EARTO Working Group
Emerging Technologies for Healthcare

EARTO Input on Health Research and Innovation for the next European Framework Programme (FP10)

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Introduction

For over thirty years, the European Framework Programmes for Research, Development and Innovation (RD&I) have been essential to Europe's efforts in tackling challenges through excellence in RD&I, promoting collaborative research, and supporting the translation of R&I for commercialisation and new business. The future Framework Programme on RD&I (FP10) is pivotal in closing Europe's competitive gap[1], by advancing cross-cutting technologies and exploiting artificial intelligence to position Europe at the forefront of digital transformation with benefits for current and future generations as well as global sustainability.

Research and Technology Organisations (RTOs) play a critical role in strengthening an end-to-end innovation chain, by **bridging the innovation gap between frontier research and market-driven innovation of new products**. RTOs identify and pave the way for emerging technologies, translating innovation into commercialisation for new or disruptive markets. RTOs are exemplary concerning their know-how, managing high-end research and technology infrastructures, and combining competence in both, technology development and the special relationship with industry. They contribute significantly to mature research output toward higher technological readiness levels (TRLs), transferring new technologies to the market for strengthening industrial competitiveness, and promoting collaboration across academia, industry, and public institutions[2]. **In the health sector, RTOs are active in all major areas, ranging from biomedicine and pharmaceuticals over medical devices to digital health, allowing for technology convergence as well as data integration and interoperability.**

The strategic significance of health in the post-pandemic era

The forthcoming FP10 must address new strategic, geopolitical, security, economic and societal challenges in parallel to reinforcing Europe's leadership and self-determination. Evolving political balances of power worldwide, the war in Ukraine, technological advances in digitalisation, automation and the rise of artificial intelligence (AI), and the COVID-19 pandemic underscore the urgency for strategic autonomy, stronger defence, technological sovereignty, and robust public health systems with the capacity to act swiftly. More specifically, Europe's healthcare sector faces mounting pressure from several factors, including ageing populations, chronic and non-communicable diseases, new climate-related health issues, mental health problems, anti-microbial resistance, future pandemics, and economically unsustainable healthcare costs. The healthcare innovation chain in Europe lacks continuity and efficient mechanisms for the adoption of new health technologies from the bench to the bedside.

Health competitiveness: To maintain technological sovereignty and co-regulate global digital standards[3], Europe needs to catch up with the USA and China[4,5] in frontier technologies, nowadays often developed in Europe while scaled elsewhere, often due to our regulatory environment[6]. Staying competitive and delivering on its promises to EU citizens, Europe must significantly boost its innovation capacity, intensity, and exploitation power of innovation at every link in the health sector's innovation chain. On the one hand, in an innovative life sciences sector, new technologies for healthcare and digitalised healthcare systems are essential to make the transition from healthcare historically based on diagnostics and treatment (reactive) to predictive and preventive health (proactive). On the other hand, the health sector itself plays a key economic role and increases economic power through new job creation, investment in RD&I, exploitation of intellectual property, the provision of critical infrastructure and a healthy workforce.

[1] Mario Draghi, https://commission.europa.eu/topics/strengthening-european-competitiveness/eu-competitiveness-looking-ahead_en.
[2] EARTO, https://www.earto.eu/wp-content/uploads/EARTO-Recommendations-No-EU-Tech-No-EU-Competitiveness-Final.pdf.
[3] McKinsey & Company, https://www.mckinsey.com/capabilities/strategy-and-corporate-finance/our-insights/securing-europes-competitiveness-addressing-its-technology-gap.
[4] EARTO, https://www.earto.eu/wp-content/uploads/SHOs-Joint-Statement-for-an-Ambitious-FP10-Final.pdf.
[5] European Parliamentary Research Service, https://www.europarl.europa.eu/RegData/etudes/STUD/2021/697184/EPRS_STU(2021)697184_EN.pdf.
[6] Enrico Letta, https://www.consilium.europa.eu/media/ny3j24sm/much-more-than-a-market-report-by-enrico-letta.pdf.

Resilience to health crises: The recent pandemic made clear that natural or human-made pandemics are a new grand societal challenge and highlighted the urgent need for swift, coordinated, and impact-oriented response to future global health crises. It includes better preparedness for detection, diagnosis, and monitoring, crisis-proof EU supply chains, health data sharing, and the adoption of digital health technologies. In a strategic framework, this is taken up by the European Health Union[7] for strengthening the performance and resilience of health systems, which aims at better health protection, joint actions between the EU and Member States, and overall preparedness and response capacity to health threats[8,9].

Artificial Intelligence (AI) in healthcare: Driving performance, efficiency and changing markets, several critical technology areas and key enabling technologies were identified to address the technological sovereignty of Europe[10,11], including technologies in the life sciences and AI. Dealing with human life and intelligence, both hold the promise to be truly transformative with wide-ranging applications across multiple sectors. AI changes fundamentally the way how research is conducted through, e.g., accelerated hypothesis generation, conducting research, discovery, and characterisation. AI in healthcare allows to exploit large amounts of data for training and building personalised models in areas of high medical need, assist healthcare professionals in decision-making and improve cost-effectiveness by better clinical intelligence.

Identified main areas of action

In light of the high relevance of the next Framework Programme for RD&I and to maximise the potential of Europe's RTOs in boosting the life sciences and frontier health technologies, the EARTO Working Group on Emerging Technologies for Healthcare highlights key considerations and recommends **7 main areas of action for the health sector to be considered when further defining the next FP for RD&I (FP10)** which build upon already made suggestions.[12]

1. Ensuring adequate funding for the health technologies of the future

Recognising RD&I as crucial for high standards of healthcare and creating a sustainable future, the current Framework Programme prominently established health as the first cluster under 'Global Challenges and European Industrial Competitiveness' (within its Pillar II). In general, this cluster aims at the **development of new tools, technologies, and pioneering innovation to boost Europe's healthcare industry.**

However, the Health Cluster **also covers the implementation of solutions** together with environment-related risk assessments, access to and efficacy of healthcare, and the social impact of diseases. The broadened scope dilutes the strategic priority of the Health Cluster and undermines collaborative research with industry, especially small and medium enterprises (SMEs) as well as collaboration between private and public partners beyond national borders to overcome fragmentation of the EU RD&I ecosystem in health, to share risks, and to optimally allocate efforts and resources.[13]

Although RTOs generally have higher participation rates in Horizon Europe under Pillar II compared to other pillars, their involvement is consistently lower in the Health Cluster relative to other clusters within Pillar II:[14]

- The share of EU contribution to EARTO members and collaborating partners in the Health Cluster is up to six time lower compared to other clusters (except CL 2).
- The number of EU projects involving EARTO members with collaborating partners in the Health Cluster is up to two-thirds lower compared to other clusters (except CL 2).

Furthermore, the Health Cluster should be better connected to research activities under Cluster 4 (Digital, Industry, and Space), the European Innovation Council (EIC) Pathfinder and EIC Transition, the EU Partnerships in the health domain, as well as the Mission Cancer and other EU Programmes such as EU4Health and Digital Europe.

To fully align and leverage the currently existing health EU related initiatives and to boost pan-EU collaborative health RD&I activities between the industry and RTOs with support from academic partners, **FP10 would need to:**

- Strengthen the geopolitical importance of the health sector across RD&I policies, by adopting an integrated and unified approach in FP10 which leverages excellence in research and impact-oriented innovation for the sector's competitiveness, sustainability, and resilience.

[7] European Policy Center, https://www.epc.eu/en/Publications/EU-health-policy-From-reaction-to-resilience~57efb8.
[8] Diplomatic Service of the European Union, https://www.eeas.europa.eu/eeas/building-european-health-union_en.
[9] WHO, https://www.who.int/publications/m/item/pathogens-prioritization-a-scientific-framework-for-epidemic-and-pandemic-research-preparedness.
[10] EC, https://ec.europa.eu/commission/presscorner/detail/en/ip_23_4735.
[11] European Parliament, https://www.europarl.europa.eu/RegData/etudes/STUD/2021/697184/EPRS_STU(2021)697184_EN.pdf.
[12] EARTO, https://www.earto.eu/wp-content/uploads/EARTO-Inputs-to-ERAC-on-FP10-Final.pdf.
[13] EARTO, https://www.earto.eu/wp-content/uploads/EARTO-Paper-on-Next-EU-MFF-Final.pdf.
[14] EARTO, https://www.earto.eu/wp-content/uploads/EARTO-Members-Participation-in-Horizon-Europe-Final.pdf.

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- Prioritise, reduce, and align strategic RD&I initiatives across all EU health related programmes, with a focus on investment in frontier technology research and development directed to new products, processes or services.[15]
- Recognise the role played by technology convergence and the importance of cross-cutting technologies in health innovation by expanding the Health Cluster's technology portfolio with dedicated technologies, some of which are currently overlooked and treated by other clusters without looking at applications in health.
- Ensure sufficient and protected funding for health RD&I in FP10, prioritise Pillar II as a decisive element for collaborative RD&I across Europe, and safeguard against budget reallocations to accommodate emerging political priorities.[16,17]
- Continue funding across the health innovation chain from early-stage research characterised by technological readiness levels (TRLs) 2-4 up to clinical feasible, regulatory compliant, and validated solutions (TRLs 5-6), thereby sharing inherent greater risks in healthcare technology development.
- Promote long-term collaborations among industry, research performing organisations, and healthcare providers through dedicated Coordination and Support Actions (CSAs) to enhance innovation networks and facilitate technology transfer into healthcare.

2. Revitalising SME participation in healthcare innovation

SMEs form the backbone of the European economy. They account for most European companies, two-thirds of jobs and more than half of gross value added. Their capacity for innovation is limited, especially in healthcare, by constraints and structural barriers[18]. While the overall RD&I investment is predominantly driven by large companies, SMEs play an important role in the healthcare ecosystem and have the potential to make significant contributions. Noticeably, the coronavirus created an innovation bottleneck for SMEs active in health by reducing RD&I activities during the pandemic. **SMEs' participation in Horizon Europe, particularly in the health sector, has decreased** compared to previous Framework Programmes:[19]

- The number of SMEs in the Health Cluster is up to three times lower than in CL 4-6, the total EU funding to SMEs in the Health Cluster (400 m€) is consistently lower compared to CL 4-6, and the share of SMEs funded in the Health Cluster (12%) is lower than in CL 4-6.
- Comparing the budget of SMEs participating across FP7-FP9 shows the budget allocated to health in FP9 (Health Cluster) sums up to 3.49 bn€ of which SMEs received 368 m€, in FP8 (Societal Challenge 1) to 6.19 bn€ of which SMEs received 963 m€, and in FP7 (SP1 Health) to 4.78 bn€ of which SMEs received 795 m€.

Contributing factors for the lower participation of SMEs include complex application processes, misaligned project scopes, reporting and discontinuities in funding mechanisms along the innovation chain making it difficult for SMEs to engage in RD&I activities.

In addition to the Health Cluster in Pillar II, Pillar III ('Innovative Europe') promotes all forms of innovation, with a focus on deep-tech start-ups and disruptive technologies. Here, the EIC is highly selective and for some calls had restricted access to those having had ERC or other eligible project funding previously, effectively cutting in SMEs from participating. In parallel, EIT networks are unattractive to SMEs due to over administrative burden.

Purposeful structures, effective instruments, and streamlined processes are needed to revitalise SMEs' participation in R&I projects and tackle the innovation bottleneck. **RTOs are suitable innovation partners for SMEs** and industry because they upgrade lower TRL to innovative prototypes, understand customer needs and alignment of R&D with business models and reimbursement strategies. Beyond R&D, RTOs support SMEs with project management and provide hands-on experience to go through regulatory certification if needed.

To revitalise SME participation and cooperation SMEs-RTOs in health as well as increase the Europe's healthcare sector's innovation intensity, **FP10 would need to:**

- Prioritise the collaboration research with industry as a crucial contributing factor to Europe's innovation capacity and prosperity, especially with a focus on incentivising SMEs through a novel SMEs' instrument that closes the gap between RD&I and commercialisation.
- Prioritise and align strategic RD&I initiatives across EU health programmes, with a focus on impactful technology development and transfer, while promoting interrelated and interdependent societal challenges separately (not in the same pillar).[17]

[15] EARTO, https://www.earto.eu/wp-content/uploads/EARTO-Paper-on-Next-EU-MFF-Final.pdf.
[16] EARTO, https://www.earto.eu/wp-content/uploads/EARTO-Inputs-to-ERAC-on-FP10-Final.pdf.
[17] Manuel Heitor, https://op.europa.eu/en/publication-detail/-/publication/2f9fc221-86bb-11ef-a67d-01aa75ed71a1/language-en.
[18] EC, https://op.europa.eu/en/publication-detail/-/publication/57281fab-431b-11ef-865a-01aa75ed71a1/language-en.
[19] Horizon Dashboard, https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/horizon-dashboard, data FP9 2021-2023, FP8 total number of years, FP7 total number of years.

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- "Bridging instrument"[20]: EARTO WG has recently proposed new SME-targeted projects for achieving short-term milestones and maximising impact on healthcare. Such projects are broken down into (1) technical feasibility assessment, 6-12 months; (2) prototype development of new device/solution, 12 months; and (3) technology demonstration and validation, 12-18 months. This approach de-risks the innovation cycle and provides actionable information to SMEs quickly. Successful bridging projects could be fast-tracked for following up with a consistent cascade of instruments, clear decision points, reduced overhead, and shortened time-to-market.
- Eliminate process shortcomings to increase efficiency, e.g., through simplification efforts aimed at reducing fragmentation, harmonising rules across calls, and streamlining application processes through a unified portal. Furthermore, adjusting funding to account for inflation and increasing support for indirect costs will ensure sustainability.
- Broaden the use of a two-stage application process especially in low-success domains to improve efficiency, while focusing R&I proposals on excellence in research and technology and sidelining generic criteria (e.g., strategic fit).

Europe remains an attractive market for medical and other health tech innovation due to its research landscape, strong talent pool, high-tech hubs, and supportive national and EU policies[21]. However, continued support, dedicated investment, and changes for optimal alignment with beneficiaries' needs are necessary to maintain this attractiveness.

3. Closing gaps in early-stage R&I to strengthen the whole healthcare innovation chain

The current Framework Programme focus on high TRLs and deployment-oriented funding has created a **gap in collaborative research** for both early-stage technology development (TRL 2-4) and demonstration and validation of mid-stage technologies (TRL 5-6).

The strongest incentive for industry partners to collaborate is in pre-competitive research, while they are less willing to engage in high-TRL collaborative research due to the risks of leaking critical knowledge. Health RD&I also requires synchronising the clinical, regulatory, and market maturation parallel to the technology innovation chain which is time-consuming and resource intensive.[20]

For instance, biotechnology has been identified as a critical technology for Europe's economic security[22]. This is due to pre-clinical and initial clinical validation required by biotech product regulation. In pioneering new medical solutions, biotechnology plays a key role in developing advanced therapies, personalised medicine, and innovative drug delivery as well as manufacturing systems. It is essential for the next generation of medical treatments that in addition to their treatment efficacy are environmentally friendly.[23]

While medical technology or digital health applications still require compliance with regulatory requirements which often include patient data, biotech innovation typically faces prolonged timelines and higher risk. This poses the challenge of ensuring continuity along the health innovation chain. While research at TRL 2-4 establishes the technological foundations, downstream at TRL 5-6 technology demonstration and validation require longer-term commitments and risk-adjusted funding[24].

To close the gap and ensure the progression of new health technologies aligned with clinical and regulatory maturity, **FP10 would need to:**

- Balance funding across the entire TRL spectrum, ensuring early-stage research is adequately supported to replenish the innovation pipeline[25].
- Commit to long-term funding that ensures continuity from early research to market-ready implementation, including checkpoints and non-technological domains like regulatory and market maturity for clinical trials.
- Create dedicated programs tailored to support biotechnology, medical devices, and digital health to recognise and reflect the unique development needs in the life sciences.
- Introduce system readiness to complement technology development with assessments of business conditions and user adoption to enhance market penetration.

[20] EARTO, https://www.earto.eu/earto-inputs-on-healthcare-research-and-innovation-for-the-next-strategic-plan-of-horizon-europe-2025-2027.
[21] Deloitte, https://www.deloitte.com/be/en/Industries/health-care/analysis/europe-medtech-attractiveness.html.
[22] EC, https://defence-industry-space.ec.europa.eu/document/download/31c246f2-f0ab-4cdf-a338-b00dc16abd36_en?filename=C_2023_6689_1_EN_ACT_part1_v8.pdf.
[23] EARTO, https://www.earto.eu/wp-content/uploads/EARTO-Paper-on-Advanced-Materials-for-Healthcare.pdf.
[24] EC, https://research-and-innovation.ec.europa.eu/document/download/47554adc-dffc-411b-8cd6-b52417514cb3_en.
[25] General Secretariat of the Council, https://data.consilium.europa.eu/doc/document/ST-10183-2024-INIT/en/pdf.

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4. Promoting cross-cutting health technology development

Cross-cutting technologies are essential for Europe's technological sovereignty and competitiveness because of their wide-ranging applications across multiple industries. The European Commission (EC) highlights six key enabling technologies, including life science technologies, advanced materials, micro/nanoelectronics and photonics, as well as AI, which are important for Europe's competitiveness, underpin technology leadership, and position the European industry for innovation in the global economy.[5]

The New Strategic Agenda 2024-29 outlines Europe's need for its capacity on key technologies such as biotechnologies, pharmaceuticals, advanced materials, semiconductors, AI, communication, and quantum technologies.[26] However, Europe is in the global lead only in next-generation materials and clean technology, i.e., only two out of ten crucial innovation-driving technologies.[27]

To address the necessary alignments of Pillar II with other Pillars and EU programmes for dedicated cross-sectoral health technologies, **FP10 would need to:**

- Build capacity on frontier and transversal technologies able to support a strong health portfolio for future medicine and treatment, including anti-microbial resistance ("silent pandemic"), climate and nutrition-related risk assessment and impact on health.
- Promote advanced biomaterials RD&I for the healthcare sector to exploit their novel functionalities (e.g., biocompatible, bio-resorbable) for breakthrough innovations in future medicine, including vaccines, drug delivery systems, better safety and sustainability, continuous monitoring and/or implantable devices, or novel regenerative medicine.[28]
- Create technology-focused programmes that leverage AI for healthcare throughout the RD&I cycle without excessive regulatory restrictions: simulation, digital twins, and AI-based modelling are vital for optimising healthcare tools, predicting outcomes, assisting healthcare professionals in decision-making, and improving cost-effectiveness. It is important to create suitable conditions in FP10 without being subject to overly broad regulatory restrictions while adhering to basic regulatory requirements in RD&I.

5. Reigniting industry collaboration with RTOs in health-focused partnerships

European Partnerships have been in the European Framework Programmes for R&I since FP6 and become a cornerstone for implementing R&I activities on a European scale.[29,30] They take a long-term and systemic approach, covering a wider set of activities by aggregating critical mass, aligning strategic agendas across borders, integrating sectorial R&I policies, and creating ties between different stakeholders from public and private. For better cohesion to Member States and EU policy priorities, Horizon Europe concentrated the partnership landscape to 49 in total, with more than two-thirds being initiated up to now.

While the new partnership approach has proven to be more effective, to fully leverage the significant potential of such bundled R&I capacities **FP10 would need to:**

- Foster broad collaboration in and across partnerships looking at healthcare by improving coherence, transparency, and synergies between them.[31] Participation rules should be simplified and harmonised, including national processes (the majority of partnerships in the Health Cluster are co-funded) to ensure collaboration of RTOs through implementation by co-funding bodies.
- Increase industry and SMEs' involvement in health partnerships, with clear integration of TRL and digital focus. Only two partnerships in the Health Cluster directly involve Europe's industry. Partnerships like IHI and EDCTP should expand their scope to health threats and new treatments while fostering collaboration with EU health initiatives. To date, the participation of EARTO members received the lowest funding contributions across Horizon Europe institutionalised partnerships in IHI and EDCPT3.[14] Specifically for partnerships in health, it is important to attract partners with clinical data for combining technology development with validation.
- Maximise the impact of recently launched partnerships through beneficial R&I conditions for Europe's RTOs: The European Partnership on Brain Health (1), ERA for Health Research (2), Chips Act (3), and AI, Data and Robotics (4) offer the opportunity for more collaborative research at the EU level, closely interlink transversal technologies with health R&I, and establish data standardisation.

[26] European Council, https://www.consilium.europa.eu/media/4aldqfl2/2024_557_new-strategic-agenda.pdf.
[27] McKinsey, https://www.mckinsey.com/capabilities/strategy-and-corporate-finance/our-insights/securing-europes-competitiveness-addressing-its-technology-gap.
[28] EARTO, https://www.earto.eu/wp-content/uploads/EARTO-Paper-on-Advanced-Materials-for-Healthcare.pdf.
[29] EC, https://projects.research-and-innovation.ec.europa.eu/en/knowledge-publications-tools-and-data/interactive-reports/performance-european-partnerships-2022.
[30] EC, https://ec.europa.eu/commission/presscorner/detail/en/ip_24_1572.
[31] EARTO, paper on EU Partnerships in FP10, draft 23.07.2024.

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- Climate change expands infectious diseases to Europe, is detrimental to health, and threatens lives.[32] As the world is heating up, negative externalities on safe access to and quality of food arise and contribute to higher morbidity and mortality.[33] New cross-sector partnerships "Health impacts of climate change" joining the health with clean and sustained tech sectors and "Health impacts of diet-related diseases and food safety" joining with the nutrition sector could address cross-sectorial challenges to pave the way for mitigating climate and nutrition-related diseases.
- Enable participation in healthcare partnerships, without or with decreased co-funding requirements, for small companies or academic or non-profit institutions.
- EIT Health has initially enriched the partnership landscape with critical mass, focusing on market-ready technologies, skills development, and KPIs driving the execution of strategy. The need for better alignment with the EIC, insufficient co-funding, e.g. for RTOs, and future positioning as a competitor for funding activities call for an assessment of their partnership value proposition to determine the sufficient complementarity and synergies under the given challenges.[16]

6. Achieving a more cohesive digital health ecosystem

Digital transformation is key to shifting healthcare to preventive, predictive, personalised, and participatory (P4) models. By leveraging health data with AI, digital health will make healthcare systems more accessible, change the way healthcare is delivered, deepen prevention, and improve patient outcomes. It also creates gains in productivity and efficiency. Healthcare costs keep rising and the EU and the Member States' digital strategies are to exploit the economic benefits of digital health and tackle the unsustainability of healthcare systems.

Fragmented digital health programmes hinder progress, however, and overcoming silos to better align initiatives, is essential for accelerating digitalisation and maximising the impact of digital health solutions across Europe which is lagging in healthcare vs other sectors.[34] There are gaps between calls, initiatives, and projects, leading to disjointed efforts and missed opportunities for sequential synergies of health RD&I.

To foster a cohesive digital health ecosystem in Europe, **FP10 would need to:**

- Establish specific policy objectives for aligning RD&I components in digital health across various programs to interconnect programmes on all relevant levels.
- Strengthen the EC's eHealth Stakeholder Group by expanding the scope to encompass digital health ("dHealth Stakeholder Group") to convene and align stakeholders for accelerated R&I, integration and adoption of digital technologies into healthcare as well as full utilisation of European Health Data space (EHDS).
- Foster the standardisation of protocols for interoperability and health data sharing, AI systems, and regulatory approaches for seamless integration of digital tools into healthcare infrastructures.
- Address the role of generative AI in medical applications, emphasising both its potential benefits and associated risks, which include its ethical and safe deployment across healthcare settings.
- Encourage training and education programs for healthcare professionals to enhance their digital literacy and proficiency and reduce resistance to adopting digital innovations, including using AI tools for diagnostics, data-driven decision-making, or robotics for surgical and therapeutic practices.

7. Sustainable Technology Infrastructures for testing and validation of health innovation

Impact-oriented conceptualisation and efficient implementation of infrastructures for the translation of health research is critical for advancing technological innovation and accelerating market uptake. These technology infrastructures facilitate prototype testing and validation while adhering to regulatory standards and improving product readiness for market deployment. In addition to Open Innovation Test Beds, Digital Innovation Hubs, Testing and Experimentation Facilities, or networks like the European Research Infrastructures Consortium, both the EHDS as an overall data governance structure and Technology Infrastructures (TIs) decisively enrich existing R&I infrastructures.

The EHDS is an essential building block of the European Health Union, critical for accessing health data in a single market for digital health in Europe and creates a health data infrastructure for primary and secondary health data, whereas the latter (TIs) provide facilities that support advanced testing and upscaling of technologies to increase TRL to just before market maturity.

Despite the advantages offered to the RD&I ecosystem, however, challenges remain to be addressed. Such as securing sustainable funding, managing complex legal frameworks, fostering collaboration among

[32] Lancet, https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(23)01859-7/fulltext.
[33] EAT-Lancet Commission, https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)31788-4/fulltext, https://eatforum.org/eat-lancet-commission/eat-lancet-commission-summary-report.
[34] World Economic Forum, https://www.weforum.org/publications/transforming-healthcare-navigating-digital-health-with-a-value-driven-approach.

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stakeholders, and ensuring data privacy, interoperability, and regulatory compliance which all must be addressed to maintain long-term viability and achieve impact.

To ensure the sustainability and effectiveness of these infrastructures for accelerating commercialisation along the health innovation chain, **FP10 would need to:**

- Establish a European strategy on Technology Infrastructures, also targeting the healthcare sector (See EARTO positions)
- Facilitate access to health data: The EHDS holds the promise to provide access to unprecedented amounts of standardised medical data pivotal to developing new technology for P4 healthcare. To this end, it is crucial to consider secondary data utilisation with equitable priority as for primary health data. This should allow for processing multi-modal data from biosensors, environmental, and contextual sensors in combination with electronic health records. RTOs can be instrumental as they combine know-how and competence as health data provider, data users for both primary and secondary data, and data facilitators for enabling healthcare technologies.
- Create controlled environments ("Regulatory Sandboxes") for testing innovative technologies like AI across R&I and the entire medicines lifecycle, specifically Generative AI to personalise prevention and therapies, and digital health, allowing for streamlining validation and subsequently aligning them with certification processes to ensure safe market entry and compliance with regulations without stifling innovation.

As pointed out in the Letta report[6], specifically, and emphasised for the pharmaceutical sector in the Drahi report[1], the **healthcare sector can benefit extensively from R&I on European scale to enhance cooperation and drive innovation**. It is insufficient to tackle these challenges at national level without the European dimension. Leveraging research and development for technology innovation in healthcare through best-in-class collaboration and for accelerating the digital health systems can improve significantly both competitiveness and efficacy in healthcare delivery for EU citizens. By addressing these issues, we can ensure that R&I investment and deployment of advanced health technologies becomes a priority which will ultimately enhance the transition toward the European Health Union.

EARTO remains ready to provide additional input on the above-mentioned considerations and topics and to further discuss the implications of this input for the healthcare industry, RTOs and the complete health RD&I ecosystem with all involved stakeholders.

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EARTO - European Association of Research and Technology Organisations: *Founded in 1999, EARTO promotes RTOs and represents their interest in Europe. EARTO network counts over 350 RTOs in more than 31 countries. EARTO members represent 228,000 highly skilled researchers and engineers managing a wide range of technology infrastructures.*

EARTO Working Group Healthcare*: the WG is composed of 100 experts coming from 38 RTOs in 19 European countries. This WG is looking at the implementation of the EU RD&I Framework Programmes (Horizon Europe) addressing the healthcare sector, and especially medical technology, pharmaceuticals, biotech. Its members are conducting technological research for biomedical and medical applications, both for large companies and SMEs. They strongly support the emergence and the growth of spin offs in healthcare technologies. This WG is also looking at how RTOs can be involved in and benefit from projects under the European Digital Programme as well as the EU4Health programme, and also about the specific role of RTOs in Institutionalised Partnerships such as Innovative Health Initiative.*

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