

## **EARTO Inputs on Healthcare Research and Innovation for the next Strategic Plan of Horizon Europe (2025-2027)**

21 February 2023

### **Introduction**

The healthcare market (pharmaceuticals, biotech products, medical devices) is the third largest industrial sector in Europe with an annual turnover of €386bn euros per year<sup>1</sup>, employing 1.6 million persons. Among the Top 1000 EU R&D investors, healthcare industrial companies represent 20% of the total R&D investment, half of them being start-ups or SMEs, and show the highest R&D intensity<sup>2</sup>. With the COVID-19 crisis, much emphasis has been given to vaccine work within EU programmes the last years, now is the time to look at the overall healthcare market including biotech products and medical devices next to pharmaceutical.

In view of the preparation of the Horizon Europe next Strategic Plan 2025-2027, the EARTO Working Group Healthcare hereby presents **5 recommendations** to further boost current EU healthcare programmes. Those recommendations are based on the analysis by our healthcare experts of the limitations and gaps experienced through their active participation in those EU programmes.

Indeed, as underlined by [EARTO analysis on RTOs participation to Horizon Europe](#), RTOs have a key role supporting industry participating in and in coordinating multi-disciplinary, large and complex collaborative applied research projects under Framework Programmes (FPs). In the first two years of Horizon Europe, the EARTO WG Healthcare members have been successful in more than 70 projects in the parts addressing healthcare challenges within pillar 2 and pillar 3. RTOs participation in EU Healthcare programmes aim to build a competitive healthcare EU industry and a more sustainable and equitable healthcare delivery for European citizens while supporting the development of SMEs and start-ups.

### **Recommendation 1. Reintegrate Advanced Enabling Technologies for Healthcare in Horizon Europe**

To answer to the current and future challenges in healthcare such as new threats and infectious diseases, new therapies for cancer, prevention and management of chronic disease, to only list a few, Europe needs strong health technology-driven portfolios. The structure of Horizon Europe, based on an **all-inclusive Pillar 2, sub-divided in application-driven clusters, is not sufficiently adapted to health technology innovation that is transversal to many industries, feeding the industrial sectors of medical devices, pharmaceuticals and biotechs. Furthermore, the Pillar 3 with the European Innovation Council (EIC) focuses on deep-tech start-ups and as such does not compensate the lack of technology-driven research of Pillar 2. A new pipeline of transversal technologies that will feed innovative solutions in healthcare is urgently needed.**

The EARTO WG Healthcare has identified the **following gaps in programming for healthcare at EU level that should be addressed in the next Horizon Europe Strategic Plan 2025-2027:**

#### **1.1. Advanced Enabling Technology for HealthCare Needed**

Advanced enabling technologies for the healthcare sector are mainly:

- **Advanced Biomaterials:** biomaterials are the core of medical progress, and patient comfort and security. Biocompatible, bioresorbable, biosourced materials such as hydrogels, polymers (cellulose, alginate, chitosan, etc.), nano-based lipids, polypeptides are the building blocks of breakthrough innovations in healthcare. They will pull the development of vaccines, drug delivery systems, microneedles, smart patches, dressings, cellular therapy, regenerative medicine, implantable smart medical devices, surgical instruments...
- **Biosensors and multi-biosensing:** they constitute enabling technologies for medical devices and pharmaceuticals and significantly contribute to the One Health approach. Compact, portable, sensitive, specific, worn biosensors are included in in-vitro diagnostics, monitoring of infectious

<sup>1</sup> [FFPIA Data Center](#) 2021, [Medtech Europe Facts and Figures](#) 2022, In the medical technology sector, Europe hosts 34000 companies, **95% are SMEs.**

<sup>2</sup> [The 2022 EU Industrial R&D Investment Scoreboard](#) 196 healthcare companies rank in the first 1000 EU R&D investors, among which 100 start-ups / SMEs. R&D intensity is the highest: 12,4%, before ICT.

threats, personal monitoring of physiological/biological parameters, environmental monitoring, biotech process analytical technology. Additionally, biosensors are critical technologies to improve the efficiency of diagnostics in healthcare pathways, e.g., allowing self-diagnosis and remote monitoring<sup>3</sup>. Their diversity requires a continuous investment in RD&I.

- **Computational modelling:** in the healthcare area, numerical simulations remain powerful means to optimise surgical procedures, minimize recovery time, analyse and validate implants, study their behaviour and the effects of implants on organs. It requires continuous efforts in RD&I to adapt models to bones, muscles, tissues, vessels, especially for biomechanical modelling.

The current programme neglects these critical areas of research<sup>4</sup> with very limited opportunities for research providing organisations (RTOs & Universities) to irrigate the healthcare RD&I sector with new technology development opportunities. RTOs are acting in RIAs of cluster 1 Health, developing, or adapting each time a customized version of their technologies for a dedicated application with limited chance of re-use. Cluster 4 does not provide significant opportunities for maturing enabling biomaterials or biosensing either.

The former FP programme on Nanotechnologies, Advanced Materials, Biotechnology and Advanced Manufacturing and Processing (so called NMBP) was more adapted and managed to tackle transversal enabling technology for healthcare. **Such topics are today forgotten in the current clusters. This lack of transversal ambition will have a detrimental impact on the capabilities of European healthcare stakeholders to access to key advanced enabling technologies in Europe in the future (i.e., start-ups, SMEs, large companies, healthcare providers and clinical researchers).**

### 1.2. Bioconvergence Approach Needed

EARTO WG Healthcare members represent more than 12,000 researchers working in a bioconvergence approach. **Bioconvergence is a coherent R&D process involving biotech, medtech and technology expertise together, and not cascaded.** In this working process, researchers do not optimise their part (either biochemistry, or electronics, or encapsulation...) separately and iteratively. They work in convergence around the biological concept that underlies all their developments. Bioconvergence allows technological research to integrate and not only to interface with biochemical or medical research. For this reason, biomaterials and biosensors are central in RTOs' work<sup>5</sup>.

**In most of the Horizon Europe healthcare related calls, innovative solutions based on biomaterials and biosensors were not in the scope description.** Innovative technologies were assumed to be available by companies, possibly subcontracted, closing the door to the high potential of bioconvergence R&D for innovative healthcare solutions while those technologies are in fact not always readily available today. **There is an urgent need to re-integrate research about Advanced Enabling Technologies for Healthcare in Horizon Europe and promote innovative biomaterials and biosensors in collaborative projects.**

### Recommendation 2. Create a Bridging instrument for Short, Fast and Innovation Kick-starting Projects with SMEs

RTOs support SMEs thanks to their capabilities and expertise to deliver innovative prototypes ready to go through medical product certification, coupled with understanding of markets, scaling-up, industrialization, and reimbursement policies. **The current structure of Horizon Europe does not facilitate the engagement of healthcare SMEs together with RTOs to kick-start innovation pathways. There are clear discontinuities between existing funding instruments for health research programmes that hinder SMEs and start-ups to engage with RTOs in Europe.**

Those barriers to RTOs-SMEs collaboration in healthcare are namely around three activities:

- The initial technical feasibilities cannot get started without investing into a 3-year project while you only need a 1 year-project,
- The short feasibility studies to assess a new device/solution, including healthy volunteers,
- The clinical studies to retarget existing technology (e.g., 12-18 months projects).

**SMEs expect lean, focused, rapid projects to de-risk or generate concrete added-valued data in a short time frame. In this context, EARTO WG Healthcare advocates to introduce a new bridging type of projects to target Healthcare SMEs with smaller budgets (500k€ to 1.5M€) and minimum consortium of 2 parties (1 SME/start-up + 1 RPO).**

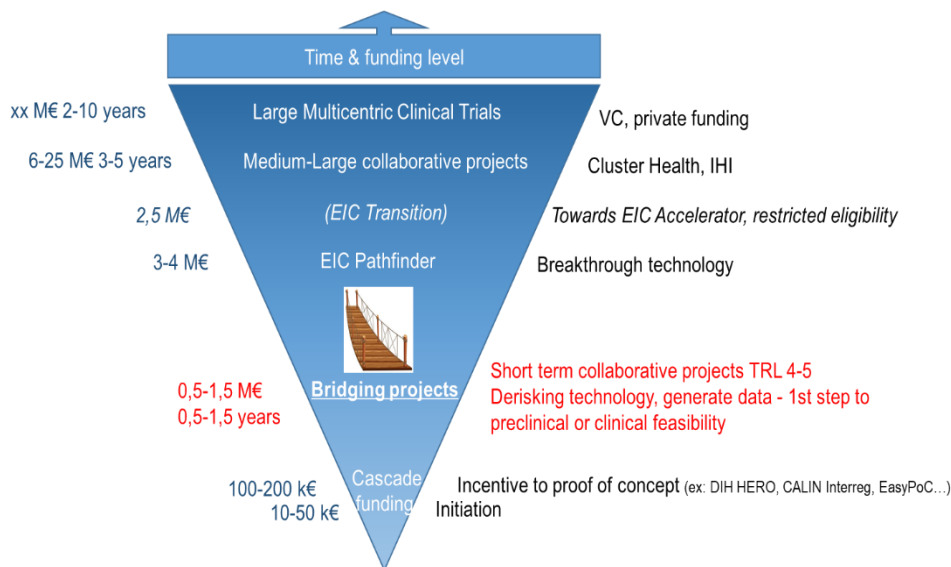
<sup>3</sup> See [The Guild's position paper](#): Health Priorities for challenge driven research in Horizon Europe, February 7 2023

<sup>4</sup> CL4-2022-RESILIENCE-01-13 Smart and multifunctional biomaterials for health innovations (RIA) **7%** success rate

<sup>5</sup> Examples: Biocompatible encapsulation for ATMPs, packaging technologies with sensory access, multi-biosensing for non-obtrusive wearables for longitudinal monitoring, in-line and real time control of biomedicines manufacturing.

The figure 1 below illustrates the missing link between incentives (cascade funding) and collaborative funding, particularly important for healthcare RD&I with SMEs.

**Figure 1: A new bridging instrument for short-term de-risking projects.**



Such a new SMEs targeting instrument could be used as a predecessor to **de-risk and generate initial data** before applying for e.g. an EIC Pathfinder or Pillar 2 Clusters' usual RIA or IA projects. It could also fund a follow-up project after successful completion of an EIC Pathfinder or within Clusters: focusing then mainly on validating the developed technology in a moderate clinical study. These bridging instruments could just be smaller versions of EIC Pathfinder or RIA projects<sup>6</sup>. Importantly, they should allow **cross-border cooperation** between SMEs/start-ups in one country and a RPO in another country (RTOs in particular are used to overcome their R&D capabilities across Europe). Ideally, a granted, and successful bridging project would be recognized as a plus to enter a follow-up instrument, like the US government phased projects like in the well-known SBIR or STTR programmes. A **consistent cascade of funding instruments with clear decision points (phase 0 proposal, phase 1 proposal, ...)** would reduce administrative overhead, facilitate SMEs and start-ups participation and in turn increase SMEs-RPOs collaboration, key for scaling-up matured technologies.

EARTO WG Healthcare recommends **launching a Coordination and Support Action (CSA) under Horizon Europe to evaluate discontinuities and obstacles for healthcare SMEs to participate to the current EU health programmes**. This CSA could therefore propose complementary instruments learning from the good practices experimented by RTOs in Europe about short and reactive projects (Interreg CALIN network, DIH HERO, Proof of Concept projects in Auvergne Rhone Alpes, etc.). Such CSA could then also recommend actions to better connect existing technology infrastructures and pilot lines managed by RTOs and TUs of interest for the healthcare sector.

### Recommendation 3. Increase the impact of EIC Transition in Healthcare

EARTO WG Healthcare members acknowledge the attention paid to medical devices and biotech topics in European Innovation Council (EIC). **For the healthcare sector, the transition phase covered by the EIC Transition instrument is mandatory and should clearly be better funded under the EIC**. Indeed, the EIC Transition part in the EIC total budget is very limited: both in funding allocated to the project (max 2,5 M€) and as a total budget (128 M€ i.e. only 8% of EIC total budget in 2023). In line with previous position on the EIC, EARTO recommends increasing the budget for Transition projects in the next Strategic Planning 2025-27 within the EIC current budget. Many EARTO WG Healthcare Members have contributed to the successes in EIC Accelerator thanks to their long-lasting cooperation (e.g. BRAINHERO with AIT, INVIVO BIONICS with SINTEF, BIOMENSIO and DESENTUM with VTT).

In addition to budget issues, eligibility requirements under the Transition Instrument is limiting current participation: **the eligibility criterium to enter the EIC Transition linked to using previous EU funded RD&I is too limiting today (i.e. attached to the budget issue, to limit oversubscription)**.

<sup>6</sup> The partnership EIT Health, during its first years of activity had experienced this model of short projects, market oriented, SMEs based, aimed at a realistic implementation in clinical settings through the CIMIT scale.

The bridging instruments proposed as #2 should be added, as these projects are valuable to de-risk and generate initial data. Additionally, there are excellent proof of concepts projects funded by national programmes, which are not in the pipeline defined by EIC.

Furthermore, EARTO WG Healthcare Members also identified limitations<sup>7</sup> in the other EIC instruments for tackling healthcare sector's challenges properly that should be looked at in the next Strategic Planning 2025-27. Especially, **EIC Pathfinder** projects in healthcare often integrate a wide range of maturity scales for the various required technology flavors (hardware, software, biotech, chemistry, materials, ...) and the biomedical application/demonstrator. Different criteria exist to judge technology (TRL) and clinical readiness (e.g., CIMIT<sup>8</sup>). Advancing to the same TRL on all components, system and achieving clinical readiness may not be feasible in the limited project duration while adhering to e.g. clinical study requirements. Some projects may primarily improve TRL while others improve other CIMIT maturity levels. Accordingly, **EARTO WG Healthcare advocates for the recognition of all maturity criteria during the evaluation process of EIC Pathfinder, to be better prepared to Transition, and for opening the eligibility criteria for the EIC Transition going hand in hand with a larger share of the EIC budget to be placed on the EIC Transition.**

#### **Recommendation 4. Better integrate Healthcare challenges in Pillar 2 - Cluster 4 - Digital, Industry and Space programme**

The Key Strategic Objective D of Horizon Europe is "*Creating a more resilient, inclusive and democratic European society, prepared and responsive to threats and disasters, addressing inequalities and providing high-quality healthcare, and empowering all citizens to act in the green and digital transitions*". However **in reality Objective D is not translated in topics addressing the stakeholders and providers of "High quality healthcare". Therefore Cluster 4 does not reach the healthcare sector and does not effectively target EU industrial leadership in medical devices, pharmaceuticals and biotechs.** This should be clearly improved, through the destination 2 - Increased Autonomy in Key Strategic Value Chains for Resilient Industry) or the destination 4 - Digital & Emerging Technologies for Competitiveness. Examples of topics to be considered are biomaterials for drug delivery, for smart wearable or implantable devices, biophotonics and medical applications, healthcare robotics, assistive technologies, educational technologies for healthcare workforce, etc. **Human well-being, healthy living and ageing, resilience of healthcare industry (reconfigurable manufacturing for instance) are essential challenges that should be dealt by cluster 4.**

#### **Recommendation 5. Improve Coordination between Horizon Europe, Digital Europe and EU4Health programmes**

There are significant efforts in **Digital Europe** programme to define health data infrastructures and promote a better access to good quality health data for secondary use. Access to health data being a major obstacle for many projects in Horizon Europe, EARTO WG Healthcare acknowledges efforts made towards this goal. Additionally, in Digital Europe programme, the **Testing & Experimenting Facility (TEF) AI&Robotics for Healthcare** will offer dedicated services to companies to test and validate their developments in real clinical settings, including health data sets from hospitals warehouses, all to directly benefit healthcare SMEs. The **European Digital Innovation Hubs (DIHs)** are also expected to support SMEs in the healthcare sector. In parallel, the **EU4Health** programme has engaged actions towards the training/education of healthcare workforce, and launched/reinforced health research networks, that we expect open to innovative health solutions. There are many initiatives, platforms, networks maintained or created in EU4Health programme.

**How these various initiatives will interface with Horizon Europe current and future projects remains unclear. There is today a high risk for discontinuities, overlaps and gaps. EARTO WG Healthcare recommends setting up an Expert group to better liaise the different components of the various EU healthcare programmes** following the public health priorities already identified (Cancer, AMR, Infectious Diseases-One Health, Pandemic preparedness, Mental Health). Representatives of large and small industry as well as RPOs should be invited.

EARTO remains ready to provide additional input on each topic mentioned above: our experts in healthcare are available for further discussion with EU institutions to ensure a successful implementation of Health RD&I programmes and a proper preparation of FP10.

---

<sup>7</sup> EARTO members already noted their disappointment in the current running of the EIC, a much-awaited instrument for RTOs' deep-tech start-ups and technology oriented projects (see the [Joint Statement paper related to IP rules](#))

<sup>8</sup> <https://www.cimit.org/publications> "Navigating the Health Tech innovation Cycle"

---

**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 150,000 highly-skilled researchers and engineers managing a wide range of innovation infrastructures.

**RTOs - Research and Technology Organisations**

From the lab to your everyday life. RTOs innovate to improve your health and well-being, your safety and security, your mobility and connectivity. RTOs' technologies cover all scientific fields. Their work ranges from basic research to new products and services' development. RTOs are non-profit organisations whose core mission is to produce, combine and bridge various types of knowledge, skills and infrastructures to deliver a range of research and development activities in collaboration with public and industrial partners of all sizes. These activities aim to result in technological and social innovations and system solutions that contribute to and mutually reinforce their economic, societal and policy impacts.

**EARTO Working Group Emerging Technologies for Healthcare:** the WG is composed of 100 experts coming from 37 RTOs in 18 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 healthtech. 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, but also about the specific role of RTOs in Institutionalised Partnerships such as Innovative Health Initiative.

**EARTO Contact:** [www.earto.eu](http://www.earto.eu)