Sustainable and Equitable Health Systems for Healthier EU Citizens

Enabling healthcare transformation through integrated and digitally-driven medical technology[(1)] solutions

Executive Summary

One of the most pressing social and economic challenges for Europe is maintaining a **sustainable and equitable health care for all citizens.** Medical technologies[1] can provide solutions to address these challenges. Public-private cooperation will be required in the next European Framework Programme for Research and Innovation to successfully enable the following actions:

- Advance **patient-centric, integrated and holistic** healthcare solutions to serve the full continuum of care;

- Develop and integrate the **full potential of digital health** into care models through connecting devices, managing data from gathering to analysis and correlation, and adapting artificial intelligence (AI), new protocols and innovative digital technologies;

- Speed up the **development of key enabling technologies** (KETs[2]) as **well as molecular technologies and next generation sequencing (NGS),** which build the basis for many innovative medical devices and *in vitro* diagnostic tests;

Actions along the innovation chain, from research and development until approval, uptake and funding by national healthcare systems, will need to overcome silos in organisations and be developed together with all stakeholders in health care. Coordination and joint investments will be required in the areas of infrastructure, education and training programmes, clinical research, care delivery, health system management, competitiveness of SMEs, funding models, adaptation of regulation, and innovative public procurement.

For medical technologies to support the transformation of healthcare systems in Europe, the following framework conditions are critical to deliver success:

- Development and adoption of holistic **value-based assessment models** for medical technologies;

- Induction of **reforms in health system management and medical practices** to enable healthcare systems to fully leverage the benefits of investments in innovative medical technologies;

- Creation and adoption of innovative, more collaborative, inclusive and **outcome-based funding and reimbursement models** to reward innovation and the value of medical technologies;

- Support to medical technology innovators for handling the increasingly complex and challenging translation of **innovations from benches and labs all the way to citizens, patients, caregivers and healthcare systems.**

By addressing the above-mentioned conditions, innovative and integrated medical technology solutions will enable the needed transformation of healthcare in Europe. Developments such as new markers for diagnosis of diseases, individualized/precision medicine, smart hospitals, remote monitoring, home care, solutions for both infectious (including Antimicrobial Resistance / Healthcare Associated Infections) and non-communicable disease prevention and treatment will contribute to deliver sustainable and equitable health and wellbeing for all EU citizens.

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[1] Medical Technologies include: *in vitro* diagnostics, in vivo diagnostics, hospital equipment, home care, imaging, medical devices and digital health

[2] KETs include: advanced materials and nanotechnology, photonics and micro-/nano-electronics, Life Sciences technologies, artificial intelligence, digital security and connectivity.

Sustainable and Equitable Health Systems for Healthier EU Citizens

Enabling healthcare transformation through integrated and digitally driven medical technology[3] solutions

A.   A bold, inspirational mission with wide societal impact

Although health and wellbeing are regarded as precious values by European citizens, maintaining a **sustainable and equitable health care for all citizens** remains one of the most pressing social and economic challenges for Europe.

Healthcare systems in Europe face growing challenges including:

- The increasing cost of healthcare;
- An ageing population associated with a rise in non-communicable diseases and comorbidities;
- A threatening increase of Antimicrobial Resistance (AMR);
- Emerging infectious diseases outbreaks;
- Shortage and uneven distribution of experienced health professionals;
- Fragmented healthcare approach;
- Inequalities in access to healthcare.

Simultaneously, massive progress in science and technology, based on significant advances in the analysis of the genetic, physiological, environmental and social background of each patient, enables the needed disruptive changes in healthcare delivery including disease prevention and personalized healthcare.

New medical technologies associated to digitization are becoming a major game changer in healthcare. The development of the Internet of Things, artificial intelligence, blockchain, learning algorithms, electronic health records, connected health technologies and "big data" will allow to precisely determine the cause and monitor the progress of a disease at a much earlier state. It will permit to treat diseases in a more targeted, integrated and efficient way. It will create opportunities for new & effective rehabilitation and for exploiting the potential of homecare solutions. Consequently, **health care becomes part of the continuum of life instead of a temporary management of patients during an episode of care.**

Unlocking the potential of digital healthcare for all European citizens highly depends on the **convergence of digitization with Key Enabling Technologies (KETs[4]), as well as molecular technologies, and next-generation sequencing (NGS).** Medical technology solutions drive this integration naturally as they have a history of integrating a large variety of KETs, such as nano and bio technologies, electronics, photonics, ICT, manufacturing, advanced materials.

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This integration enables the development of digitized smart and connected devices that further advances diagnosis, monitoring, drug delivery, treatment and rehabilitation.

Despite the potential of digitization and technology integration, **Europe is in danger of lagging behind in the global innovation race** thus losing control of the needed healthcare transformation. US companies such as Google or Amazon have already started collaboration with medical technology companies to integrate their large data pools with medical data ("digital" markers). Europe has both the excellent fundamental science and a vibrant innovative medical technology industry but it needs support to get back on the top of the digitization wave with European solutions and standards.

B. A clear research and innovation agenda with timed and measurable objectives and targeted actions

B.1. A clear research and innovation agenda

Medical technologies can provide solutions to address the challenges of delivering sustainable and equitable health and wellbeing to EU citizens. Public-private cooperation in the next European Framework Programme for Research and Innovation will be required to successfully enable the following actions:

- Advance **patient centric, integrated and holistic** healthcare solutions to serve the full continuum of care;

- Develop and integrate the **full potential of digital health** into care models through connecting devices, managing data from gathering to analysis and correlation, adapting artificial intelligence, new protocols and innovative digital technologies;

- Speed up the **development of key enabling technologies** (KETs) as well as **artificial intelligence, molecular technologies and next generation sequencing,** which build the basis for many innovative medical devices and *in vitro* diagnostic tests;

B.2. Timed and measurable objectives

Measuring impact will only be possible if European healthcare statistics provided by Eurostat are tailored to the corresponding objectives. For instance, impact could be measured through the following economic and social indicators:

- Within twenty (20) years, a stable or decreasing ratio of healthcare expenditure/GDP in Europe, without significant difference between countries;

- Within fifteen (15) years, in Europe, 1000 innovative solutions developed that drive better patient and system outcomes ;

- Within ten years (10), in Europe, 300 new start-ups and SMEs in the health technology sector that commercialize products and services for sustainable healthcare and well-being;

- Within five years (5), ten pilot territories for equitable access to these solutions thanks to digital convergence, and added medical technology value generated at a local level;

- By 2027, reduction in Antimicrobial Resistance (AMR), Health-care Associated Infections (HAI), as well as cancer and other chronic diseases.

B.3. Targeted Research and Innovation actions

Collaboration and feedback loops between basic research (e.g. new markers, artificial organs), applied research (e.g. rapid diagnostic tools), and social, entrepreneurial innovation (such as incorporating patient self-treatment and preventive habits in the care cycle) will be essential. Such knowledge-based research and innovation should work in conjunction with regulatory and governance actions to see that the mission target is reached.

The following suggestions would have a global impact if implemented simultaneously and in a coordinated manner:

- Invest in science for research into new technologies and discovery of new biomarkers;

- Improve research capacities through collaboration between European researchers (doctoral and post-doctoral students) and the medical technology industry;

- Support competitiveness of the European medical technology sector, especially SMEs, through accelerating late-stage product development and market access (European Innovation Council);

- De-risk medical technology product development through the European Investment Bank's instruments;

- Co-fund research to develop universally accepted methodologies and processes to demonstrate the value of innovative medical technology solutions for patients and healthcare systems;

- Encourage public-private partnerships between medical technology and digital industries, clinicians, research organisations, regulatory bodies and patients to develop tools adapted to the needs;

- Support implementation, health system and behavioral research necessary for the uptake of innovative tools;

- Support research and adoption of innovative procurement for medical technology innovations.

Since the innovation cycle for new medical technologies is relatively short (12-36 months), considerable results can be expected by the end of FP9.

B.4. Critical success factors to solve

For medical technologies to support the transformation of healthcare systems in Europe, the following framework conditions are critical to address in order to deliver success:

- Development and adoption of holistic **value-based assessment models** for medical technologies;

- Induction of **reforms in health system management and medical practices** to enable healthcare systems to fully leverage the benefits of investments in innovative medical technologies;

- Creation and adoption of innovative, more collaborative, inclusive and **outcome-based funding and reimbursement models** to reward innovation and the value of medical technologies;

- Support to medical technology innovators for handling the increasingly complex and challenging translation of **innovations from benches and labs all the way to citizens/patients**, caregivers and healthcare systems.

By addressing the above-mentioned conditions, innovative and integrated medical technology solutions will enable the needed transformation of healthcare in Europe. Developments such as new markers for diagnosis of diseases, individualized/precision medicine, smart hospitals of the future, remote monitoring, home care, solutions for both infectious (including AMR/HAI) and non-communicable diseases, will contribute in delivering sustainable and equitable health and wellbeing for all EU citizens.

C. Cross-disciplinary, cross-sectoral and cross-actor innovation to develop bottom- up solutions

Implementing the mission will require an integral approach to master the multi-layered challenges ahead. To create maximum impact, it should ensure a fertile and inspiring ecosystem with a continuum of funding systems all along the new cross-technology and cross-industry value chains from research until it reaches patients and healthcare systems. Its implementation should overcome silos in administration, industry, organizations, Member States and it should propose a holistic and inclusive approach with all stakeholders.

An initial comprehensive set of proposals to address the related technological, economic and social questions of the mission have been worked out by the **medical technology industry driven initiative ESTHER**, which was initiated by the European Commission and MedTech Europe in May 2015. The ESTHER task force has formulated a holistic concept based on the inclusion and consent of all stakeholders such as patients, clinicians, industry, healthcare providers, regulators, payers, the EU and Member States administrations and the society at large.

About MedTech Europe

MedTech Europe is the European trade association representing the medical technology industries, from diagnosis to cure. Our members are companies involved in researching, developing and distributing innovative medical solutions in *in vitro* diagnostics, in vivo diagnostics, monitoring, medical devices including hospital equipment and home care solutions, as well as digital health. Also, over 35 national medical technology associations operating in Europe and worldwide are members of MedTech Europe.

There are more than 500,000 medical technology products, 50,000 *in vitro* diagnostics tests, services and solutions currently made available by the medical technology industry and used every day by patients, healthcare professionals, hospitals, rehabilitation centres and in homecare. These range from disease screening tests, AMR testing, pregnancy tests, glucose monitors, bandages, mechanical beds, surgery equipment, hearing implants , pacemakers, artificial hips, surgical robots, scanners, and MRIs.

The Medical Technology industry is research and innovation-driven and is the #1 industry in filing patent applications (20% more than the ICT industry and double that of the pharmaceutical industry).

The medical technology industry is a strong and dynamic contributor to the economic development in Europe as it generates annually over € 120 billion of activity, employs more than 675,000 people through a network of more than 27,000 medical technology companies, of which 95% are SMEs.

About ESTHER

ESTHER is an Industry Driven Initiative on Emerging and Smart Technologies for Healthcare, jointly initiated by the European Commission, MedTech Europe and ETP-Nanomedicine in May 2015. It brings together stakeholders from industry (medical technology, imaging, and pharmaceuticals), regions and clusters, technology providers, and hospitals.

The objective of ESTHER is to accomplish the changes necessary to reduce health inequalities by making European healthcare systems sustainable and affordable for all European citizens regardless of their regional or social environment. ESTHER sets up a global and systemic approach of health technologies and healthcare, overcoming silos in organisations and implementing a large inclusiveness of stakeholders along the innovation chain of health technologies.

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 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.