January 18, 2017

Comment to the DEI WG2 1. Report

A contribution from ESTHER, the Industry Driven Initiative on Emerging and Strategic Technologies for Healthcare

A **paradigm shift** currently taking place in healthcare from symptomatic treatment of (acute) diseases by blockbusters towards Predictive, Preventive, Personalized, Participatory and Precision medicine will offer new opportunities for patients and the healthcare systems in Europe.

One example to illustrate the new possibilities but also the complexity of the new medical options are **smart wearable or implantable devices** for providing therapeutic treatments and monitoring their effect. For example, in cardiac rhythm management or neuromodulation, beyond existing products, integrated solutions are needed, which can sense various electrophysiological stimuli, biomarkers or other health indicators (dehydration, stress, BMI, muscle fatigue, balance etc.) as well as the therapeutic products themselves. Integrated signal processing algorithms will be needed to monitor and alert for significant physiological changes as a means of monitoring disease, as well as providing feedback on the efficacy of a treatment programme. These systems will communicate with relevant electronic medical record (EMR) systems and prompt action by healthcare professionals as applicable based on sophisticated algorithms designed to identify patterns or ranges of concern (i.e. using data analysis and IT communication tools to inform unambiguously clinical decision protocols). These smart wearable and implantable systems will therefore require multi-Key Enabling Technologies (KET) capabilities, involving integration of micro- and nanoelectronics, microsystems, photonics, likely including integrated circuits for miniaturisation and power efficiency, energy harvesting and storage technology, advanced sensors, embedded software for signal processing, safe and secure RFID and wireless connectivity, data encryption, and communication to EMR system. They will also require biocompatible packaging (advanced materials) and encapsulation, and need to combine precision engineering and electronic/photonic assembly.

Such developments are driven by the convergence **of Key Enabling Technologies (KETs)** namely nanotechnologies, advanced materials, micro/nano electronics, photonics, biotechnologies, and advanced manufacturing in combination with **IT and digital technologies,** which will increasingly connect all healthcare sectors and technologies. The marriage of multi-KETs smart medical devices with the Digital Single Market will create **new industrial platforms for healthcare** characterized by **a profound transition** in the coming years towards a more collaborative approach of the healthcare industries, namely Pharma, Medtech, IVD, Biotech and Digital Medicine.

To establish such new platforms able to master the described complexity of the new smart and connected medical solutions, it is necessary to provide an interface between largely disconnected **multibillion euros industries** that have very different innovation processes and time frames to work and share technologies together. For example, Medtech is very different from Pharma by the much shorter life cycle of its products, of about 3-5 years vs 10-15 years in Pharma. These differences not only create big challenges for the involved industries but also for the related scientific R&D communities, especially SMEs, which will mainly provide the multi-KETs innovations needed for the digitisation of healthcare.

The **Medtech industry** has a central role in setting up the new healthcare platforms, since it will not only develop the devices and In-Vitro Diagnostic (IVD) systems ready for integration of digital and IT features of smart and connected medical systems for more personalised diagnostics, but also the

delivery systems for the targeted therapeutic approaches developed by the Pharma industry (e. g. Companion products). Due to this central role, the Medtech and IVD industry represented by MedTech Europe has launched an initiative together with the European Commission represented by DG RTD in 2015 called ESTHER.

ESTHER stands for "Emerging and strategic technologies for Healthcare" and represents a European stakeholder platform aiming at:

- **Interfacing different science and technology** communities to define and agree on cross-KET R&D topics suitable to be integrated with digital components to assemble smart and connected devices and applications
- **aligning the R&D topics** with industrial strategies and clinical and digital needs
- **interfacing different industries** to create new business models and value chains (pharma, medtech, IVD, IT and electronics companies)
- **supporting SMEs** as drivers of innovation in medtech (95% of medtech companies are SMEs)
- **sensitising regulators and HTA agencies** for new smart and connected applications
- **training users** (doctors, patients, other care providers) to cope with digital healthcare

The ESTHER stakeholders have already defined a **holistic concept** from R&D to market access with concrete actions to overpass the silos of technologies (in ETPs), of business models and of industries (Pharma, medtech, Imaging, e-Health), and to interface EU-, national or regional initiatives. Due to the key role of the European Commission in organizing and funding the cross-KET digitization of healthcare DG RTD, DG GROW, DG CONNECT, DG REGIO, DG SANTE have contributed and support the ESTHER concept as well as other European organisations like EIB which are also key players in this ecosystem.

The ESTHER concept is currently being tested at small scale by bridging stakeholders all along the value chain.

Initiated actions are:

- Joint meetings of complementary key enabling technology platforms represented by: ETPN (nanomedicine), EPOSS (Integrated Systems), Photonics21, EuMAT (materials), ESB (biomaterials), EuTextile, and SPARCS (robotics).
- Collection of input and support for the ESTHER concept from industry associations such as Medtech-Europe, EFPIA and COCIR.
- Organization of several meetings and a concept paper of relevant European regions, like the 17 members of the ESTHER-Vanguard-Initiative network of regions.
- Invitation to Key Opinion Leaders identifying the unmet clinical needs represented by UEMS and public hospitals represented by their public procurers in innovation to join a new working group of ESTHER.

Specific activities proposed in the concepts which could help to implement the Vision:

1. Establish a platform for all relevant stakeholders to

- define a **Strategic Research and Innovation Agenda (SRIA)** for smart connected Medtech systems as a basis for coherent public and private funding opportunities

- **facilitate the cross-technology and cross-industry networking** to develop new products and solutions through collaborative projects
- **increase the budget and adapt financial tools available** at the European, national or even regional levels, for co-funding product development along the complete value chains for the MedTech sector (TRL 1-7), and make information about the different funding instruments available for all MedTech actors
- **define new cross-industry business models** for cross-cutting technology solutions (TRL 8-9)
- **promote definition of User Requirement Specifications** and **Target Product Profiles** for developing new products (procurement)
- **initiate update of clinical care protocols** for appropriate diagnosis, treatment and follow-up of patients
- establish a **dialogue** based on studies of the impact of changing regulation systems on economic success and availability of new products for patients **with regulators**, Health Technology Assessment agencies, payers and patients, to jointly define **methods for value-based technology evaluations and reimbursement models**
- define **technology and safety standards** for the new smart and connected medical products and implement European standards at the global scale
- discuss and handle the **socioeconomic impact of cross-KETs smart medical products** on the transitions in the healthcare system by conducting **post-market research** showing the value of smart medical solutions for patients and the healthcare system in Europe and abroad
- provide **training** of young scientists and employees on cross-KETS and regulation issues through various initiatives including international networks and Marie Curie programs

2. Specific support for SMEs representing more than 90 % of the MedTech companies by

- providing **information and guidance** on the regulatory and market access requirements for new products in a changing regulatory environment in Europe
- upgrading and interfacing **regional clusters** embracing cross-KETs R&D centres, technology providers and companies needed to develop complex connected smart medical devices
- **benchmarking MedTech markets and regulations** in the main regions of the world to support and accelerate export activities of European companies

All relevant stakeholder groups have been approached by ESTHER Task Force in the past 18 months in order to establish step by step a coherent initiative to support the development of smart medical technologies. By building on the commitment of these stakeholders and by implementing the holistic concept the ESTHER initiative can help to accelerate the implementation of digital and cross-KETs smart and connected medical technologies in Europe.

Contacts :

- Patrick BOISSEAU, Coordinator of ESTHER Task Force, patrick.boisseau@cea.fr
- Klaus-Michael WELTRING, main author, Member of ESTHER Task Force, weltring@bioanalytik-muenster.de
- Serge BERNASCONI, CEO, Medtech-Europe, s.bernasconi@medtecheurope.org