The European Health Data & Evidence Network

What is it?

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All too often real world research is a challenging journey....
What we need is infrastructure and a network to conduct real world research in the 21\textsuperscript{st} Century....
IMI: a unique Public-Private Partnership (PPP) between the pharmaceutical industry represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Union represented by the European Commission.
Federated distributed data networks reflect real world patients with greater phenotypic resolution: ‘big data’

A federated data network is based around a common platform to facilitate bi-directional data flow, data harmonisation (from diverse sources) and connectivity for research reuse; supported by a harmonisation fund and certified/qualified SME network.

RWD is about diversity of source as no one data source is the whole truth. A federated data network retains local provenance and governance while facilitating remote connectivity with RWD for research reuse.

There are a multitude of use cases for RWD, but the more reflective of populations, cohorts and real world patient trajectories the more reliability can be attributed to RWD/RWE.

For value and outcomes, patients, their treatment episodes, and outcomes need to be tracked longitudinally across health domains.
Key Components of Collaborative Data Projects....
EH DEN Public & EFPIA Consortium Working on Full Project Proposal

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<tr>
<th>Institute</th>
<th>Country</th>
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<tr>
<td>Erasmus MC</td>
<td>The Netherlands</td>
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<tr>
<td>Synapse Research Management</td>
<td>Spain</td>
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<tr>
<td>Oxford University</td>
<td>UK</td>
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<td>Tartu Ulikool</td>
<td>Estonia</td>
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<td>University of Aveiro</td>
<td>Portugal</td>
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<td>The Hyve</td>
<td>The Netherlands</td>
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<td>Odysseus Data Services</td>
<td>Czech Republic</td>
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<td>European Patients Forum</td>
<td>Luxembourg</td>
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<td>National Institute for Health and Care Excellence (NICE)</td>
<td>UK</td>
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<td>Stiftelsen WHO Collaborating Centre for International Drug Monitoring</td>
<td>Sweden</td>
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<tr>
<td>International Consortium for Health Outcomes Measurement (ICHOM)</td>
<td>UK</td>
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Current Progress on EHDEN - 2018

- EHDEN is an IMI flagship project
- Key stakeholders and actors in this domain recognise the RWD → RWE process in the EU is inadequate
- For the coming year pre-project preparation is critical for a Q4 start

Key Activities Q1-Q3

Consortium Development

Vision Alignment

Work Packages
- Advancing Short Project Proposal
- Aligning Consortium
- Linkage with e.g. OHDSI
- Developing ‘The Plan’

Final Project Proposal submitted 15th May
EHDEN: Vision, Mission & Values

**Vision:** The European Health Data & Evidence Network (EHDEN) aspires to be the trusted observational research ecosystem to enable better health decisions, outcomes and care.

**Mission:** Our mission is to provide a new paradigm for the discovery and analysis of health data in Europe, by building a large-scale, federated network of data sources standardised to a common data model.

**Values:**
- Diversity
- Excellence
- Perseverance
- Education
- Openness
- Beneficence
- Reproducibility
- Sustainability
- Coverage
- Efficiency
- Community
European Health Data & Evidence Network

- Representative and diverse real world data across the EU
- Adaptation of global open science initiative to EU needs
- A framework for 21st Century real world research
- Impact: Meeting the needs of a single digital market for digital citizens in healthcare
European Health Data & Evidence Network

- Therapy and disease area agnostic
- Insights and evidence generation in the health domain
- Reflecting real world clinical management, care and outcomes
- Impact: enabling better health decisions, outcomes and care for the EU
European Health Data & Evidence Network

- Harmonised 100 million records, mapped to the OMOP common data model
- Ecosystem of certified/qualified SMEs harmonising data sources, supported by €17mio fund via open series of calls
- Federated analytics via OHDSI tooling, ARACHNE and EMIF platforms
- Impact: Improving trust and reusability of real world data for key stakeholders
European Health Data & Evidence Network

Use case driven, incorporating PROMs/PREMs, digital biomarkers, and predictive analytics

Incorporating ICHOM standards, HTA and Regulatory input on methodology

Clinically meaningful evidence from research impacting on practice

Impact: Evidence-driven improvements in patient outcomes, leading to precision medicine
European Health Data & Evidence Network

A federated network of diverse, high quality data sources

A collaboration based on mutual need and shared value propositions

Governance and provenance remains local, supportive also of GDPR

Impact: A region-wide well trained, active and sustainable open science community
# EHDEN Proposed Work Packages

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<th>Build</th>
<th>Fuel</th>
<th>Drive</th>
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<td>Incorporating the use cases for supporting development and validation of the EHDEN socio-technical approach, inclusive of BD4BO projects.</td>
<td>Related to all activities specific to e.g. BD4BO projects outcome focus, and ICHOM standards incorporation.</td>
<td>Focusing on the support of outcomes/value based healthcare, inclusive of clinical prediction models, with the incorporation of ‘novel’ patient data.</td>
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<td>Key priority is socio-technical development of the EHDEN federated framework and relevant services.</td>
<td>Development, oversight and evaluation of the ecosystem development from SME qualification/certification to data source engagement, OMOP CDM mapping and evaluation.</td>
<td>Ensuring the development of value propositions for key stakeholders, and developing the sustainable operational model for EHDEN during and post IMI phase.</td>
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<td>Concentrating on intra-project project management, internal communications and external dissemination, and responding to IMI deliverables.</td>
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EHDEN is not a blank canvas project....

- EHDEN will utilise the best from prior and current (IMI) projects and platforms to develop its own infrastructure.

- It will be developing its federated framework, but also analytical tooling and processes to support observational research in the EU, closely associated with the OHDSI EU/Global Open Science/Open Source collaboration.
Critical at the heart of EHDEN is the OMOP CDM and OHDSI Collaboration
What is the flow through EHDEN?

A multitude of data sources in the EU

Developing the SME domain in the EU
EHDEN: In Summary

• EHDEN is a bold step in recognising that a flagship project is needed to address conducting real world research for the 21st Century

• At its heart is the acknowledgement that we need to develop a community via a federated network, within an ecosystem, all based on a *quid pro quo* around data for research use

• The Open Science/Open Source community of OHDSI, and the OMOP CDM are critical enablers and partners for EHDEN in this endeavour
What is the European Health Data & Evidence Network (EHDEN)?

The aim is to map 100 million health records across the EU via a common data model (OMOP), supporting research, the BD4BO IMI2 programme, and outcomes-based healthcare.

- Infrastructure
  - Building on prior and current (IMI) projects
  - Accelerate the platform and supporting research process

- Harmonisation
  - Advance the skill base in the EU via certified & qualified SMEs
  - Harmonisation fund to support mapping to CDM

- Ecosystem
  - A federated network of increasing number of Data Custodians and Sources
  - Evaluation and incorporation of ‘novel’ data sources
  - Utilisation of FAIR Principles

- Outcomes
  - Incorporation of outcome standards (e.g. ICHOM)
  - Supporting the evidence base in the EU for outcomes-based research and medicine

EHDEN will be an IMI consortium of 11 EFPIA partners and a public consortium of 11 partners, commencing c. October 2018.