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CENTER FOR THE GOVERNANCE OF CHANGE

# TECHNICAL ADVANCEMENTS AND PATHWAY INTEGRATION

Policy Brief
Center for the Governance of Change
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## EXECUTIVE SUMMARY

AI and digital technologies hold promise for a more efficient and effective care delivery. In order to maximise the potential of these emerging technologies and enable their effective integration into European healthcare systems, a concerted, multi-stakeholder effort is necessary, with a particular focus on:

**Pursuing need-oriented innovation** by identifying key areas of systemic need where high-impact innovative solutions can lead to meaningful change for patients and healthcare professionals.

**Increasing funding of innovative medical technologies** by reducing investment risk for private venture capital funds to support highly innovative early-stage ventures.

**Enabling early real-world testing** of post proof-of-concept digital products to allow for early user feedback and thus more effective product development.

**Democratising access to healthcare data** by nation-wide and pan-European initiatives aimed at data harmonisation and effective sharing of clinical data.

**Creating inclusive health technologies** by educating future healthcare professionals on tech innovation and entrepreneurship, and by prioritising and championing the role of patients in technology creation, testing, and implementation.

# DISCUSSION

**A diverse group of European stakeholders representing the medical profession, regulatory bodies, the pharmaceutical industry, innovative health tech businesses, research and policy organisations and academia, met on 11th November 2020 to discuss the regulatory and technical issues around Technical Advancements and Pathway Integration for AI in healthcare. Having considered the entirety of the care pathway, the discussants elucidated priority high-impact areas for short- to mid-term improvement and proposed the following actions:**

## 1. ACCELERATE TECHNOLOGY INNOVATION IN CRITICAL AREAS OF NEED

European healthcare systems currently underperform in a number of care delivery areas. Geographically, low-density, rural communities located away from urban centres have virtually no access to specialists, making the treatment of complex conditions extremely challenging. Consequently, such regions experience high logistical costs, care delivery inefficiencies, and—ultimately—poorer health outcomes compared to urban areas. Indication-wise, critical emergencies such as internal bleeding and haemorrhages constitute some of the major causes of death in A&E wards, as they need to be identified quickly and accurately, which not always can be achieved under current systems of work and using available tools.

**This introduces one question:**

HOW CAN AI-ENABLED TECHNOLOGIES IMPACT THESE CRITICAL AREAS WHERE WE CURRENTLY, SYSTEMATICALLY UNDERPERFORM?

**Solution: Need-oriented innovation**—one of the lessons Covid-19 taught us is that when we unify around a well-defined challenge, changes in legislation, perception and trust and dedicated investment can enable rapid implementation of emerging technologies to solve the pressing challenge.

**Actions to take:**

— Review the relative performance of healthcare providers—through national and pan-European initiatives—by systematically collecting and analysing data on care outcomes, cost-effectiveness, and patient satisfaction.

— At the national level, identify the main areas of need where healthcare systems currently underperform and underdeliver.

— At the local commissioning level, clearly define the associated challenges which, if solved, would represent high-impact interventions for care efficiency and outcomes.

## 2. FUND EARLY-STAGE MEDTECH INNOVATION

Despite numerous venture capital (VC) funds operating in Europe, early-stage medtech innovators—many of whom represent digital health ventures—struggle to finance their businesses. Due to its complexity, long development process and demanding regulatory environment, medtech poses significant risks many early-stage investors are unprepared to accept. In addition, compared to therapeutics, the medtech business models are often less obvious and the products often do not benefit from the same economies of scale.

While the Covid-19 pandemic has generally improved investors' interest in medtech, the trend is clear—most medtech investments are still made at later development stages, where the solution has been validated and market traction demonstrated. Crucially, however—without adequate financial support for early-stage health technologies, European science will struggle to translate into viable healthcare solutions.

**This introduces one question:**

### HOW TO SUPPORT EFFECTIVE INVESTMENT INTO EARLY-STAGE HEALTH TECHNOLOGIES?

**Solution: Problem-based funding—**developers seeking to solve challenges in the key areas of need should have easier access to funding. Goal-directed strategies can lead to quicker and more effective innovation in underperforming areas of healthcare.

**Actions to take:**

— Increase governmental support for provide VC vehicles to reduce private investors' risk in strategically important health technology areas.

— Explore how the Covid-19 Recovery Funds can be used to facilitate early technology testing in under-performing areas of healthcare.

— Strengthen the startup–academia integration to support joint research work by academia and early-stage start-ups working in priority areas.

## 3. ENABLE EARLY REAL-WORLD TESTING

At the core of success of AI-based and digital solutions, both on the practical and technical level, is the interaction with users—that is, patients and healthcare professionals. Through early interactions and feedback, users effectively co-create the solution helping both train the methods as well as optimise the interaction interface for maximum efficiency. Yet, currently, entry into the clinic is typically possible only after the product is registered and certified, with earlier clinical uses taking place within relatively narrow and highly controlled research environments.

For the identified key areas of need, a leaner access to testing is desperately needed. While early presence in the clinical practice facilitates collection of valuable complementary data and performance feedback, three different levels of safety must be ensured: (a) health safety, (b) data/privacy safety, and (c) digital exclusion. Once safety assurances are met, and given the strong potential of AI-driven technologies to improve care, the development and adoption of novel purpose-driven evidence generation models can follow.

**This introduces one question:**

### HOW TO SUPPORT EFFECTIVE INVESTMENT INTO EARLY-STAGE HEALTH TECHNOLOGIES?

**Solution: Adapting the concept of a clinical trial—** Real-world data (RWD), collected from diverse sources during routine clinical practice, complements trial safety and efficacy data with insights about technology performance in realistic scenarios of care across heterogeneous patient cohorts, measured against multiple standards of care. Digital health and AI have a role in enabling the RWD collection and analysis, e.g., through wearable biosensors and deep learning algorithms. However, these innovative technologies can also benefit from more agile licensing pathways.

**Actions to take:**

— Leverage digital technology to access patient-reported outcomes for real-world testing, improved quality of care, and better accountability.

— Ensure proofs-of-concept actually measure how healthcare professionals and patients engage with technology, to enable joint co-creation.

— Run local pilot programs, similar to the Medicines Adaptive Pathways to Patients programme, and seek success in specific areas and communities.

## 4. DEMOCRATISE HEALTHCARE DATA:

Presently, European medical data is organised in isolated silos, with datasets showing significant gaps in quality and lacking standardisation. While in the short-term AI and digital technologies have the highest potential to improve healthcare by driving care efficiency and decision accuracy, their success largely depends on the quality and accessibility of healthcare data. Firstly, data is essential for training of AI algorithms and predictive analytical models. Secondly, effective data gathering and dissemination is crucial to inform clinical practices, identify underperforming areas of practice, and detect risks ultimately to improve patient outcomes.

**This introduces one question:**

HOW TO ENSURE THE WEALTH OF EUROPEAN HEALTHCARE DATA IS USED RESPONSIBLY AND EFFECTIVELY TO ENABLE THE MUCH-NEEDED SUCCESS OF AI AND DIGITAL HEALTH TECHNOLOGIES?

**Solution: Cross-border data harmonisation—** Nation-wide and pan-European schemes aimed to harmonise and share effectively clinical data are needed to ensure clinical data is useful and accessible, while maintaining highest possible standards of patient privacy and data security. While national efforts are key for short-term local gains, these developments should support pan-European goals for highest possible impact.

**Actions to take:**

— Link national governmental funding supporting medical data generation and digitisation to data management implementation, specifying clearly data organisation and accessibility rules.

— Create incentives at the local level to pursue quality data management and sharing at the national level to improve accessibility.

— Implement actionable national guidelines on medical dataset organisation standards while harmonising data quality management frameworks across the EU.

## 5. CREATE INCLUSIVE HEALTH TECH:

Old habits, resistance to change, confidence in existing methods and skills, and general distrust toward novelty all contribute to slower-than-necessary uptake of innovative solutions to pressing healthcare problems.

**This introduces one question:**

### HOW TO RAISE AWARENESS OF THE POTENTIAL BENEFITS OF HEALTH TECHNOLOGY AND IMPROVE THE LEVELS OF USAGE AMONG CLINICIANS AND DECISION MAKERS?

**Solution: Education and patient engagement—** Despite the unquestionable role of technology innovation in the advancement of healthcare in the past several decades, medical education in Europe has generally not embraced innovation and entrepreneurship as core teaching elements. Raising awareness about innovative venture development as part of teaching courses as well as directly engaging patients in a process of co-creation can generate increased trust and adoption.

**Actions to take:**

— Include technology innovation as an obligatory element of medical education with a particular focus on entrepreneurship and product clinical development and testing.

— Support and engage charitable research organisations and patient groups for their active involvement in product testing, implementation, and system-level adoption of technologies.

— Work with patients as innovation partners and advocates for change to develop “safety platforms” enabling testing and implementation of novel care delivery tools.

# BACKGROUND

In the landmark June 2020 report *"Innovation, Sustainability, and the Future of Healthcare: How is AI reshaping healthcare in Europe"*, researchers from IE University's Centre for Governance of Change (CGC) discussed the future of the healthcare system in Europe, focusing on the integration of AI in the clinical practice *(Figure 1)*, and the policy challenges associated with it. The report identified key needs associated with the implementation of digital technologies, their growing impact on care delivery, and the collective actions necessary for widespread and effective adoption, which included the following:

— the need to improve care delivery pathways to respond effectively to the most demanding challenges posed by healthcare today,

— the requirement to innovate social and personal care as means of reducing the unsustainable economic burden of healthcare, and

— the requisite for European stakeholders to engage in a mature conversation to foster action while mitigating risks associated with technology adoption.

Building on the conclusions of the report, the Centre seeks to create a platform to enable critical conversations between relevant European stakeholders. Through a series of roundtable discussions, the Centre aims to build consensus, formulate attainable short-term objectives, and identify stakeholder-specific actions.

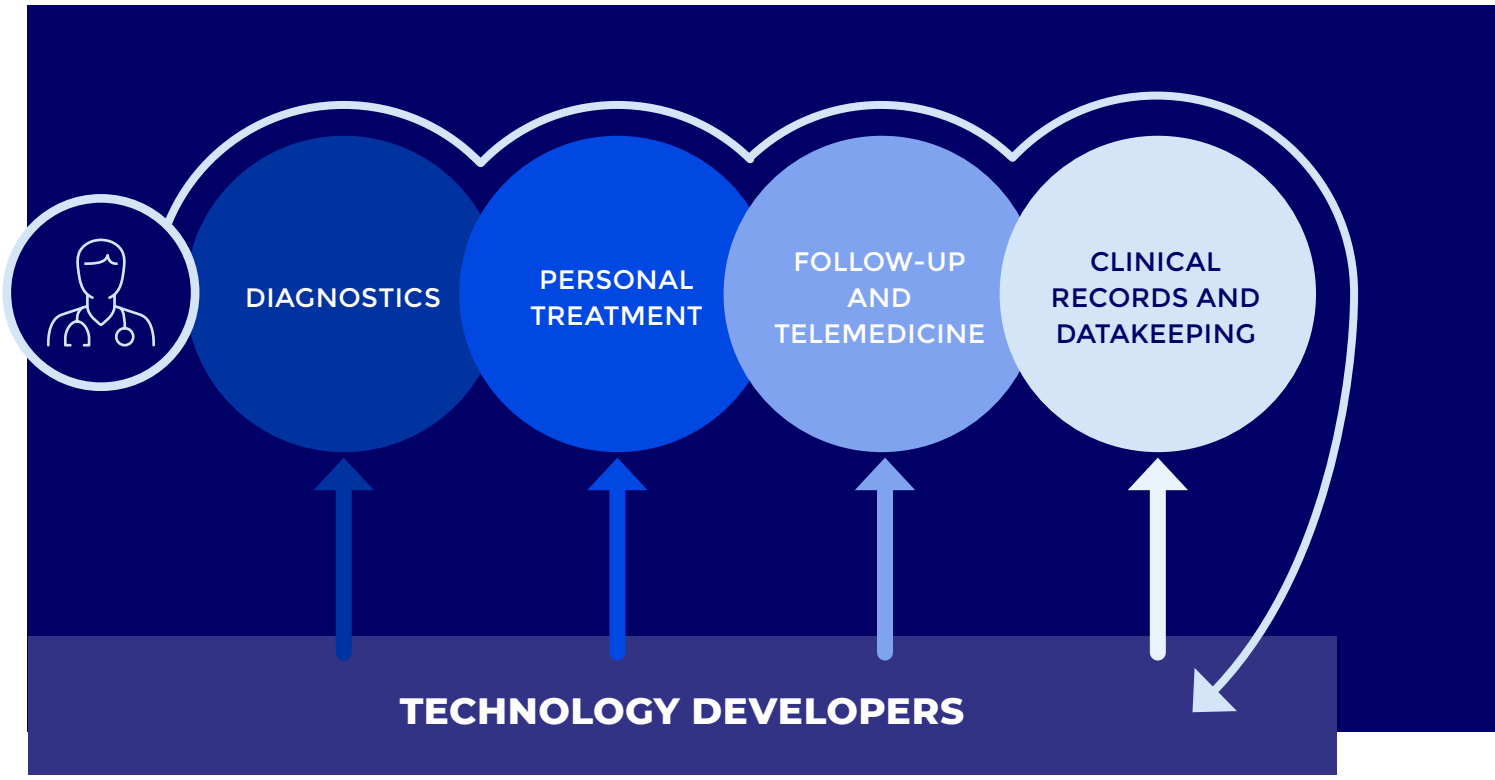


**Figure 1.** Moving away from improving individual 'moments' of care, technology developers should strive to work with healthcare data from the entire care pathway to contribute more effectively to improved system performance and patient care.

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— Michal Wlodarski (described above)

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