



# EHDEN

EUROPEAN HEALTH DATA & EVIDENCE NETWORK

## An Update

**Nigel Hughes**

Project Lead, EHDEN  
Scientific Director, Epidemiology, Janssen R&D





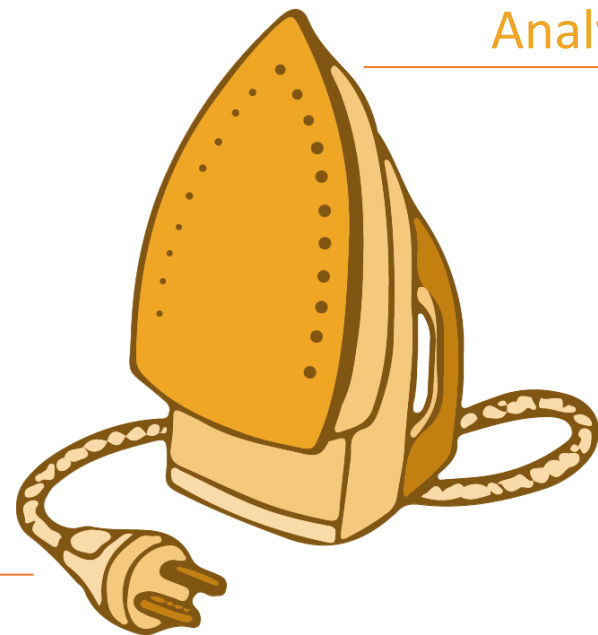


# EUROPE: AN OCEAN OF DATA, A DESERT FOR ANALYSIS





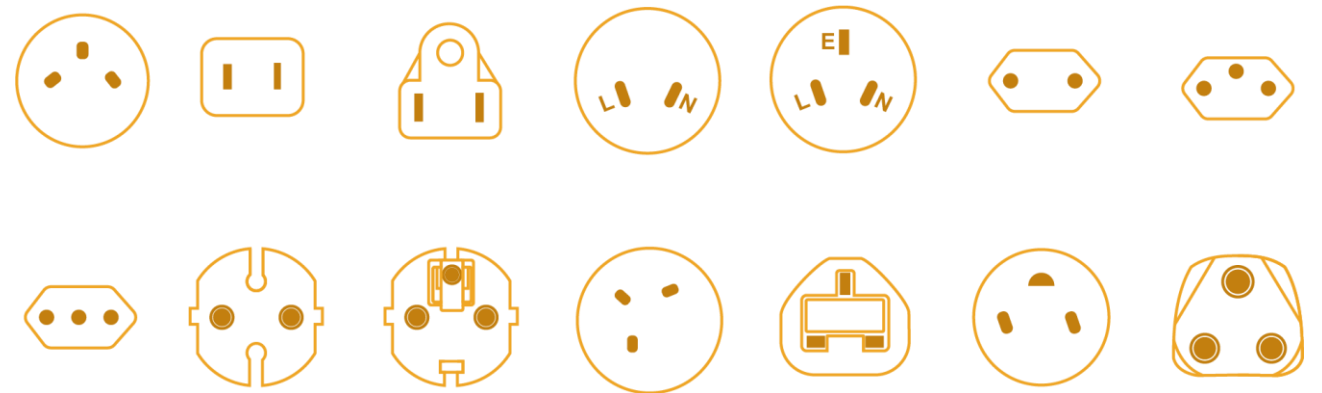
# WHY IS THIS NOT CURRENT PRACTICE?



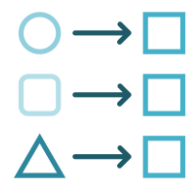
Analytical method

Link to data

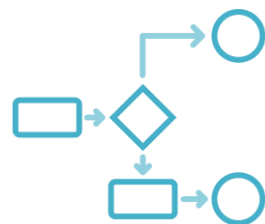
The data...



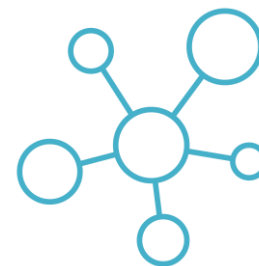
## What will it require?



Data interoperability



Standardised analytics



Data network



Strong community



## 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 standardized to a common data model





# EHDEN CONSORTIUM



Start date: 1 Nov 2018  
End date: 30 Apr 2024  
Duration: 66 months



24 partners



~€30 million

## Universities, public bodies and research organisations

**Erasmus MC Academic coordinator**  
Universiteit Medisch Centrum Rotterdam

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Uppsala Monitoring Centre      universidade de aveiro

NICE National Institute for Health and Care Excellence      TARTU ÜLIKOOL • SISENS UNIVERSITAS TARTUENSIS 1632      UNIVERSITY OF OXFORD

## SME & Mid-sized companies

SYNAPSE RESEARCH MANAGEMENT PARTNERS      ODYSSEUS DATA SERVICES INC

The Hyve

## Non-profit organisations

EPF European Patients Forum      ICHOM

## EFPIA & Associated partners

Janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson      Celgene      Pfizer      Lilly

EFPIA Lead      BAYER      abbvie      Boehringer Ingelheim      AstraZeneca

SANOFI      ucb      NOVARTIS      SERVIER

Lundbeck



# EHDEN IS ABOUT...

## FEDERATION

Creation of an EU-wide architecture for federated analyses of real world data

## HARMONISATION

Harmonise more than 100 million anonymised health records to the OMOP common data model



## COMMUNITY

Establish a self-sustaining open science collaboration in Europe, supporting academia, industry, regulators, payers, government, NGOs and others

## OUTCOMES

Enabling outcomes driven healthcare at a European level

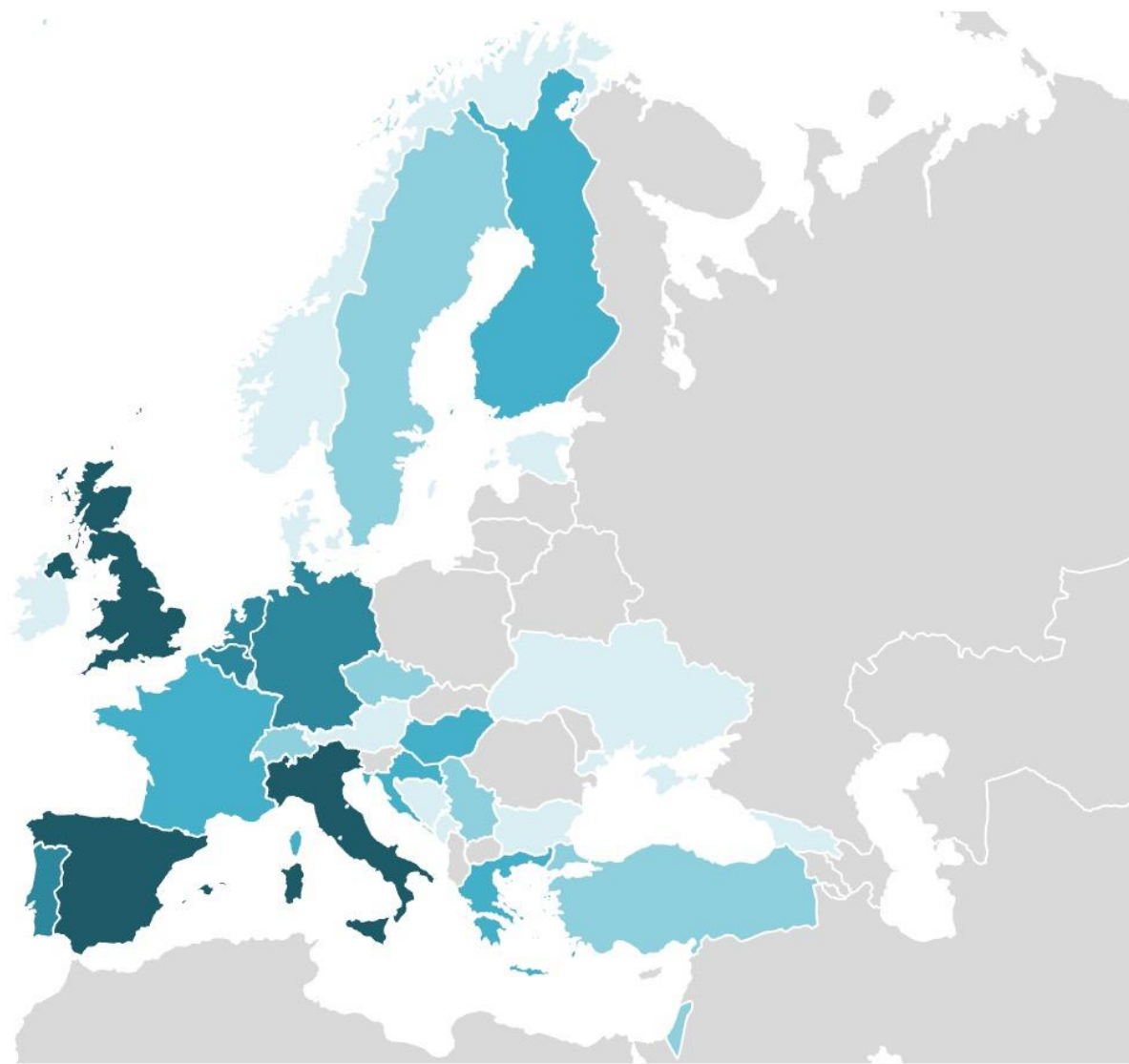
## EDUCATION

The establishment of an EHDEN Academy, webinars and face-to-face training sessions to train all stakeholders

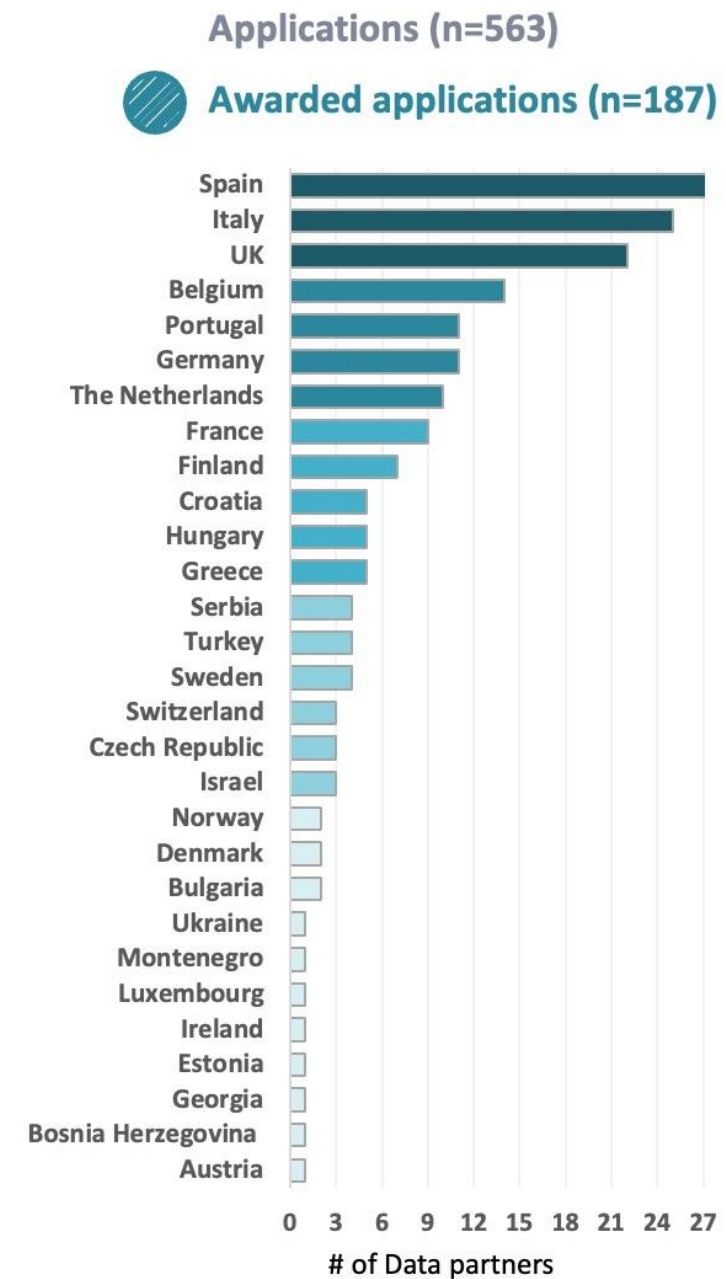


# OVERVIEW DATA PARTNER CALLS [AFTER 7 CALLS]

<https://www.ehden.eu/datapartners/>



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

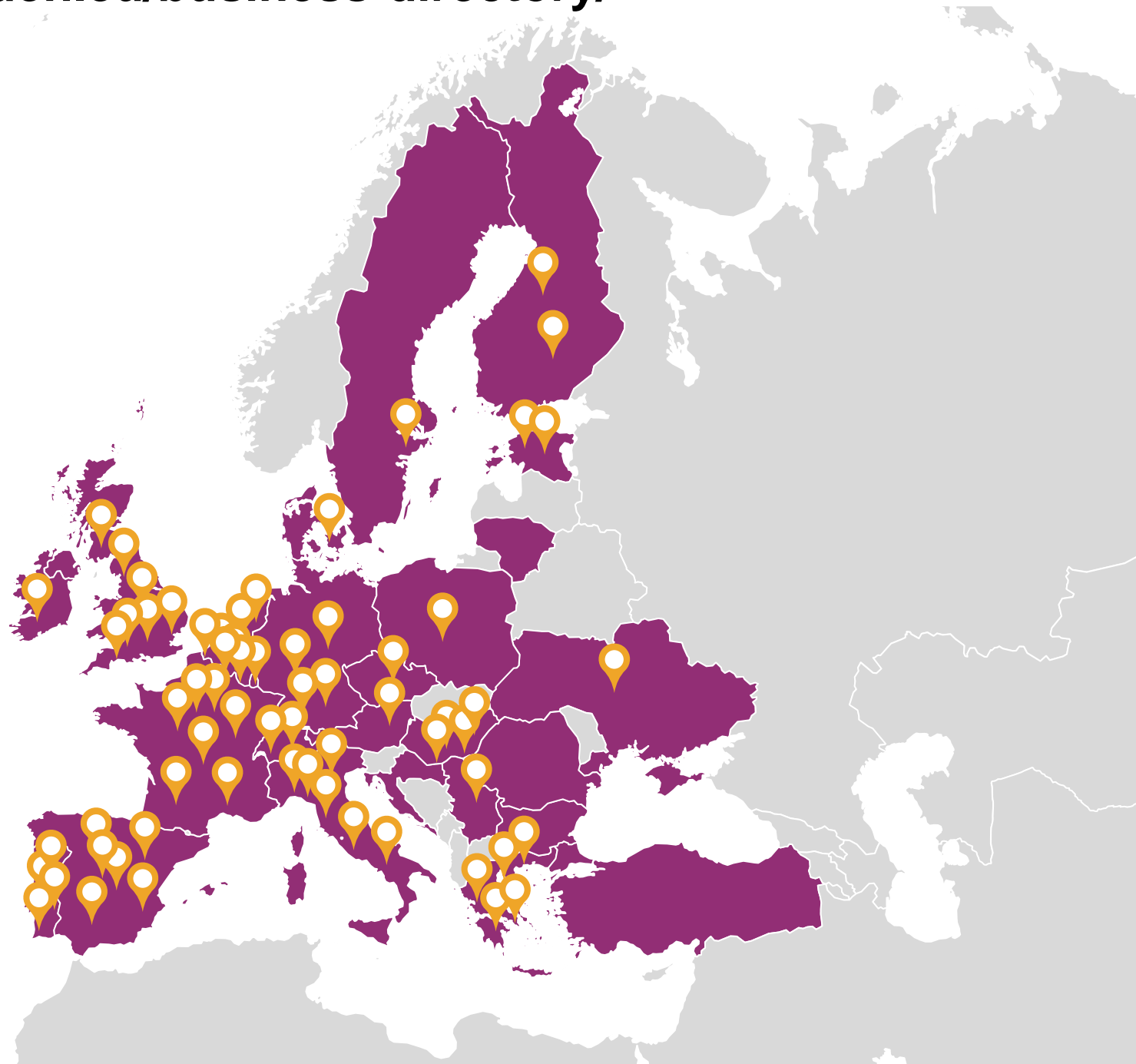


~830 million  
anonymous records  
being mapped to  
OMOP CDM



# SMEs CERTIFICATIONS AFTER CALL 4: A UNIQUE GLOBAL RESOURCE

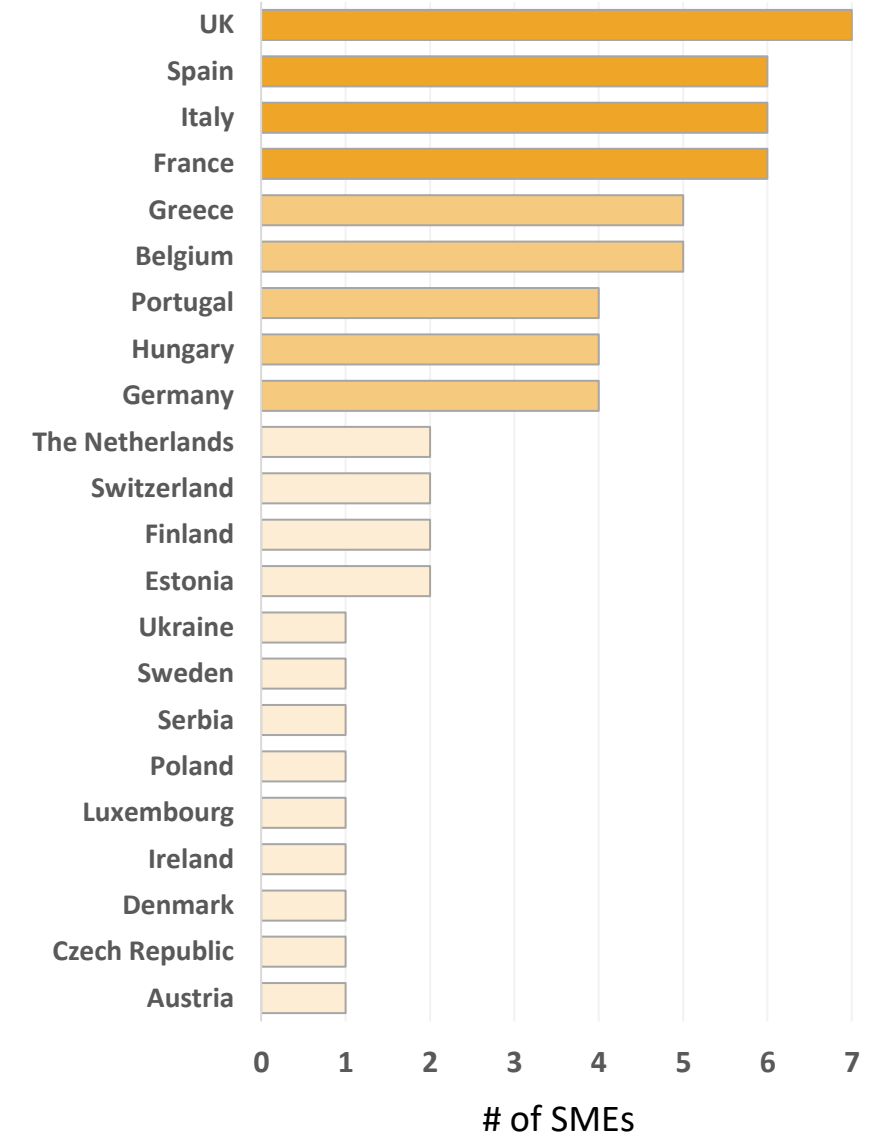
<https://www.ehden.eu/business-directory/>



Certified SMEs (n=64)



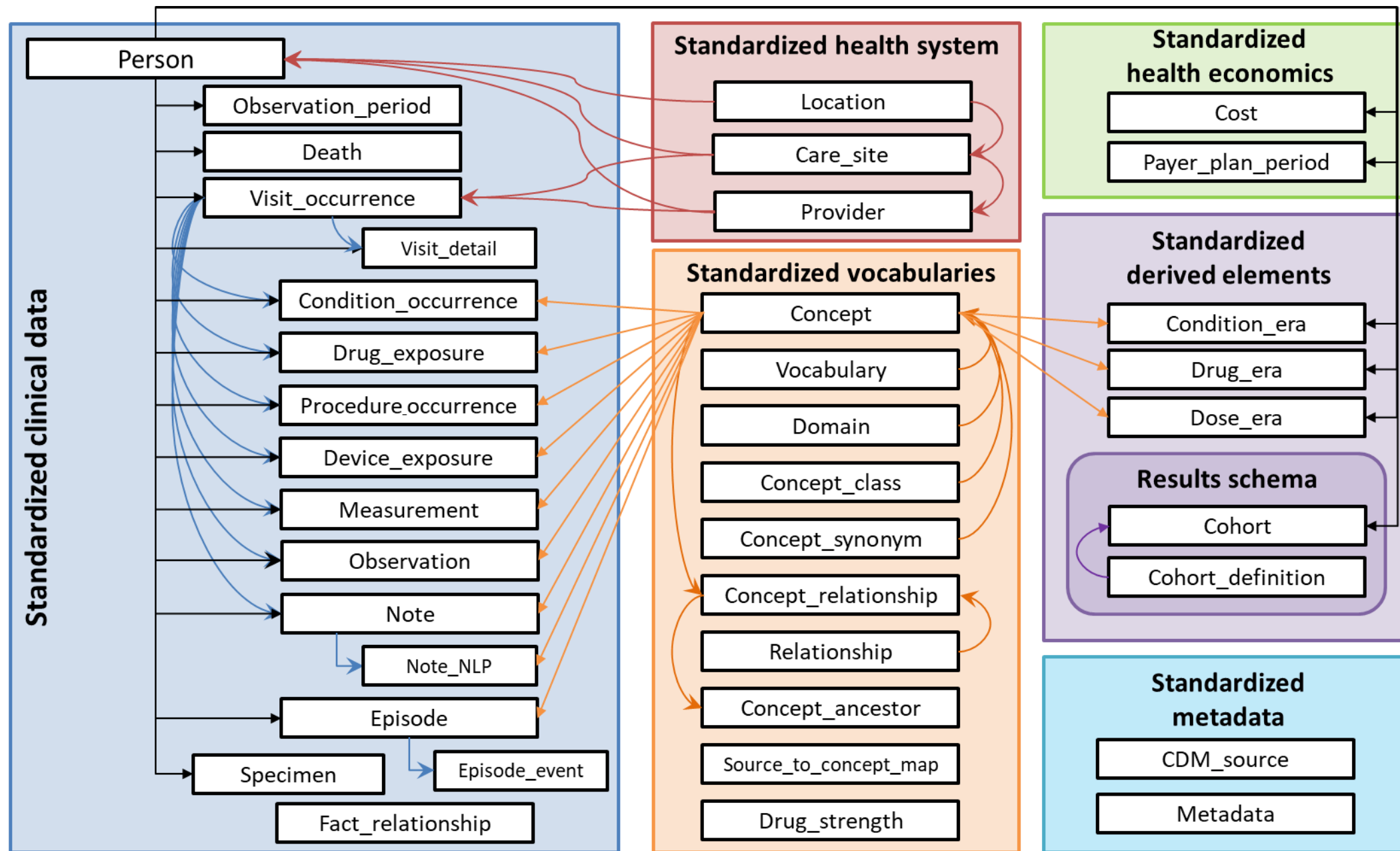
Applications (n=143)





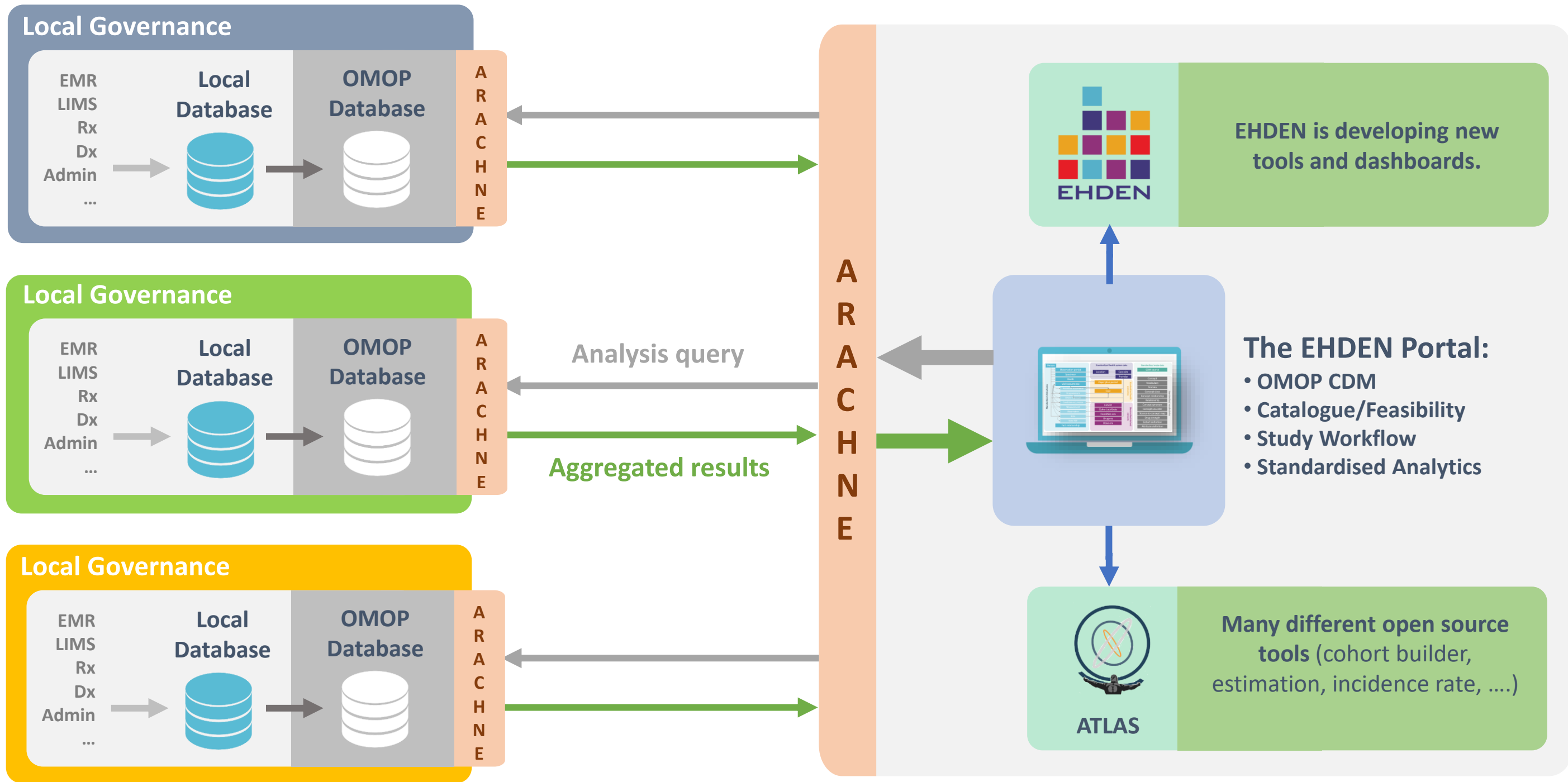


# THE OMOP COMMON DATA MODEL



Patient-centric  
Tabular  
Extendable  
Built for analytics  
Relational design

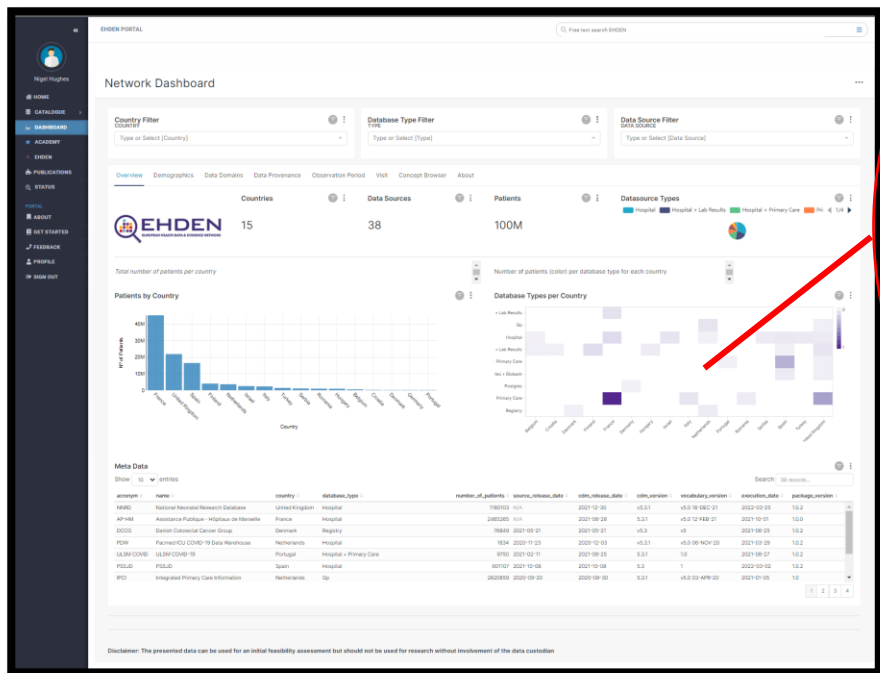
v 5.4





# THE VISION OF THE EHDEN PORTAL – ONE-STOP-SHOP LAUNCHED 26<sup>TH</sup> JUNE 2022

<https://www.ehden.eu/ehden-portal/>



**Free Enrolment**

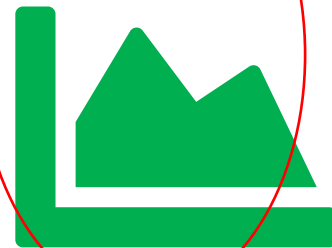


Evidence

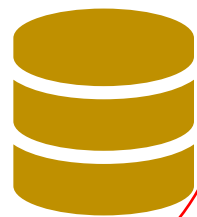


Data Analytics

Network Dashboards



Database Catalogue



Academy



Support



Study Management





# ACADEMIC/SCIENTIFIC IMPACT: ~60 METHODOLOGICAL & SCIENTIFIC PUBLICATIONS

COVID-19 – Support for our author and subscriber community

**Body Mass Index and Risk of COVID-19 Diagnosis, Hospitalization, and Death: A Cohort Study of 2 524 926 Catalans** **FREE**

Martina Recalde, et al.

A comprehensive understanding of the association between body mass index (BMI) and coronavirus disease 2019 (COVID-19) is still lacking. The objective of this study was to investigate associations between BMI and risk of COVID-19 diagnosis, hospitalization with COVID-19, and death after a COVID-19 diagnosis or hospitalization (subsequent death), accounting for potential effect modification by age and sex.

**Latest Issue**  
Volume 106, Issue 12  
December 2021

Advertisement: SMART. Smart for you. Smart for your patients. ADVANZ PHARMACEUTICALS THE SMARTER CHOICE.

BMI in COVID-19: JCEM pick of the week!!

RESEARCH

OPEN ACCESS

For numbered affiliations see end of article.  
Correspondence to: P Ryan  
ryan@ohdsi.org  
<http://orcid.org/0000-0002-9727-2138>  
Additional material is published online only. To view please visit the journal online  
Cite this as: *BMJ* 2021;373:n1038  
<http://dx.doi.org/10.1136/bmj.n1038>  
Accepted: 16 April 2021

## Use of repurposed and adjuvant drugs in hospital patients with covid-19: multinational network cohort study

Albert Prats-Urbe,<sup>1</sup> Anthony G Sena,<sup>2,3</sup> Lana Yin Hui Lai,<sup>4</sup> Waheed-Ul-Rahman Ahmed,<sup>5,6</sup> Heba Alghoul,<sup>7</sup> Osaid Alser,<sup>8</sup> Thamir M Alshammari,<sup>9</sup> Carlos Areia,<sup>10</sup> William Carter,<sup>11</sup> Paula Casajust,<sup>12</sup> Dalia Dawoud,<sup>13</sup> Asieh Golozar,<sup>15,16</sup> Jitendra Jonnagaddala,<sup>17</sup> Paras P Mehta,<sup>18</sup> Mengchun Gong,<sup>19</sup> Daniel R Morales,<sup>20</sup> Fredrik Nyberg,<sup>22</sup> Jose D Posada,<sup>23</sup> Martina Recalde,<sup>24,25</sup> Elena Roel,<sup>24,25</sup> Karishma Shah,<sup>5</sup> Nigam H Shah,<sup>23</sup> Lisa M Schilling,<sup>11</sup> Vignesh Subbian,<sup>26</sup> David Vizcaya,<sup>27</sup> Lin Zhang,<sup>28,29</sup> Ying Zhang,<sup>19</sup> Hong Zhu,<sup>30</sup> Li Liu,<sup>30</sup> Jaehyeong Cho,<sup>31</sup> Kristine E Lynch,<sup>32</sup> Michael E Matheny,<sup>33,34</sup> Seng Chan You,<sup>35</sup> Peter R Rijnbeek,<sup>3</sup> George Hripcsak,<sup>36</sup> Jennifer CE Lane,<sup>5</sup> Edward Burn,<sup>1,24</sup> Christian Reich,<sup>37</sup> Marc A Suchard,<sup>38</sup> Talita Duarte-Salles,<sup>24</sup> Kristin Kostka,<sup>37,39</sup> Patrick B Ryan,<sup>2,40</sup> Daniel Prieto-Alhambra<sup>1</sup>

RESEARCH: SPECIAL PAPER

OPEN ACCESS

**FAST TRACK**

## Characterising the background incidence rates of adverse events of special interest for covid-19 vaccines in eight countries: multinational network cohort study

Xintong Li,<sup>1</sup> Anna Ostropolets,<sup>2</sup> Rupa Makadia,<sup>3</sup> Azza Shoaibi,<sup>3</sup> Gowtham Rao,<sup>3</sup> Anthony G Sena,<sup>3,6</sup> Eugenia Martinez-Hernandez,<sup>4</sup> Antonella Delmestri,<sup>1</sup> Katia Verhamme,<sup>6,7</sup> Peter R Rijnbeek,<sup>6</sup> Talita Duarte-Salles,<sup>5</sup> Marc A Suchard,<sup>8,9</sup> Patrick B Ryan,<sup>2,3</sup> George Hripcsak,<sup>2</sup> Daniel Prieto-Alhambra<sup>1,6</sup>



# REGULATORY IMPACT DURING COVID-19 AND BEYOND



**THE LANCET**  
Rheumatology

Articles

**Risk of hydroxychloroquine alone and in combination with azithromycin in the treatment of rheumatoid arthritis: a multinational, retrospective study**

Jennifer C E Lane\*, James Weaver\*, Kristin Kostka, Talita Duarte-Salles, Maria Tereza F Abrahao, Heba Alghoul, Osaid Alser, Thamer M Alshammari, Patricia Biedermann, Juan M Banda, Edward Burn, Paula Casajust, Mitchell M Conover, Aedin C Culhane, Alexander Davydov, Scott L DuVall, Dmitry Dymshyts, Sergio Fernandez-Bertolin, Kristina Fišter, Jill Hardin, Laura Hester, George Hripsak, Benjamin Skov Kaas-Hansen, Seamus Kent, Sajan Khosla, Spyros Kolovos, Christophe G Lambert, Johan van der Lei, Kristine E Lynch, Rupa Makadia, Andrea V Margulis, Michael E Matheny, Paras Mehta, Daniel R Morales, Henry Morgan-Stewart, Mees Mosseveld, Danielle Newby, Fredrik Nyberg, Anna Ostropelets, Rae Woong Park, Albert Prats-Urbe, Gowtham A Rao, Christian Reich, Jenna Reys, Peter Rijnbeek, Selva Muthu Kumaran Sathappan, Martijn Schuemie, Sarah Seager, Anthony G Sena, Azza Shoaibi, Matthew Spotnitz, Marc A Suchard, Carmen O Torre, David Vizcaya, Haini Wen, Marcel de Wilde, Junqing Xie, Seng Chan You, Lin Zhang, Oleg Zhuk, Patrick Ryan, Daniel Prieto-Alhambra, on behalf of the OHDSI-COVID-19 consortium

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**COVID-19: reminder of risk of serious side effects with chloroquine and hydroxychloroquine**

News 23/04/2020



Chloroquine and hydroxychloroquine are known to potentially cause heart rhythm problems, and these could be exacerbated if treatment is combined with other medicines, such as the antibiotic azithromycin, that have similar effects on the heart.

Recent studies<sup>1,2</sup> have reported serious, in some cases fatal, heart rhythm problems with chloroquine or hydroxychloroquine, particularly when taken at high doses or in combination with the antibiotic azithromycin.

European Union Risk Management Plan  
ChAdOx1-S (recombinant) (AZD1222)

AstraZeneca  
Version: 4, Succession number: 2

European Union Risk Management Plan	
Drug Substance	ChAdOx1-S (recombinant) (AZD1222)
Version Number	4
Succession number	2
Data lock point	25 June 2021
Date of final sign-off	See e-signature page

**EUROPEAN UNION RISK MANAGEMENT PLAN (EU RMP) FOR VAXZEVRIA (ChAdOx1-S [RECOMBINANT])**

European Union Risk Management Plan  
ChAdOx1-S (recombinant) (AZD1222)

AstraZeneca  
Version: 4, Succession number: 2

**LIST OF REFERENCES**

**ACEP 2020**  
ACEP (American College of Emergency Physicians). Emergency department COVID-19 severity classification. 2020 [19 October 2020]. Available at: [https://www.acep.org/globalassets/sites/acep/media/covid-19-main/acep\\_evidencecare\\_covid19severitytool.pdf](https://www.acep.org/globalassets/sites/acep/media/covid-19-main/acep_evidencecare_covid19severitytool.pdf). Accessed on 19 October 2020.

**Andreas Greinacher et al 2021**  
Greinacher A, Thiele T, Warkentin TE, Weisser K, Kyle PA, Eichinger S. Thrombotic Thrombocytopenia after ChAdOx1 nCov-19 Vaccination. N Eng J Med. Published online on 09 April 2021. DOI: 10.1056/NEJMoa2104840.

**Arentz et al 2020**  
Arentz M, Yim E, Klaff L, Lokhandwala S, Riedo FX, Chong M et al. Characteristics and Outcomes of 21 Critically Ill Patients With COVID-19 in Washington State. JAMA. 2020;323(16):1612-4.

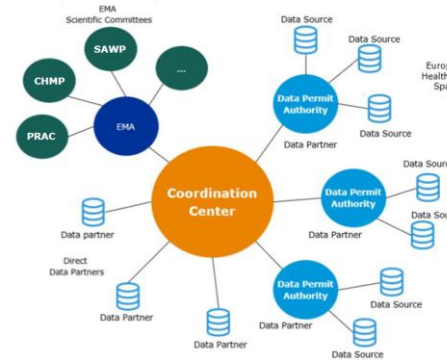
**Baxter et al 2016**  
Baxter R, Lewis E, Goddard K, Fireman B, Bakshi N, DeStefano F, et al. Acute Demyelinating Events Following Vaccines: A Case-Centered Analysis. Clin Inf Dis. 2016; 63(11): 1456-62.

**Brighton Collaboration 2021**  
Brighton Collaboration. Updated Proposed Brighton Collaboration process for developing a standard case definition for study of new clinical syndrome X, as applied to Thrombocytopenia Syndrome (TTS). 18 May 2021. Available at: <https://brightoncollaboration.us/wp-content/uploads/2021/05/TTS-Interim-Case-Definition-v10.16.3-May-23-2021.pdf>.

**Burns et al 2021**  
Burn E, Li X, Kostka K, Stewart H.M., Reich C., Seager., Salles T., et al. Background rates of five thrombosis with thrombocytopenia syndromes of special interest for COVID-19 vaccine safety surveillance: incidence between 2017 and 2019 and patient profiles from 20.6 million people in six European countries. 14 May 2021. <https://doi.org/10.1101/2021.05.12.21257083>.

**Cao et al 2020**  
Cao J, Tu W-J, Cheng W, Yu L, Liu Y-K, Hu X et al. Clinical features and short-term outcomes of 102 patients with coronavirus disease 2019 in Wuhan, China. CID. 2020;71(15):748-55.

DARWIN EU® is a federated network of data, expertise and services that supports better decision-making throughout the product lifecycle by generating reliable evidence from real world healthcare data



**FEDERATED NETWORK PRINCIPLES**

- Data stays local
- Use of Common Data Model (where applicable) to perform studies in a timely manner and increase consistency of results

8

Classified as public by the European Medicines Agency



# ETHICAL FRAMEWORKS FOR FEDERATED DATA NETWORKS

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PERSPECTIVE article

Front. Big Data, 16 September 2022  
Sec. Cybersecurity and Privacy  
<https://doi.org/10.3389/fdata.2022.945739>

This article is part of the Research Topic  
Informed Consent and Privacy Issues in Electronic Medical Records and  
Biomedical Research  
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Edited by

 Mohammed Sajedur Rahman  
Emporia State University, United States

Reviewed by

 Griffin M. Weber  
Harvard University, United States

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TABLE OF CONTENTS

- Abstract
- Background
- The concentric circles view: Local, people-centered data relationships
- Using the CCV to conceptualize data relations
- Maintaining context integrity
- The CCV and the promise of the FDN
- Discussion: Confronting challenges
- Data availability statement
- Author contributions
- Funding
- Conflict of interest

<https://bit.ly/3SI7Z9m>; accessed 20/09/22

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## A concentric circles view of health data relations facilitates understanding of sociotechnical challenges for learning health systems and the role of federated data networks

 Richard Milne<sup>1,2</sup>,  Mark Sheehan<sup>3,4</sup>,  Brendan Barnes<sup>5</sup>,  Janek Kapper<sup>6</sup>,  Nathan Lea<sup>7</sup>,  
 James N'Dow<sup>8</sup>,  Gurparkash Singh<sup>9</sup>,  Amelia Martin-Uranga<sup>10</sup> and  Nigel Hughes<sup>11\*</sup>

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- <sup>2</sup> Kavli Centre for Ethics, Science and the Public, Faculty of Education, University of Cambridge, Cambridge, United Kingdom
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- <sup>10</sup> Farmaindustria, Madrid, Spain
- <sup>11</sup> Janssen Research and Development, Beerse, Belgium

The ability to use clinical and research data at scale is central to hopes for data-driven medicine. However, in using such data researchers often encounter hurdles—both technical, such as differing data security requirements, and social, such as the terms of informed consent, legal requirements and patient and public trust. Federated or distributed data networks have been proposed and adopted in response to these hurdles. However, to date there has been little consideration of how FDNs respond to both technical and social constraints on data use. In this Perspective we propose an approach to thinking about data in terms that make it easier to navigate the health data space and understand the value of differing approaches to data collection, storage and sharing. We set out a *socio-technical* model of data systems that we call the “Concentric Circles View” (CCV) of data-relationships. The aim is to enable a consistent understanding of the fit between the local relationships within which data are produced and the extended socio-technical systems that enable their use. The paper suggests this model can help understand and tackle challenges associated with the use of real-world data in the health setting. We use the model to understand not only how but *why* federated networks may be well





# EHDEN SUSTAINABILITY – WHAT SERVICES WILL BE OFFERED?

## Advisory

Initial guidance or advice, e.g., preliminary study exploration, or methodological

## Data Landscaping

Provisional look at Data Partner network datasets, e.g., variable detection

## Feasibility

Feasibility study/studies on likelihood of full study implementation

## Simple Studies

Rapid, quick to deploy studies, dashboards and/or recurrent

## Complex Studies

More time consuming, complicated (methodologically) and with customisations

## Study-a-thon-in-a-box

Deployment of study-a-thons as study/training events with core capabilities

## Research Programmes

Public Private Partnership multi-year research programmes in specific TAs



# FDNs ARE IMPACTFUL TODAY

- National and regional developments escalating, bearing in mind iterative development for phased use in evidence generation
- We are building one of the largest international collaborative research networks on the planet within EHDEN and OHDSI
- DARWIN EU<sup>®</sup> is a critical milestone in the development of FDNs
- EHDEN has contributed to the understanding of, and response to COVID-19, but also research in wider therapeutic areas already
- We are informing, educating and working with a remarkable network across OHDSI and EHDEN
- EHDEN IMI phase will end in 2024, but we will continue as a start-up legal entity (created 2021), currently working on sustainability and long-term funding



[www.ehden.eu](http://www.ehden.eu)



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[IMI\\_EHDEN](https://www.linkedin.com/company/IMI_EHDEN)



[github.com/EHDEN](https://github.com/EHDEN)



This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU) under grant agreement No 806968. The JU receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.