PIONEER EHDEN EUROPEAN HEALTH DATA & EVIDENCE NETWORK BigData@Heart HARMONY ALLIANCE ROADMAP

Big Data 4 Better Outcomes: Recommendations for the European Health Data Space

In light of our experience in various projects of the Innovative Medicines Initiative's Big Data 4 Better Outcomes programme (IMI BD4BOs), we would like to highlight the following points and make recommendations to inform EU decision makers in order to respond to the public consultation on the European Health Data Space (EHDS).

a. **Trustworthy data use**
Building trust with EU citizens on data sharing initiatives involves demonstrating results on issues which are meaningful to people's everyday health and life. It needs to be possible for anyone in Europe to see real world outcomes of care and treatment, whilst supporting research for therapeutic innovation as a societal good. IMI BD4BO projects are a good example of this, where research questions of value to patients as well as clinicians, commercial and academic researchers are being addressed using the data platforms. Also, patients are part of the governance mechanisms of each project and involved in the development of Patient Reported Outcome Measures. Transparency, in terms of public disclosure of research results is also an important part of trustworthy data use, as this ultimately demonstrates how data are being used to meet the needs of patients. The need for transparency must be balanced with the measures to protect data subjects rights under the General Data Protection Regulation (GDPR).

b. **Tomorrows EHDS is already being built today**
Data sharing infrastructures are already being built across Europe in multiple programmes with substantial European Commission investment to realise a connected European health community – the IMI BD4BO projects are examples of these which are already well down the road to achieving results for EU citizens and patients. Importantly, the EHDS can make use of the European and international multi-stakeholder **communities and networks** which have been created and the efforts which have brought together patients, clinicians, researchers and health care providers with data scientists, bioinformatics and statisticians. Continued resourcing of such projects ensures proper use of Commission funds, avoiding unnecessary duplication and re-invention. There is no need for the EHDS to start from scratch. These data will be useful for new technologies that can assist with the delivery of better diagnosis and care, such as Artificial Intelligence.

c. **Investment at pace and scale**
Investment at scale in standards and practices (use of common data models) to address the heterogeneity of health digitalisation in Member States will support both clinical care and research – financial and other incentives need to be found to bring all EU member states on board.

d. **Common architectures**
There need to be common, interoperable architectures to facilitate secure data flows for clinical and research use across Europe – a one size fits all infrastructure will limit progress. The EHDS governance structure needs to be flexible enough to cope with and support different national and regional models.

e. **Harmonisation of interpretation**
We must ensure that the high level governance models flow to every day clinical and research practice. Codes of Conduct could be helpful ways to explain and interpret areas of GDPR to certain sectors, such as health research. This could help strengthen common understanding of tightening citizen rights whilst facilitating research use. In the spirit of GDPR Article 40, the development of these codes need to be led by the communities that are responsible for putting them into practice and must be meaningful for their use in daily practice. These codes should also be practical and aligned to other relevant regulation where applicable, such as the clinical trial regulation (and the ethics approval process) so as to avoid overlap and duplication.

Background on Big Data 4 Better Outcomes

In 2016, the Innovative Medicines Initiative (IMI) launched a programme called Big Data for Better Outcomes (BD4BO) to explore new, improved and ethical ways for researchers to unleash the collective power of healthcare datasets, with the ultimate aim of researching real-life outcomes of patients. The programme recognised that Big Data has the potential to have a transformative effect across a board spectrum of areas including healthcare systems, patient stratification and disease treatment, clinical guidelines, trial and product design and patient use of medical technologies. However, the potential of Big Data will only be unlocked when healthcare systems move beyond the basic collection of large amounts of data. To achieve its potential, previously separated data sets must be securely linked and analysed using suitable Big Data analytics. This approach will offer all stakeholders novel ways to accelerate research and to identify the right treatment for individual patients (personalised medicine). Access to large combined data sets that present a more comprehensive picture of patients allows patient-reported outcomes to be measured more expansively. If the datasets are of high enough quality and/or supported by other findings such as clinical trial data they can support decision-makers in shaping patient focused healthcare systems.

The BD4BO programme was built around different IMI projects, each centered on a particular disease: ROADMAP(Alzheimer's disease) HARMONY and HARMONY PLUS (Haemato-Oncology), BigData@Heart (Cardiac disease) and PIONEER (Prostate cancer). In addition, the DO->IT project was the coordinating 'entity' during the early phase of the programme and was intended to help to coordinate the different activities of the data-driven IMI projects that make up the BD4BO programme, raise awareness of their existence, and communicate to the scientific community their findings, results and educational materials. The EHDEN project is building a federated data network of Data Partners, allowing analysis of health data standardised to a common data model for large-scale evidence generation. At the heart of the project is a group of trained, certified small and medium-sized enterprises (SMEs) responsible for transforming the data owned by Data Partners to the common data model. The data will remain under complete control of the original data owner, thereby ensuring ethical and local data privacy rules are respected.

The BD4BO projects are funded through the IMI2 Joint Undertaking. The joint undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.