

Accelerating the Digitization and Market Access of Emerging Technologies for Healthcare - The Pivotal Role of RTOs

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Background

The healthcare market (pharmaceuticals, biotech products, medical devices) is the third largest industrial sector in Europe with an annual turnover of €358bn euros per year¹, right after transport and ICT sectors². The medical technologies³ (medtech) sector represents an annual production of €110bn i.e. the triple of the European semiconductor market⁴, mostly composed of SMEs (27.000, representing 95% of the sector) and employs more than 675.000 people. It covers a wide range of products and applications, which remain fragmented and operated mostly by SMEs or even very small enterprises. Although constrained by a growing request for cost containment in public healthcare systems, this sector is constantly innovating on technologies and business models, growing at a pace of 6% per year with an average R&D intensity of 6% of annual revenue.

In addition of being a European strategic economic asset, the medtech sector is an inestimable provider of preventive and personalised solutions in diagnosing, monitoring, assessing predispositions, and treating patients. Digitally-enabled medical technologies transform health care delivery outcomes, across the care continuum, to answer to the growing financial pressure on healthcare systems.

In view of the preparation of the next EU Framework Programme Horizon Europe as well as the EU Digital Europe Programme, the EARTO Working Group Emerging Technologies for Healthcare hereby would like to present the key role of RTOs in the medtech sector through four policy recommendations. It shows the specific contribution of RTOs in medtech and healthcare sectors: how RTOs help to build a more sustainable and equitable healthcare delivery for European citizens and how RTOs contribute to the transformation towards digital healthcare.

RTOs are incubators of talents for medtech companies

RTOs have provided breakthrough solutions for several decades in medical technology. Well-known examples are: the detectors for medical imaging of the CEA-LETI, the ophthalmologic biomaterials of CIDETEC, the photonic biosensors of TNO (spin-off Delta Diagnostics), the microfluidic devices for *in vitro* diagnostics of SINTEF (spin-off Spinchip), the brain imaging analytics of VTT (spin off Combinostics).

RTOs also lead the development of innovation hubs⁵: RTOs act as key transducers at the local/regional level between academic research and companies, connecting start-ups and SMEs to multinational companies, providing access to world-class level technological infrastructures, facilitating contacts with public and private investors, working with clinical centers and health professionals or educating technical staff. RTOs have a significant regional footprint in serving medtech SMEs and start-ups, through dedicated services offers. The Hub4AIM in France, the PIME in Catalonia, the Basque Cluster, the Norway Health Tech in Oslo are good examples of such innovation hubs supported by a key RTO.

Today, the medtech sector is facing three major challenges: digitization, sustainability of healthcare systems and new EU regulatory framework. More than ever RTOs help reducing the risks associated with this transition. EARTO's Working Group Emerging Technologies for Healthcare hereby provides **4 recommendations** to take advantage of associated opportunities.

¹ [The 2017 EU Industrial R&D Investment Scoreboard](#), European Commission, JRC/DG RTD. Pharmaceuticals + biotech sector counts for €248bn, medtech for €110bn (2016 figures).

² See *ibid*, Automobile and transport sector €967bn, ICT sector €516bn (2016 figures).

³ Medical technology or medical devices are products intended to perform a therapeutic or diagnostic action on human beings by physical means. It includes *in-vitro* medical devices - products which provide medically useful diagnostic information by examination of a specimen derived from the human body (source Medtech Europe).

⁴ €34bn in 2017, source [ESIA](#).

⁵ EARTO position paper [European Innovation Hubs: An Ecosystem Approach to Accelerate the Uptake of Innovation in Key Enabling Technologies, 23 February 2018](#).

Recommendation 1: Maturation of health technologies (from research to proof of concept ready for clinical studies) is a risky process, RTOs should receive special incentives to accelerate market access

RTOs have strong partnerships with health professionals, and this is mainly based on volunteering and good relationships. There are few dedicated funding instruments, at regional, national or European levels, to encourage such collaboration from KETs research and integration to regulatory approval and clinical studies. This is a long and risky process, and excellent solutions developed by RTOs, their spin-off, or their industrial partners, have been lost by a limited investment to go from the TRL4 to the TRL7. Medical progress and patient benefits are therefore hampered by the lack of coherence between risks assumed by RTOs and their industry partners and the level of exigence required by regulation authorities, for a safe translation into clinics (which are both much higher than in other industrial value chain).

In addition, entering in clinical studies will require much more efforts than in the past. A traditional translational medicine approach is not valid anymore for medtech innovation.

RTOs should receive financial incentives to mitigate risks associated with the TRL7 target: working as early as possible with health professionals and patients (human factors design), gaining expertise about regulatory approval, health technology assessment (HTA) and advanced manufacturing.

Recommendation 2: Support KETs (Key Enabling Technologies) projects and infrastructures to answer to the needs of innovative medtech SMEs

RTOs are at the forefront of KETs development thanks to their tight link to academia. They act as nodes towards SMEs and industry translate academic knowledge and expertise into innovative products. The medtech sector rarely develops its own key technologies, but rather uses technologies already developed by other sectors⁶. The medtech companies usually assemble existing technologies, optimise them for medical use, manufacture them and perform clinical, and regulatory approval to deliver them to the market. A genuine core service provided by RTOs is their ability to implement KETs in innovative solutions and facilitate their incorporation by companies, especially SMEs. It is RTOs' *raison d'être*: many SMEs in Europe trust their professional expertise to help research, development, and the first steps of industrialisation.

RTOs working on applied research have established specialized infrastructures⁷ for upscaling and manufacturing of KETs, as well as characterization and testing. These technology infrastructures are dedicated to support the development of new medical devices from the early development phase up to validation including regulation acceptance. Prototyping, manufacturing, characterization, testing (*in vitro* and *in vivo*), safety and clinical testing are well connected in order to reduce time to market and to generate robust data and clinical evidence.

KETs projects and technology infrastructures are critical to medtech industry: new equipment and capabilities, combined with specialized interdisciplinary teams capable to move faster from proof of concept to clinical validations are essential for a strong and innovative industry in Europe. Therefore, **a clear support to KETs integration projects in collaboration with medtech companies is necessary.**

Recommendation 3: Digital Europe initiatives for Healthcare should focus on security/reliability/availability of medical data

Health data are generated by all kind of sensors and measures performed by medical devices. Health data is considered as a critical resource to improve the whole healthcare cycle (from risk factors to diagnosis and treatment). EU RD&I funding programmes should pay attention to data acquired and processed at the sensor level. RTOs have a strong expertise developed for years through several EU funded programmes⁸. Sensing signals and biological parameters, formatting

⁶ For instance materials, microelectronics, photonics, nanoelectronics, miniaturised energy storage, etc.

⁷ i.e. a pilot plant operating under GMP for the manufacturing of nanopharmaceuticals at CIDETEC.

⁸ See in particular the MNBS (micro-nano-bio-info technologies for integrated systems) programme: 39 projects and a total funding of 180 M€ in FP7 and H2020 (source A. Lymberis, DG CONNECT).

and pre-processing data issued from human behaviour and human body function is not easy. Digital health initiatives should not forget these very first conditions of healthcare digitisation, which are crucial for the enhancement of healthcare services provided (diagnosis, treatment etc.), and the containment of healthcare costs.

RTOs should be supported in their efforts to increase security, reliability and availability of healthcare data:

- Data acquired by sensors,
- Data processing,
- Data aggregation,
- Cybersecurity,
- Interoperability.

Artificial intelligence, big data, cybersecurity, etc. are domains that require advanced digital skills. By their connections to digital technologies in other sectors (see recommendation 1), RTOs are at the core of Digital Europe programme ambitions.

Recommendation 4: Connecting Innovation Regional Hubs in health technologies would increase RTOs impact

RTOs act as central players in healthcare technologies' innovation process at regional, national and European scale. They develop and integrate KETs in smart medtech systems, cooperate with clinical centers to design and validate a product, test the medical devices before the CE marking, support industries on their industrialisation pathway and therefore increase chances of a positive assessment by regulation agencies. Europe has a specific general regulatory framework recently upgraded but the healthcare systems refer mainly to national policies. In this context, RTOs act as local guides for foreign companies to support them adapt their technologies or devices to local safety, regulatory or pricing rules.

RTOs connect their industrial partners to many stakeholders in their regional and national environment, including funding aspects for innovative companies⁹. Some of them can also include clinical dedicated infrastructures (CEA-LETI/Clinattec), living labs (IMEC, LEITAT), specific facilities for human interventional studies (Eurecat Reus), or dedicated platforms at the hospital (IMEC with KU Leuven, Tyndall with UCC Cork). The local feature is particularly important since patients and healthy volunteers stay close of their clinical and care environment.

Connecting these regional specificities and assets would clearly reinforce the European attractiveness for global medtech companies, as well as streamline Union's efforts for health innovation.

EARTO remains of course ready to further discuss these recommendations with the European Institutions' representatives.

Note to the reader:

EARTO - European Association of Research and Technology Organisations

Founded in 1999, EARTO promotes Research and Technology Organisations and represents their interest in Europe. EARTO network counts over 350 RTOs in more than 20 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 with public missions to support society. To do so, they closely cooperate with industries, large and small, as well as a wide array of public actors.

EARTO Working Group Emerging Technologies for Healthcare is composed of 40 EU Affairs Specialists working within our membership.

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⁹ RTOs already work in mix-funding schemes (FP, ERDF, national and regional grants, charities, industry).