

Outputs from the IMI Stakeholder Forum 2019 'Brain health and disease in the digital era – 2020 and beyond'

Background

The theme of the IMI Stakeholder Forum 2019 was 'Brain health and disease in the digital era - 2020 & beyond'. Held on 12 June 2019 in Brussels, Belgium, the goal of the event was to explore ways of building IMI Call topics that converge around this relatively new space and which could open up new channels where fresh voices and minds could join established players in the field to solve one of the biggest healthcare challenges of this century.

Throughout the day, academics, representatives of multiple industry sectors (pharmaceuticals, diagnostics, digital, imaging), patient groups, clinicians, regulators, legal experts, ethicists and health economists offered their perspectives on how digital technologies can advance prevention, diagnosis, treatment and care.

This document summarises the main outputs of the event. The full list of speakers, presentations, and recordings of all the sessions can be found on the [event web page](#).

Understanding brain health and disease basis via development of relevant biomarkers

How do we relate genetic and environmental causes with the consequences of a disease? Medicine is moving from symptoms to causes: whether they are environmental, molecular, linked to the microbiome, human genome, etc. If we want to progress in prevention and early diagnosis, we have to increase our understanding of the generation of a disease. This is also necessary if we want to provide specific markers and treatments for complex individual diseases, and not only palliative care.

IMI could consider projects on phenotype / genotype transition, linking causes and consequences, even if they are more exploratory than translational. Relevant biomarkers of state transitions should be delivered as a toolbox containing multiple tools - some driven by qualitative data, others by quantitative data derived from clinical research – driven by both prospective and retrospective data. Digital information should be interpreted in the context of genetic and family history factors via hybrid longitudinal studies and using artificial intelligence (AI) supported modelling and simulation.

Towards a normative standard of brain health

Brain health should be part of a holistic approach to a 'healthy everything' vision: healthy life, healthy individuals, healthy environments, healthy healthcare systems. We need large normal cohorts, as a wealth of knowledge can be gained by analysing more people and not only patients.

IMI should consider projects building cohorts of healthy populations, analysing what defines a healthy individual, and define a normative standard to benchmark brain health. An algorithm able to identify which components may cause a low health score, track and monitor changes, and drive interventions should be sought. IMI could provide guidelines and best practices clarifying the pre-certification of datasets, help partners clearly with a roadmap to be GDPR-compliant and to overcome the regulatory obstacles as fast as possible to critically enable such AI based approaches.

Benchmarking of digital products

Evaluating and benchmarking is an essential piece of the product development chain. Benchmarking should include the appropriate environment, datasets, tools, and should be open and provide continuous evaluation of methods and systems. Benchmarking is important for method developers, companies and providers, final users, practitioners and citizens alike. It is better carried out by trusted public parties, and helps develop standards and provide communities with specific goals. Benchmarking digital systems might require regulators' adaptation from a reactive to a proactive role.

Technology for digital devices is still at an early phase; most systems were not developed for medical applications. IMI should focus on developing digital solutions for specific diseases, and contribute to the development of standards and procedures. IMI could help by developing projects in benchmarking of digital products, define standard of reference for measuring technology performance, and set objective performance criteria. Consequently, a clinical and regulatory pathway should be defined. New fit-for-purpose business models that are evidence driven and of high credibility should be developed to incentivise implementation of digital innovation in the real world.

Longitudinal FAIRification of biomedical data

Biomedical data is characterised by large volumes. It is complex, heterogeneous, difficult to access and subject to privacy rules. This generates issues with ownership, privacy and economical value and limits its use and re-use. There are already multiple EU initiatives, projects and infrastructures (i.e. ELIXIR) dealing with data, data regulation, technical access to data and data interoperability. Only a limited number of IMI projects are directly dealing with data.

IMI could coordinate and harmonise developments across the EU by providing a defined medical goal and specific applications. IMI should have a role in coordinating and participating in the many existing initiatives (e.g. 1 million genomes); contributing to standards, annotations and federation models to make data accessible; and develop projects to make data accessible for specific applications. This include longitudinal data sets with deep phenotyping (including samples and biobanks available for new technical developments) as well as data from continuous monitoring; linking electronic health records and other biomedical sources of phenotypic and medical information (e.g. self reports). When such data sets are not available they should be created, thus projects should be both retrospective and prospective. Data analytics will be needed for analysis of multiple data level clusters of heterogeneous sources, formats, knowledge and scales. The aim is an innovative entity-centric model, where the relationship between entity and its attributes can change constantly (e.g. deep learning).

An integrated platform bridging mental and physical health for new patient-centric treatments for brain disease

The pharmaceutical industry has not come up with transformative breakthroughs in psychiatry or neurology in 40 years. This is because there is poor understanding of both the patient and the disease, based on symptomatic classification, and because the biology is not sufficiently understood. There is increased evidence for an important link between physical and mental health and disease (e.g. diabetes and dementia).

IMI could support studies for understanding what happens in mental health when you study a novel compound in other fields, e.g. immunology or oncology. Research funders could leverage more by thinking across diseases. IMI could integrate this aspect in trials or observational studies in a whole range of different disorders. In this context, digital technology is an enabler to get a handle on the behavioural, cognitive and physiological processes. Understanding the patient with the aid of technology in the real world and beyond rigid disease classic classification boundaries will identify circuits and systems that can drive new approaches.

Digital therapeutics

Digital therapeutics that can be used in combination with a medication or on their own. There are initial success stories on their regulatory approval and reimbursement, but still many challenges. Digital technologies could be targeted solutions ('functional prosthetics') that could facilitate healthy lifestyles to maximise brain health (e.g. e-coaches) and disease prevention, or optimise treatment.

IMI could support projects for an 'all stakeholders approach' for the future possibility to deliver and combine digital interventions, and provide more personalised interventions. Feasibility studies in a controlled environment, carried out in partnership with regulators, could provide a first round of data for future directions. Many new tools do not get enough regulatory input at the start of the programme. In order to be innovative, developers should think of how a tool could be a usable product with a user in mind (both the patient and the healthcare provider). The project should also look at health technology assessment, financing models, and the adaptation process to the healthcare system, delivering data to progress the clinical and regulatory pathways and facilitate patient access to innovation.

Digital support plan for people in need of care: an app of nearby services

There are digital help and support plans already in place for patients that are seen rather as 'people in need of care'. A digital technology platform, in the form of an app, could develop a 24 hour support and solution scheme within a community, in order to organise and provide collective care to a person in need. This app would allow the sharing of key information and the burden of care with other family or community members, by listing nearby services available to people with dementia or their caregivers.

IMI could support this project with its scientific base to create databases of services which would be studied, duplicated and analysed – and help understand how to bring these services to households in need.

Digital technology in the continuum of treatment and care

There is a continuum between disease treatment and care especially in the case of brain disorders where a cure is mostly missing. Digital solutions can put the individual with a disorder in the driving seat. Brain diseases can be highly stigmatising for patients, but digital solutions can allow them to manage their treatment and care better.

IMI can provide incentives for collaborative research including patients, healthcare providers and digital developers. Directly reported outcomes can change the way digital solutions are designed. Thus tools and methods are needed to capture patient experience in the value framework, as this aspect is needed to facilitate patient-centric healthcare. The patient-healthcare provider duo will have to be in the driving seat of this work and a framework should be delivered for digital innovation development taking into consideration the healthcare perspective.