sector carried out by the EIB advisory hub[[42]](#footnote-42) confirmed that the global space economy grew by 6.7% on average per year between 2005 and 2017, partially driven by New Space phenomenon. The size of total investments into space companies grew 3.5x in 2012-2017 compared to the previous 6-year period. This signals the increasing attractiveness of the commercial aspects of space and positive prospects of space market future development.

Access to finance emerges as a critical component in fostering an entrepreneurial space ecosystem, especially for scale-ups. However, a coherent and integrated suite of dedicated funding instruments for space companies in Europe is lacking. Space-based SMEs in EU vis-à-vis their equivalent in US find particularly hard to access larger size loan finance instruments (e.g. above 1M€) as well as a refusal rate almost double that the universe of reference (14% vs 8%).

Measures have been deployed to support SMEs and entrepreneurs operating in the field of space technologies and services both at National and European level. In Europe, activities include the business incubation centres (BICs) programme carried out by the European Space Agency (ESA) as well as various EU initiatives such as the Copernicus and Galileo Masters and Prizes and Incubation. For what concerns access to risk finance, several initiatives are being tested. This is the case with Seraphim Capital, Space Ventures and Interstellar Ventures in Germany and the United Kingdom, the recently established Astra Ventures in Italy, CosmiCapital in France, the upcoming space fund in Luxembourg. Furthermore, a few space infrastructure projects have benefited from the success of EFSI (e.g. OHB, Terma, Sener, Skeleton Technologies) whilst the downstream space sector, services and applications, are lagging behind.

Although there is growing interest from the private sector in embarking in space ventures, the access to finance landscape for space and space-based companies remains scarce, fragmented and some market segments remain significantly riskier than others due to the high upfront investments, immature markets and high technological and regulatory uncertainty.

European space entrepreneurs – both in upstream and downstream sectors – face a lack of private financing sources and financing challenges such as (i) insufficient volume and size of European venture capital investments, in particular for commercialisation and growth; (ii) inaccessible business loans from commercial banks, notably for start-ups; (iii) a lack of public anchor tenants to stimulate the sector. Because of this scarcity of scale-up funding in Europe, companies often seek for alternatives in non-EU countries such as the US.

From an investor point of view, space is perceived as a risky sector since it is an immature market with questionable demand, it has high technology risks, high capital needs and there are no clear exit opportunities (a lack of follow-on finance has led to a number of early IPOs). Besides, investors often lack background and investment expertise in space sector. This can lead to poor understanding of actual risks, market potential and business models.

In this perspective, EU financial instruments can play an important role in unlocking private capital for the space sector and in helping to reap the benefits coming from the Union space programme infrastructures for the creation of new space technologies, services and applications and further supporting and scaling up projects that have already received funding under Union public programmes (e.g. Horizon 2020, ESA BICs, Galileo and Copernicus start up programme).

1. The Economic Rationale for Public R&I Funding and its Impact (2017), p.4 [↑](#footnote-ref-1)
2. Commission services calculations based on Eurostat data. [↑](#footnote-ref-2)
3. Rees M. (2017). ‘Quasi-Equity: A New Financial Structure for a New Challenge’, EIB News/Blog, 16 January. http://www.eib.org/infocentre/blog/all/quasi-equitya-new-financial-structure-for-a-new-challenge.htm [↑](#footnote-ref-3)
4. [Access-to-finance conditions for Research and Technology Organisations (RTOs) and their academic and industrial partners](https://www.eib.org/attachments/pj/access_to_finance_conditions_for_rto_en.pdf), March 2017 [↑](#footnote-ref-4)
5. <https://ec.europa.eu/growth/industry/innovation/facts-figures/scoreboards_en> [↑](#footnote-ref-5)
6. The Bioeconomy sector holds huge economic potential for agriculture, forestry, fisheries, food, bio-energy, and novel bio-based industries, which rely on a myriad of bio-based products that are currently being developed and rolled out across the continent. In Bioeconomy, natural raw materials (e.g. wood) can be successfully used in an environmentally sustainably way to produce bio-based products and replace fossil resources in a circular and sustainable way. By developing biodegradable, compostable and bio-based alternatives to plastic, the bioeconomy sector also provides solutions to the environment's plastic pollution problem. [↑](#footnote-ref-6)
7. Green infrastructure is a strategically planned network of natural and semi-natural areas with other environmental features designed and managed to deliver a wide range of ecosystem services such as water purification, air quality, space for recreation and climate mitigation and adaptation [↑](#footnote-ref-7)
8. Climate services: transforming climate-related data and other information into customised products such as projections, trends, economic analysis, advice on best practices, development and evaluation of solutions, and any other climate-related service liable to benefit that may be of use for the society [↑](#footnote-ref-8)
9. Natural capital: An extension of the economic notion of capital (manufactured means of production) to environmental 'goods and services'. It refers to a stock (e.g., a forest) which produces a flow of goods (e.g., new trees) and services (e.g., carbon sequestration, erosion control, habitat). [↑](#footnote-ref-9)
10. Nature Based Solutions: nature-based solutions to societal challenges are solutions that are inspired and supported by nature, which are cost-effective, simultaneously provide environmental, social and economic benefits and help build resilience. Such solutions bring more, and more diverse, nature and natural features and processes into cities, landscapes and seascapes, through locally adapted, resource-efficient and systemic interventions.   [↑](#footnote-ref-10)
11. <https://ec.europa.eu/info/sites/info/files/research_and_innovation/knowledge_publications_tools_and_data/documents/accelerating_circular_economy_032019.pdf> [↑](#footnote-ref-11)
12. EIB InnovFin Advisory Study “Feeding future generations: the role of finance in upscaling agri-food innovations” (2019) <https://www.eib.org/attachments/thematic/feeding_future_generation_summary_en.pdf> [↑](#footnote-ref-12)
13. COM (2018) 738 final [↑](#footnote-ref-13)
14. EIB InnovFin Advisory Study on “Access-to-finance conditions for investments in Bio-based industries” (2017) [↑](#footnote-ref-14)
15. EIB InnovFin Advisory Study “Feeding future generations: the role of finance in upscaling agri-food innovations” (2019) <https://www.eib.org/attachments/thematic/feeding_future_generation_summary_en.pdf> [↑](#footnote-ref-15)
16. EIB InnovFin Advisory Study on “Access-to-finance conditions for Projects supporting the Circular Economy” (2015) [↑](#footnote-ref-16)
17. The expected levee cost reduction of investments required for construction and operative costs for flood protection (given different storm return periods) due to the shift towards hybrid flood risk management has been estimated for amount to a total 12.7 billions euros for 15 countries of the EU– thanks to the  reduction in wave heights and intensity obtained through interaction between foreshore vegetation and incoming waves. These estimated impacts are based on the tool developed by the FAST project  called MI-SAFE.(https://fast.openearth.eu/) [↑](#footnote-ref-17)
18. EEA Report on “Financing Urban Adaptation to Climate Change” (2017) (<https://www.eea.europa.eu/publications/financing-urban-adaptation-to-climate-change/at_download/file> ) [↑](#footnote-ref-18)
19. Environmental Observation: The capacity to observe the environment, including space-based, in-situ-based (air, sea, land) observation, and citizen observations. [↑](#footnote-ref-19)
20. The Summary for Policy Makers of the IPBES Global Assessment Report on Biodiversity and Ecosystem Services informs that Nature-based solutions with safeguards are estimated to provide 37 per cent of climate change mitigation needed until 2030 to keep global warming well below 2°C with likely co-benefits for biodiversity. [↑](#footnote-ref-20)
21. Climate change, impacts and vulnerability in Europe 2012, EEA Report No 12/2012', European Environment Agency, 2012. [↑](#footnote-ref-21)
22. COACCH (CO-designing the Assessment of Climate CHange costs): http://www.coacch.eu/ [↑](#footnote-ref-22)
23. Number will change under Brexit. [↑](#footnote-ref-23)
24. <https://ec.europa.eu/research/bioeconomy/pdf/ec_bioeconomy_strategy_2018.pdf#view=fit&pagemode=none> [↑](#footnote-ref-24)
25. <https://ec.europa.eu/maritimeaffairs/policy_en> [↑](#footnote-ref-25)
26. Article 2 on General Objectives of the IMP includes that the IMP Programme shall promote the protection of the marine environment, in particular its biodiversity, and the sustainable use of marine and coastal resources and to further define the boundaries of the sustainability of human activities that have an impact on the marine environment, in particular in the framework of Directive 2008/56/EC (the Marine Strategy Framework Directive). [↑](#footnote-ref-26)
27. <http://ec.europa.eu/research/bioeconomy/index.cfm?pg=policy&lib=food2030> [↑](#footnote-ref-27)
28. <https://publications.europa.eu/en/publication-detail/-/publication/aee1a34c-3b0c-11e9-8d04-01aa75ed71a1/language-en>) [↑](#footnote-ref-28)
29. Ibid, p.11 [↑](#footnote-ref-29)
30. <http://ec.europa.eu/research/energy/pdf/innovative_financial_instruments_for_FOAK_in_the_field_of_Energy.pdf> [↑](#footnote-ref-30)
31. <https://op.europa.eu/en/publication-detail/-/publication/906bea83-b6fe-11e8-99ee-01aa75ed71a1> [↑](#footnote-ref-31)
32. <https://www.eib.org/attachments/pj/access_to_finance_study_on_innovative_road_transport_en.pdf> [↑](#footnote-ref-32)
33. https://eiah.eib.org/publications/attachments/cef-blending-facility-market-study-en.pdf [↑](#footnote-ref-33)
34. <https://www.eib.org/attachments/pj/access_to_finance_conditions_for_life_sciences_r_d_en.pdf> [↑](#footnote-ref-34)
35. <https://www.eib.org/attachments/pj/access_to_finance_conditions_for_life_sciences_r_d_en.pdf> [↑](#footnote-ref-35)
36. Only applicable if a specific fund on AMR under InnovFin does not get established. [↑](#footnote-ref-36)
37. <https://eiah.eib.org/publications/attachments/report-health-sector-study-20180322-en.pdf> [↑](#footnote-ref-37)
38. <https://www.eib.org/en/publications/financing-the-deep-tech-revolution> [↑](#footnote-ref-38)
39. <https://www.eib.org/en/publications/financing-the-future-of-supercomputing> [↑](#footnote-ref-39)
40. <https://www.eib.org/attachments/pj/access_to_finance_study_for_kets_en.pdf> [↑](#footnote-ref-40)
41. With a view to developing this product sheet DG ECFIN organised two workshops (in April and June 2019) involving the defence industry, representatives of ministries of defence, the EIB Group, several National Promotional Banks, the European Defence Agency and specialised investors. [↑](#footnote-ref-41)
42. <https://www.eib.org/en/infocentre/publications/all/the-future-of-the-european-space-sector-report.htm> [↑](#footnote-ref-42)