The European Health Data and Evidence Network (EHDEN) – liberating evidence via harmonisation of EU real world data

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Background

The European Union, comprising 508 million peoples, is the third largest population in the world, with commensurate healthcare systems generating vast amounts of primary health data. Unfortunately, real world, observational research is generally slow, complicated, expensive and with considerable gaps in available data. Several programmes and projects have to date worked to improve upon this situation, including the IMI European Medical Information Project (EMIF; ending June 2018). Within EMIF, ten data sources were mapped to the OMOP CDM, with growing collaboration to the OHDSI network.
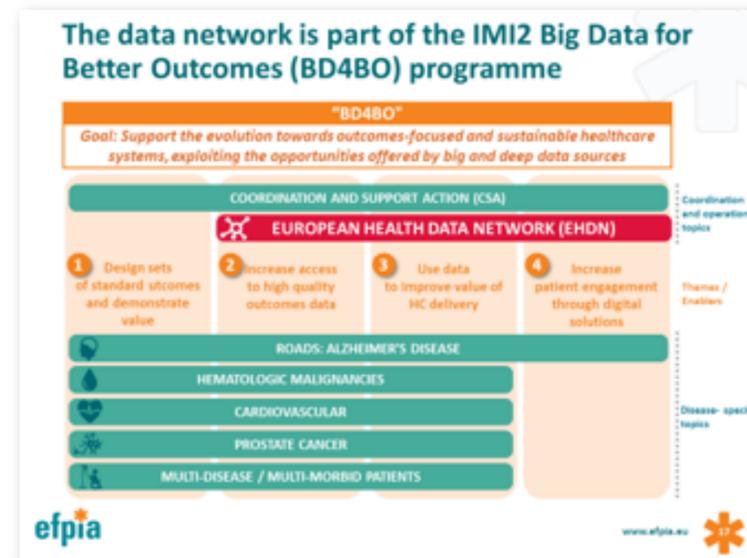
A follow-on project, the IMI European Health Data and Evidence Network (EHDEN; formerly EHDN) is now being developed with a proposed start in Q4 2018, for five years. EHDEN is a consortium of 11 public and 12 EFPIA partners, currently working on a full project proposal with IMI. It will focus on a 'build, fuel and drive' strategy to develop an EU ecosystem for real world health research, supported by technology, engagement and outreach with data sources and data users. EHDEN will progress to harmonise ~100 million EU records, facilitated by qualified and certified SMEs, to support outcomes-based research across the wider IMI 'Big Data for Better Outcomes' (BD4BO) programme, and for clinical care and decision-making, utilising outcome standards, and FAIR principles.

Results

Critical to the success of EHDEN will be a number of steps:

- The development of a federation of data source (e.g. hospital, GP network, integrated regional database) and data user ecosystem to support observational, real world research
- Representative and heterogenous data source federated network across the EU geography, ensuring data meets FAIR principles
- Qualification and certification of SMEs to support OMOP CDM mapping at scale (within a currently fragmented market)
- An agreed value proposition and *quid pro quo* for data sources to collaborate within the EHDEN network
- Potential domains, driven initially by BD4BO projects, for health outcomes research, incorporating outcome standards
- Application of outcomes to support value based healthcare and clinical decision making, with acceptability of evidence as trustworthy
- Building upon current and prior projects for technical development, e.g. EMIF, EHR4CR and Hospital Network scale up, GetReal, et al – EHDEN is not a blank canvas project starting from a zero base
- A sustainable operational and business model from day one to ensure a service orientated development during the IMI project, and as a post-IMI entity

Methods

EHDEN will be implement via the following proposed work package (WP) structure:

- **WP1: Evidence Workflow Development**
  - Incorporating the use cases for supporting development and validation of the EHDEN socio-technical approach, inclusive of BD4BO projects
- **WP2: Outcome Driven Healthcare**
  - Related to all activities specific to e.g. BD4BO projects outcome focus, and outcome standards incorporation
- **WP3: Personalized Medicine**
  - Focusing on the support of outcomes/value based healthcare, inclusive of clinical prediction models, with the incorporation of 'novel' patient data
- **WP4: Technical Implementation**
  - Key priority is socio-technical development of the EHDEN federated framework and relevant services
- **WP5: Data Workflow Implementation and Service Deployment**
  - With development, oversight and evaluation of the ecosystem development from SME qualification/certification to data source engagement, OMOP CDM mapping and evaluation (the 'whole cycle')
- **WP6: Outreach and Sustainability**
  - Ensuring the development of stakeholder mapping and engagement with regards to use of RWD, and acceptability of RWE, while developing the sustainable operational model for EHDEN during and post IMI phase
- **WP7: Project Management and Dissemination**
  - Concentrating on intra-project project management, internal communications and external dissemination, and responding to IMI deliverables

Conclusions

EHDEN will be a EU IMI flagship project for five years, but with a need to ensure early outputs from year one onwards and long term sustainability post IMI. A number of challenges will need to be addressed:

- What is the value proposition for data sources and for SMEs to be involved in the EHDEN ecosystem via a federated network, utilisation of the OMOP CDM and collaboration with OHDSI community
- Incorporation of privacy by design to ensure concordance with the impending implementation of the General Data Protection Regulation (GDPR)
- Building upon existing open source technologies from prior and current projects to create the underpinning EHDEN platform and integrations
- Prioritisation of disease domains of interest for health outcomes and personalised medicine, also in support of BD4BO projects

As of now, the consortium is working on the IMI full project proposal, prior to a grant and consortium agreement steps prior to project commencement in Q4.

More information on EHDEN is currently available via:
https://www.imi.europa.eu/sites/default/files/archive/uploads/documents/Future_Topics/IndicativeTopic_EHDN.pdf and https://www.imi.europa.eu/sites/default/files/uploads/documents/news-events/events/2017/EHDN_slides.pdf

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