Federated network studies within a country: the OHDSI UK experience

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AGENDA

- Open science and federated analytics
- Standardised data -> Standardised analyses
- Impactful examples
- True impact: DARWIN EU and FAIRS UK

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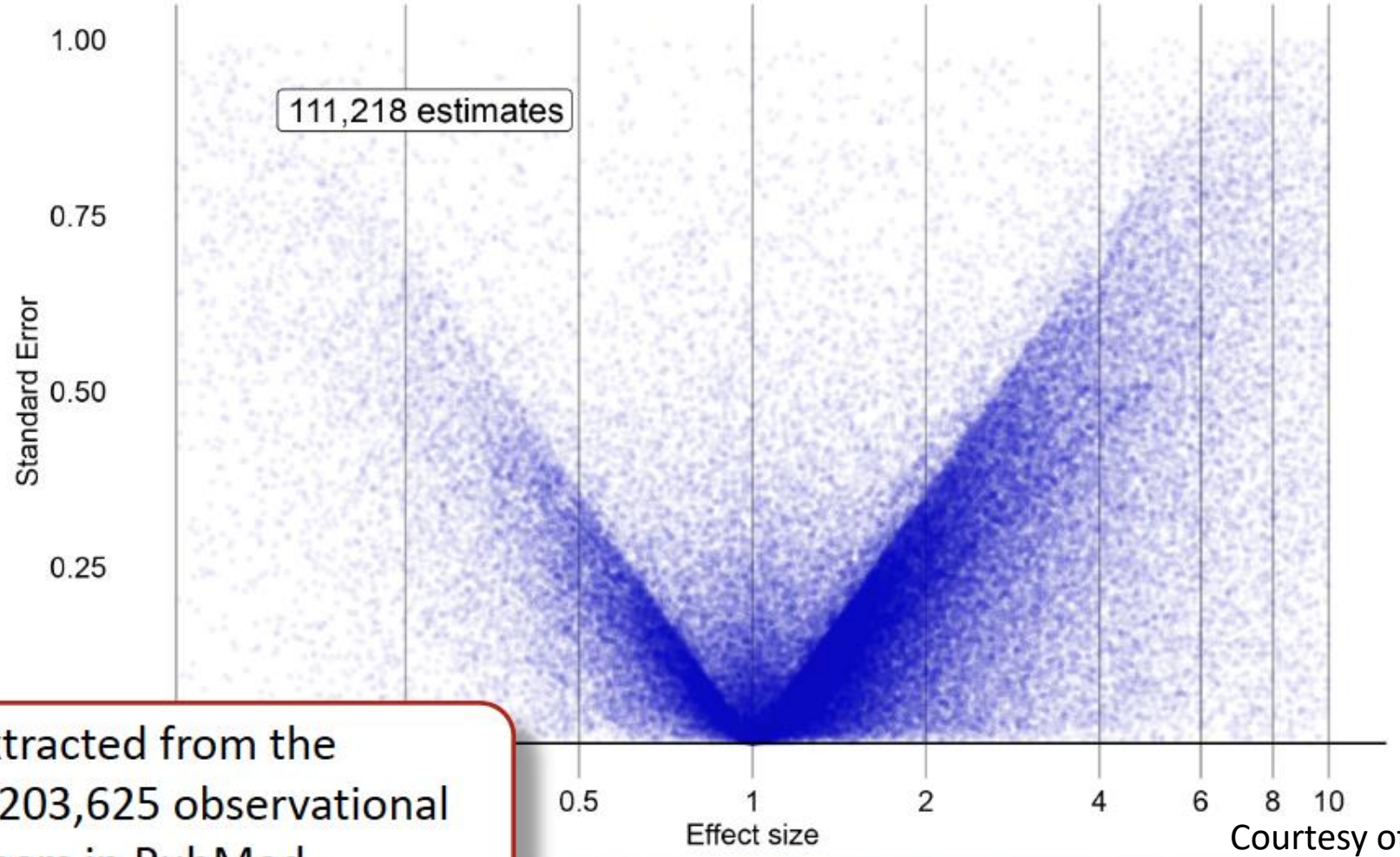
We MUST NOT do ‘silo’ Health Data Sci

Published observational study results



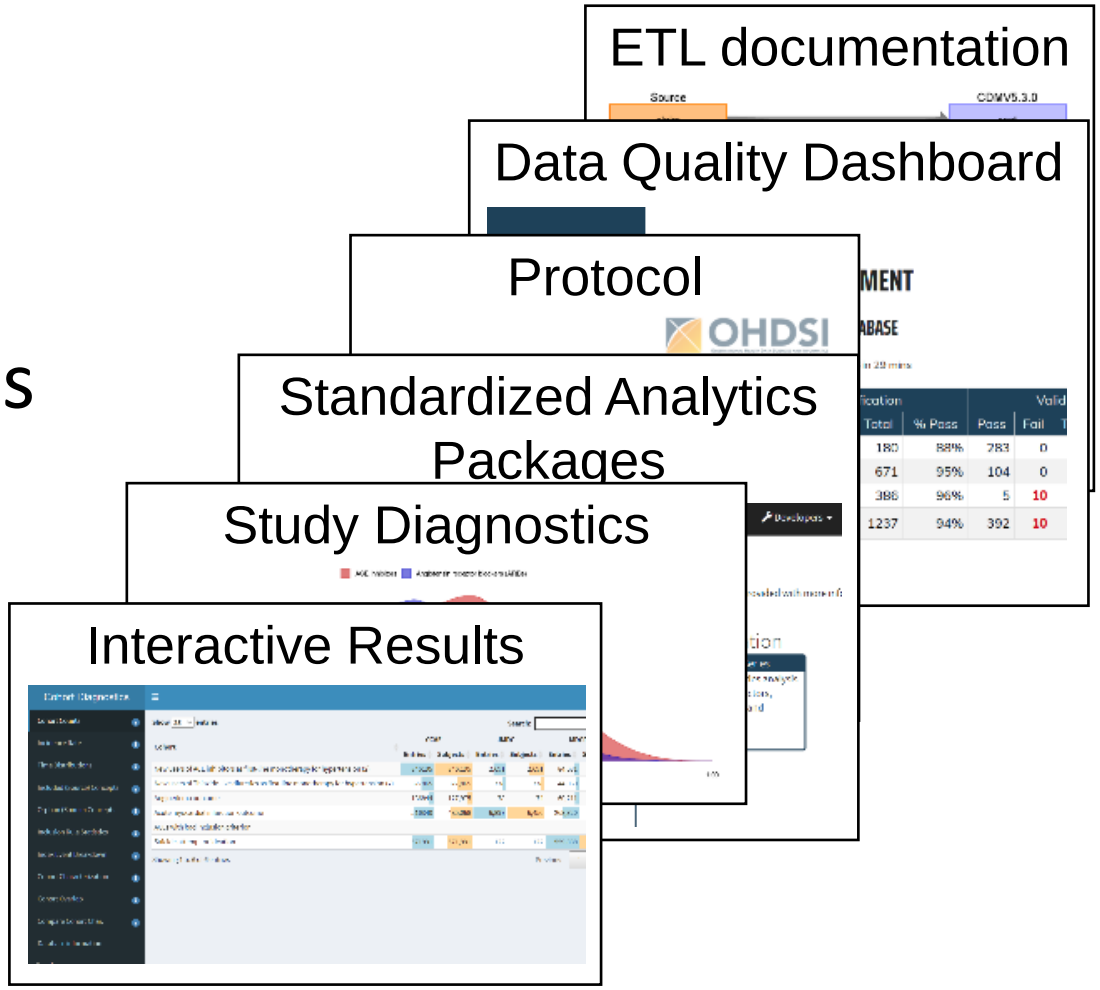
Estimates extracted from the abstracts of 203,625 observational research papers in PubMed.

Courtesy of M Schuemie

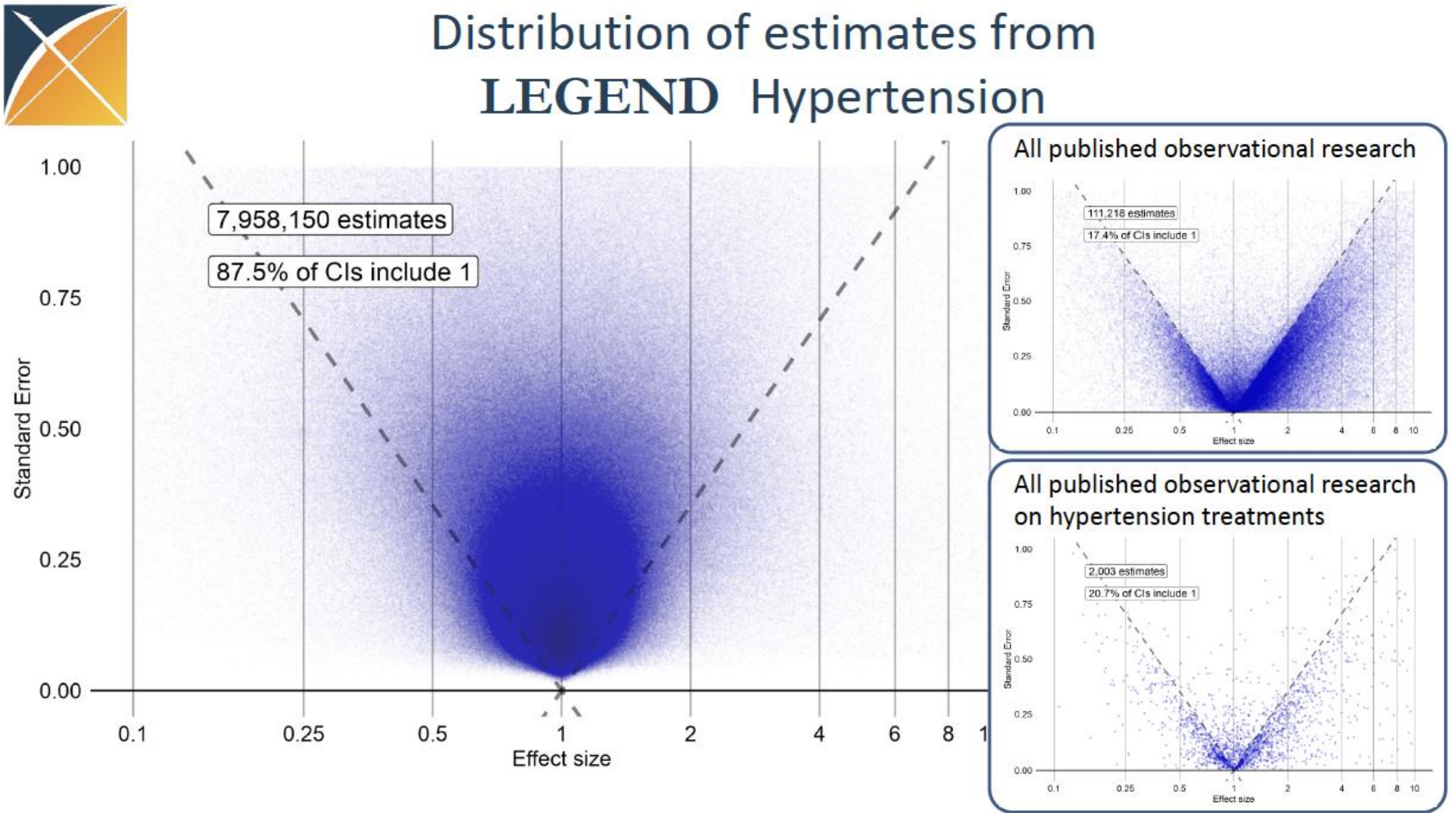
OPEN SCIENCE principles in Federated Analytics

- We need to declare a protocol
- We need to share ALL our code
- We need to share ALL our results

- Transparency is key to
  - **Reproducibility**
  - **Interpretability**
  - **Trustworthiness**



Here is the result!



Suchard M et al. Lancet 2020

Courtesy of M Schuemie

HOW WE GREW (in Europe) – The EHDEN journey

Data Sources

SMEs

EHDEN Portal

Open Calls

- Series of in-project calls across the EU
- Tailored for project objectives and sustainability

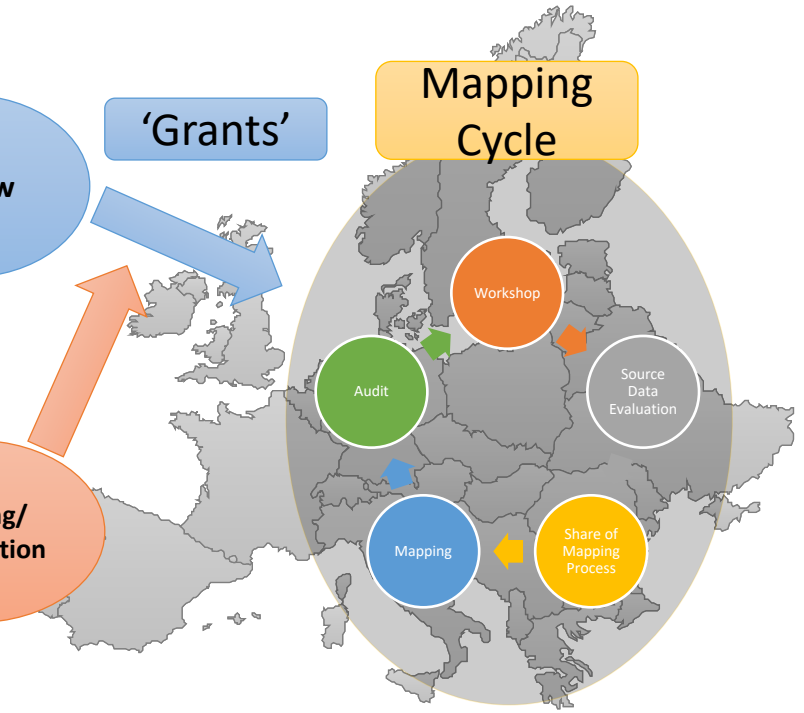
Open Calls

- Continuous open call across the EU
- Focusing on SME representation to support mapping and sustainability

Review

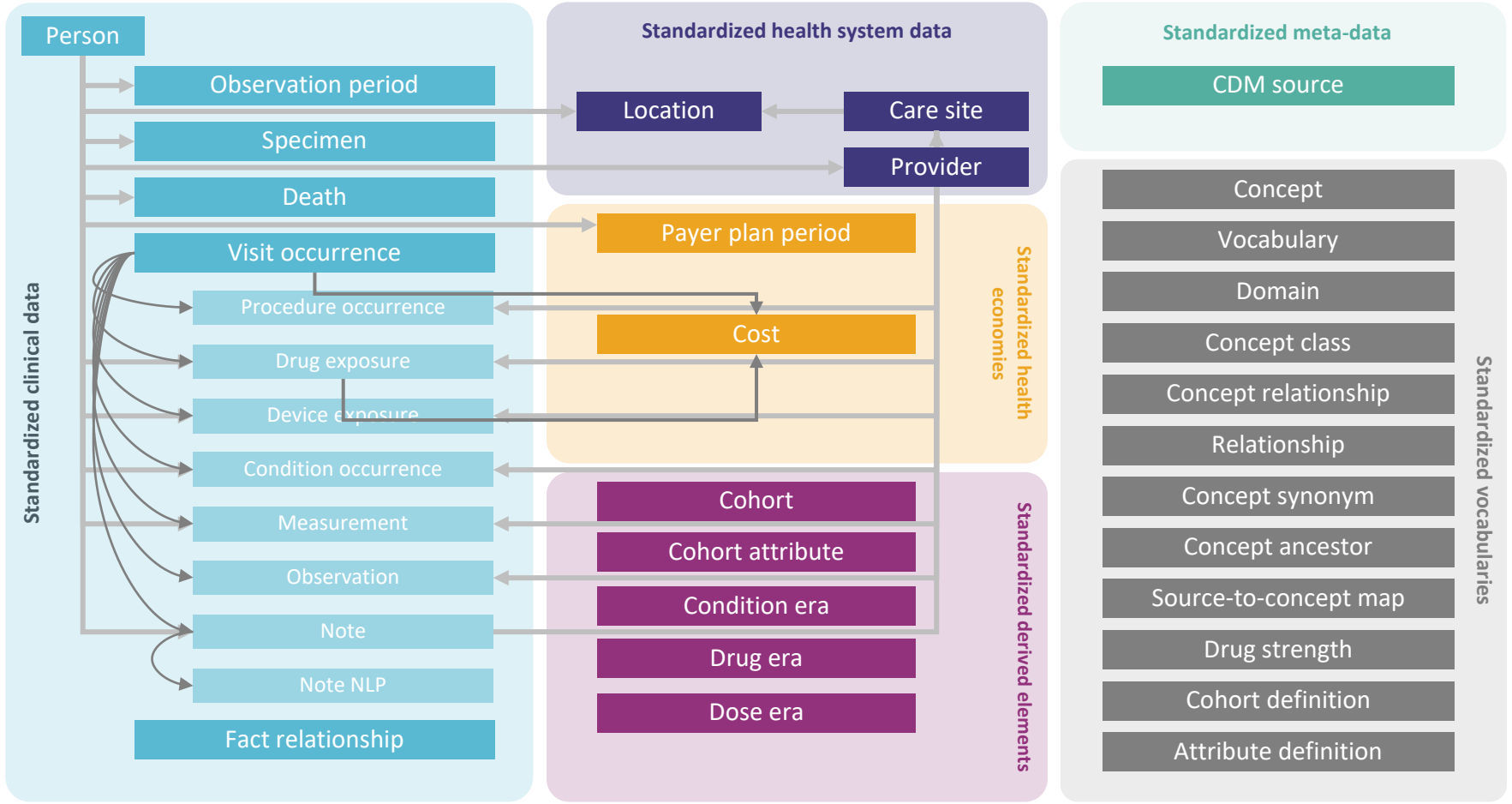
‘Grants’

Training/ Certification



- ‘Grants’ are provided via milestone payments to Data Sources
- SMEs will support Mapping Cycle and be paid via the Data Source ‘grant’, following certification by EHDEN

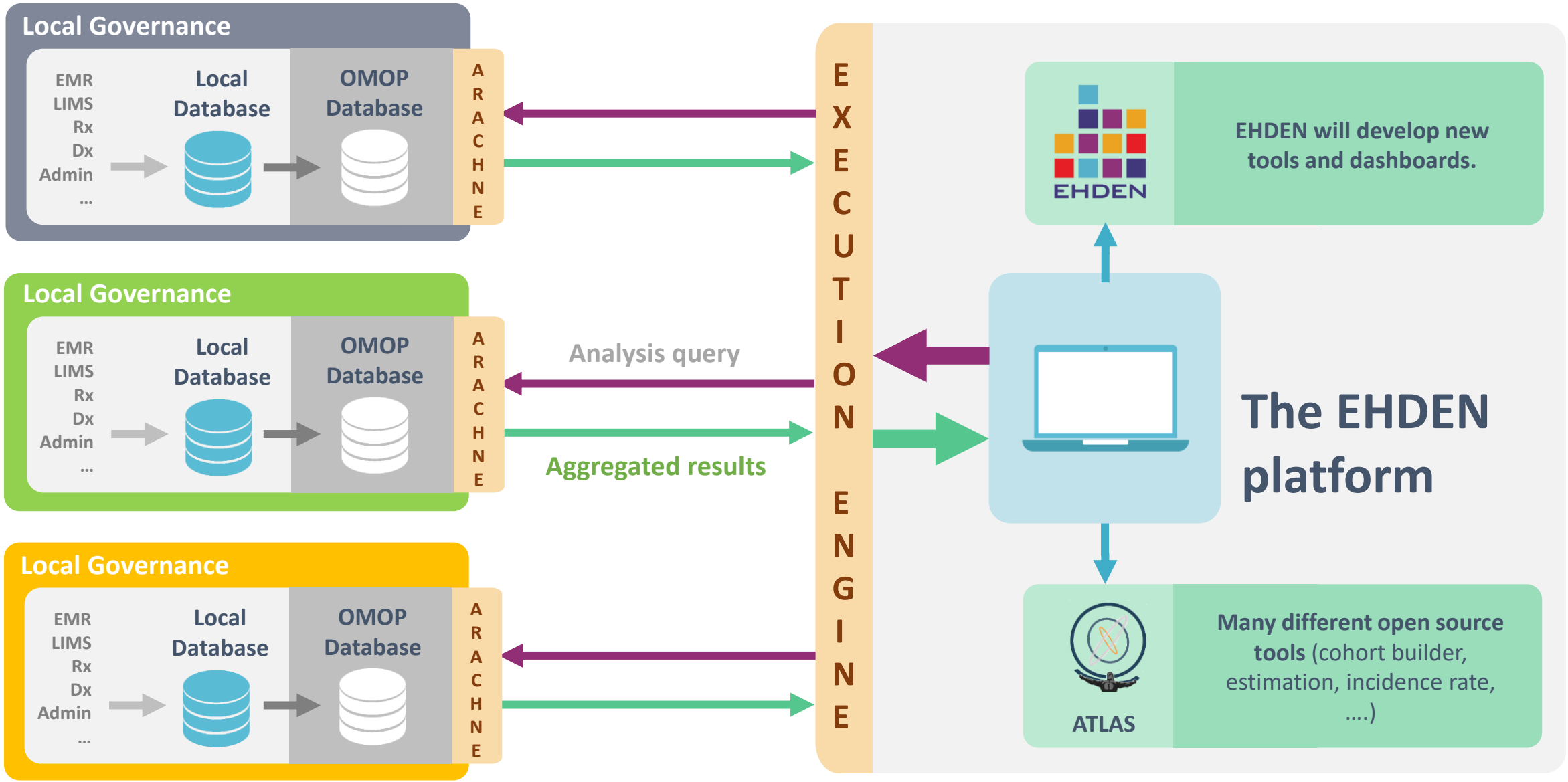
The OMOP common data model



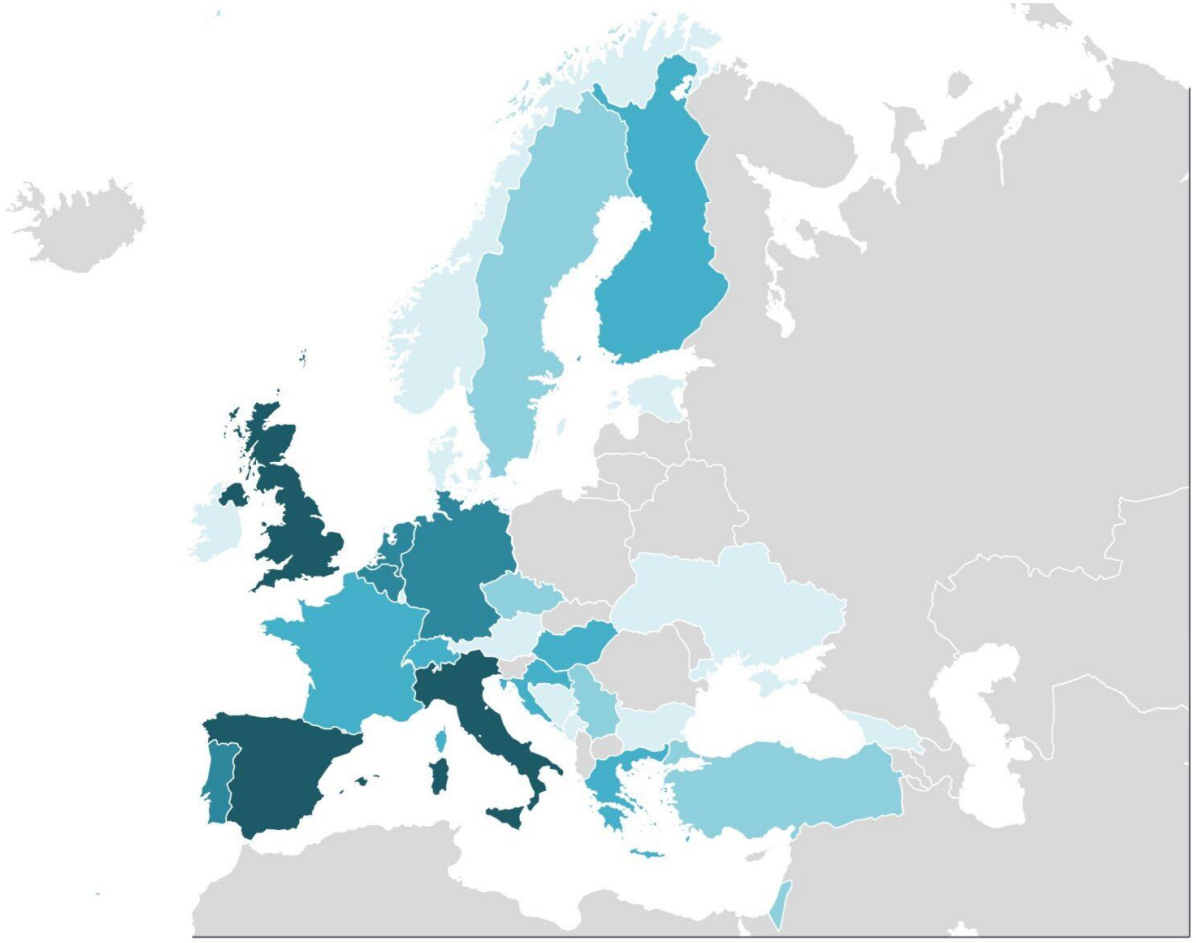
- Patient-centric
- Tabular
- Extendable
- Built for analytics
- Relational design

v 5.0.1

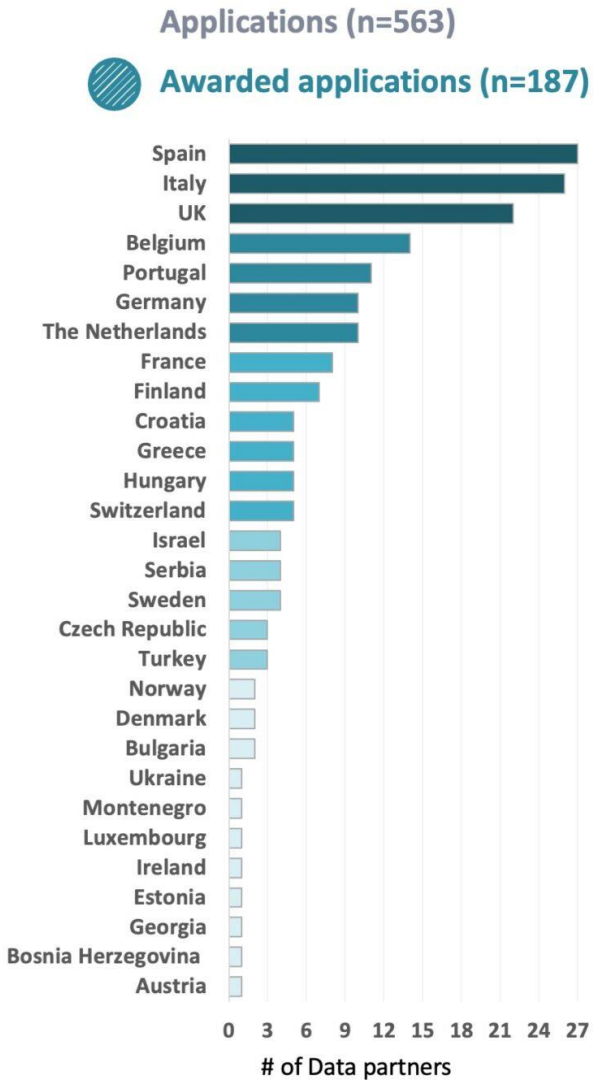
FEDERATED ANALYTICS



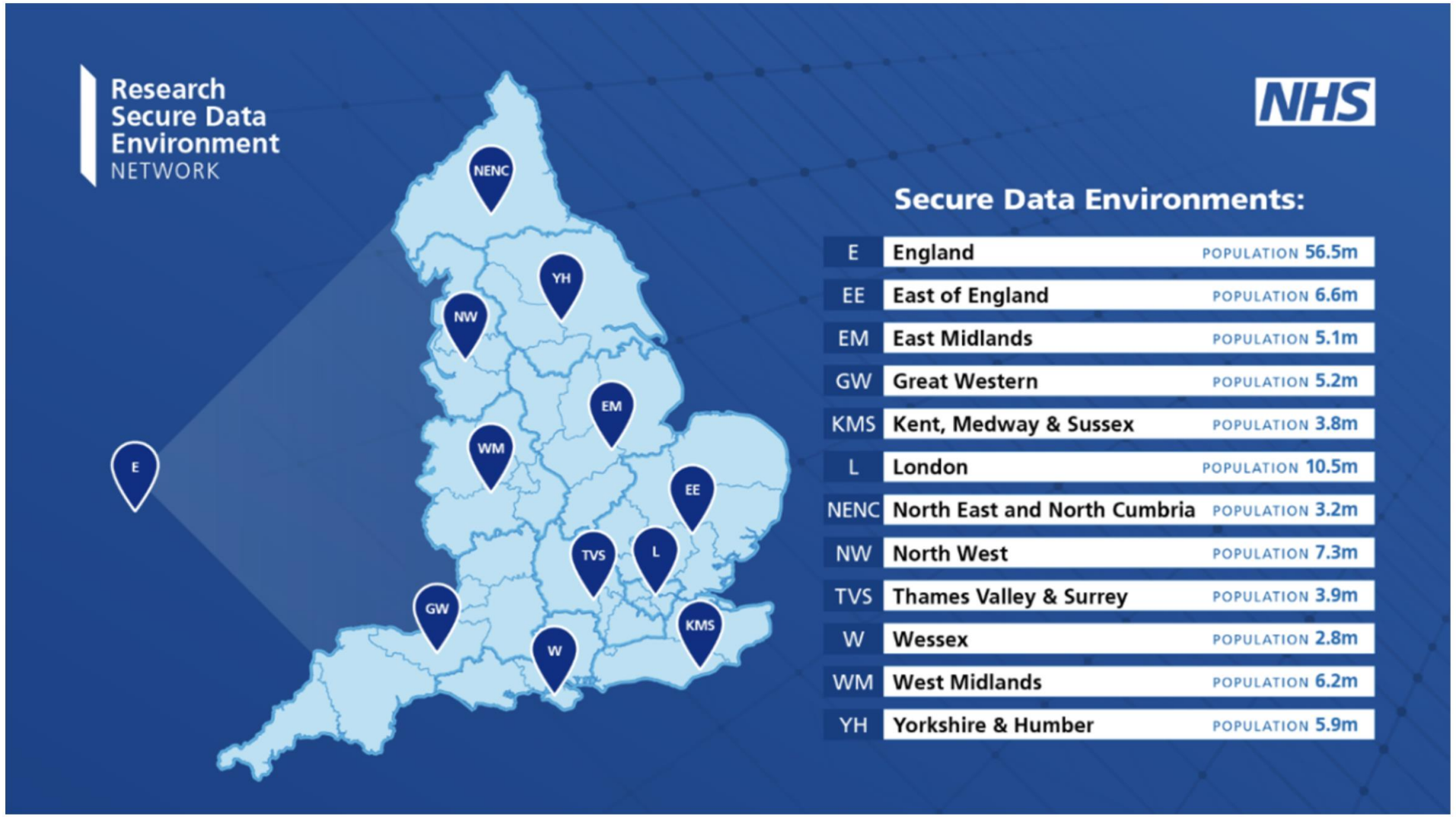
THE EHDEN NETWORK OF OMOP-MAPPED DATA PARTNERS



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



Meantime, in the UK…



Meantime, in the UK… (2)

HDRUK
Health Data Research UK

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Opinion

NHS Research SDE Network agrees to adopt common data model

15 August 2023 | Author: Dr Chris Russell, Head of Delivery, Data for R&D at NHS England

Our healthcare system is complex and has evolved over time rather than developing in line with an agreed grand plan. Health data is no different and while the benefits from a more standardised approach to data are enormous, achieving this presents a significant challenge. Dr Chris Russell, Head of Delivery, Data for Research and Development at NHS England, discusses how adoption of a common data model can help.

Contact
Dr Chris Russell
@DrChrisRussell
LinkedIn profile

Partners
NHS England

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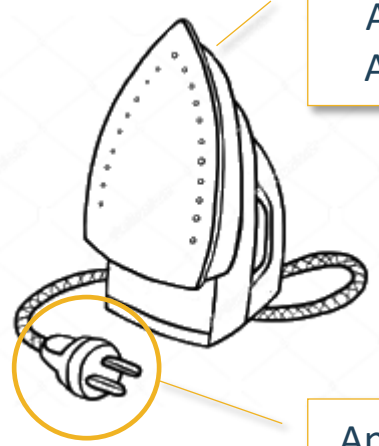
- True impact: DARWIN EU and FAIRS UK

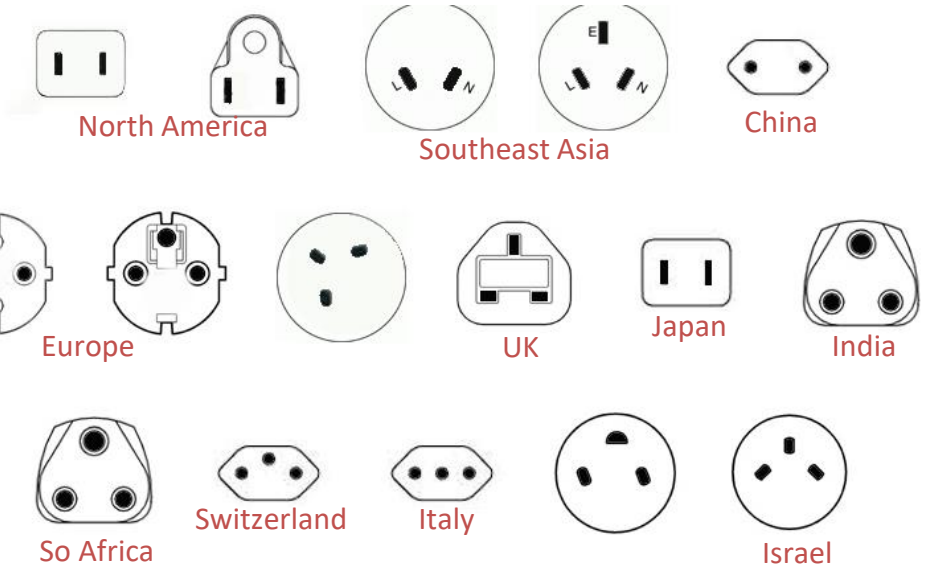
From standardised data to standardised analytics

"What's the adherence to my drug in the data assets I own?"

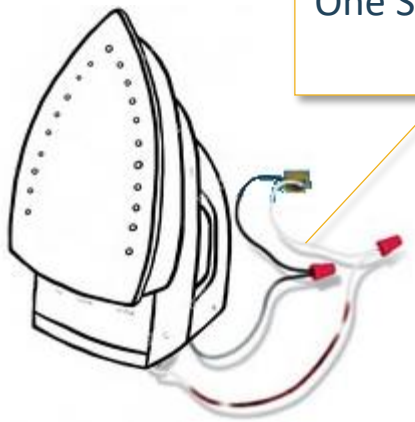


Analytical method: Adherence to Drug

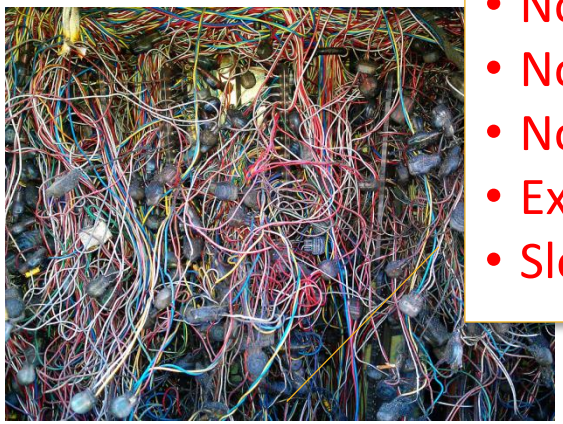
Application to data



Current solution:

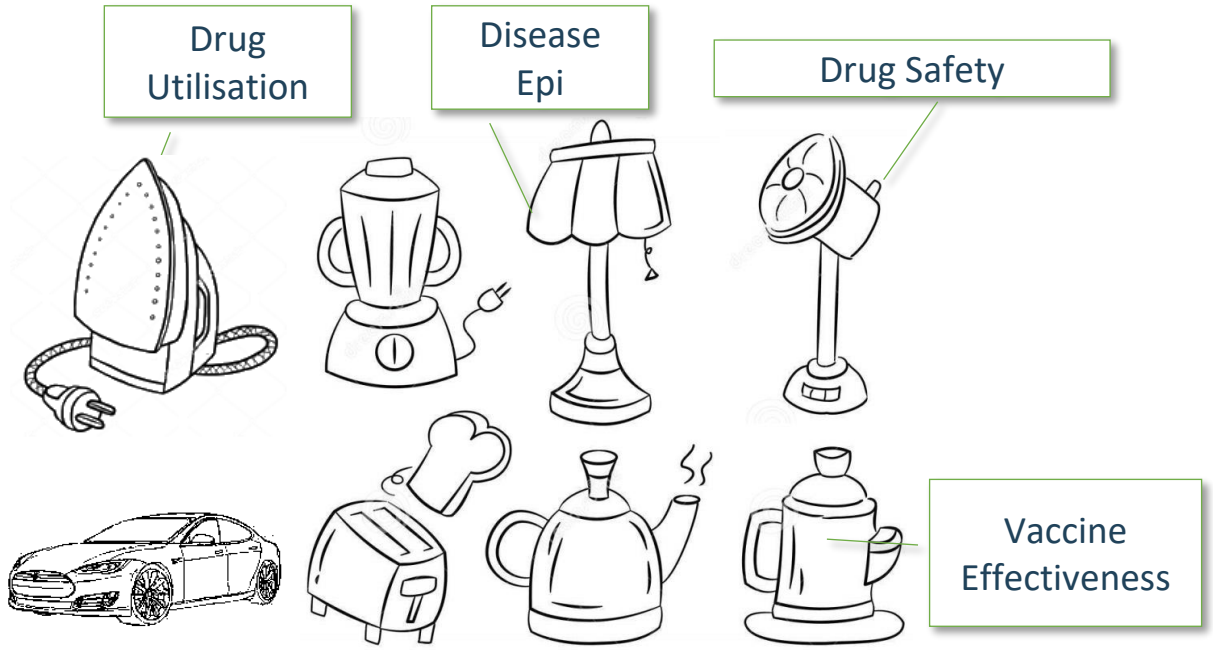


One SAS or R script for each study



- Not scalable
- Not transparent
- Not reproducible
- Expensive
- Slow

From Data Standardization To Standardised Analytics



Standardized analytics → Standardized data

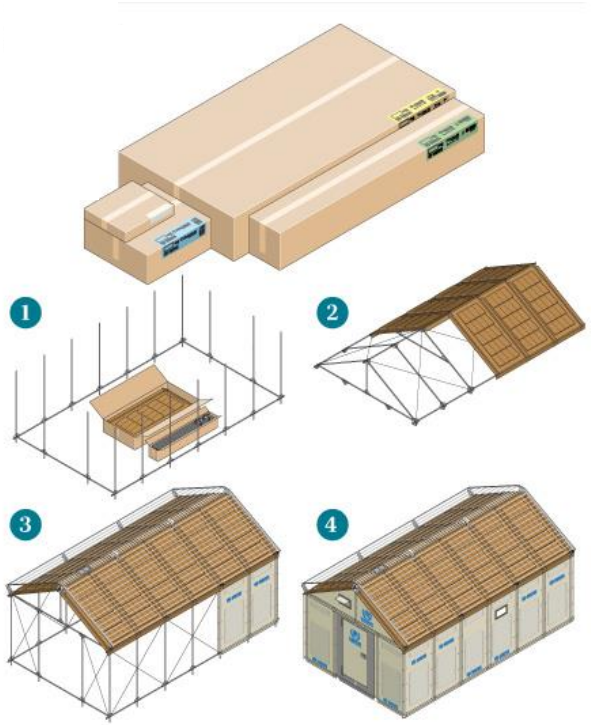
14

The challenge: TRUE scalability

	Year 1	Year 2	Year 3	Year 4	Year 5
Phases	Phase I	Phase II	Phase III	Option 1	Option 2
Routine Repeated analysis	At least 1 study	-	30	60	60
Off the shelf studies	At least 2 studies	6 + 8	30	60	60
Complex Studies	1	4	12	24	24
Very Complex Studies	0	0	0	1	1

Hacking a hard problem: Scaling up

Off the shelf
Fully STD



Complex
Pre-specified
(some bespoke)

Very complex
Bespoke code

Catalogue of Standard Data Analyses

Off-the-shelf studies

These are mainly characterisation questions that can be executed with a generic protocol. This includes disease epidemiology, for example the estimation of the prevalence, incidence of health outcomes in defined time periods and population groups, or drug utilization studies at the population or patient level.

- Patient-level characterisation
- Patient-level DUS analyses
- Population-level DUS analyses
- Population-level descriptive epidemiology

Complex

These are studies requiring development or customisation of specific study designs, protocols, analytics, phenotypes. This includes studies on the safety and effectiveness of medicines and vaccines.

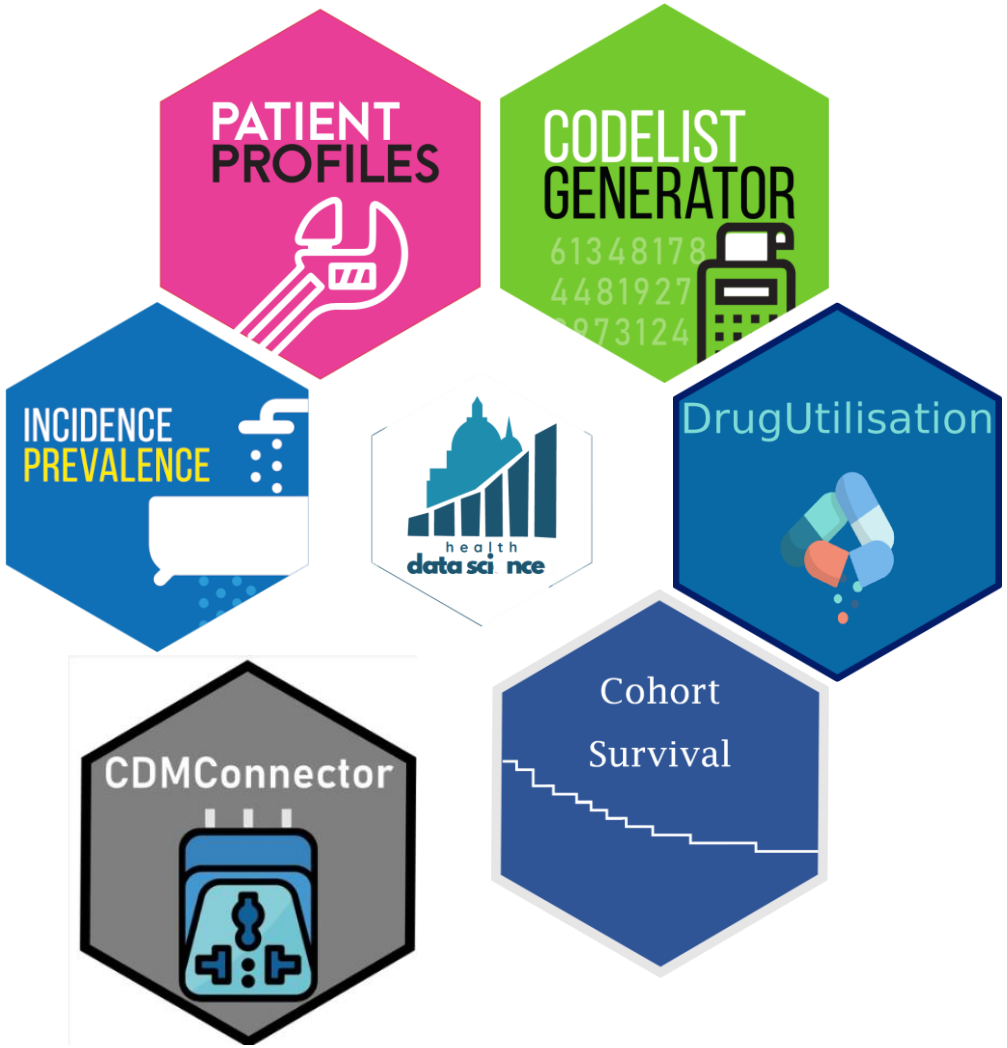
- Prevalent user active comparator cohort studies
- New user active comparator cohort
- Self-controlled case risk interval
- Self-controlled case series
- Time series analyses and Difference-in-difference studies
- RMM effectiveness

Draft Catalogue of Standard Analyses:
Off-the-shelf studies and examples

Standard Analysis	Regulatory example
Population-level disease epidemiology	• Prevalence of rare disease/s • Background rates of AESI or DMEs
Patient-level disease epidemiology	• Natural history/prognosis • Current practice/treatment patterns
Population-level DUS	• Incidence and prevalence of use of medicine/s over time
Patient-level DUS	• Describing indication/s for drug/s • Treatment duration, cumulative use

Building the tools

Developing OMOP-Std Analytical Pipelines



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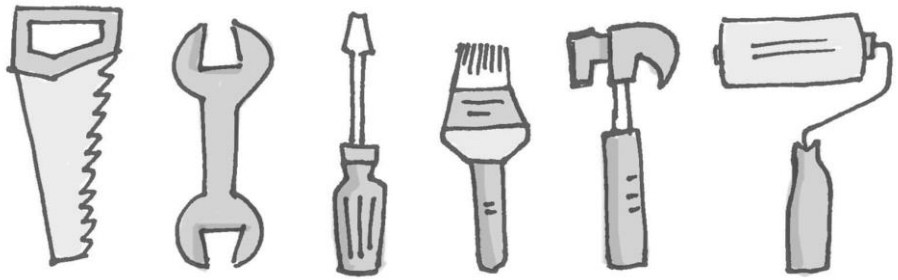
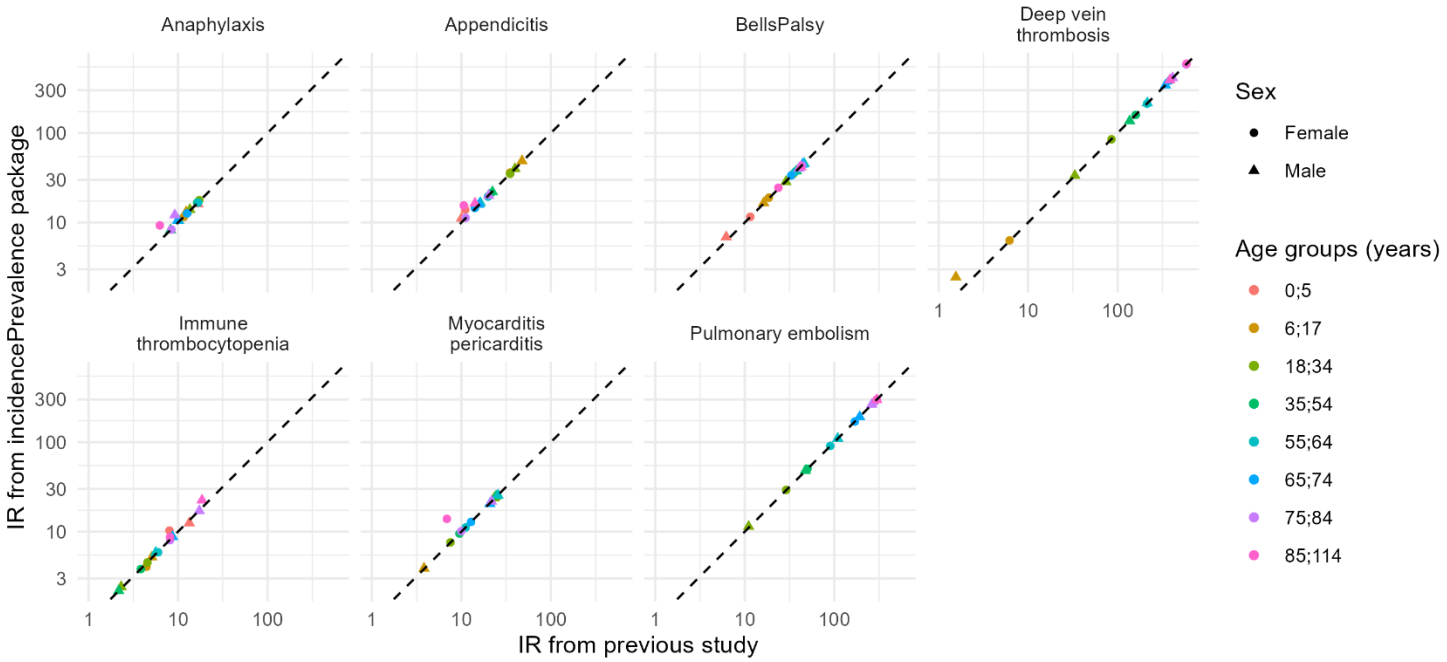
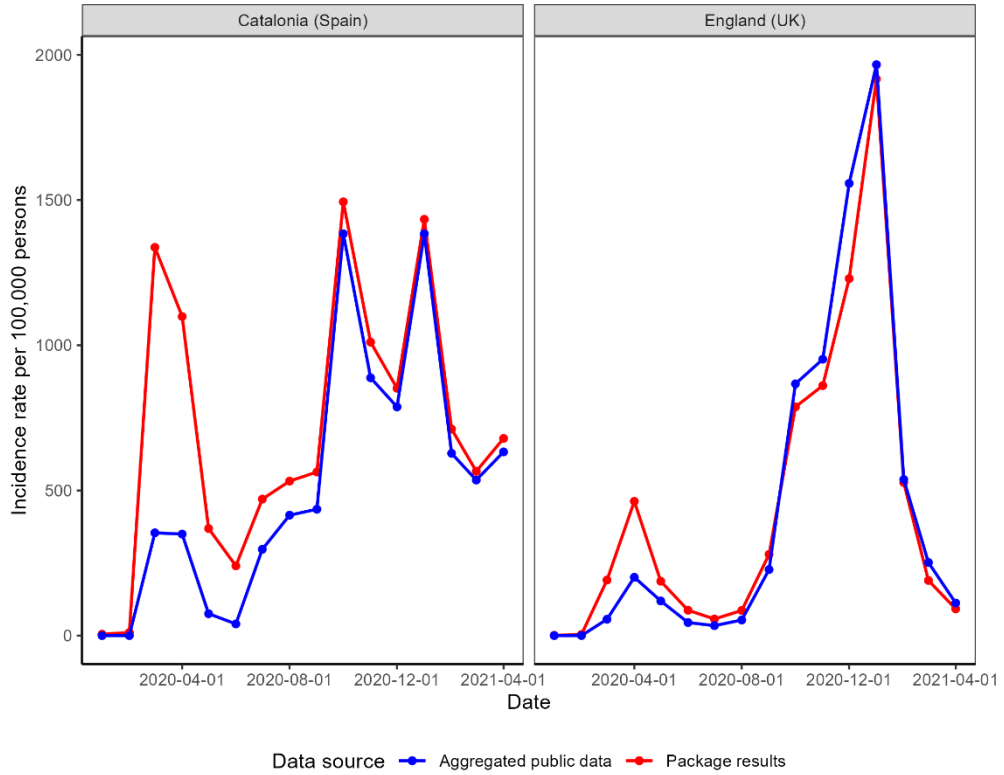


The first DARWIN EU® package: IncidencePrevalence, a package to estimate population-based incidence/prevalence





Software performance

Task	CPRD AURUM (n=39,999,011)	CPRD GOLD (n=15,662,217)	SIDIAP (n=8,265,343)	IPCI (n=2,612,850)
Generating denominator (8 cohorts)	19 mins	8 mins	3 mins	1 min
Yearly period prevalence	11 mins	5 mins	5 mins	1 min
Monthly period prevalence	17 mins	6 mins	8 mins	2 mins
Yearly incidence	8 mins	3 mins	4 mins	1 min
Monthly incidence	13 mins	5 mins	7 mins	1 min

Software dissemination

IncidencePrevalence: Estimate Incidence and Prevalence using the OMOP Common Data Model

Calculate incidence and prevalence using data mapped to the Observational Medical Outcomes Partnership (OMOP) common data model. Incidence and prevalence can be estimated for the total population in a database or for a stratification cohort.

Version:	0.4.1
Depends:	R (≥ 4.0)
Imports:	CDMConnector (≥ 1.0.0), checkmate (≥ 2.0.0), cli (≥ 3.0.0), DBI (≥ 1.0.0), dbplyr (≥ 2.0.0), dplyr (≥ 1.1.0), glue (≥ 1.5.0), ggplot2 (≥ 3.4.0), scales (≥ 1.1.0), lubridate (≥ 1.0.0), magrittr (≥ 2.0.0), purrr (≥ 0.3.5), rlang (≥ 1.0.0), stringr (≥ 1.5.0), tidyr (≥ 1.2.0), tidyselect (≥ 1.2.0), zip (≥ 2.2.0)
Suggests:	knitr, rmarkdown, RPostgres, tibble, duckdb, odbc, here, Hmisc, epitools, tictoc, testthat (≥ 0.3.1), spelling, PaRe
Published:	2023-07-11
Author:	Edward Burn [aut, cre], Berta Raventos [aut], Marti Catala [aut], Mike Du [ctb], Yuchen Guo [ctb], Adam Black [ctb], Ger Inberg [ctb], Kim Lopez [ctb]
Maintainer:	Edward Burn <edward.burn at ndorms.ox.ac.uk>
License:	Apache License (≥ 2)
URL:	https://darwin-eu.github.io/IncidencePrevalence/
NeedsCompilation:	no
Language:	en-US
Materials:	README
CRAN checks:	IncidencePrevalence results

Documentation:

Reference manual:	IncidencePrevalence.pdf
Vignettes:	a01_Introduction_to_IncidencePrevalence a02_Creating_denominator_cohorts a03_Creating_outcome_cohorts a05_Calculating_prevalence a06_Calculating_incidence

Downloads:

Package source:	IncidencePrevalence_0.4.1.tar.gz
Windows binaries:	r-devel: IncidencePrevalence_0.4.1.zip, r-release: IncidencePrevalence_0.4.1.zip, r-oldrel: IncidencePrevalence_0.4.1.zip
macOS binaries:	r-release (arm64): IncidencePrevalence_0.4.1.tgz, r-oldrel (arm64): IncidencePrevalence_0.4.1.tgz, r-release (x86_64): IncidencePrevalence_0.4.1.tgz, r-oldrel (x86_64): IncidencePrevalence_0.4.1.tgz
Old sources:	IncidencePrevalence archive

Received: 30 May 2023 | Revised: 27 September 2023 | Accepted: 2 October 2023
DOI: 10.1002/pds.5717

ORIGINAL ARTICLE

WILEY

IncidencePrevalence: An R package to calculate population-level incidence rates and prevalence using the OMOP common data model

Berta Raventós[1,2] | Martí Català[3] | Mike Du[3] | Yuchen Guo[3] | Adam Black[4] | Ger Inberg[5] | Xintong Li[3] | Kim López-Güell[3] | Danielle Newby[3] | Maria de Ridder[5] | Cesar Barboza[5] | Talita Duarte-Salles[1,5] | Katia Verhamme[5] | Peter Rijnbeek[5] | Daniel Prieto Alhambra[3,5] | Edward Burn[3]

[1]Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAPJGol), Barcelona, Spain
[2]Universitat Autònoma de Barcelona, Bellaterra (Cerdanyola del Vallès), Barcelona, Spain
[3]Centre for Statistics in Medicine (CSM), Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDROMS), University of Oxford, Oxford, UK
[4]Odysseus Data Services, Cambridge, Massachusetts, USA
[5]Department of Medical Informatics, Erasmus University Medical Center, Rotterdam, The Netherlands

Correspondence
Edward Burn, Botnar Research Centre, Windmill Road, OX37LD, Oxford, UK.
Email: edward.burn@ndorms.ox.ac.uk

Funding information
European Medicines Agency

Abstract

Purpose: Real-world data (RWD) offers a valuable resource for generating population-level disease epidemiology metrics. We aimed to develop a well-tested and user-friendly R package to compute incidence rates and prevalence in data mapped to the observational medical outcomes partnership (OMOP) common data model (CDM).

Materials and Methods: We created IncidencePrevalence, an R package to support the analysis of population-level incidence rates and point- and period-prevalence in OMOP-formatted data. On top of unit testing, we assessed the face validity of the package. To do so, we calculated incidence rates of COVID-19 using RWD from Spain (SIDIAP) and the United Kingdom (CPRD Aurum), and replicated two previously published studies using data from the Netherlands (IPCI) and the United Kingdom (CPRD Gold). We compared the obtained results to those previously published, and measured execution times by running a benchmark analysis across databases.

Results: IncidencePrevalence achieved high agreement to previously published data in CPRD Gold and IPCI, and showed good performance across databases. For COVID-19, incidence calculated by the package was similar to public data after the first-wave of the pandemic.

Conclusion: For data mapped to the OMOP CDM, the IncidencePrevalence R package can support descriptive epidemiological research. It enables reliable estimation of incidence and prevalence from large real-world data sets. It represents a simple, but

Berta Raventós and Martí Català should be considered as joint first-authors

This work has been presented as a Software Demonstration in the Observational Health Data Sciences and Informatics (OHDSI) Symposium held in Bethesda, USA, on 14–16 October 2022.

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“Simple” characterisation

RESEARCH

OPEN ACCESS

Check for updates

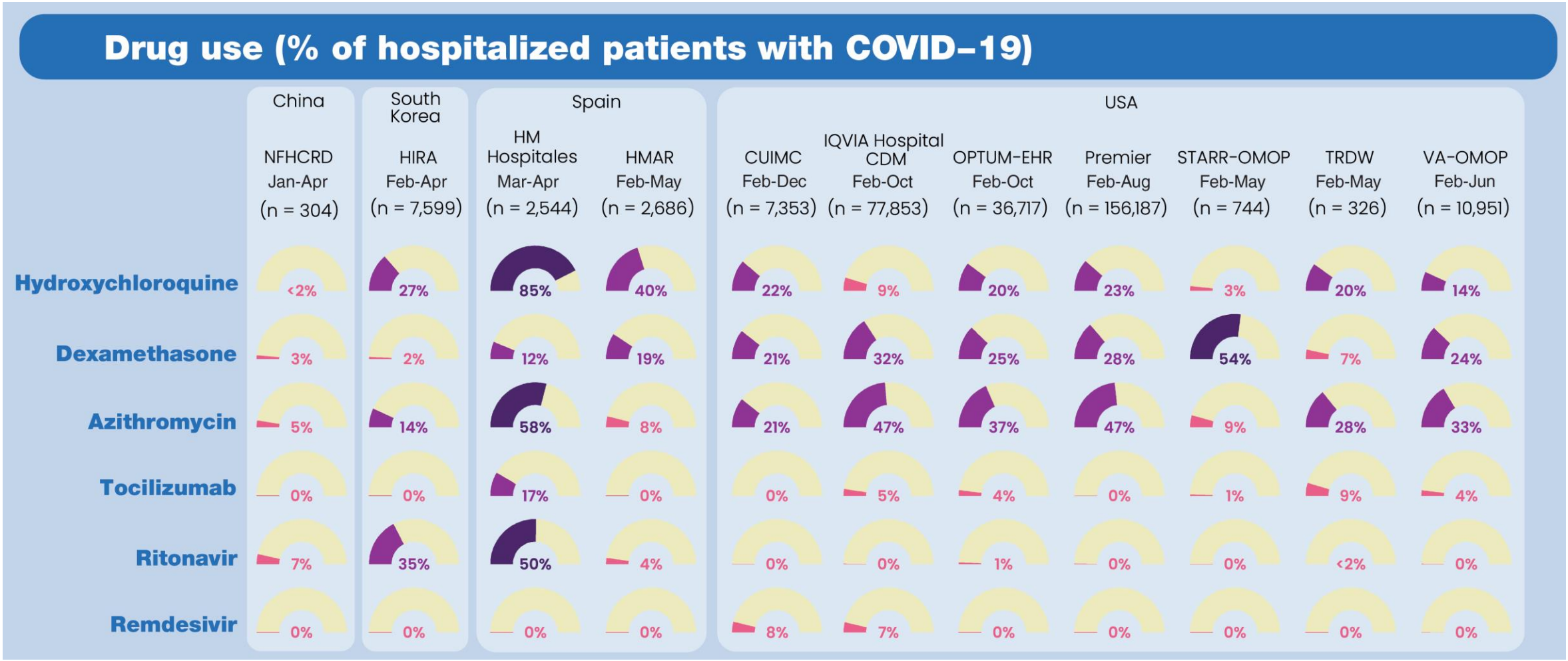
Use of repurposed and adjuvant drugs in hospital patients with covid-19: multinational network cohort study

Albert Prats-Uribe,[1] Anthony G Sena,[2,3] Lana Yin Hui Lai,[4] Waheed-Ul-Rahman Ahmed,[5,6] Heba Alghoul,[7] Osaid Alser,[8] Thamir M Alshammari,[9] Carlos Areia,[10] William Carter,[11] Paula Casajust,[12] Dalia Dawoud,[13,14] Asieh Golozar,[15,16] Jitendra Jonnagaddala,[17] Paras P Mehta,[18] Mengchun Gong,[19] Daniel R Morales,[20,21] Fredrik Nyberg,[22] Jose D Posada,[23] Martina Recalde,[24,25] Elena Roel,[24,25] Karishma Shah,[5] Nigam H Shah,[23] Lisa M Schilling,[11] Vignesh Subbian,[26] David Vizcaya,[27] Lin Zhang,[28,29] Ying Zhang,[19] Hong Zhu,[30] Li Liu,[30] Jaehyeong Cho,[31] Kristine E Lynch,[32] Michael E Matheny,[33,34] Seng Chan You,[35] Peter R Rijnbeek,[3] George Hripcsak,[36] Jennifer CE Lane,[5] Edward Burn,[1,24] Christian Reich,[37] Marc A Suchard,[38] Talita Duarte-Salles,[24] Kristin Kostka,[37,39] Patrick B Ryan,[2,40] Daniel Prieto-Alhambra[1]

thebmj

Prats-Uribe et al. BMJ 2021

DRUG UTILISATION WITHIN 30D OF HOSP.



A Prats-Uribe et al. BMJ 2021

THE RISE AND FALL OF HCQ (BEFORE TRIALS)

February 2020
4 February Wang et al - Remdesivir and chloroquine effectively inhibit covid-19 in vitro

March 2020
9 March Yao et al - Hydroxychloroquine shows superior in vitro activity to chloroquine
19 March President Trump promotes hydroxychloroquine in press conference
20 March Gautret et al - Open-label non-randomized clinical trial shows effectiveness
28 March US Food and Drug Administration issues an emergency use authorisation
31 March Chen et al - Preprint of a randomised controlled trial suggests that hydroxychloroquine reduces time to clinical recovery

April 2020
10 April Lane et al - Observational data shows that azithromycin combined with hydroxychloroquine may increase cardiovascular mortality
24 April FDA and European Medicines Agency caution against the use of hydroxychloroquine owing to potential heart rhythm problems

May 2020
7 May Geleris et al - Lack of effectiveness of hydroxychloroquine on observational data
28 May WHO halts hydroxychloroquine arm of Solidarity trial

June 2020
8 June Recovery trial press note shows that hydroxychloroquine has no effect on covid-19
15 June FDA revokes emergency use ruling for hydroxychloroquine

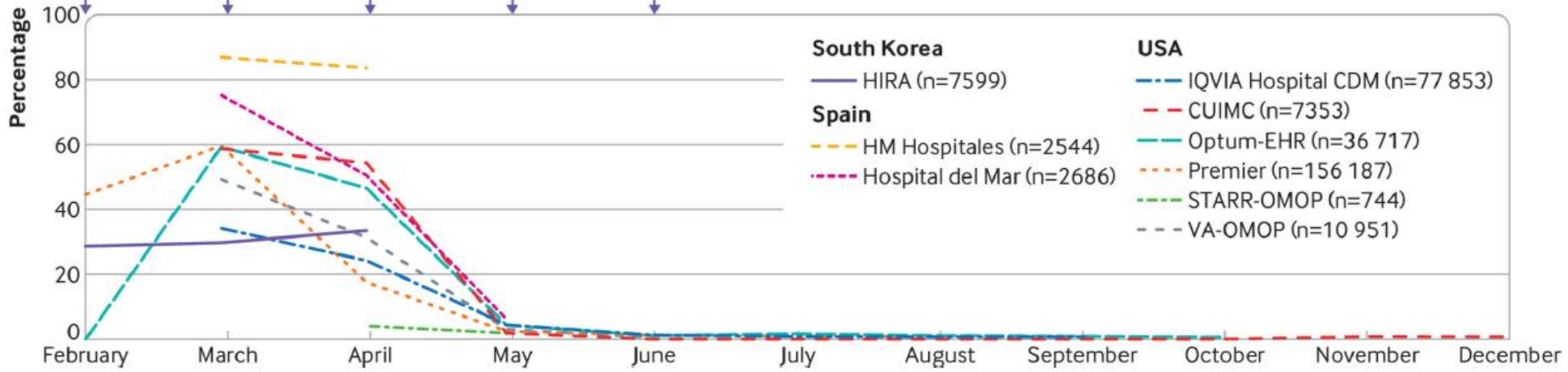


Fig 4 | Time trends in hydroxychloroquine use on days 0 to 30 after hospital admission in patients with a positive test result for or diagnosis of covid-19 by month. CUIMC=Columbia University Irving Medical Center; HIRA=Health Insurance Review and Assessment; OMOP=Observational Medical Outcomes Partnership; Optum-EHR=Optum deidentified electronic health record dataset; STARR=STAnford medicine Research data Repository; TRDW=Tufts Research Data Warehouse; VA=Veterans Affairs

Comparative safety

RESEARCH

OPEN ACCESS

Check for updates

Comparative risk of thrombosis with thrombocytopenia syndrome or thromboembolic events associated with different covid-19 vaccines: international network cohort study from five European countries and the US

Xintong Li,[1] Edward Burn,[1,2] Talita Duarte-Salles,[2] Can Yin,[3] Christian Reich,[3] Antonella Delmestri,[1] Katia Verhamme,[4] Peter Rijnbeek,[4] Marc A Suchard,[5,6] Kelly Li,[5] Mees Mosseveld,[4] Luis H John,[4] Miguel-Angel Mayer,[7] Juan-Manuel Ramirez-Anguita,[7] Catherine Cohet,[8] Victoria Strauss,[1] Daniel Prieto-Alhambra[1,4]

thebmj

Xintong Li et al. BMJ 2022

AIMS & METHODS

- **Objective**: To quantify the comparative risk of thrombosis +/- thrombocytopenia associated with adenovirus- vs mRNA-based COVID vaccination

- **Design**: International active comparator cohort study incl data from DE, ES, FR, NL, UK, and USA

- **Analysis**:
  1. Large-scale PS matching
  2. Incidence rate ratios 28-d post-each dose
  3. Meta-analysis across databases (where I2<40%)

CONTRIBUTING DATA SOURCES/PARTNERS

Table 1 | Descriptions of medical records databases used in study

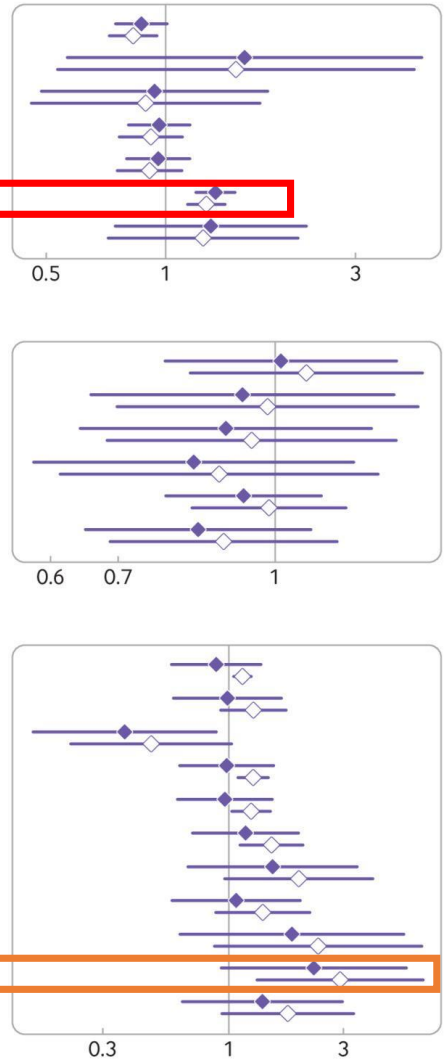
Database full (short) names	Country	Active size of database (by mid-2021; No of people)	Latest data available time	Key data available				
				Covid-19 vaccines	Hospital treatments	Hospital outcomes	Outpatient treatments	Platelet counts
Clinical Practice Research Datalink Aurum (UK CPRD)	UK	13m	May 2021	Complete	No	Incomplete	Yes	Yes
Information System for Research in Primary Care with minimum basic set of hospital discharge data (CMBD-HA; Spain SIDIAP)	Spain	6m	June 2021	Complete	No	Linked	Yes	Yes
Integrated Primary Care Information (Netherlands IPCI)	The Netherlands	2m	June 2021	Incomplete	No	Incomplete	Yes	Yes
IQVIA Longitudinal Patient Data France (France LPD)	France	2.3m	September 2021	Incomplete	No	Incomplete	Yes	Yes
IQVIA Disease Analyser Germany (Germany DA)	Germany	8.5m	August 2021	Incomplete	No	Incomplete	Yes	Yes
Medical and Institutional Claims (US Open Claims)	US	187m	September 2021	Incomplete	Incomplete	Incomplete	Yes	Yes
Charge Data Master (US Hospital CDM)	US	30m	July 2021	Incomplete	Yes	Yes	Incomplete	Incomplete

RESULTS

Meta-analytical estimates

Outcome	Calibrated incidence rate ratio (95% CI)	I^2	UK CPRD	Germany DA	Netherlands IPCI	France LPD
ChAdOx1-S first dose *v* BNT162b2 first dose						
Arterial thromboembolism	0.87 (0.75 to 1.01)	0	X	X	X	X
Deep vein thrombosis	1.58 (0.56 to 4.42)	0.86	X	X	X	
Ischemic stroke	0.94 (0.48 to 1.81)	0.51	X	X	X	
Myocardial infarction	0.96 (0.8 to 1.15)	0	X	X	X	X
Pulmonary embolism	0.96 (0.79 to 1.15)	0	X	X	X	
Thrombocytopenia	1.33 (1.18 to 1.5)	0	X	X	X	X
Venous thromboembolism	1.3 (0.75 to 2.26)	0.65	X	X	X	X
ChAdOx1-S second dose *v* BNT162b2 second dose						
Arterial thromboembolism	1.01 (0.78 to 1.32)	0	X	X	X	
Deep vein thrombosis	0.93 (0.66 to 1.31)	0	X		X	
Myocardial infarction	0.89 (0.64 to 1.25)	0	X	X	X	
Pulmonary embolism	0.83 (0.58 to 1.2)	0	X	X		
Thrombocytopenia	0.93 (0.78 to 1.11)	0	X	X	X	
Venous thromboembolism	0.84 (0.65 to 1.09)	0	X	X	X	

Outcome	Calibrated incidence rate ratio (95% CI)	I^2	Germany DA	Spain SIDIAP	Netherlands IPCI	US Open Claims
Ad26.COV2.S *v* BNT162b2 first dose						
Arterial thromboembolism	0.89 (0.58 to 1.37)	0	X	X	X	X
Deep vein thrombosis	0.99 (0.58 to 1.67)	0.14	X	X		X
Intestinal infarction	0.37 (0.15 to 0.89)	0		X		X
Ischemic stroke	0.99 (0.63 to 1.55)	0	X	X		X
Myocardial infarction	0.97 (0.61 to 1.53)	0	X	X	X	X
Pulmonary embolism	1.17 (0.7 to 1.97)	0.06	X	X		X
Splanchnic and visceral thrombosis	1.52 (0.67 to 3.47)	0		X		X
Thrombocytopenia	1.08 (0.58 to 1.99)	0.78	X	X		X
TTS Deep vein thrombosis	1.83 (0.62 to 5.38)	0		X		X
TTS Venous thromboembolism	2.26 (0.93 to 5.52)	0		X		X
Venous thromboembolism	1.38 (0.64 to 2.99)	0.73	X	X		X



Xintong Li et al. BMJ 2022; 379:bmj-2022-071594

Conclusions

-No differential risk of ‘common’ thromboembolic events, venous or arterial

-A 30% increased risk of thrombocytopenia

-A trend towards an increased risk of TTS-VTE

RMM Effectiveness

Measuring the effect of regulatory action

Results of the first OHDSI UK Study-a-thon

Background

- Fluoroquinolones are popular antibiotics for the treatment of minor (eg UTI) as well as major (eg severe kidney) infections

- Their use increased over the years, and then we learned of potential severe side effects, including tendon rupture

Background (2)

- These seem more common in certain population subgroups, like older people and those using corticosteroids

- Based on this, a number of regulators have imposed risk minimization measures to reduce the use of fluoroquinolones

Aim

- In collaboration with the UK national drugs and medical device regulator (MHRA), we conducted a Study-A-Thon to estimate the impact of regulatory actions on the use of fluoroquinolones nationally
  - In primary care/outpatient vs Inpatient data
  - In older vs younger people

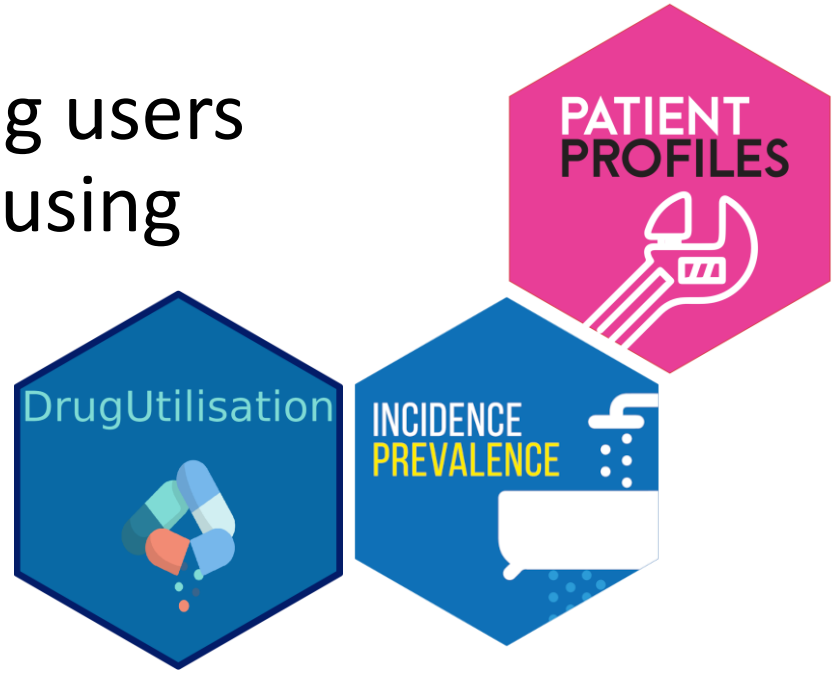
What data?

- Different healthcare settings
  - Primary care (CPRD GOLD and Aurum)
  - Hospital data (Barts Health)
  - Linked data (HIC Dundee)

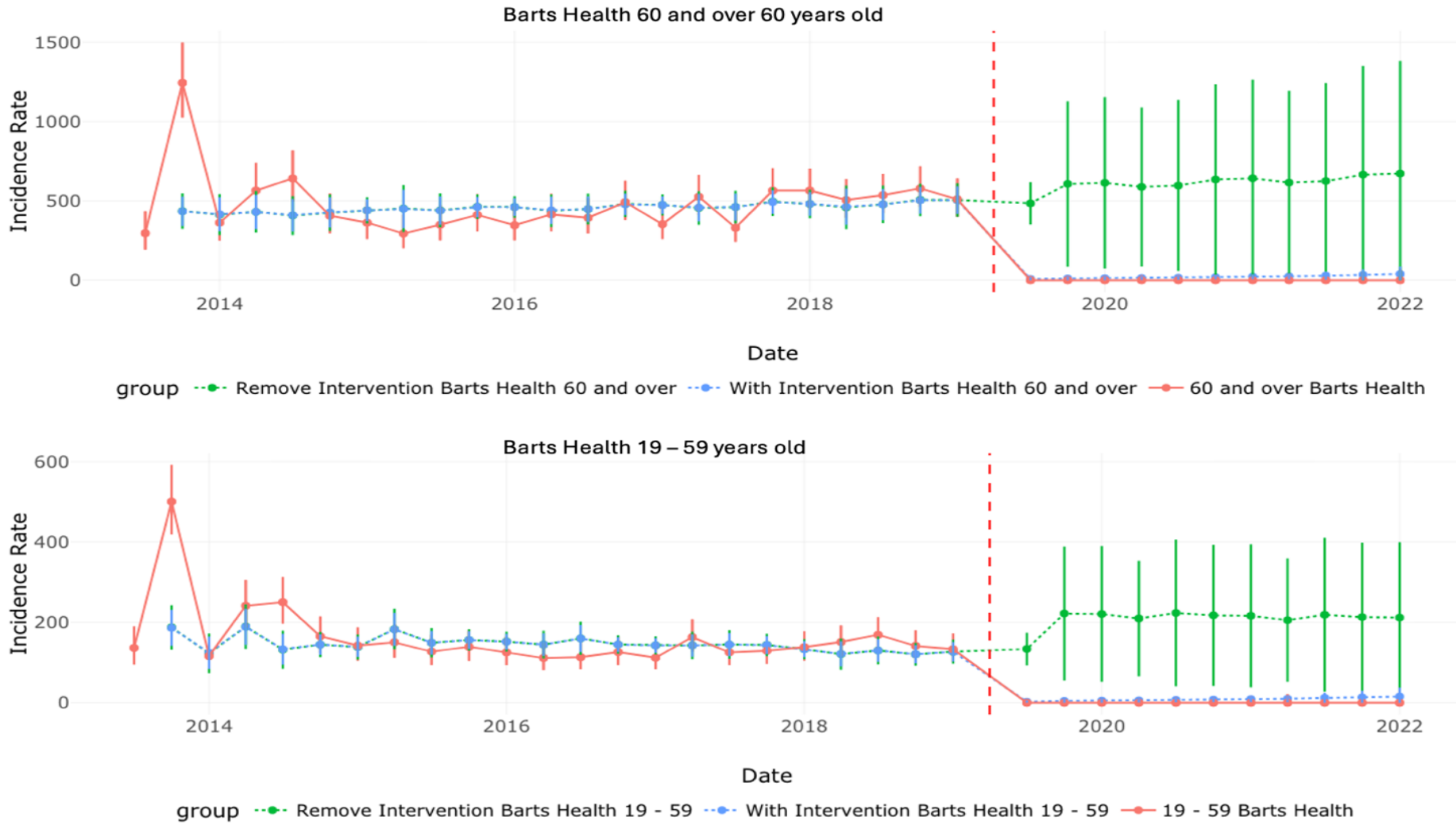
- Different geographies/health regions with different protocols/etc
  - CPRD GOLD: mostly Scotland and Northern Ireland
  - CPRD Aurum: only England
  - Barts Health: London
  - HIC Dundee: Scotland

(Standardised) Analytics

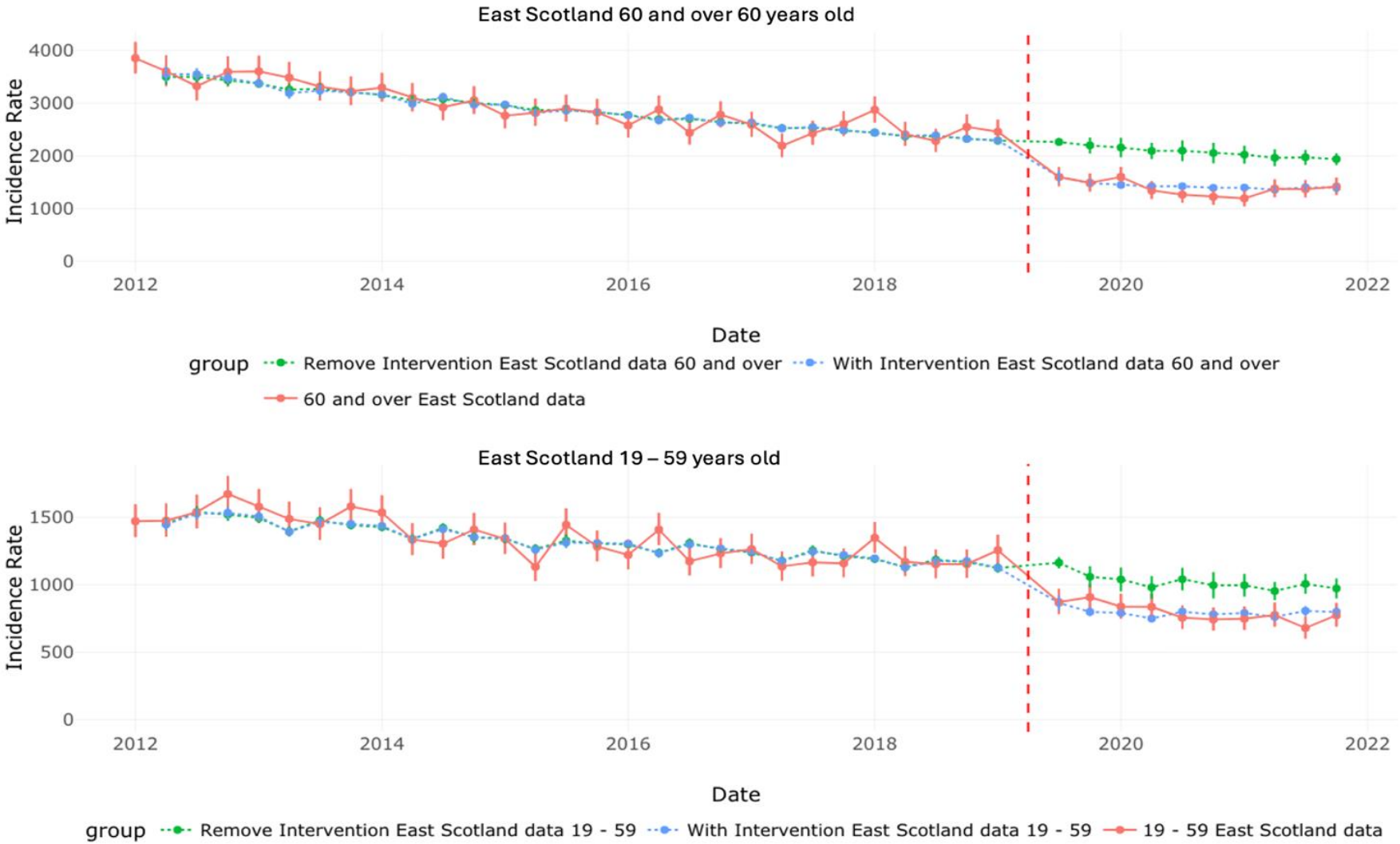
- Monthly incidence rates of use, stratified by time, age (<=60 vs >60), and sex calculated using IncidencePrevalence
- Patient-level characterization of new drug users to identify indication, comorbidities, etc using PatientProfiles and DrugUtilisation
- Interrupted time series
- ARIMA



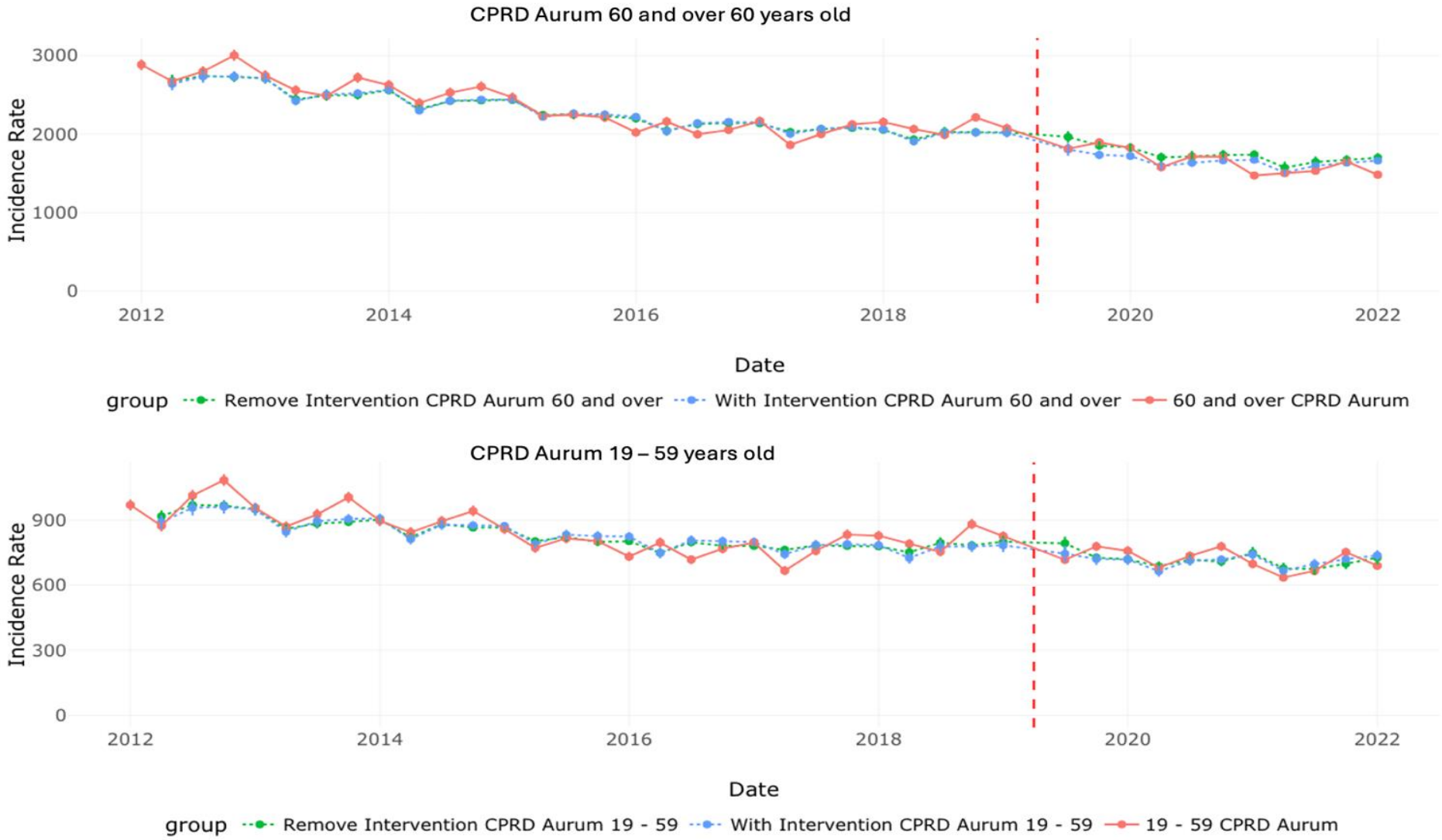
Results (1) – ITS - London hospital



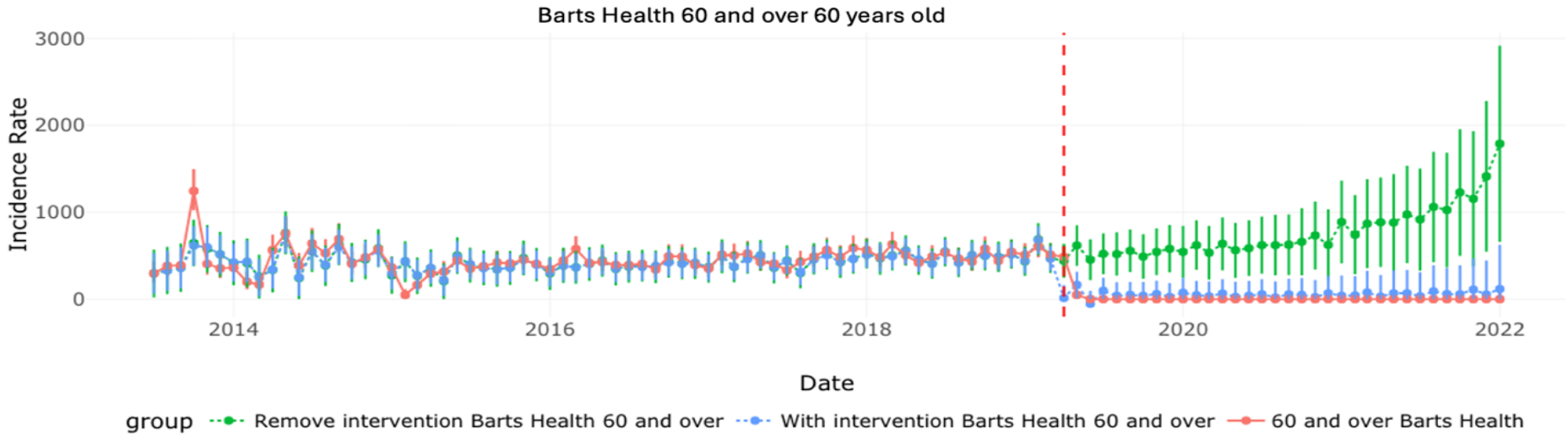
Results (2) – ITS - Scottish linked data

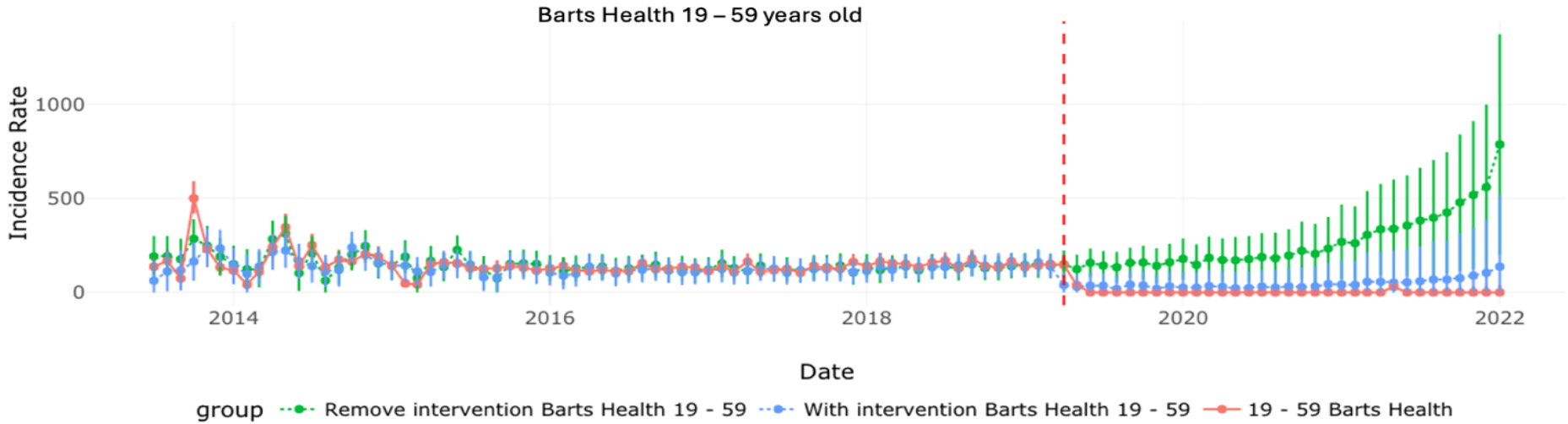


Results (3) – ITS – Eng primary care data

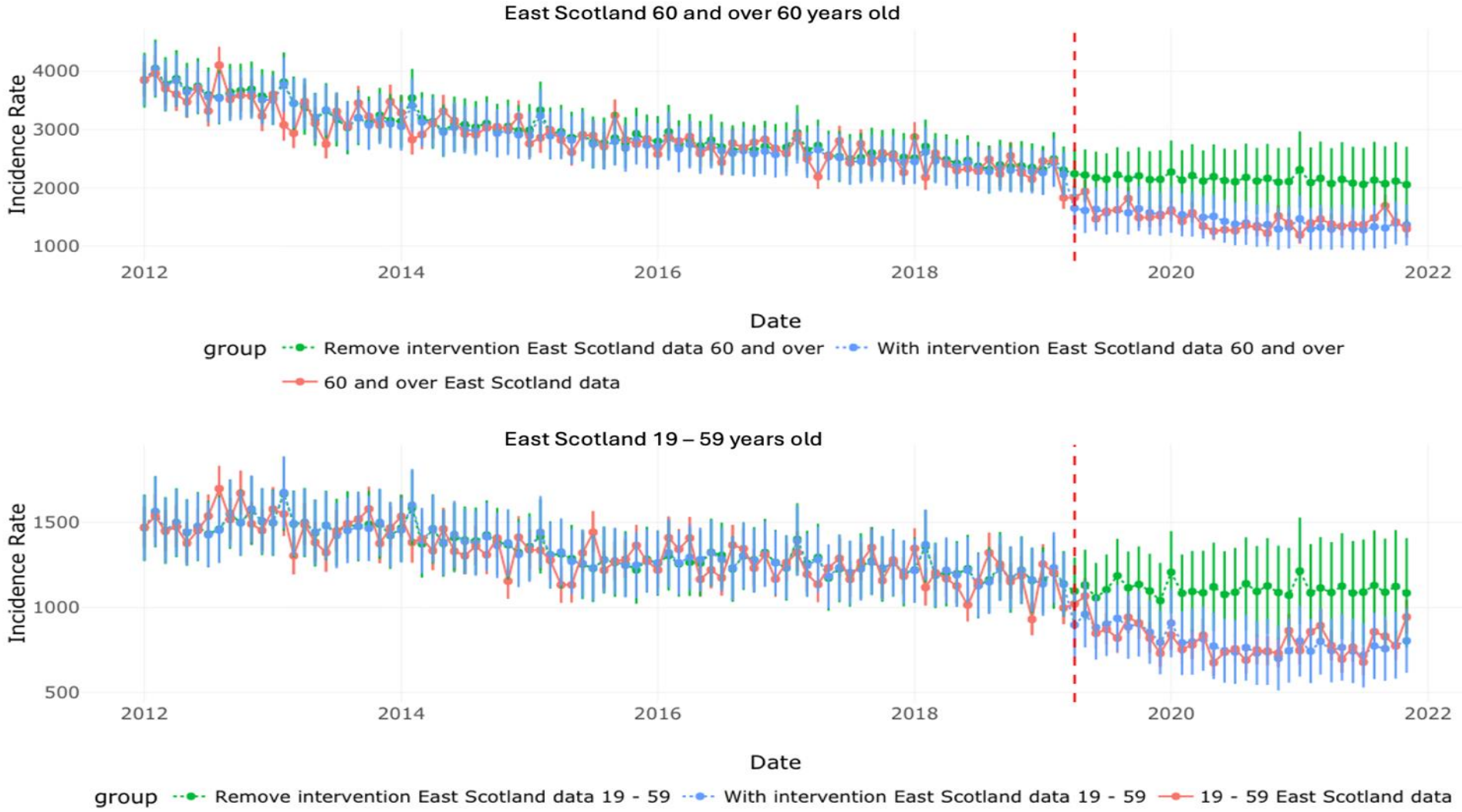


Results (4) – ARIMA - London hospital

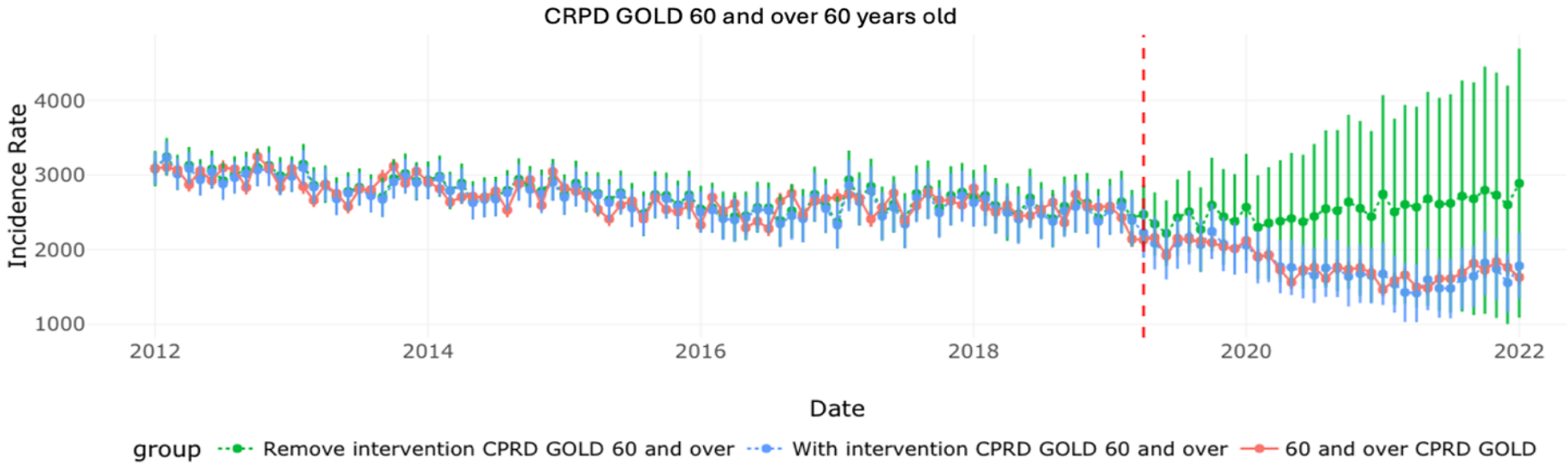


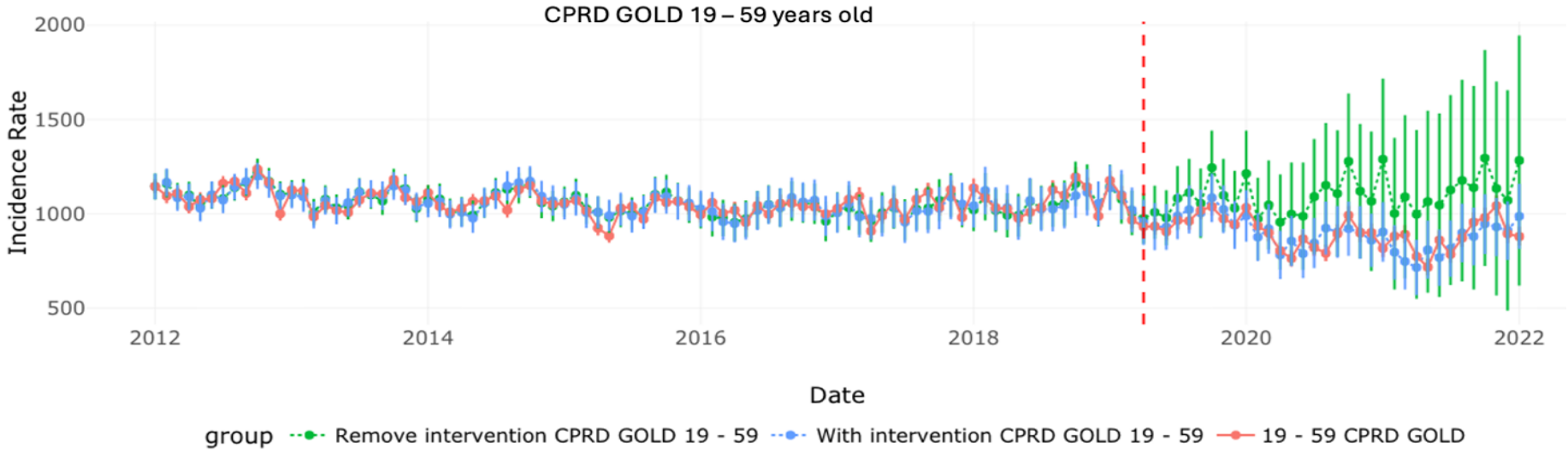


Results (5) – ARIMA - Scottish linked data



Results (6) – ARIMA – GOLD GP data





DISCUSSION

- We leveraged previously tested and regulatory-proof tools for standardized analytics, and completed the whole study in just over a few weeks
- We showed differences that matter for national regulators
  - Geographic heterogeneity
  - Differences by healthcare setting
- We showed proof-of-concept for how a regulatory network could help MHRA fulfil their mission

AGENDA

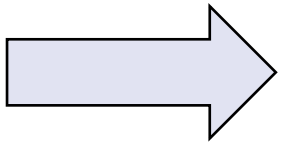
- Open science and federated analytics
- Standardised data -> Standardised analyses
- Impactful examples
- True impact: DARWIN EU and FAIRS UK

Disclosure

This presentation represents the views of the DARWIN EU® Coordination Centre only and cannot be interpreted as reflecting those of the European Medicines Agency or the European Medicines Regulatory Network.

Generating Real-World Evidence (RWE) from Real-World Data (RWD)

Real-World Data (RWD): routinely collected data relating to patient health status or the delivery of health care from a variety of sources other than traditional clinical trials

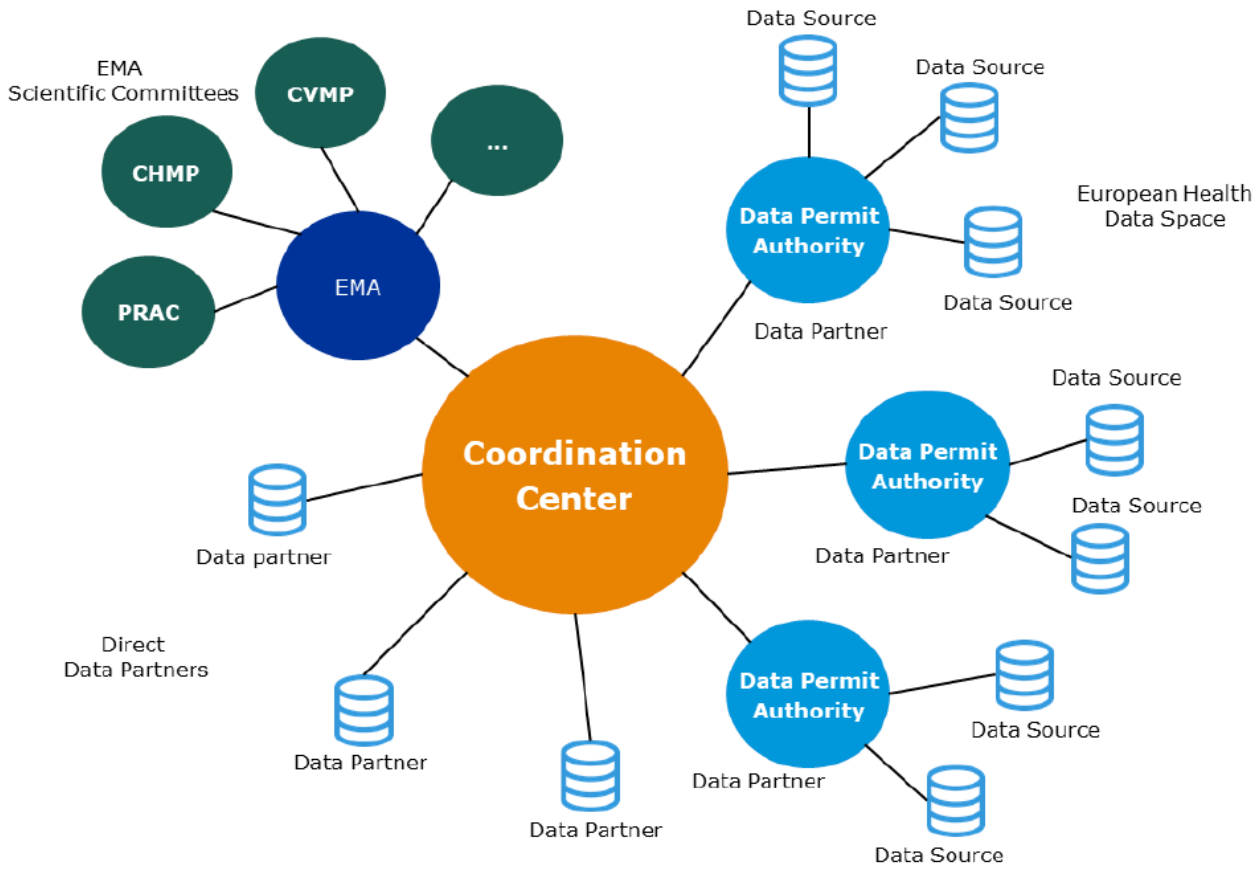


Real-World Evidence (RWE): information derived from analysis of real-world data

RWE for regulatory purposes needs to be:

- **Fast, transparent, scalable and reproducible**
- Representative (of EU regions)

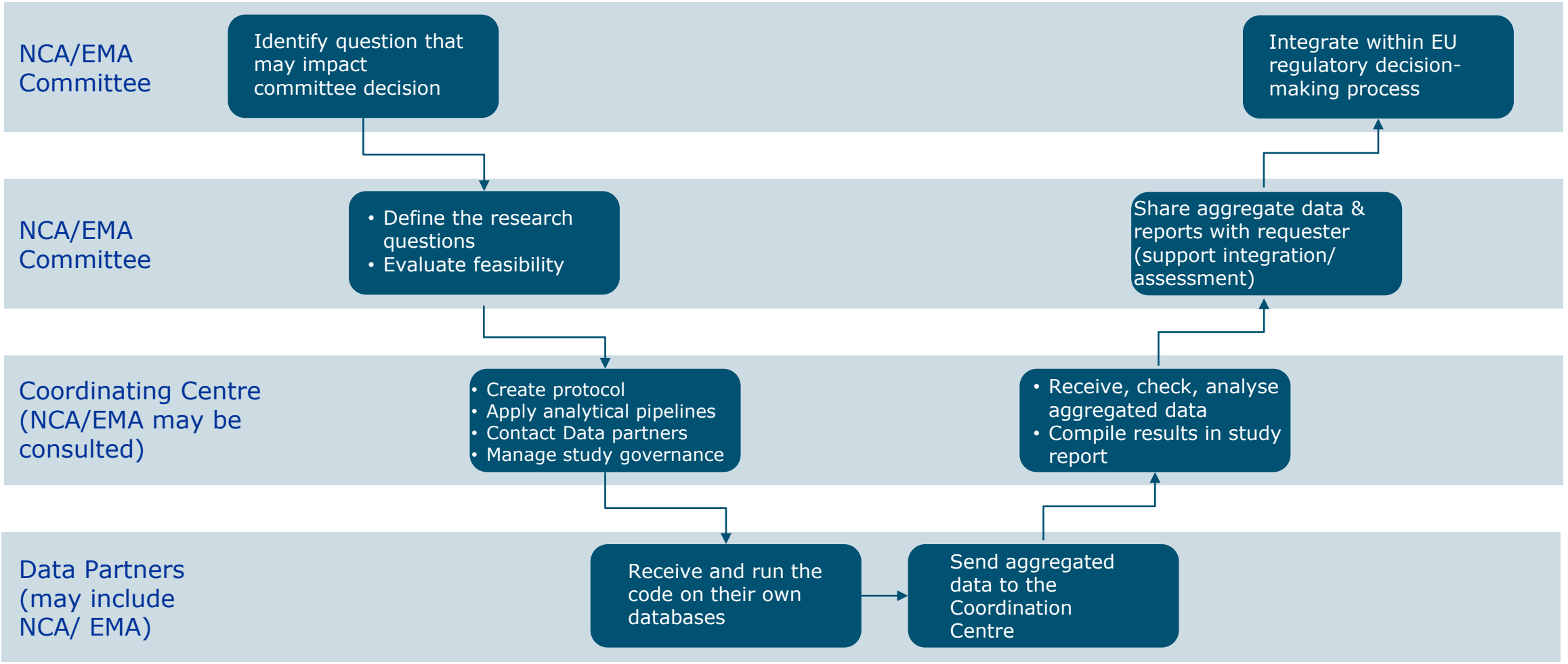
DARWIN EU® is a federated **network** of **data**, **expertise** and **services** that supports better decision-making throughout the product lifecycle by generating reliable **evidence from real world healthcare data**



FEDERATED NETWORK PRINCIPLES

- Data stays **local**
- **Use of Common Data Model** to perform studies in a timely manner and increase consistency of results

What is the DARWIN EU® process for conducting studies?



Data Partners – Phase I

UK

1. Clinical Practice Research Datalink (CPRD GOLD)

Belgium

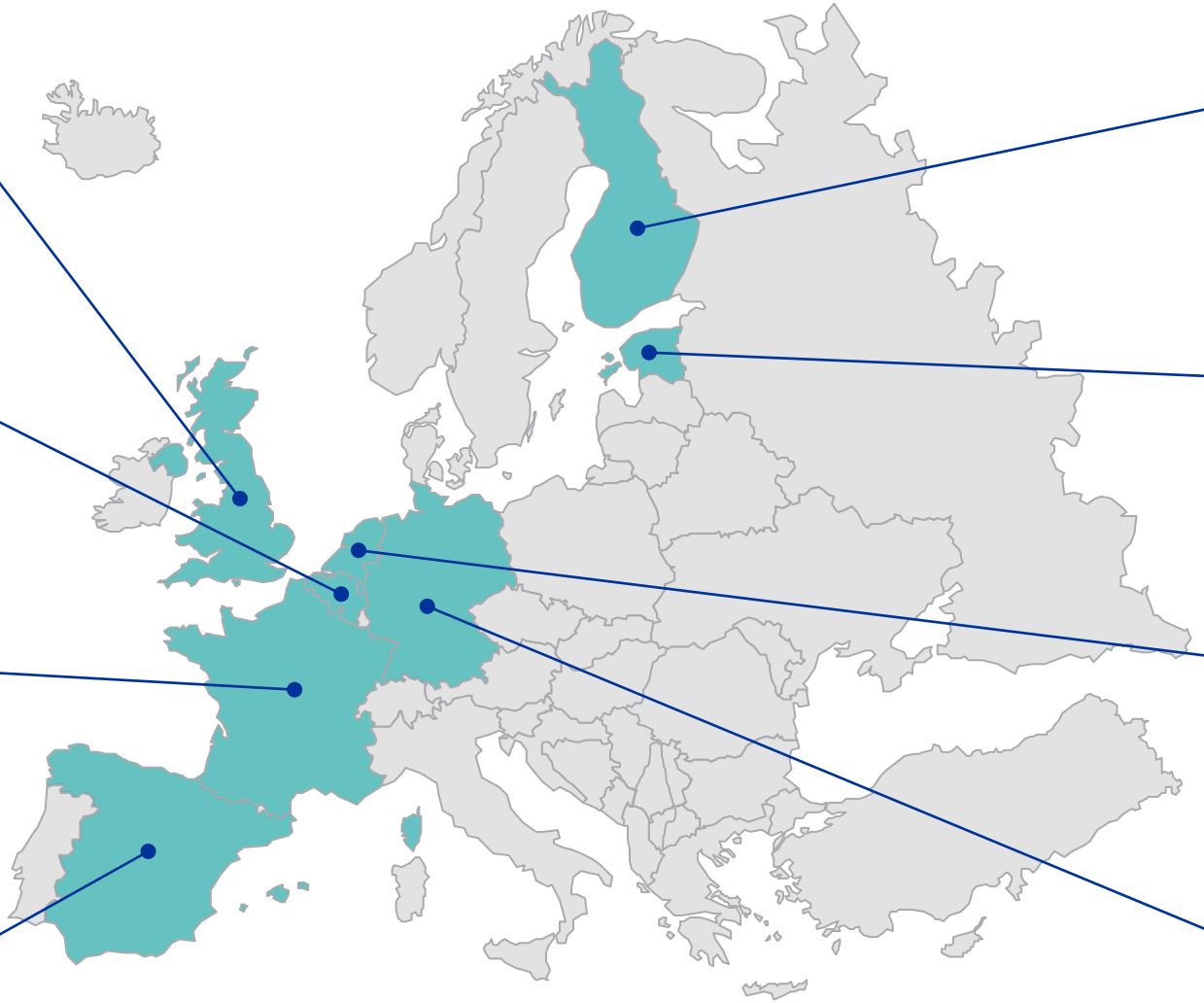
2. IQVIA Belgium Longitudinal Patient Data

France

3. Bordeaux University Hospital

Spain

4. IDIAPJGol
5. Parc Salut Mar Barcelona, Hospital del Mar (IMIM)



Finland

6. Auria Clinical Informatics at Hospital District of Southwest Finland (HDSF)

Estonia

7. University of Tartu (EE Biobank)

Netherlands

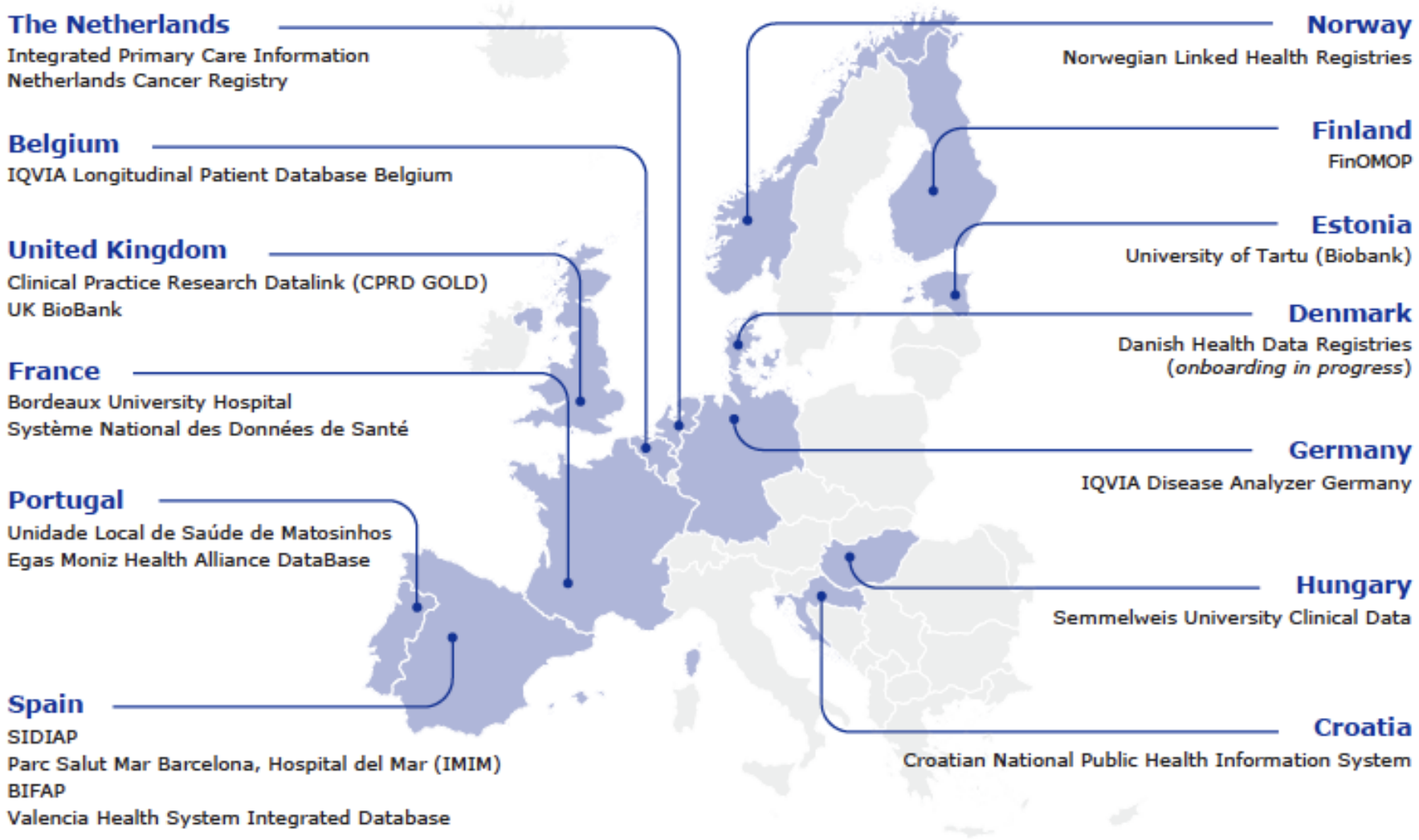
8. Integrated Primary Care Information
9. Netherlands Comprehensive Cancer Organisation

Germany

10. IQVIA Germany Disease Analyser

~26 million active patients

Data Partners – Phase II

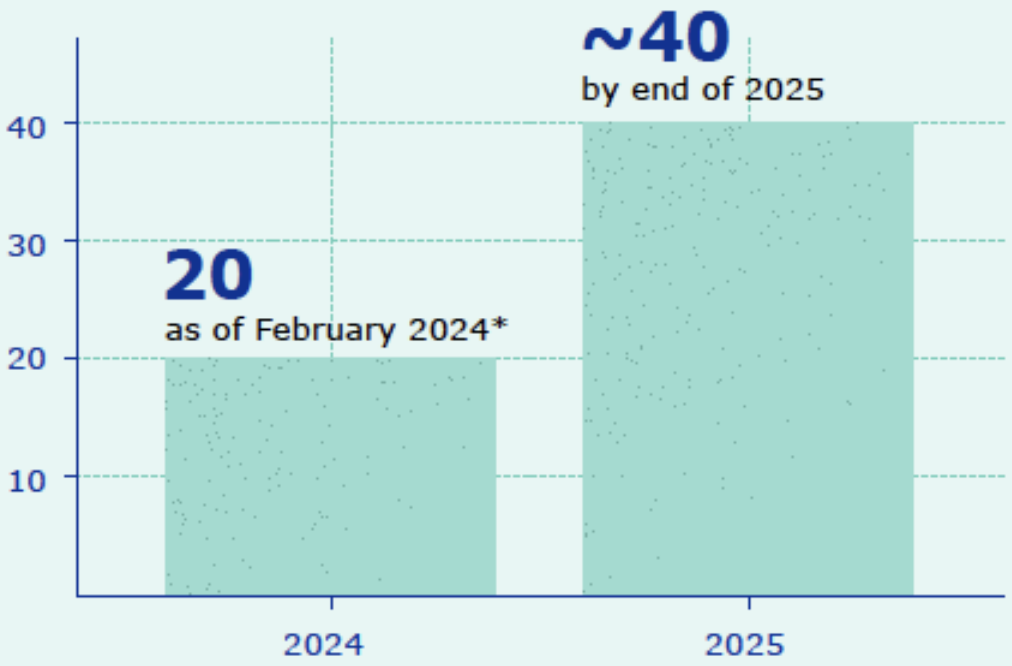


Data Partners – Phase II

Key figures

Since 2022, 20 data partners have been onboarded. In 2024 and 2025, additional ten data partners per year will join the network.

Data partners



* in 13 European countries

Access to data from
~130 million
patients in Europe, in 2024

140+
studies delivered per year from 2025

DARWIN EU® Studies – Phase I (all complete)

Type	Studies	Data Partners	Planned RWE use	Committee
OTS	**Population level epidemiology** study on prevalence of **rare blood cancers** from 2010.	NL, ES, UK, BE, DE	Support COMP in orphan designation decision making	COMP
OTS	Patient level **drug utilisation** study of **valproate-containing medicinal products** in women of childbearing potential from 2010	NL, ES, UK, BE, DE, FI	Assess the use of valproate after safety referral	PRAC
OTS	Patient level **drug utilisation** study of **antibiotics** on the Watch list of the WHO AWaRe classification, 2010-2021	NL, FR, ES, DE, UK	Inform PRAC/CHMP decision making	PRAC – CHMP AMR strategy
Com plex	Background all-cause **mortality rates in patients with severe asthma aged ≥12 years** old		Support CHMP evaluation and post-authorisation informing future decision making	CHMP

STUDIES YEAR 2 (1)

Study Title	Committees	Study Type	Type of analysis	Data bases	Status
DARWIN EU® - **Multiple myeloma**: patient characterisation, treatments and survival in the period 2012-2022	HTA/Payers	OTS	Disease Epidemiology and Treatment Pattern analysis	IQVIA DA (Ge) SIDIAP (Spain) IMASIS (Spain) Estonian Biobank ACI Varha (Fi) CHUBX (France) IKNL (Nl)	Ongoing
DARWIN EU® **Drug Utilisation Study** of **prescription opioids**.	PRAC	OTS	Drug Utilisation Study	Estonian Biobank IPCI (NL)	Ongoing
DARW **Natu** **COVI** **vacc** conte					
DARW endo and p (PDE **hypertension** (PAH)					

Year 2 (Feb 23 to Jan 24)

- 16 studies completed / being reviewed

Year 3 (Feb 24 to Jan 25)

- Over 70 studies to be delivered, including 12 complex ones

FAIRS UK

A UK national regulatory science network using OMOP

Application details

Competition name
UK Regulatory Science and Innovation Networks – Discovery phase

Application name
Federated Analytics Initiative for Regulatory Science in the UK: FAIRS-UK

Stage 1 awarded. Stage 2 to be submitted this summer

FAIRS UK

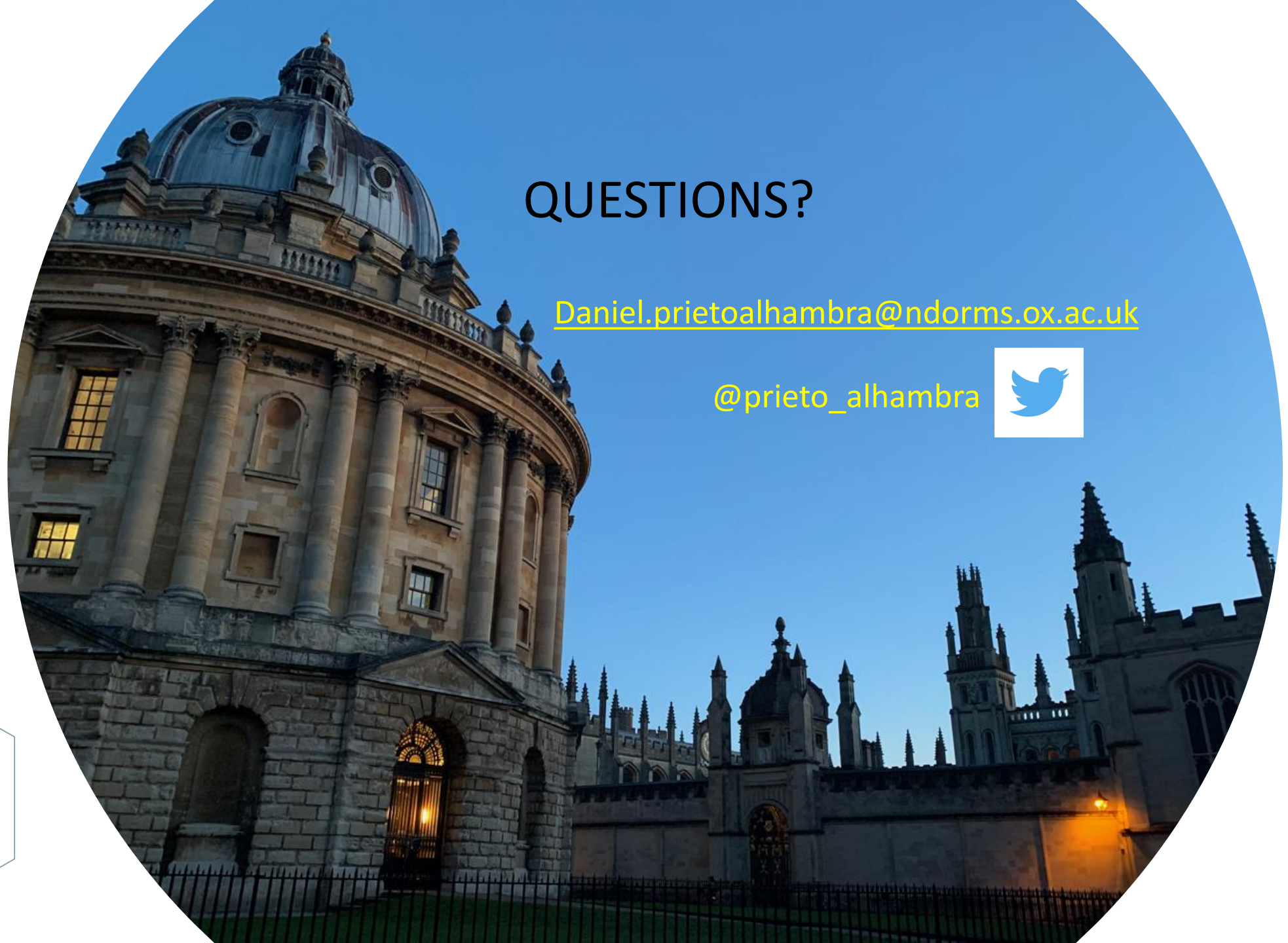
Data Partners

Acronym	Coverage	Provenance
CPRD-HES	UK-wide	Primary care (with linked hospital admissions)
UK Biobank	UK-wide	Biobank, genetics, linked EHR
Barts Health NHS Trust	London	Hospital EHR
Lancashire Hospitals NHS Trust	North-West England	Hospital EHR
Great Olmond Street Hospital	London	Paediatric specialist hospital
HIC – NHS Tayside and Fife	Scotland	Linked NHS data
SAIL	Wales	Linked data

FAIRS UK

A UK national regulatory science network using OMOP

- Open science and federated analytics
- OMOP CDM
- Standardised analytics for regulatory decision making (MHRA)



QUESTIONS?

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health data sciences