Scaling up the reuse of real world data for clinical research in Europe

Professor Dipak Kalra, President

iHD The European Institute for Innovation through Health Data

Japanese Academic Research Organization Workshop
15th November 2024

Patient recruitment a major cause of trial delays

- Identifying and recruiting suitable patients and trial sites are principal causes of trial delays

The percentage of studies that complete enrolment on time:

18% in Europe,

7% in the US[1]

Almost

half of all trial

delays caused by patient recruitment problems[2]

Each day a drug is delayed from market, sponsors lose up to

$8m[3]

50%

of today's clinical trials fail to achieve the target recruitment rate[4]

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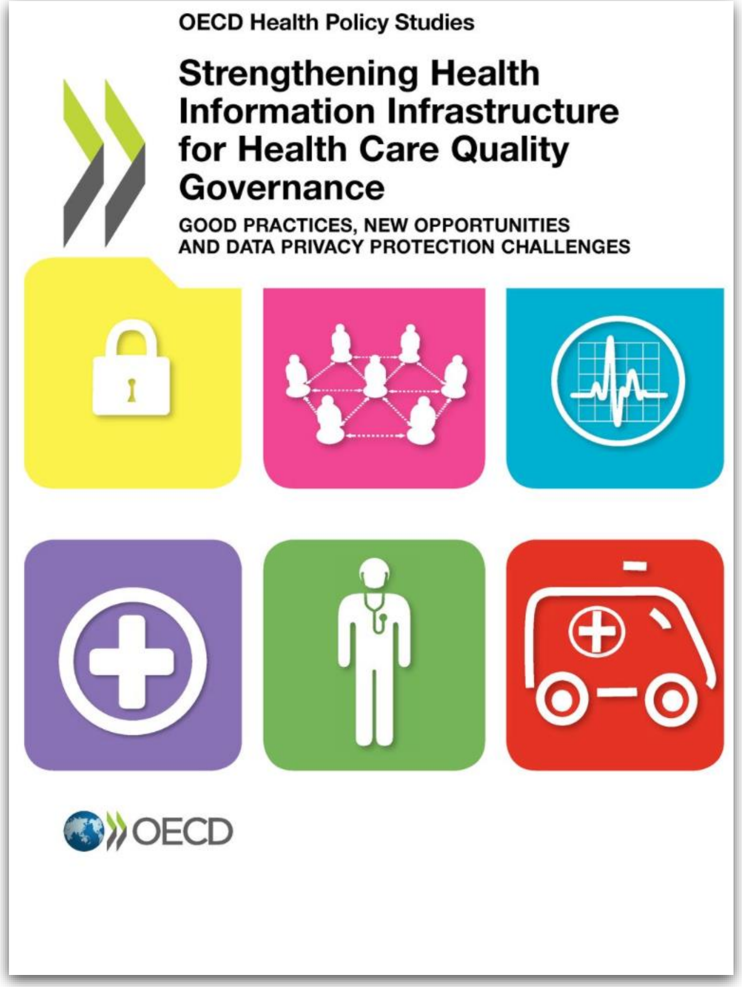
1. State of the Clinical Trials Industry: A Sourcebook of Charts and Statistics, Center Watch, 2008.
2. Study Participant Recruitment and Retention in Clinical Trials: Emerging strategies in Europe, the US and Asia, Business Insights, June 2007.
3. Beasley, "Recruiting" 2008
4. Tufts -http://clinicalperformancepartners.com/wp-content/uploads/2012/07/Fixing-Feasibility-Final-Jan-2012.pdf

There is growing recognition of the value of re-using EHRs for Clinical Research

"Health data constitutes a significant resource in most OECD countries and it makes economic and ethical sense to use this data as much as possible: to improve population health and to improve the effectiveness, safety and patient centeredness of health care systems"



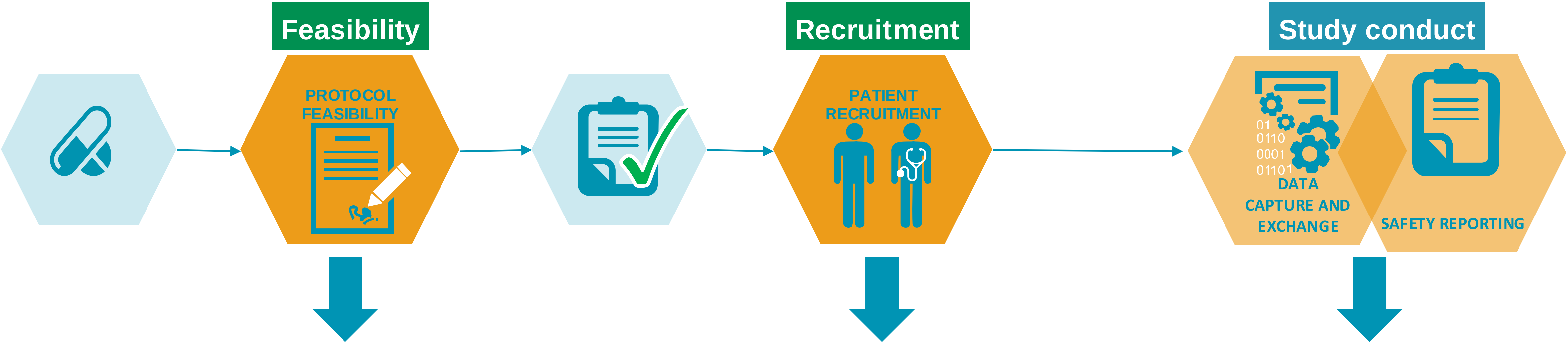
OECD Health Policy Studies

Strengthening Health Information Infrastructure for Health Care Quality Governance

GOOD PRACTICES, NEW OPPORTUNITIES AND DATA PRIVACY PROTECTION CHALLENGES

OECD

The critical scenarios

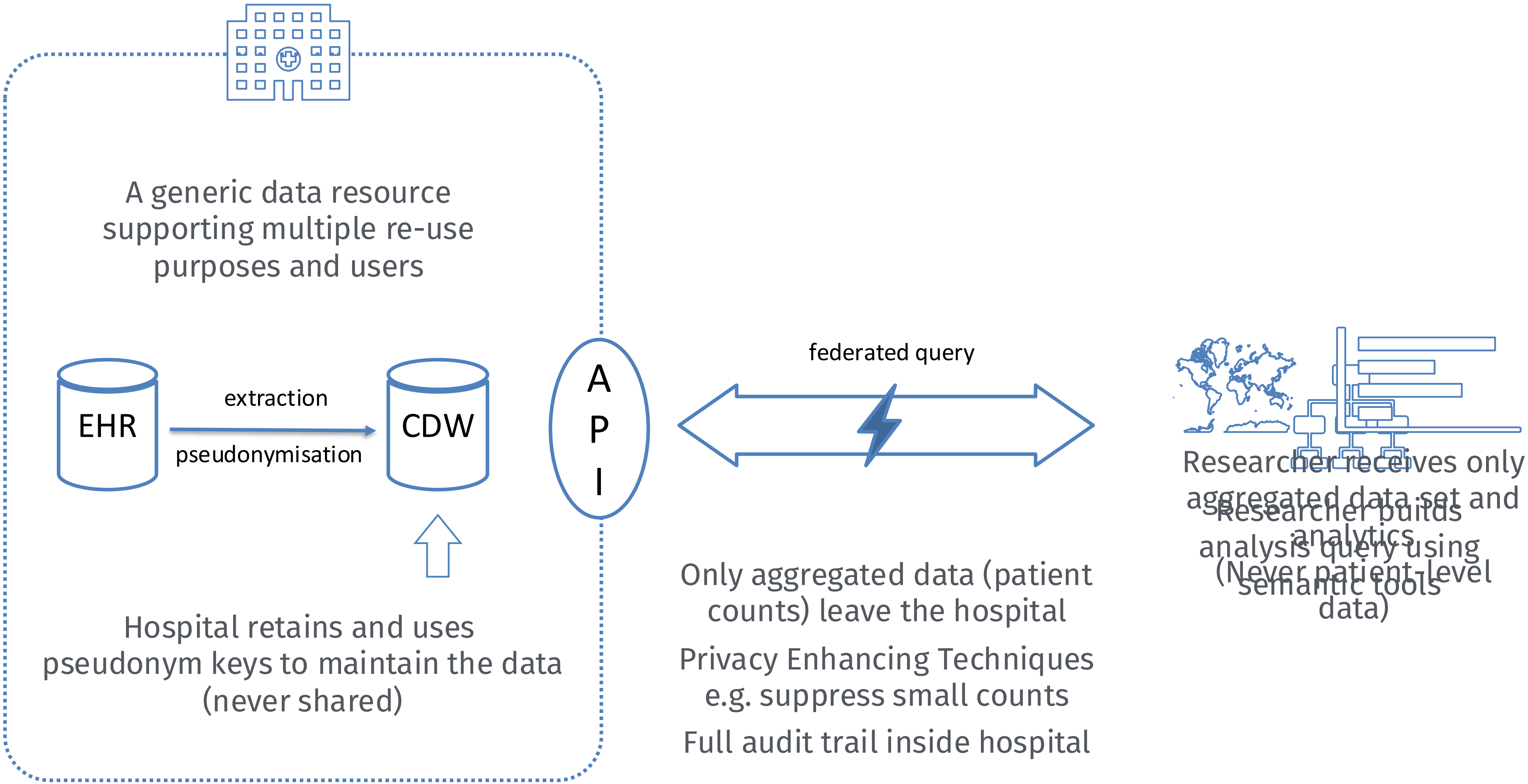

Feasibility
PROTOCOL FEASIBILITY
Recruitment
PATIENT RECRUITMENT
Study conduct
01
0110
0001
01101
DATA CAPTURE AND EXCHANGE
SAFETY REPORTING

Enabling **protocol testing with real world data** in potential trial sites rather than with guestimates.

Speeding up recruitment by making EHR data searchable for investigators and establishing a unified communication path between sponsors and sites.

Facilitating **EHR data extraction** for applications used during trial execution (e.g. pre-filling of CRFs and of SAE reports).

The federated query data flow


EHR
extraction
pseudonymisation
CDW
A
P
I
federated query

A generic data resource supporting multiple re-use purposes and users

Hospital retains and uses pseudonym keys to maintain the data (never shared)

Only aggregated data (patient counts) leave the hospital

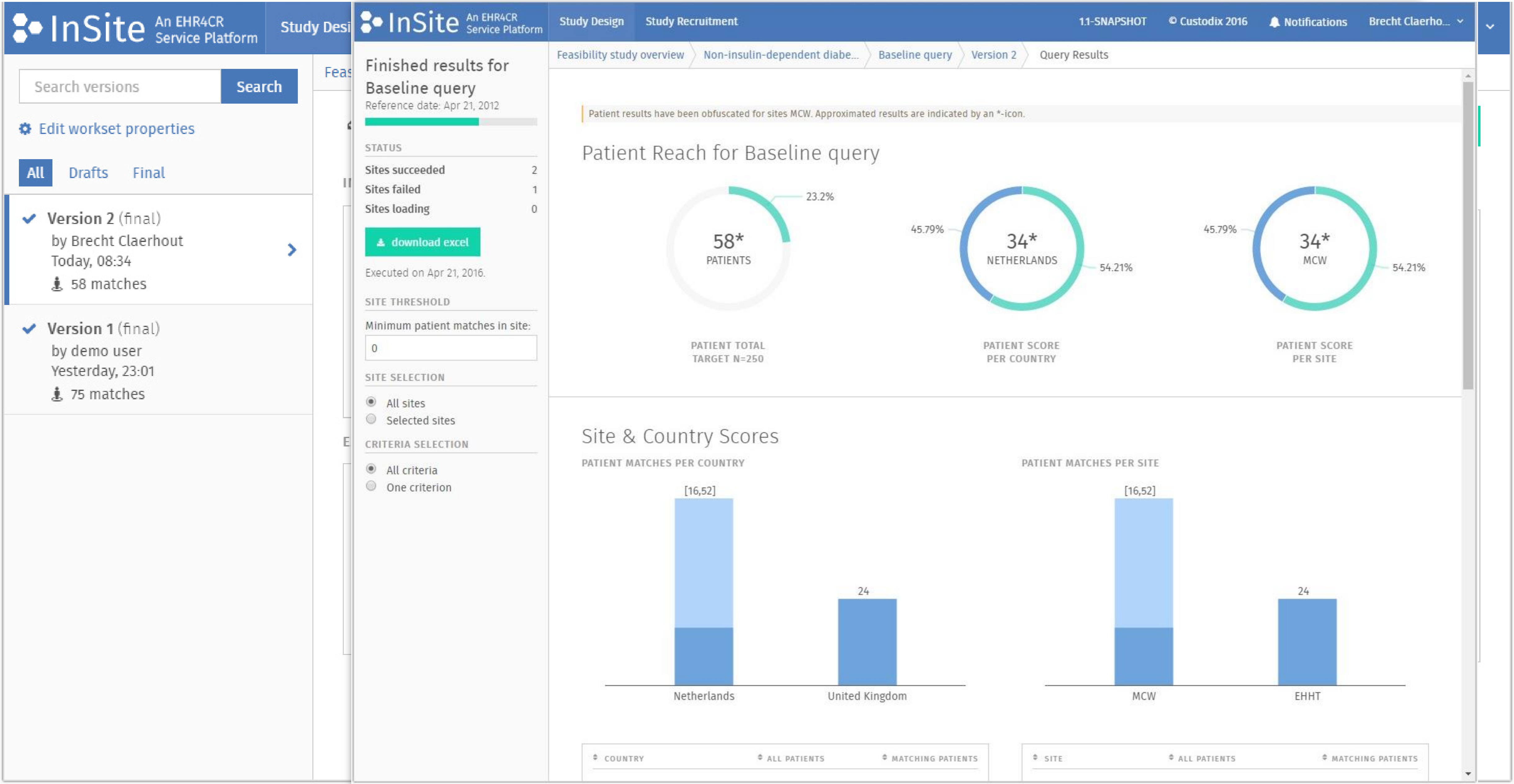
Privacy Enhancing Techniques e.g. suppress small counts

Full audit trail inside hospital

Researcher receives only aggregated data set and analysis (Never patient-level data)

Researcher builds analytics query using semantic tools

InSite – Protocol feasibility query


InSite An EHR4CR Service Platform
Study Desi
Search versions
Search
Edit workset properties
All
Drafts
Final
Feas
Study Design
Study Recruitment
1.1-SNAPSHOT
© Custodix 2016
Notifications
Brecht Claerho...
Feasibility study overview
Non-insulin-dependent diabe...
Baseline query
Version 2
Query Results
download excel

✓ **Version 2** (final)
by Brecht Claerhout
Today, 08:34
58 matches

✓ **Version 1** (final)
by demo user
Yesterday, 23:01
75 matches

Finished results for Baseline query
Reference date: Apr 21, 2012

STATUS

Sites succeeded	2
Sites failed	1
Sites loading	0

Executed on Apr 21, 2016.

SITE THRESHOLD

Minimum patient matches in site: 0

SITE SELECTION

● All sites
○ Selected sites

CRITERIA SELECTION

● All criteria
○ One criterion

Patient results have been obfuscated for sites MCW. Approximated results are indicated by an *-icon.

Patient Reach for Baseline query

58*
PATIENTS
23.2%
PATIENT TOTAL
TARGET N=250
34*
NETHERLANDS
45.79%
54.21%
PATIENT SCORE
PER COUNTRY
34*
MCW
45.79%
54.21%
PATIENT SCORE
PER SITE

Site & Country Scores

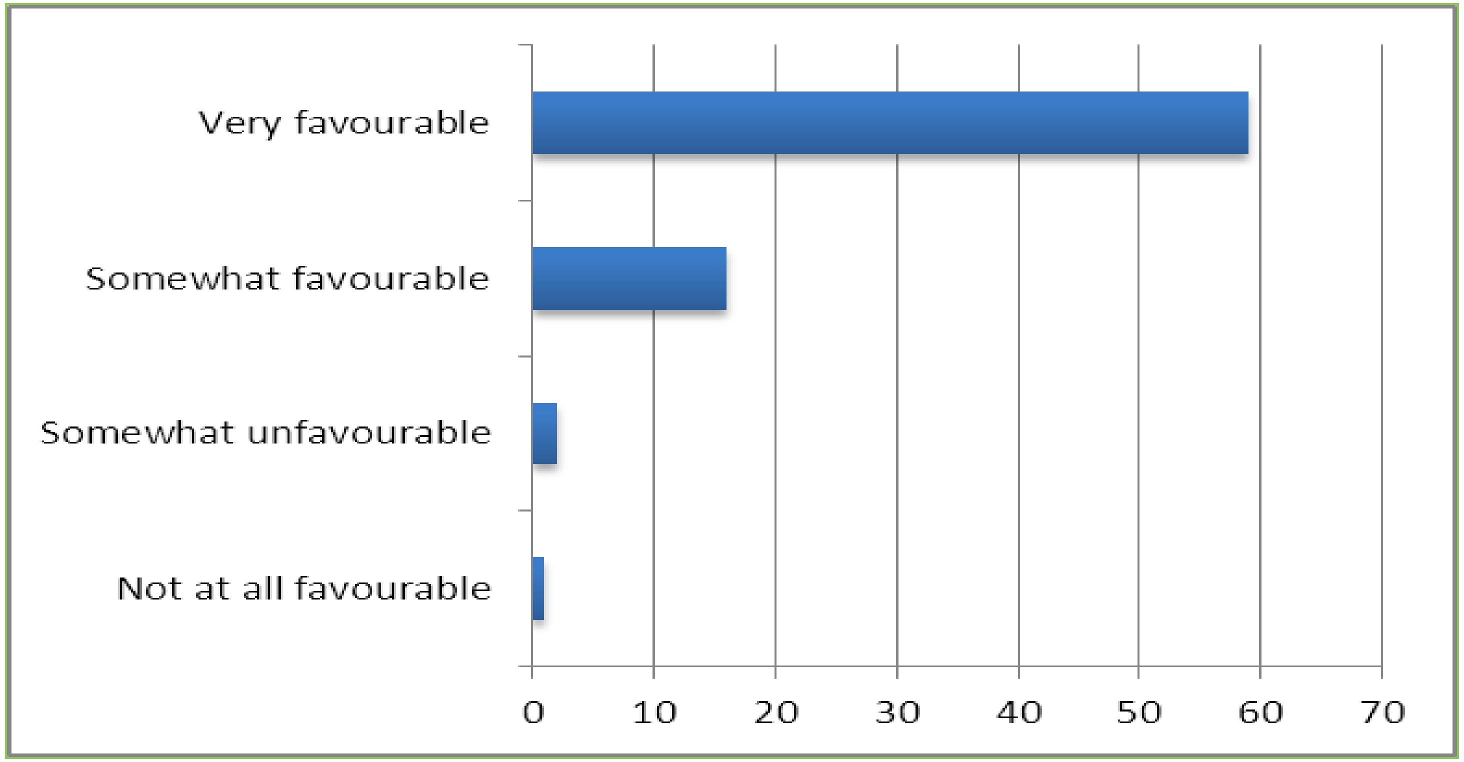
PATIENT MATCHES PER COUNTRY
[16,52]
24
Netherlands
United Kingdom
PATIENT MATCHES PER SITE
[16,52]
24
MCW
EHHT

COUNTRY	ALL PATIENTS	MATCHING PATIENTS

SITE	ALL PATIENTS	MATCHING PATIENTS

Confirming public acceptance

- High percentage of public/patient respondents were in favour of re-using EHR data for research

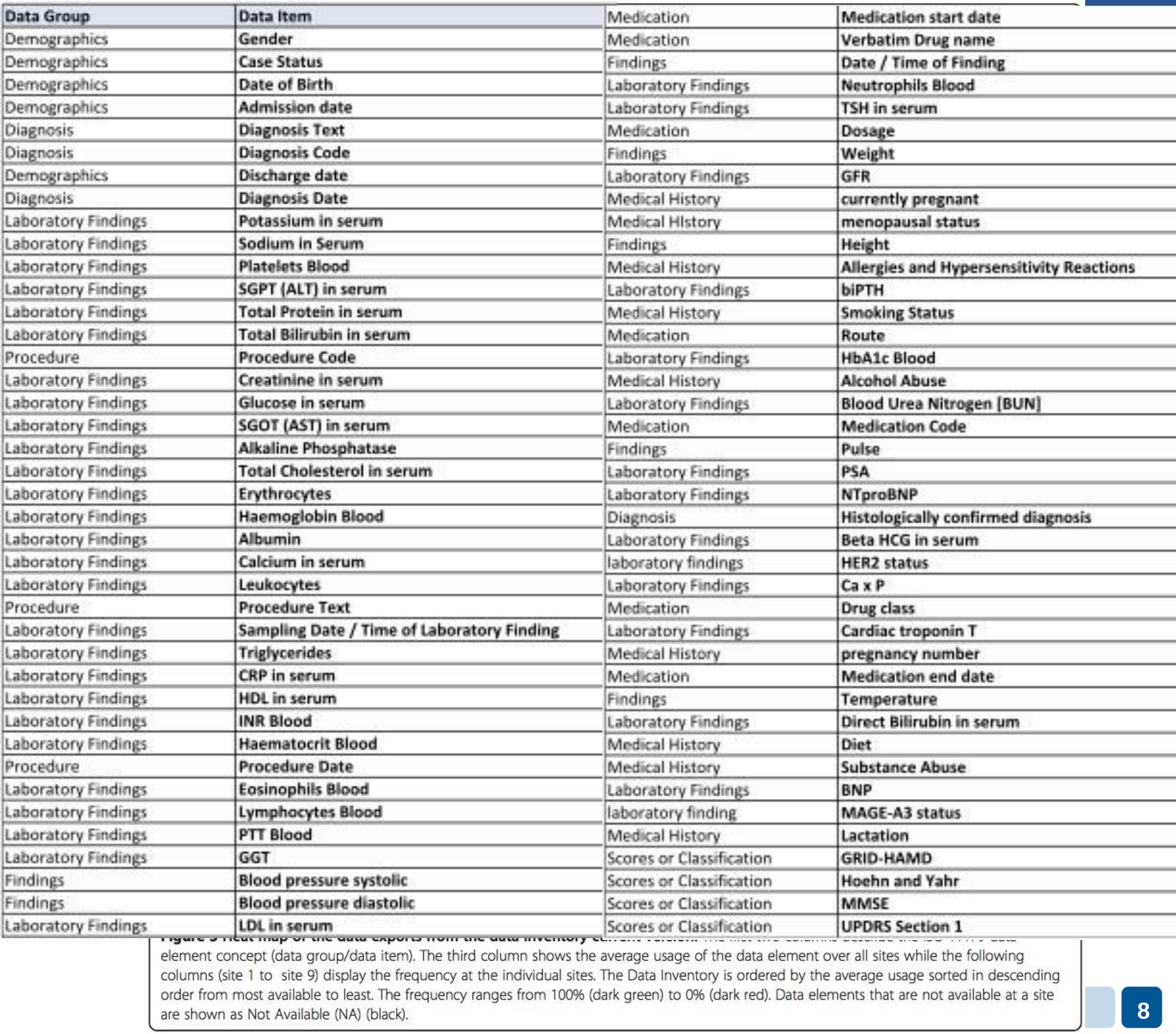


Confirming data availability

A European inventory of common electronic health record data elements for clinical trial feasibility

Justin Doods, Florence Botteri, Martin Dugas, Fleur Fritz and on behalf of EHR4CR WP7

Trials 2014, 15:18
http://www.trialsjournal.com/content/15/1/18



Data Group	Data Item
Demographics	Gender
Demographics	Case Status
Demographics	Date of Birth
Demographics	Admission date
Diagnosis	Diagnosis Text
Diagnosis	Diagnosis Code
Demographics	Discharge date
Diagnosis	Diagnosis Date
Laboratory Findings	Potassium in serum
Laboratory Findings	Sodium in Serum
Laboratory Findings	Platelets Blood
Laboratory Findings	SGPT (ALT) in serum
Laboratory Findings	Total Protein in serum
Laboratory Findings	Total Bilirubin in serum
Procedure	Procedure Code
Laboratory Findings	Creatinine in serum
Laboratory Findings	Glucose in serum
Laboratory Findings	SGOT (AST) in serum
Laboratory Findings	Alkaline Phosphatase
Laboratory Findings	Total Cholesterol in serum
Laboratory Findings	Erythrocytes
Laboratory Findings	Haemoglobin Blood
Laboratory Findings	Albumin
Laboratory Findings	Calcium in serum
Laboratory Findings	Leukocytes
Procedure	Procedure Text
Laboratory Findings	Sampling Date / Time of Laboratory Finding
Laboratory Findings	Triglycerides
Laboratory Findings	CRP in serum
Laboratory Findings	HDL in serum
Laboratory Findings	INR Blood
Laboratory Findings	Haematocrit Blood
Procedure	Procedure Date
Laboratory Findings	Eosinophils Blood
Laboratory Findings	Lymphocytes Blood
Laboratory Findings	PTT Blood
Laboratory Findings	GGT
Findings	Blood pressure systolic
Findings	Blood pressure diastolic
Laboratory Findings	LDL in serum
Medication	Medication start date
Medication	Verbatim Drug name
Findings	Date / Time of Finding
Laboratory Findings	Neutrophils Blood
Laboratory Findings	TSH in serum
Medication	Dosage
Findings	Weight
Laboratory Findings	GFR
Medical History	currently pregnant
Medical HIstory	menopausal status
Findings	Height
Medical History	Allergies and Hypersensitivity Reactions
Laboratory Findings	biPTH
Medical History	Smoking Status
Medication	Route
Laboratory Findings	HbA1c Blood
Medical History	Alcohol Abuse
Laboratory Findings	Blood Urea Nitrogen [BUN]
Medication	Medication Code
Findings	Pulse
Laboratory Findings	PSA
Laboratory Findings	NTproBNP
Diagnosis	Histologically confirmed diagnosis
Laboratory Findings	Beta HCG in serum
laboratory findings	HER2 status
Laboratory Findings	Ca x P
Medication	Drug class
Laboratory Findings	Cardiac troponin T
Medical History	pregnancy number
Medication	Medication end date
Findings	Temperature
Laboratory Findings	Direct Bilirubin in serum
Medical History	Diet
Medical History	Substance Abuse
Laboratory Findings	BNP
laboratory finding	MAGE-A3 status
Medical History	Lactation
Scores or Classification	GRID-HAMD
Scores or Classification	Hoehn and Yahr
Scores or Classification	MMSE
Scores or Classification	UPDRS Section 1

element concept (data group/data item). The third column shows the average usage of the data element over all sites while the following columns (site 1 to site 9) display the frequency at the individual sites. The Data Inventory is ordered by the average usage sorted in descending order from most available to least. The frequency ranges from 100% (dark green) to 0% (dark red). Data elements that are not available at a site are shown as Not Available (NA) (black).

Redundant data entry

- Clinical trial data are manually entered into dedicated electronic clinical trial systems (EDC) and the same information is often also entered into EHR systems
  - Cumbersome and slow processes
  - Transcription inconsistencies

Over

40%

of clinical trial data are entered into the patient's health record, the clinical trial EDC system, and, possibly, a third paper copy[1]

Investigational sites estimate that over

70%

of data are duplicated between EHR and clinical trial systems[2]

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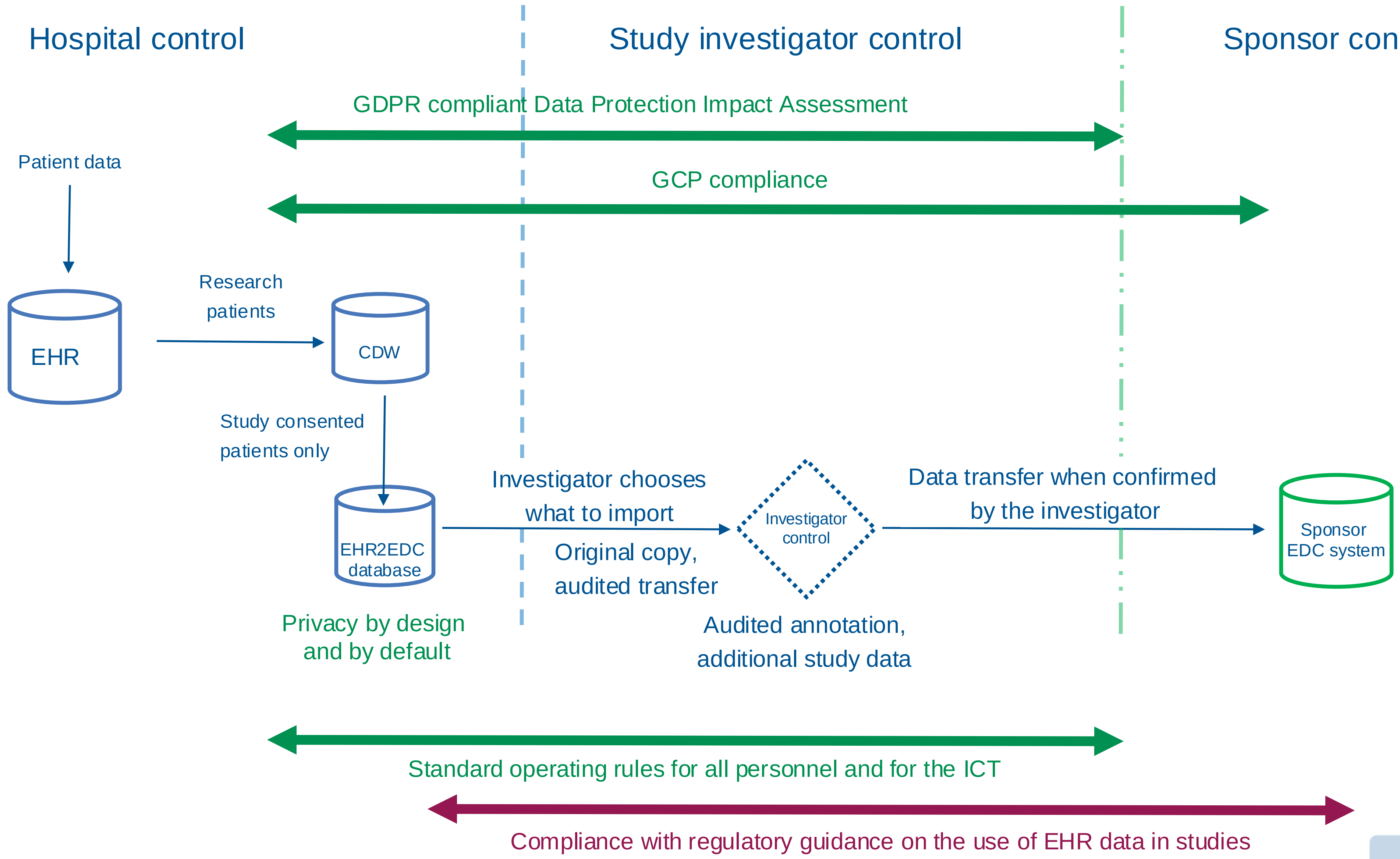
1. Integrating Electronic Health Records and Clinical Trials: An Examination of Pragmatic Issues, Michael Kahn, University of Colorado.
2. EDC Site Survey: Investigational Site Perspectives on Clinical Trial Information Systems, eClinical Forum 2009. Available at: www.eclinicalforum.org (accessed December 1, 2011).

EHR2EDC Data Flow



Hospital control

Study investigator control

Sponsor control

GDPR compliant Data Protection Impact Assessment

GCP compliance

Patient data

EHR

Research patients

CDW

Study consented patients only

EHR2EDC database

Privacy by design and by default

Investigator chooses what to import

Original copy, audited transfer

Investigator control

Audited annotation, additional study data

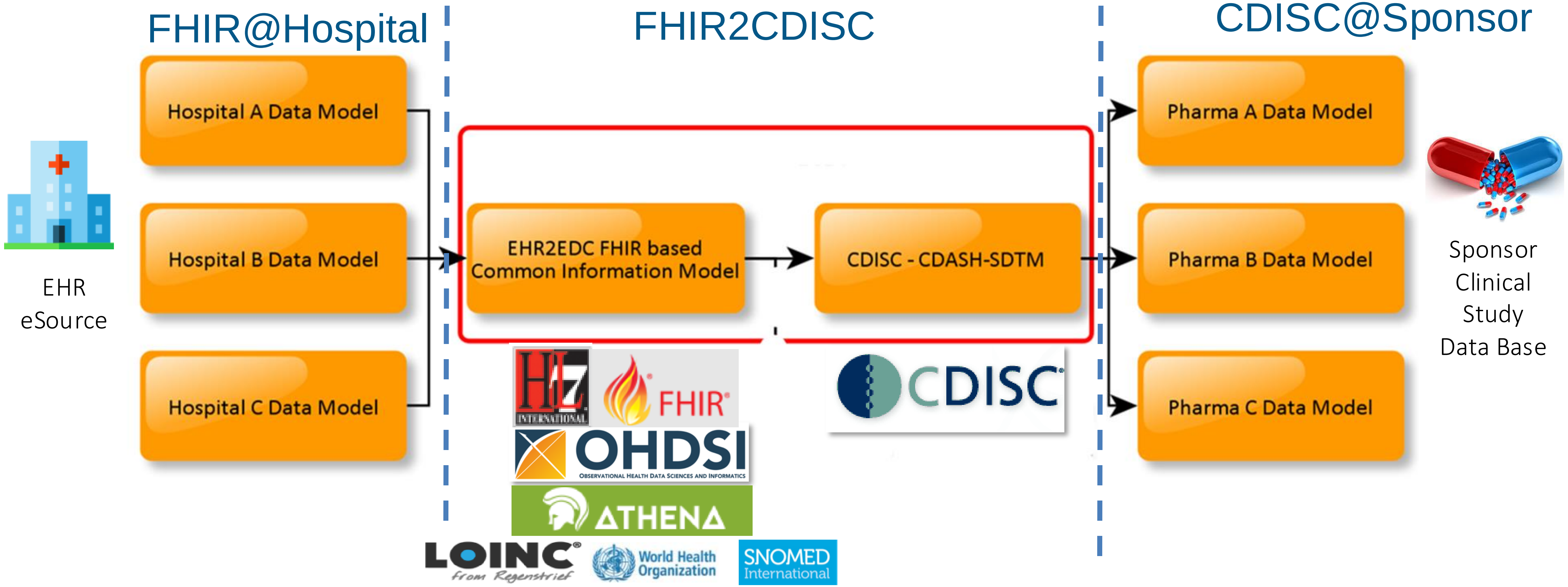
Data transfer when confirmed by the investigator

Sponsor EDC system

Standard operating rules for all personnel and for the ICT

Compliance with regulatory guidance on the use of EHR data in studies

Mapping eSource EHR Data Standards



FHIR@Hospital

FHIR2CDISC

CDISC@Sponsor

EHR
eSource

Hospital A Data Model

Hospital B Data Model

Hospital C Data Model

EHR2EDC FHIR based Common Information Model

CDISC - CDASH-SDTM

Pharma A Data Model

Pharma B Data Model

Pharma C Data Model

Sponsor
Clinical
Study
Data Base

Slide courtesy of Christel Daniel @ AP-HP

Value to hospitals + value to all health stakeholders

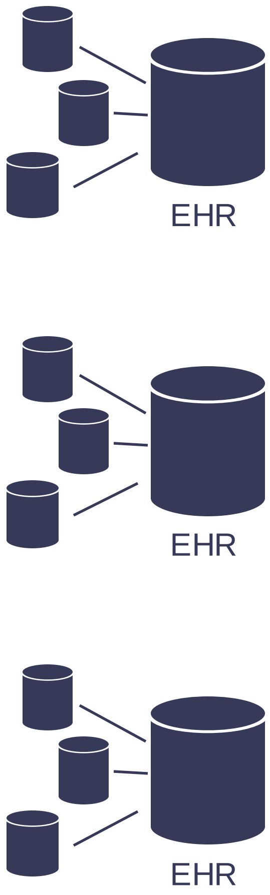
Better data access, and tools, to analyse their own data

Efficient capability to conduct research

Stronger drive to improve data quality

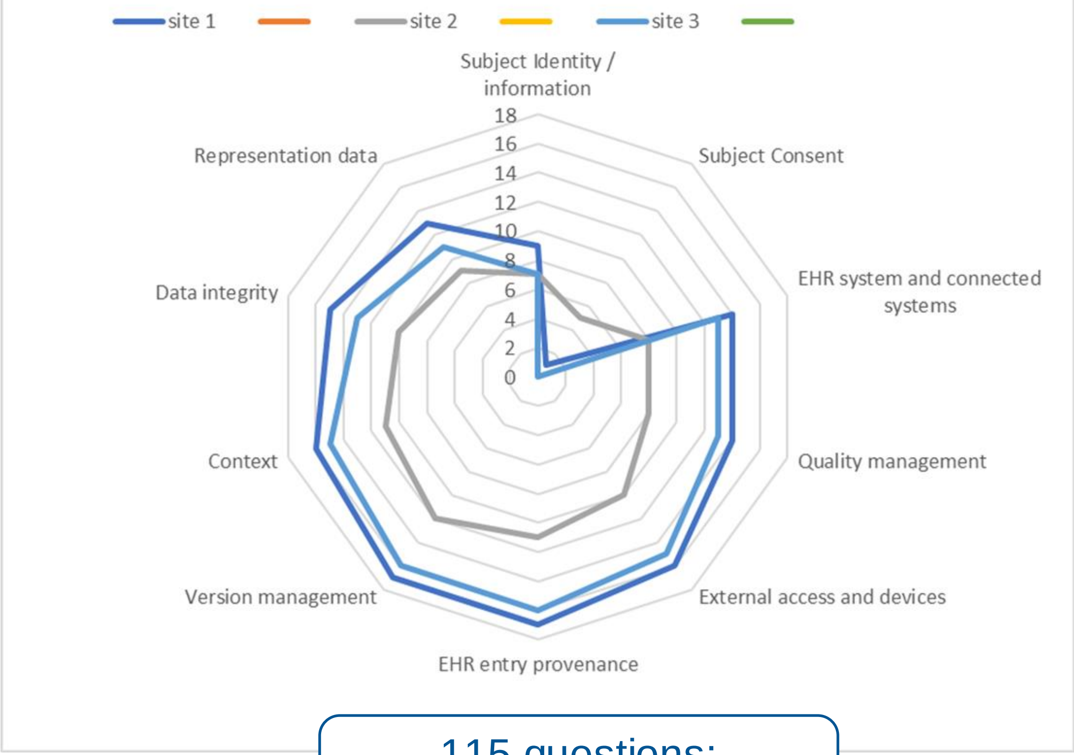
Ability to measure health outcomes and improve care

Sustaining a high quality data and technology ecosystem for clinical research



Is a hospital EHR system of a sufficient maturity for its data to be used in clinical trials?

eSource online survey, completed by hospitals



115 questions:
20 tier one (must haves)
and 95 tier two

Promote uptake across Europe

EHDEN: VISION AND MISSION

Vision

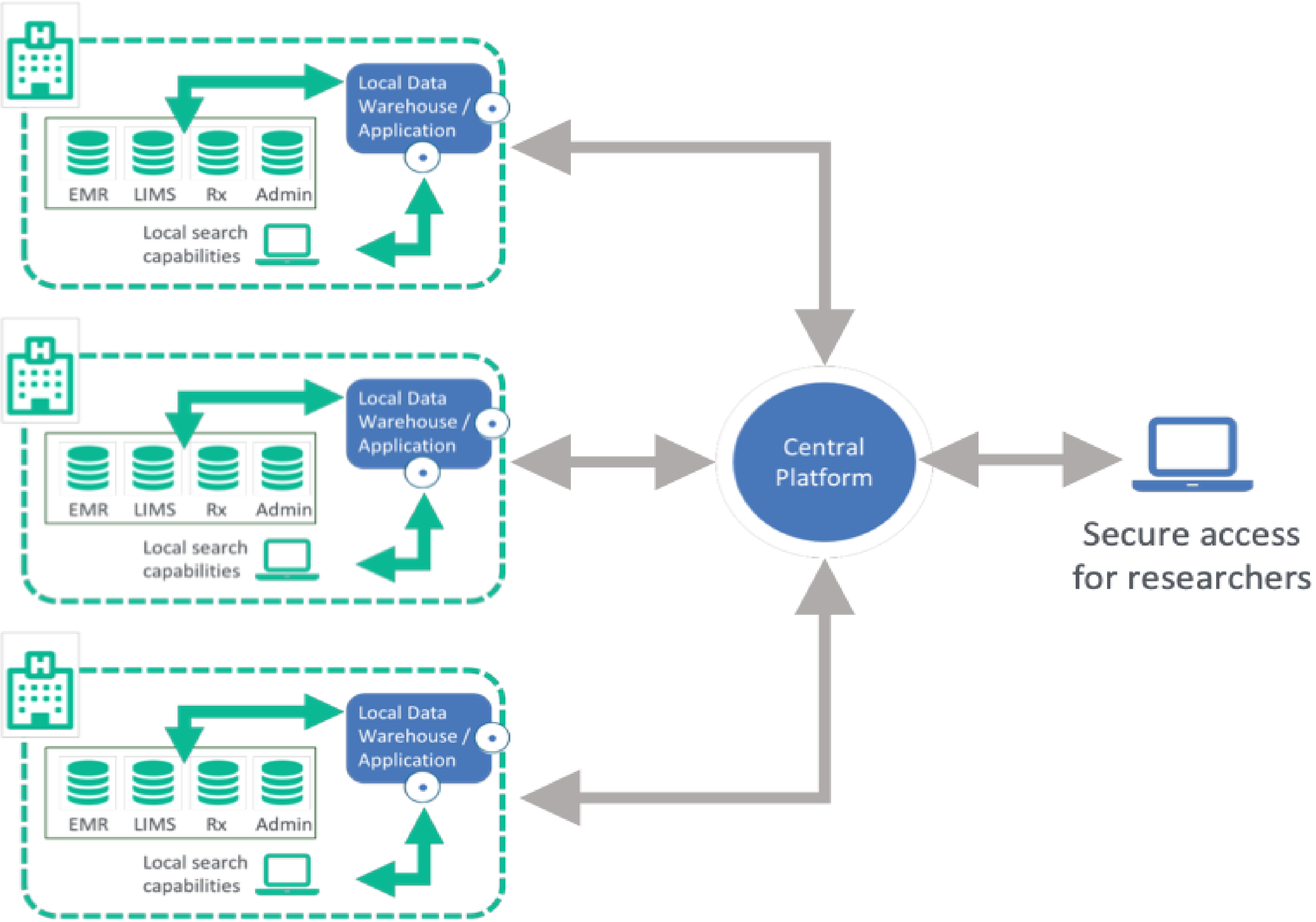
The European Health Data & Evidence Network (EHDEN) aspires to be the trusted observational research ecosystem to enable better health decisions, outcomes and care

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

Slide courtesy of Nigel Hughes, Janssen

European Health Data & Evidence Network

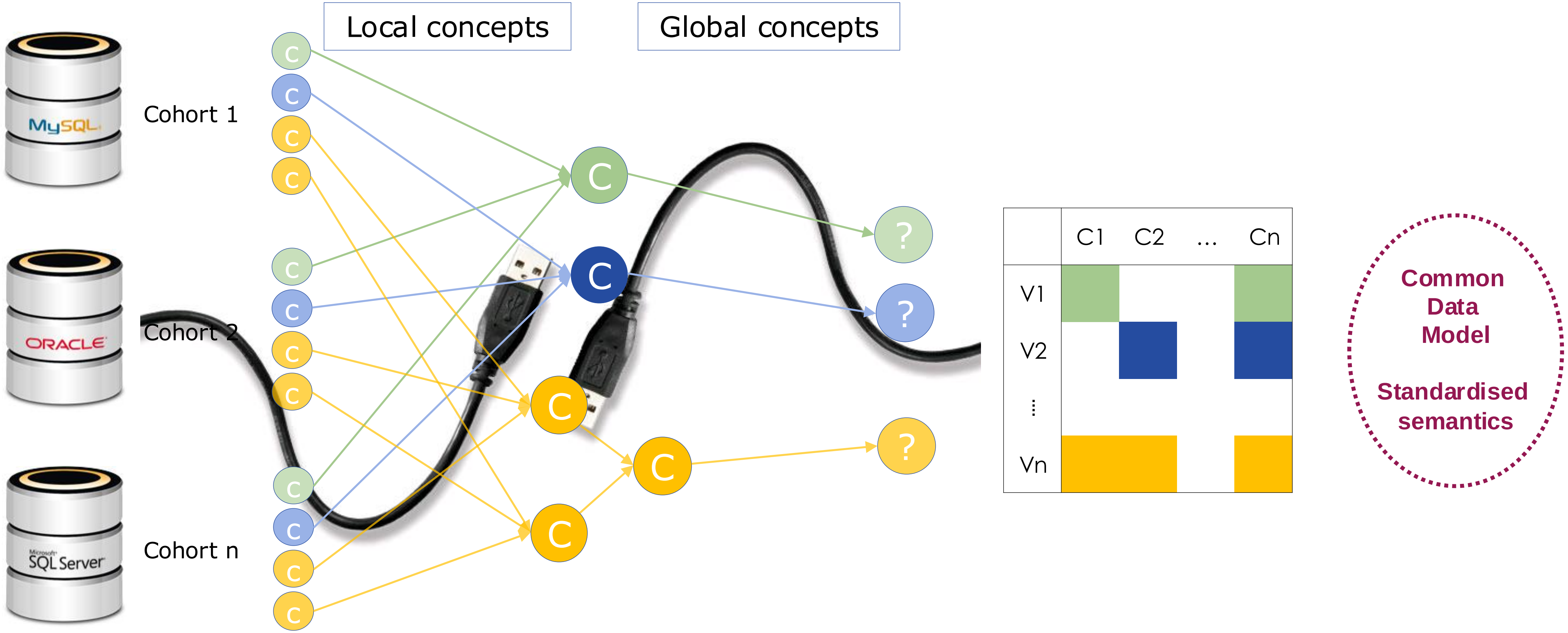

Local Data Warehouse / Application
EMR
LIMS
Rx
Admin
Local search capabilities
Local Data Warehouse / Application
EMR
LIMS
Rx
Admin
Local search capabilities
Local Data Warehouse / Application
EMR
LIMS
Rx
Admin
Local search capabilities
Central Platform
Secure access for researchers

Benefits of federated networks

- Data remains under the control of the data owner
- Locally required legal and ethical approvals apply
- No patient level data leaves the owner's site, only aggregated counts, thereby ensuring patient privacy
- GDPR – *'Privacy by Design'*
- Analysis is "brought to the data" rather than creating central data repository
- Use of common data model allows for efficient search / analysis across multiple data sets
- Requires close collaboration with data owners which builds trust

Slide courtesy of Nigel Hughes, Janssen

Data harmonisation



Local concepts
Global concepts
MySQL
Cohort 1
ORACLE
Cohort 2
SQL Server
Cohort n
c
C
?

	C1	C2	…	Cn
V1	🟩			🟩
V2		🟦		🟦
⋮				
Vn	🟨	🟨		🟨

Common Data Model

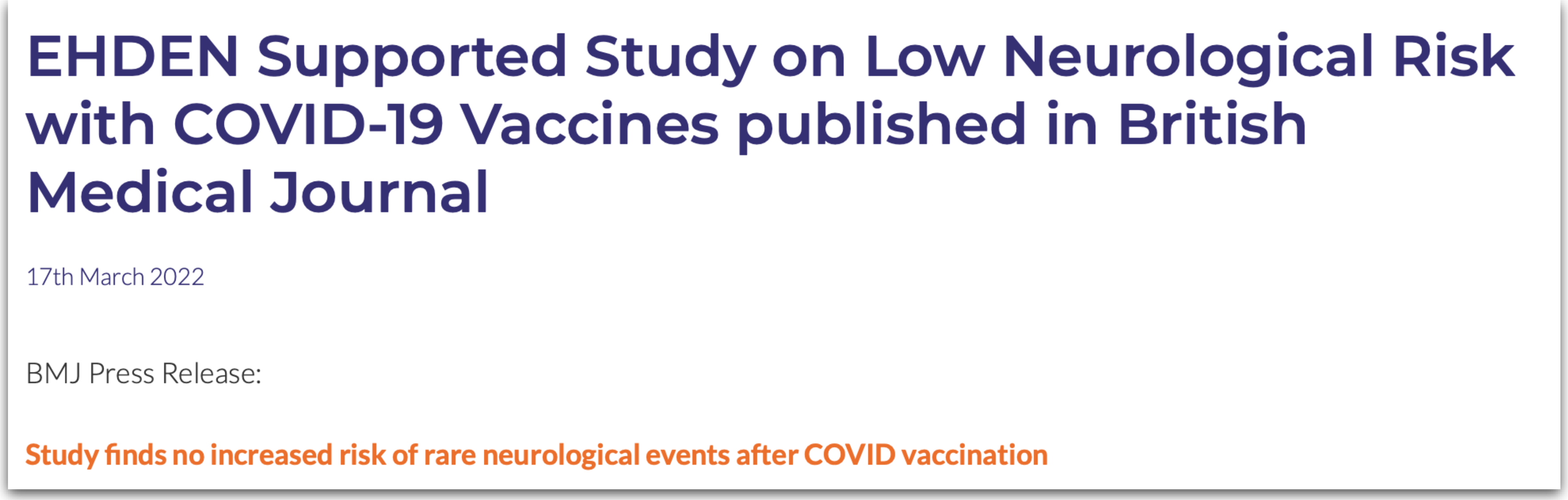
Standardised semantics

Data custodians
- Identify local concepts
- Specify mappings
- Define security

Community
- Specify global and derived concepts
- Define research groups

Source: Rudi Verbeeck and Michel Van Speybroeck - Janssen

Why we need big health data



EHDEN Supported Study on Low Neurological Risk with COVID-19 Vaccines published in British Medical Journal

17th March 2022

BMJ Press Release:

Study finds no increased risk of rare neurological events after COVID vaccination

OPEN ACCESS

Association between covid-19 vaccination, SARS-CoV-2 infection, and risk of immune mediated neurological events: population based cohort and self-controlled case series analysis

Xintong Li,[1] Berta Raventós,[2,3] Elena Roel,[2,3] Andrea Pistillo,[2] Eugenia Martinez-Hernandez,[4] Antonella Delmestri,[1] Carlen Reyes,[2] Victoria Strauss,[1] Daniel Prieto-Alhambra,[1,5] Edward Burn,[1,2] Talita Duarte-Salles[2]

[1] Centre for Statistics in Medicine, Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Sciences (NDORMS), University of Oxford, Oxford OX3 7LD, UK

[2] Fundació Institut Universitari per a la recerca a l'Atenció Primària de Salut Jordi Gol i Gurina (IDIAPJGol), Barcelona, Spain

[3] Universitat Autònoma de Barcelona, Bellaterra (Cerdanyola del Vallès), Barcelona, Spain

[4] Neurology Department, Hospital Clinic de Barcelona and University of Barcelona, Barcelona, Spain

[5] Department of Medical Informatics, Erasmus University Medical Center, Rotterdam, Netherlands

Correspondence to: D Prieto-Alhambra daniel.prietoalhambra@ndorms.ox.ac.uk (or @prieto_alhambra on Twitter; ORCID 0000-0002-3950-6346)

Additional material is published online only. To view please visit the journal online.

Cite this as: *BMJ* 2022;376:e068373
http://dx.doi.org/10.1136/bmj-2021-068373

Accepted: 27 January 2022

ABSTRACT

OBJECTIVE

To study the association between covid-19 vaccines, SARS-CoV-2 infection, and risk of immune mediated neurological events.

DESIGN

Population based historical rate comparison study and self-controlled case series analysis.

SETTING

Primary care records from the United Kingdom, and primary care records from Spain linked to hospital data.

PARTICIPANTS

8 330 497 people who received at least one dose of covid-19 vaccines ChAdOx1 nCoV-19, BNT162b2, mRNA-1273, or Ad.26.COV2.S between the rollout of the vaccination campaigns and end of data availability (UK: 9 May 2021; Spain: 30 June 2021). The study sample also comprised a cohort of 735 870 unvaccinated individuals with a first positive reverse transcription polymerase chain reaction test result for SARS-CoV-2 from 1 September 2020, and 14 330 080 participants from the general population.

MAIN OUTCOME MEASURES

Outcomes were incidence of Bell's palsy, encephalomyelitis, Guillain-Barré syndrome, and transverse myelitis. Incidence rates were estimated in the 21 days after the first vaccine dose, 90 days after a positive test result for SARS-CoV-2, and between 2017 and 2019 for background rates in the general population cohort. Indirectly standardised incidence ratios were estimated. Adjusted incidence rate ratios were estimated from the self-controlled case series.

RESULTS

The study included 4 376 535 people who received ChAdOx1 nCoV-19, 3 588 318 who received BNT162b2, 244 913 who received mRNA-1273, and 120 731 who received Ad26.CoV.2; 735 870 people with SARS-CoV-2 infection; and 14 330 080 people from the general population. Overall, post-vaccine rates were consistent with expected (background) rates for Bell's palsy, encephalomyelitis, and Guillain-Barré syndrome. Self-controlled case series was conducted only for Bell's palsy, given limited statistical power, but with no safety signal seen for those vaccinated. Rates were, however, higher than expected after SARS-CoV-2 infection. For example, in the data from the UK, the standardised incidence ratio for Bell's palsy was 1.33 (1.02 to 1.74), for encephalomyelitis was 6.89 (3.82 to 12.44), and for Guillain-Barré syndrome was 3.53 (1.83 to 6.77). Transverse myelitis was rare (<5 events in all vaccinated cohorts) and could not be analysed.

CONCLUSIONS

No safety signal was observed between covid-19 vaccines and the immune mediated neurological events of Bell's palsy, encephalomyelitis, Guillain-Barré syndrome, and transverse myelitis. An increased risk of Bell's palsy, encephalomyelitis, and Guillain-Barré syndrome was, however, observed for people with SARS-CoV-2 infection.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Spontaneous reporting indicated a potential association between immune mediated neurological disorders after covid-19 vaccination

The European Medicines Agency has listed Guillain-Barré syndrome as a rare side effect of exposure to viral vector vaccines

To date, however, the results from research into the risk of immune mediated neurological disorders after covid-19 vaccination have been mixed

WHAT THIS STUDY ADDS

Using routinely collected data from the UK and Spain, this study found no safety signal after covid-19 vaccination for the immune mediated neurological events of Bell's palsy, encephalomyelitis, Guillain-Barré syndrome, and transverse myelitis

An increased risk of Bell's palsy, encephalomyelitis, and Guillain-Barré syndrome was, however, seen after SARS-CoV-2 infection

Introduction

As of 13 January 2022, the covid-19 pandemic has resulted in more than 5.5 million deaths worldwide. After the rapid development of anti-SARS-CoV-2 vaccines, 9.2 billion doses have been administered through national vaccination programmes.[1] To date, five vaccines against SARS-CoV-2 have received a conditional marketing authorisation by the European Medicines Agency. These include two mRNA vaccines: BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna); two viral vector vaccines: ChAdOx1 nCoV-19 (Oxford-AstraZeneca) and Ad.26.COV2.S (Janssen/Johnson & Johnson); and one adjuvanted, recombinant spike protein nanoparticle vaccine: NVX-CoV2373 (Novavax).[2] All of these vaccines have shown high efficacy in preventing severe covid-19 and acceptable safety profiles in clinical trials.[3-7] However, potential adverse events related to these new vaccines have been reported, and continuous vaccine safety surveillance is needed as mass immunisation against covid-19 continues.

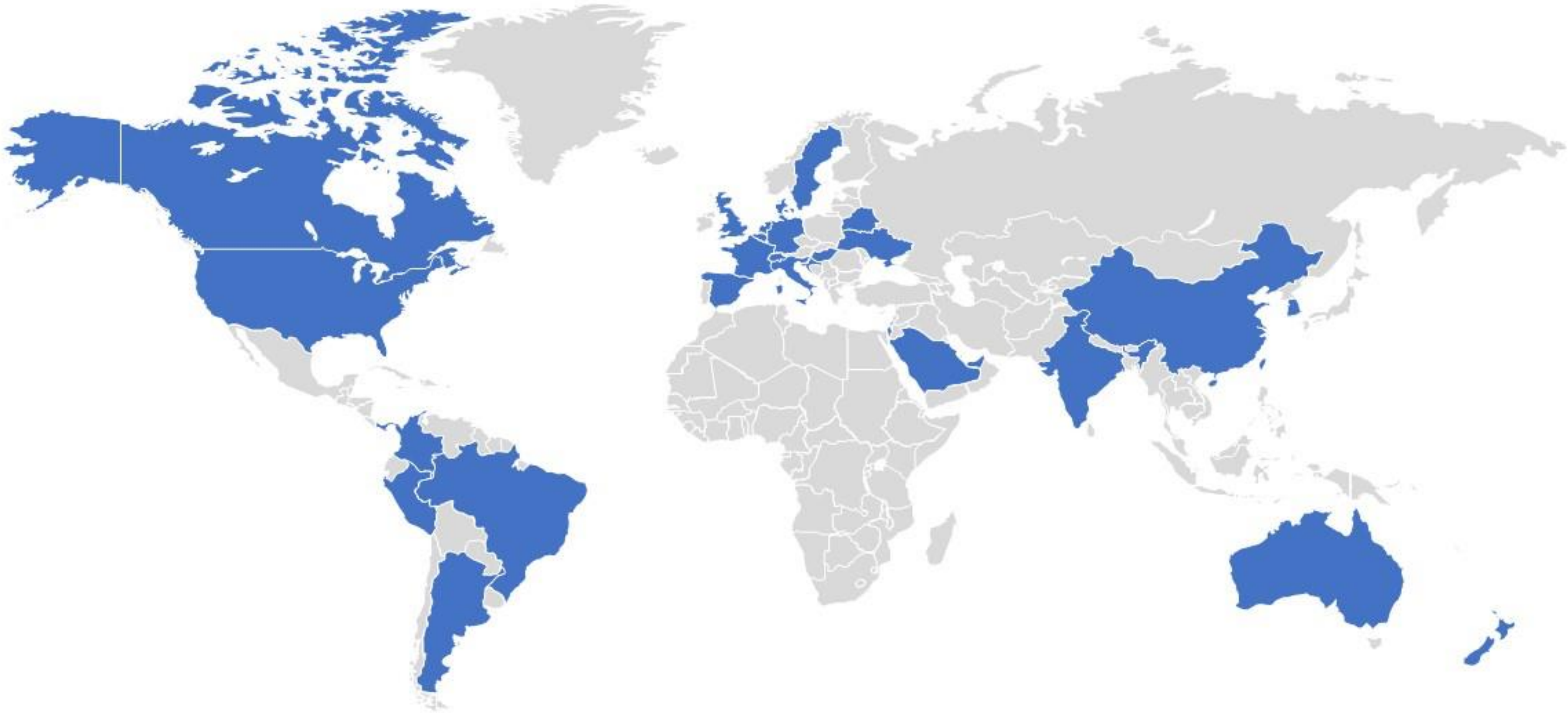
BMJ: first published as 10.1136/bmj-2021-068373 on 16 March 2022. Downloaded from http://www.bmj.com/ on 23 March 2022 by guest. Protected by copyright.

8 330 497 people who received at least one dose of covid-19 vaccines

735 870 unvaccinated individuals with a first positive reverse transcription polymerase chain reaction test result

14 330 080 participants from the general population (control group)

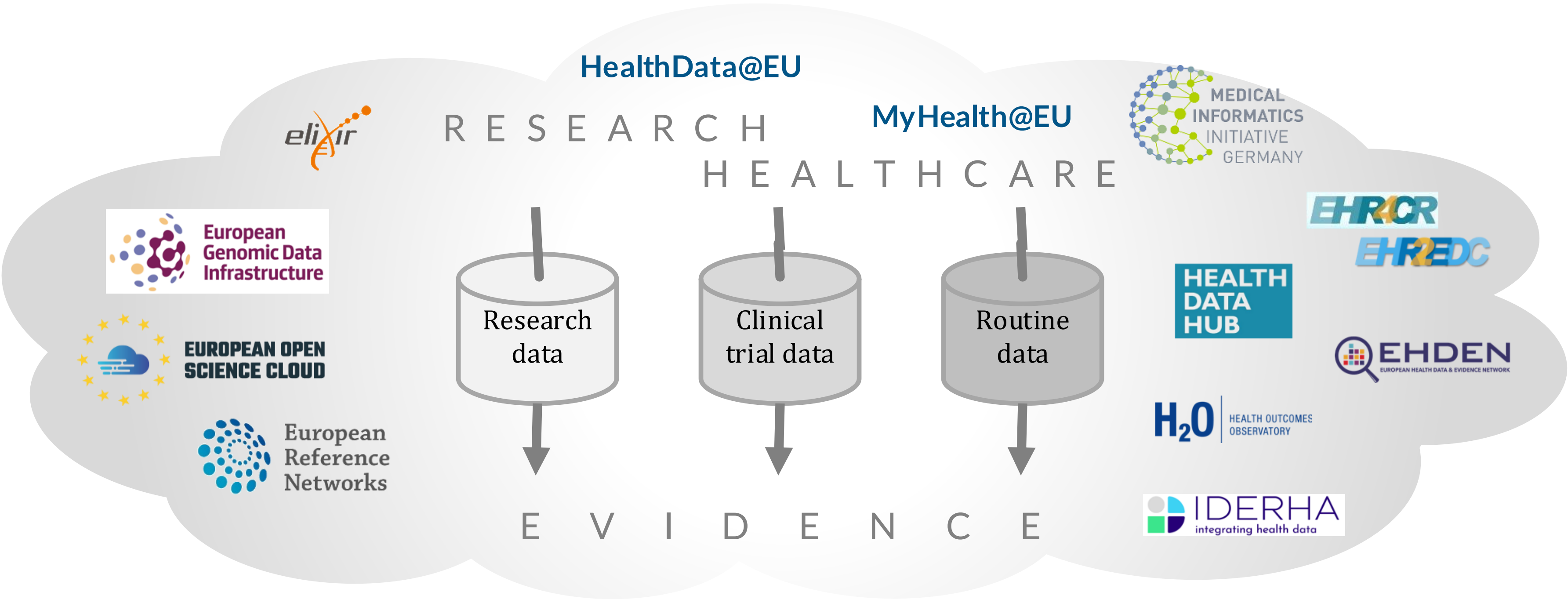
The OHDSI* community who took part



* The Observational Health Data Sciences and Informatics (OHDSI) programme. https://ohdsi.org

Big health data sharing initiatives

- Multiple initiatives are scaling up health data access
  - across jurisdictional, institutional and domain borders, for care or for research
- Emerging paradigm for analysing personally-identifiable health data:
  - federated infrastructure model: network of repositories with an overarching governance and interoperability layer



HealthData@EU

MyHealth@EU

RESEARCH

HEALTHCARE

Research data

Clinical trial data

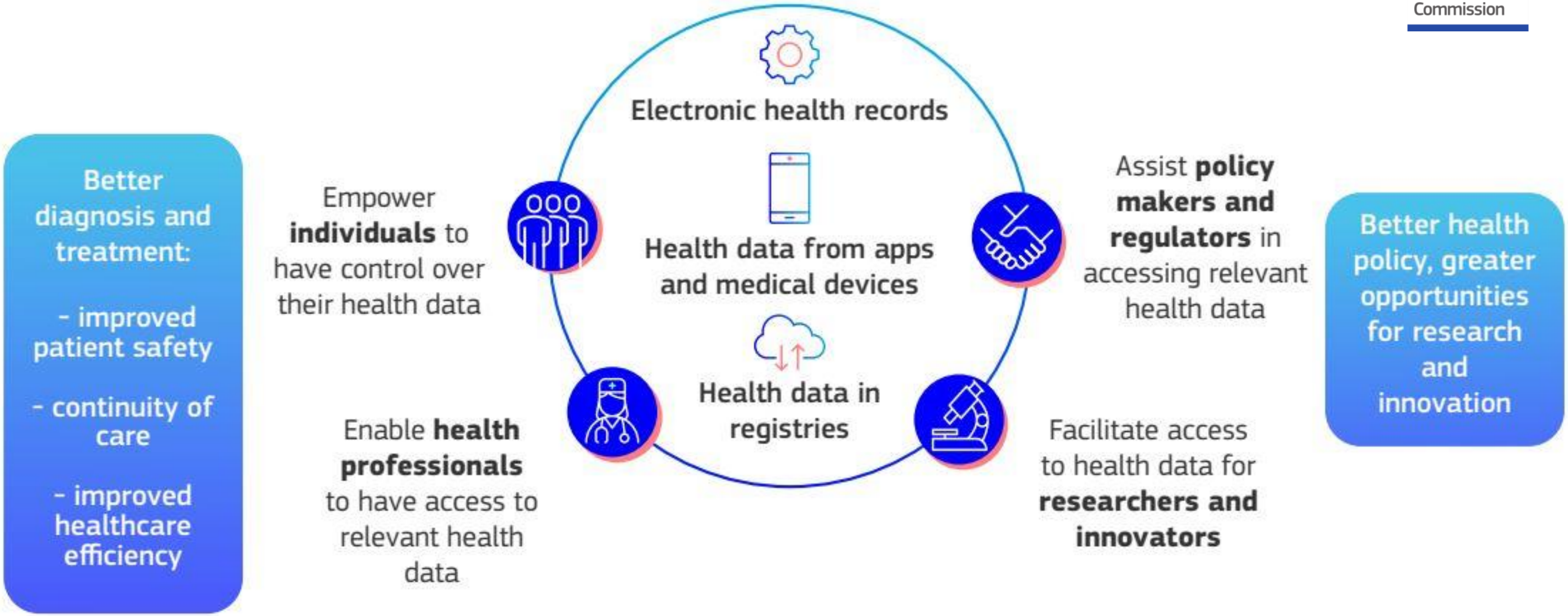
Routine data

EVIDENCE

elixir
European Genomic Data Infrastructure
EUROPEAN OPEN SCIENCE CLOUD
European Reference Networks
MEDICAL INFORMATICS INITIATIVE GERMANY
EHR4CR
EHR2EDC
HEALTH DATA HUB
EHDEN
EUROPEAN HEALTH DATA & EVIDENCE NETWORK
H2O
HEALTH OUTCOMES OBSERVATORY
IDERHA
integrating health data

Slide originally created by Oliver Zobell and Stefan Bujok

The European Health Data Space



Better diagnosis and treatment:

- improved patient safety

- continuity of care

- improved healthcare efficiency

Empower **individuals** to have control over their health data

Enable **health professionals** to have access to relevant health data

Electronic health records

Health data from apps and medical devices

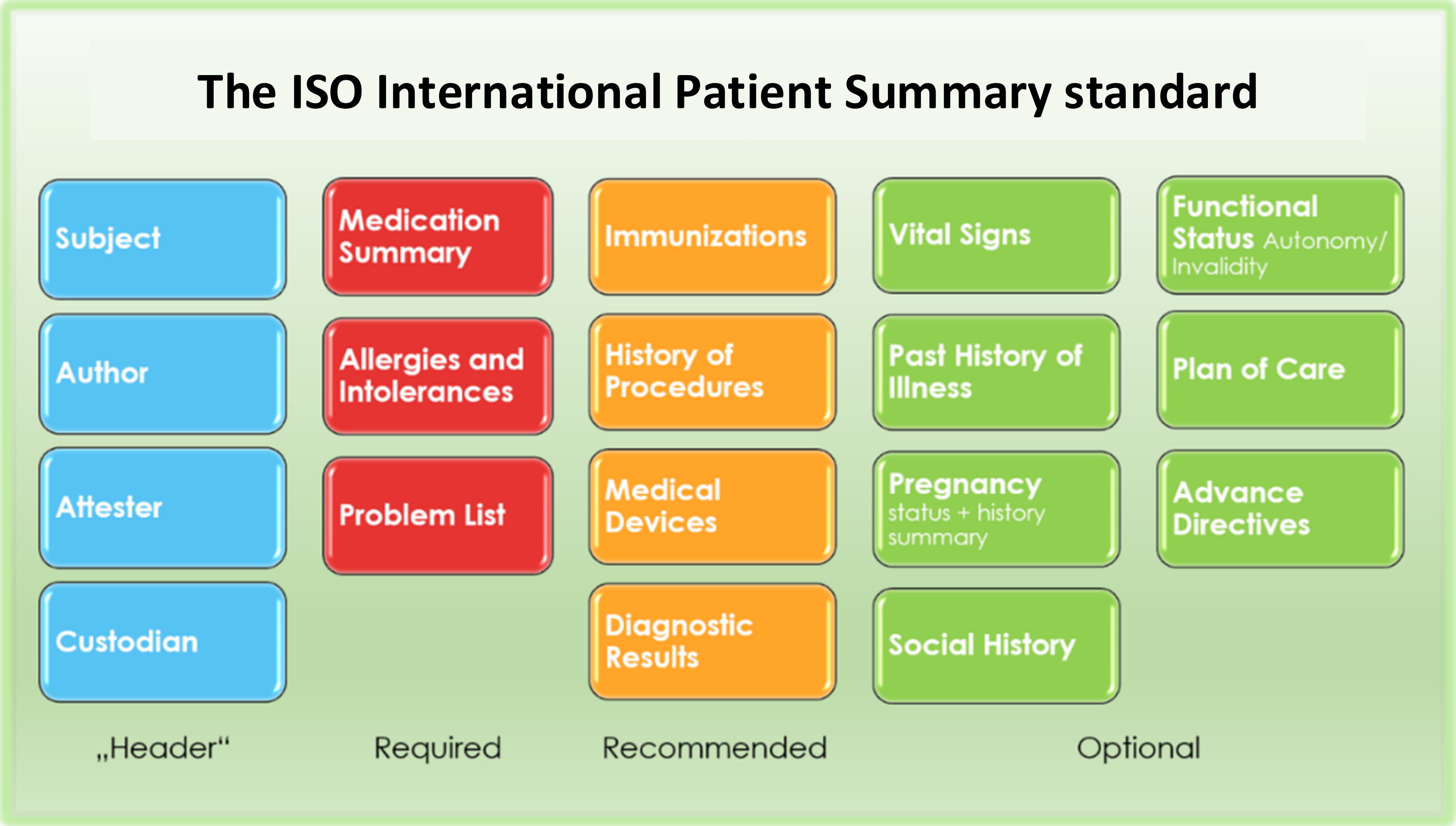
Health data in registries

Assist **policy makers and regulators** in accessing relevant health data

Facilitate access to health data for **researchers and innovators**

Better health policy, greater opportunities for research and innovation

Priority EHR data categories for primary use



The ISO International Patient Summary standard

„Header“
- Subject
- Author
- Attester
- Custodian

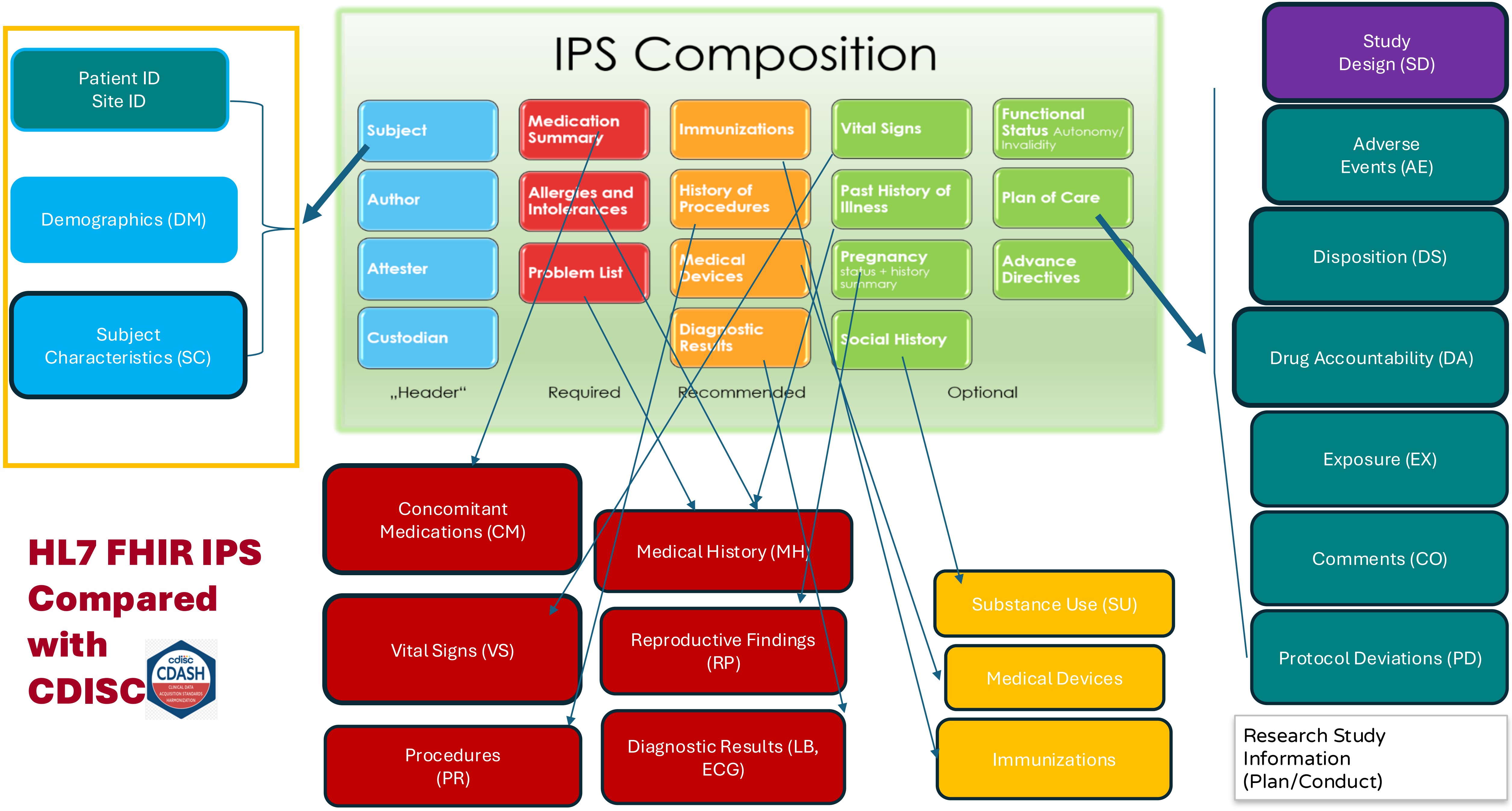
Required
- Medication Summary
- Allergies and Intolerances
- Problem List

Recommended
- Immunizations
- History of Procedures
- Medical Devices
- Diagnostic Results

Optional
- Vital Signs
- Past History of Illness
- Pregnancy status + history summary
- Social History
- Functional Status Autonomy/ Invalidity
- Plan of Care
- Advance Directives

Plus:
Prescriptions
Lab results
Radiology reports
Discharge summaries

HL7 FHIR IPS Compared with CDISC



Patient ID
Site ID

Demographics (DM)

Subject Characteristics (SC)

IPS Composition

„Header“	Required	Recommended	Optional	
Subject	Medication Summary	Immunizations	Vital Signs	Functional Status Autonomy/ Invalidity
Author	Allergies and Intolerances	History of Procedures	Past History of Illness	Plan of Care
Attester	Problem List	Medical Devices	Pregnancy status + history summary	Advance Directives
Custodian		Diagnostic Results	Social History	

Concomitant Medications (CM)

Vital Signs (VS)

Procedures (PR)

Medical History (MH)

Reproductive Findings (RP)

Diagnostic Results (LB, ECG)

Substance Use (SU)

Medical Devices

Immunizations

Study Design (SD)

Adverse Events (AE)

Disposition (DS)

Drug Accountability (DA)

Exposure (EX)

Comments (CO)

Protocol Deviations (PD)

Research Study Information (Plan/Conduct)

1) Data Element Sources → 2)Core Element Set → 3) Terminology Assessment

IPS Composition

„Header“	Required	Recommended	Optional	
Subject	Medication Summary	Immunizations	Vital Signs	Functional Status Autonomy/ Invalidity
Author	Allergies and Intolerances	History of Procedures	Past History of Illness	Plan of Care
Attester	Problem List	Medical Devices	Pregnancy status + history summary	Advance Directives
Custodian		Diagnostic Results	Social History	

ISO- IPS 27269

Mandatory	Patient attributes	Allergies & intolerances	Problems incl. diagnosis	Medication summary	Cross organization ★		
Required If Known	Healthcare provider	Address-book ★	History of procedures	Immunization (incl. Vaccinations)	Medical Devices (incl. implants)	Results	Alerts
Optional	History of past illness	Advance directives (i.e., living wills)	Care plan	History of Pregnancy	Vital signs	Functional status	Patient's Story ★
	Social history (incl. lifestyle						

Integrating the Healthcare Enterprise

IHE

IHE Patient Care Coordination Technical Framework Supplement

International Patient Summary (IPS)

Revision 1.2 – Trial Implementation

ISO

International Standard

ISO 27269:2021

Health informatics — International patient summary

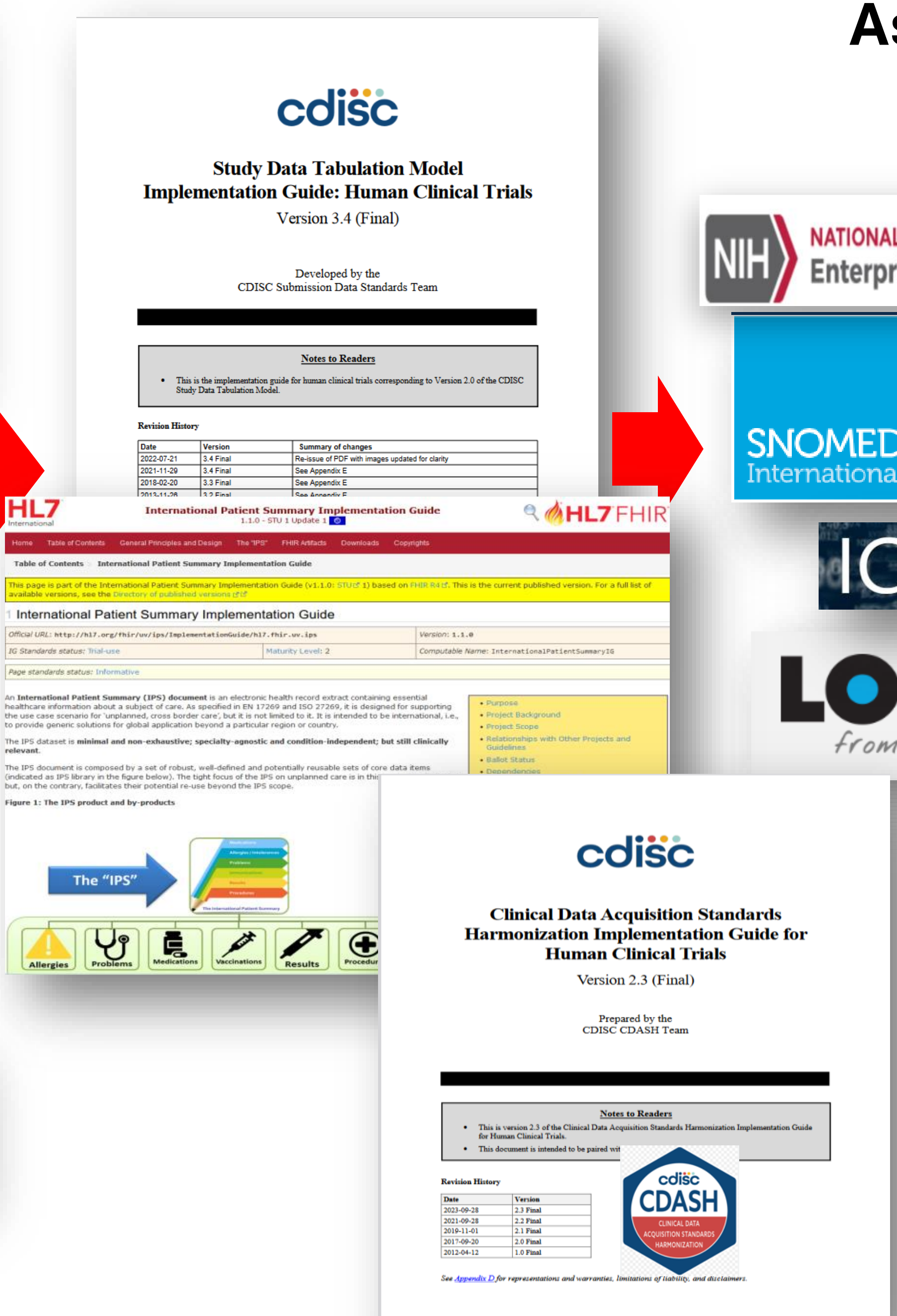
Edition 1 2021-04

iHD

PHIRI Population Health Information Research Infrastructure

EHR4CR

EHR2EDC



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Study Data Tabulation Model Implementation Guide: Human Clinical Trials

Version 3.4 (Final)

Developed by the CDISC Submission Data Standards Team

Notes to Readers

- This is the implementation guide for human clinical trials corresponding to Version 2.0 of the CDISC Study Data Tabulation Model.

Revision History

Date	Version	Summary of changes
2022-07-21	3.4 Final	Re-issue of PDF with images updated for clarity
2021-11-29	3.4 Final	See Appendix E
2018-02-20	3.3 Final	See Appendix E

HL7 International

International Patient Summary Implementation Guide

1.1.0 - STU 1 Update 1

HL7 FHIR

Home Table of Contents General Principles and Design The "IPS" FHIR Artifacts Downloads Copyrights

Table of Contents International Patient Summary Implementation Guide

This page is part of the International Patient Summary Implementation Guide (v1.1.0: STU 1) based on FHIR R4. This is the current published version. For a full list of available versions, see the Directory of published versions

1 International Patient Summary Implementation Guide

Official URL: http://hl7.org/fhir/uv/ips/ImplementationGuide/hl7.fhir.uv.ips		Version: 1.1.0
IG Standards status: Trial-use	Maturity Level: 2	Computable Name: InternationalPatientSummaryIG

Page standards status: Informative

An **International Patient Summary (IPS) document** is an electronic health record extract containing essential healthcare information about a subject of care. As specified in EN 17269 and ISO 27269, it is designed for supporting the use case scenario for 'unplanned, cross border care', but it is not limited to it. It is intended to be international, i.e., to provide generic solutions for global application beyond a particular region or country.

The IPS dataset is **minimal and non-exhaustive; specialty-agnostic and condition-independent; but still clinically relevant**.

The IPS document is composed by a set of robust, well-defined and potentially reusable sets of core data items (indicated as IPS library in the figure below). The tight focus of the IPS on unplanned care is in thi… but, on the contrary, facilitates their potential re-use beyond the IPS scope.

- Purpose
- Project Background
- Project Scope
- Relationships with Other Projects and Guidelines
- Ballot Status
- Dependencies

Figure 1: The IPS product and by-products

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Clinical Data Acquisition Standards Harmonization Implementation Guide for Human Clinical Trials

Version 2.3 (Final)

Prepared by the CDISC CDASH Team

Notes to Readers

- This is version 2.3 of the Clinical Data Acquisition Standards Harmonization Implementation Guide for Human Clinical Trials.
- This document is intended to be paired wit…

Revision History

Date	Version
2023-09-28	2.3 Final
2021-09-28	2.2 Final
2019-11-01	2.1 Final
2017-09-20	2.0 Final
2012-04-12	1.0 Final

cdisc CDASH CLINICAL DATA ACQUISITION STANDARDS HARMONIZATION

See Appendix D for representations and warranties, limitations of liability, and disclaimers.

NIH NATIONAL CANCER INSTITUTE Enterprise Vocabulary Services

SNOMED International Leading healthcare terminology, worldwide

ICD-11

LOINC® from Regenstrief

Share EHR Xchange Format

Share
EHR Xchange Format

DOMAIN/CATEGORY:
IPS-Subject = CDISC-Demographics (DM)
Subject Characteristics (SC)

- **Subject Characteristic /Demographic Item**
- **Subject Characteristic/Demographic Result**
- **Collection Date**

Demographics/Subject Characteristics – Specific Requested Items:

- **Research Subject Identifier**
- **Research Study Identifier**
- Age
  - Age Units
- Birth Date
- Gender/Sex*
- Death
  - Death Date
  - Death Time
  - Subject Death Flag

*Terms not precisely defined

IPS-Problem List = CDISC- Medication History (MH)**

- Problem/Condition/Medical History Reported Term
- Medical History Event Collection Date
- Medical History Event Start Date
- Medical History Event End Date
- Hypertension
- Diabetes
- Chronic obstructive pulmonary disease
- Alcohol Abuse
- Drug Abuse
- Allergy

IPS-History of Procedures = CDISC- Procedures (PR)

- Name of Procedure
- Procedure Start Date
- Procedure Indication
- Ongoing Procedure
- Procedure End Date

DOMAIN/CATEGORY:
IPS Diagnostic Results= CDISC- Laboratory Results (LB)
Microbiology Results (MB); Body Systems Findings**

- **Diagnostic/Laboratory/Micro Test Name**
  - **Diagnostic/Lab/Micro Result in Original Units Value**
  - **Diagnostic/Lab/Micro Original Units**
  - **Diagnostic/Lab/Micro Specimen Collection Date**
  - **Diagnostic/Lab/Micro Specimen Collection Time**
  - **Diagnostic/Lab/Micro Specimen Type**
  - **Diagnostic/Lab Fasting Status**
  - **Diagnostic/Lab/Micro Specimen/Reference ID**
  - **Lab Ref Range Lower Limit in Original Unit**
  - **Lab Ref Range Upper Limit in Original Unit**
  - **Diagnostic/Lab/Micro Specimen Collection Location**
  - **Diagnostic/Lab/Micro Method of Test/Exam**
  - **Microbiology Examination Detail**

**Body Systems Findings each have specific domain with the same variables (e.g., CVTEST/CVORRES for Cardiovascular).

DOMAIN/CATEGORY:
IPS-Medication Summary = CDISC- Concomitant Meds (CM)

- **Medication/Drug/Product Name**
  - **Medication Start Date**
  - **Medication End Date**
  - **Dose**
    - **Dose Units**
  - **Dose Form**
  - **Dose Frequency**
  - **Route of Administration**
  - **Medication Indication**

IPS-Vital Signs = CDISC- Vital Signs (VS)

- Vital Signs Test Name
- Vital Signs Date
- Vital Signs Time
- Vital Signs Result of Finding in Original Units
- Vital Signs Original Units

IPS- Pregnancy status + history summary =
CDISC- Reproductive Findings (RP)

- Pregnancy Status
- Reproductive Finding Name
- Reproductive Result or Finding in Original Units
- Reproductive Original Units
- Reproductive System Finding Date
- There are a number of discrete pregnancy related outcomes that were mapped to CDISC SDTM since there were discrete data elements in IPS (code system/code/label) available – potential public health use case

IPS-Social History = CDISC- Substance Use (SU)

- Tobacco Use (Smoking Status)
- Alcohol Use
- Name of Substance
- Never/Current/Former Usage
- Substance Dose
- Substance Dose Units
- Substance Use Frequency
- Substance Use Start Date
- Substance Use End Date
- Substance Use Duration
- Substance Use Duration Unit

DOMAIN/CATEGORY:
IPS-Data Element = CDISC- Adverse Encounters (AE)

- Allergies and Intolerances
  - Start Date
  - End Date
  - Reaction
  - Manifestation
  - Severity

- Adverse Event Term
  - **Adverse Event Start Date**
  - **Ongoing Adverse Event**
  - **Adverse Event End Date**
  - **Adverse Event Severity**
  - **Serious Criteria Met**
  - **AE Result in Death**
  - **Death Date**
  - **AE Life Threatening**
  - **AE Hospitalization**
  - **AE Disability or Permanent Damage**
  - **AE Congenital Anomaly or Birth Defect**
  - **AE Needs Intervention to Prevent Impairment**
  - **AE Other Serious Important Medical Event**
  - **Action Taken with Study Treatment**
  - **Outcome**

Category Not in HL7 FHIR IPS IG
Essential to research – likely not found in health care records

DOMAIN/CATEGORY:
IPS-Data Element = CDISC- Healthcare Encounters (HO)

- **Hospital Stay**
  - **Admission Date**
  - **Discharge Date**
- **Healthcare Encounter**
  - **Reason for Healthcare Encounter**
  - **Reported Term for Healthcare Encounter**
  - **Healthcare Encounter Start Date**
  - **Healthcare Encounter End Date**

Category Not in HL7 FHIR IPS IG
ISO IPS and IPS IHE have discharge summary information

eSource Scale Up Task Force

Coordinated by i~HD for member organizations to drive data interoperability and champion EHR as eSource

Purpose

- Drive and scaling the adoption of Electronic Health Record (EHR) as eSource technology across pharma/biotech companies and hospitals
- Promote alignment across members to adopt harmonized and efficient practices and processes
- Engage with relevant organisations and stakeholders involved in eSource EHR initiatives

Outputs

- Published reports, publications, webinars, position papers, recommendation, presentations, meetings

Modus Operandi

- Collaboration using "Chatham House rules" under i~HD membership banner

Founding members

Cambridge University Hospitals NHS Foundation Trust
Memorial Sloan Kettering Cancer Center
SANOFI
REGENERON
janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson
AstraZeneca
i~HD The European Institute for Innovation through Health Data

Key stakeholders

cdisc
TransCelerate BIOPHARMA INC.
VULCAN HL7 FHIR
SCDM Society for Clinical Data Management DATA DRIVEN
EUROPEAN MEDICINES AGENCY
SCRS Society for Clinical Research Sites
FDA
+Industry
+Vendors
+Study Sites

https://www.chathamhouse.org/about-us/chatham-house-rule