The European Health Data & Evidence Network
- Sharing the OHDSI journey and a vision of evidence today, not in several tomorrows –

Hughes, N[1], Prieto-Alhambra, D[2], Diaz, C[3], Rijnbeek, P[4], on behalf of the EHDEN Consortium

1. Janssen R&D, Belgium 2. University of Oxford, UK 3. Synapse Research Management Partners, Madrid, Spain 4. Erasmus University Medical Centre, Rotterdam, The Netherlands

INTRODUCTION

Today, in Europe, we are challenged to generate insights and evidence from real world clinical data at scale, to support patients, clinicians, payers, regulators, governments, and the pharmaceutical industry in understanding wellbeing, disease, treatments, outcomes and new therapeutics and devices. Unfortunately, such data is difficult to use at scale, in a myriad of languages, systems and structures, with challenging policy restrictions and technology considerations.

In response to this, the European Health data and Evidence Network (EHDEN) project was launched as a public private partnership under the framework of the Innovative Medicines Initiative (IMI,) running from November 2018 until April 2024.

EHDEN's aspirations are significant:
- Establish a self-sustaining **open science collaboration** in Europe, supporting academia, industry, regulators, payers, government, NGOs and others
- **Harmonise more than 100 million anonymised health records to the OMOP common data model**, supported by an ecosystem of certified and qualified SMEs, and technical architecture for a federated network
- **Impact** on our understanding of, and improvement of, **clinical outcomes** for patients within diverse health systems in the EU

Three pillars support EHDEN's goals and aims:
- **Infrastructure:**
  - Open calls for data sources and institutions to map their data to the OMOP CDM
  - Open calls for Small and medium-sized enterprises (SMEs) to be trained and certified in supporting the conversions of data to the OMOP CDM
  - Creation of an EU-wide architecture for federated analyses of real world data
- **Research & Outcomes**
  - Execution of research use cases to drive tool development and to evaluate the validity and veracity of the EHDEN federated network
  - Collaboration on consistent methodologies in real world research
  - Close collaboration with the global OHDSI research network
- **Education**
  - The establishment of an EHDEN Academy, webinars and face-to-face training sessions to train all stakeholders
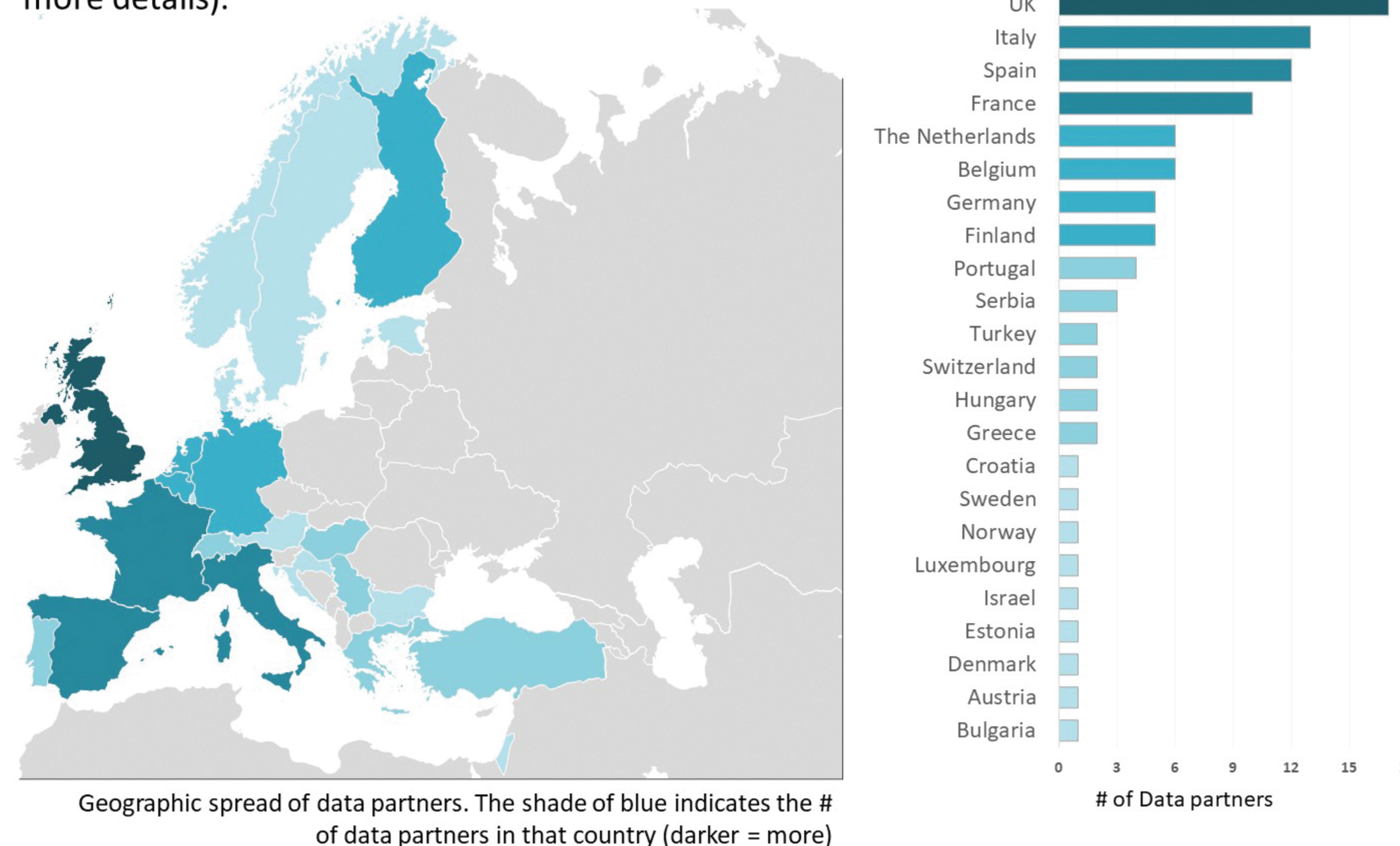
To achieve these goals, EHDEN brings together 23 partners from across 12 countries. The consortium is evenly divided with eleven public partners, led by Erasmus University Medical Centre, The Netherlands, and twelve pharmaceutical partners, led by Janssen Pharmaceutica Nv, Belgium.

STATE OF THE FEDERATED NETWORK

Following the 4 open calls to date we have organised, we currently have 98 data partners from 23 different countries at various stages of completing their mapping to the OMOP CDM, with greater than **400 million records** across the European region. This includes several EHDEN project partners who have also mapped their data to the OMOP CDM for use in the federated network. (See www.ehden.eu/datapartners/ for more details). More open calls will follow. Call #2 was specifically for COVID-19 in 2020, with 25 data partners (as part of the 98) included on a rapid ETL cycle via an internal taskforce.

Additionally, EHDEN has trained and certified 26 small-to-medium sized enterprises (SMEs) in a rigorous consistent **ETL methodology** to contract with Data Partners and has recently selected 23 additional SMEs across Europe. (See www.ehden.eu/business-directory/ for more details).

Geographic spread of data partners. The shade of blue indicates the # of data partners in that country (darker = more)

OUTREACH AND EDUCATION

As OHDSI and EHDEN are at the front line of developing new methodologies, analytical tools and use cases for observational health research, there is a strong need to educate colleagues. Ensuring standardised education for epidemiologists, data scientists, informaticians, and others involved in research utilising observational data is also key to improving research quality in OHDSI. To this end, the **EHDEN Academy** was launched in April 2020, providing educational content. Via an open-source platform, free to enrol and supported by the community for the community, the Academy meets the needs of the project and over time OHDSI as the go-to, global educational resource. To date, the EHDEN Academy offers 10 different courses, and have over 1500 users who've taken one or more of our courses.

EHDEN is supporting other **IMI projects** who adopted the OMOP CDM, for instance in prostate cancer (PIONEER), inclusive of their own study-a-thon (March 2021), and patient-reported outcomes observatories (H2O). EHDEN is also providing input into the EU Joint Action, Towards the European Health Data Space (TEHDAS).

Further developing and growing the **EHDEN** and **OHDSI community** in an open science mindset for the benefit of all is a continuous effort. To this end, we've developed value propositions for all relevant stakeholders and are now working on a path beyond the project end, coalescing around the launch of a **not-for-profit** legal entity that will be based in The Netherlands.

DATA PARTNER CATALOGUE & TOOL DEVELOPMENT

A core objective of the EHDEN consortium is to provide all the necessary services that enable a distributed European data network to perform fast, scalable and highly reproducible research, while respecting privacy regulations, local data provenance and governance.

- EHDEN is building its **central portal** to provide a metadata-driven Data Partner catalogue, inclusive of data characterisation and data quality dashboards. All data, however, is not centralised and always remains local with the Data Partner. We aim to launch this portal in the second half of 2021.

- This will include **services and tools** to perform data standardization, analytical pipelines, tools to share study results, and tools for stakeholder engagement and training (e.g., ATLAS and HADES). The development of the EHDEN infrastructure and new tools is driven by the needs of other work packages in EHDEN.

- To enable a transition towards **outcomes-driven healthcare** systems in Europe, EHDEN is working to ensure that the EHDEN framework is usable in a regulatory, HTA and payer context.

GENERATING EVIDENCE

With a strong foundation of 98 DPs at various stages of their mapping cycle, and 49 SMEs certified or in the process of certification, EHDEN already has engaged in evidence generation previously through network studies and study-a-thons, for example in response to COVID-19 with our OHDSI colleagues. These studies have directly impacted patient care and treatment, and most notably, saw regulatory interest at the start of the pandemic.

We have created an 'Evidence Taskforce' to facilitate a focus on evidence generation through use cases and network studies, as well as expanding our educational activities via 'e-thons', or focused evidence generation events to work with newly mapped DPs. We recently organised our first e-thon on adverse events of special interest (AESIs) for COVID-19. Meanwhile, we continue work on 3 EHDEN proof-of-concept studies: (i) Drug and device safety, (ii) Drug utilisation and (III), health technology assessment (HTA).

All deliverables, preprints and peer-reviewed papers are freely accessible via the EHDEN Zenodo page, which can be accessed via https://zenodo.org/communities/ehden, inclusive of 36 publications to date, some joint between OHDSI and EHDEN.

LOOKING AHEAD

For the second half of the project, EHDEN will continue to add Data Partners to the network, but is expanding our evidence generation. To evaluate the mapping to the OMOP CDM, but also to integrate and educate new Data Partners, a new 'evidence-a-thon' cycle has been initiated, re-running R packages and widening existing study results dynamically.

Meanwhile, a research operating model, is being refined to accompany an EHDEN not-for-profit in parallel to the remainder of the project, and ultimately superseding it for longer term sustainability. National nodes, or local country networks, are being evaluated within OHDSI Europe and EHDEN to support those countries wanting to embed the federated data network ethos within their own national strategy.