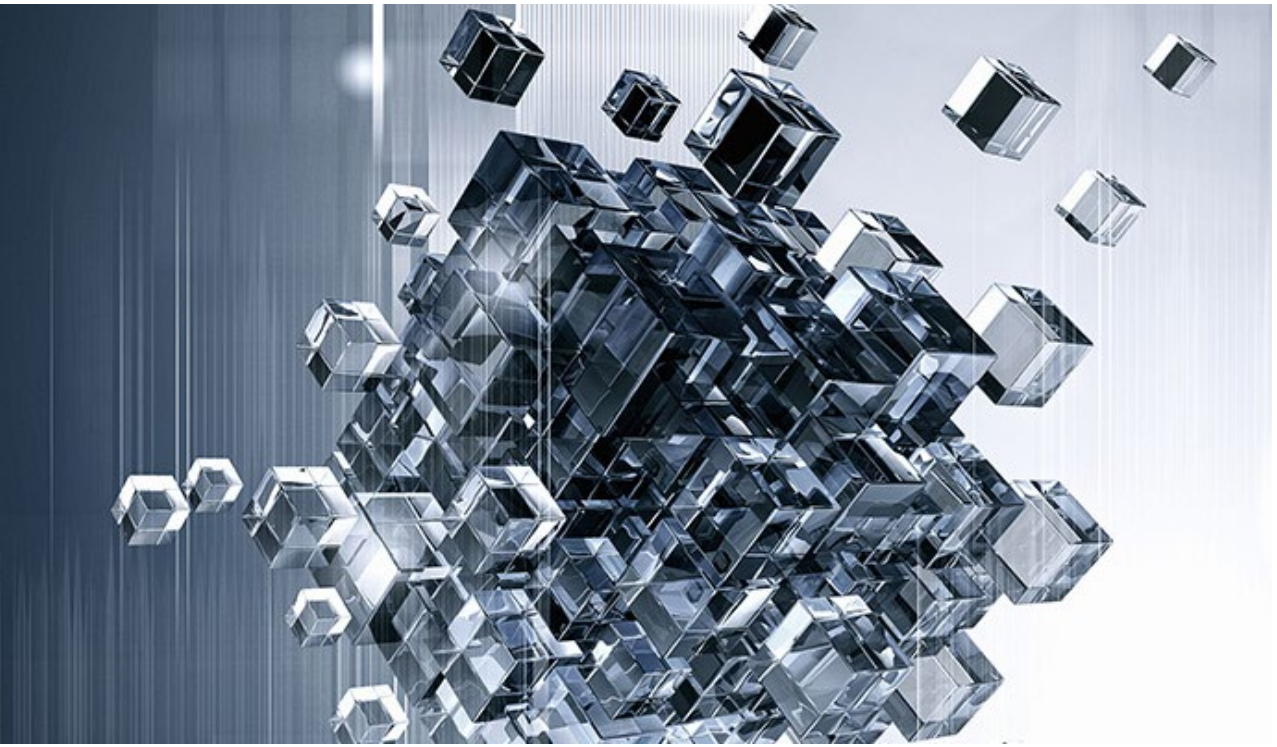
Health data drives innovation

Learning Health Community



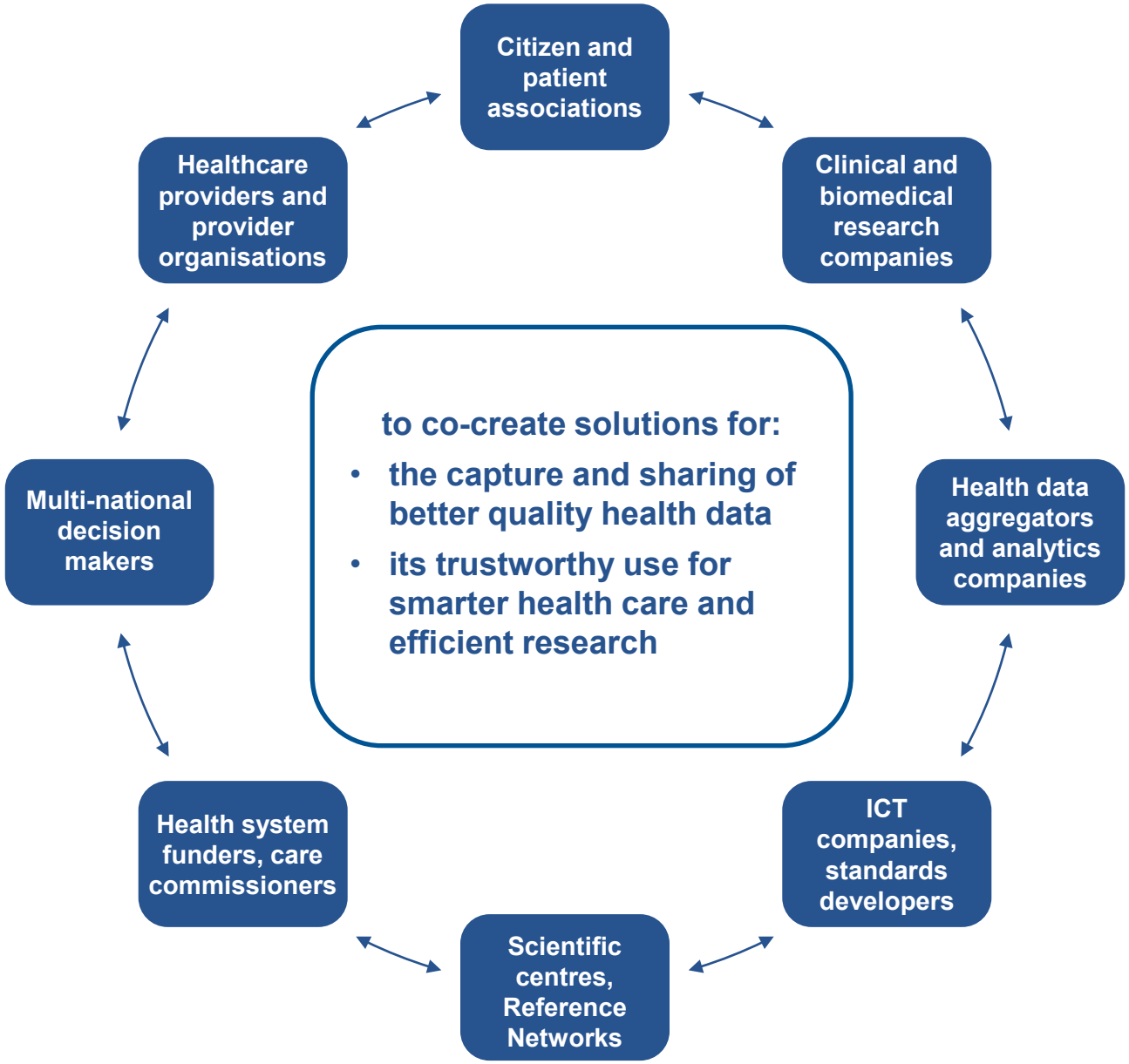
Scaling up trustworthy RWD for clinical research

The momentum in Europe

The European Institute for Innovation through Health Data

Professor Dipak Kalra
President

i~HD is a neutral, not-for-profit, European institute uniting stakeholders



Clinical Research needs

Healthcare needs

INFORMATION GOVERNANCE

iHD

QUALITY OF HEALTH DATA

TRUSTWORTHY HEALTH ICT SYSTEMS

DATA INTEROPERABILITY STANDARDS

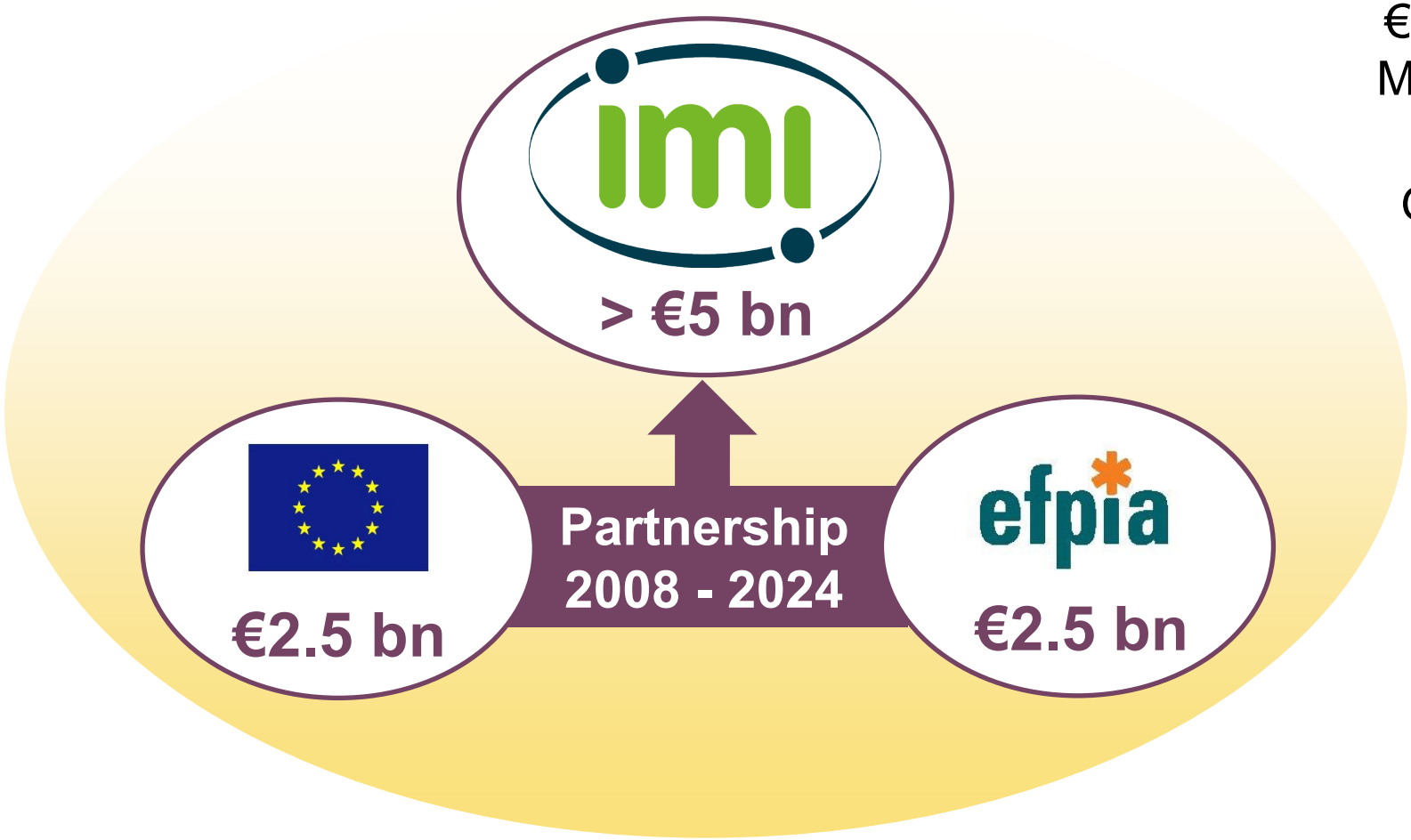
QUALITY LABELS: CERTIFICATES & SEALS

SCALING UP THE HEALTH ECOSYSTEM

IMI – Europe's partnership for health

IMI1: 2008-2013
€2 bn budget
59 projects

IMI2: 2014-2024
€3.3 bn budget
More ambitious
More open
Greater scope



Slide courtesy of Pierre Meulien, Executive Director of IMI / IHI

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]

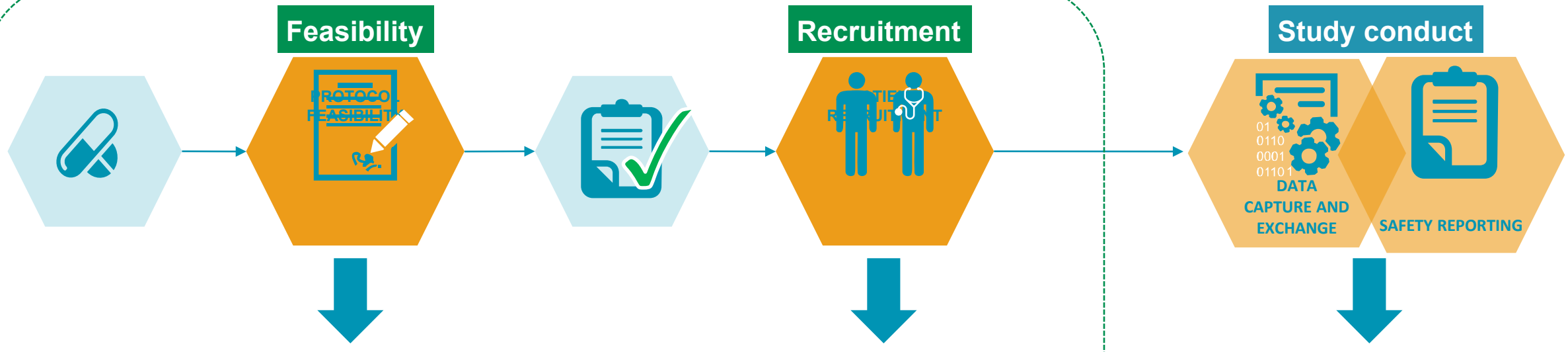
1. State of the Clinical Trials Industry: A Sourcebook of Charts and Statistics, Center Watch, 2008.
2. Study Participant Recruitment and Retention in Clinical Trials: Emerging strategies in Europe, the US and Asia, Business Insights, June 2007.
3. Beasley, "Recruiting" 2008
4. Tufts -http://clinicalperformancepartners.com/wp-content/uploads/2012/07/Fixing-Feasi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

The EHR4CR project

- EHR4CR – Electronic Health Records for Clinical Research
  - 4+1 year project (2011-2016), 35 partners, budget >17M€
- Objectives & Scope
  - Provide a platform for **trustworthy re-use of EHR data** to support innovation in clinical research and healthcare operations.
  - Unlocking **Health data** for optimising clinical trials
  - **7 pilot sites across Europe**
- Status
  - Extended into 2016 for making the transition to a sustainable platform.
  - Initiated a **Champion Programme**, connecting hospitals to an operational platform, building up experience with pharma
  - The **European Institute for Innovation through Health Data** – an independent governance body

For more information:
http://www.ehr4cr.eu/

The critical scenarios



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

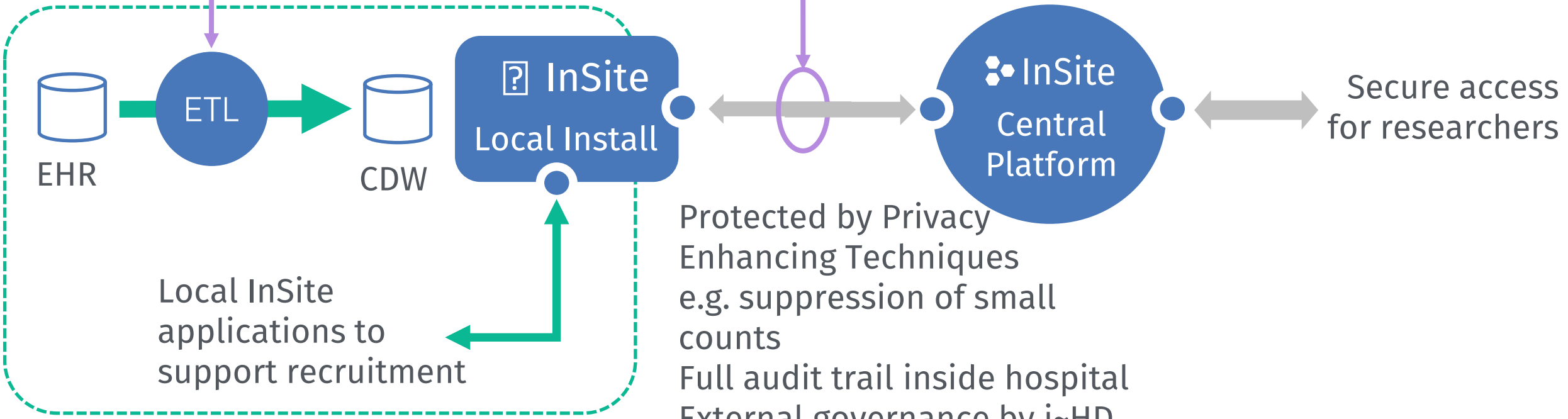
Speeding up recruitment by making EHR data **searchable for investigators** and establishing a **unified communication path** between sponsors and sites.

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

InSite – Technical Overview, for Protocol feasibility

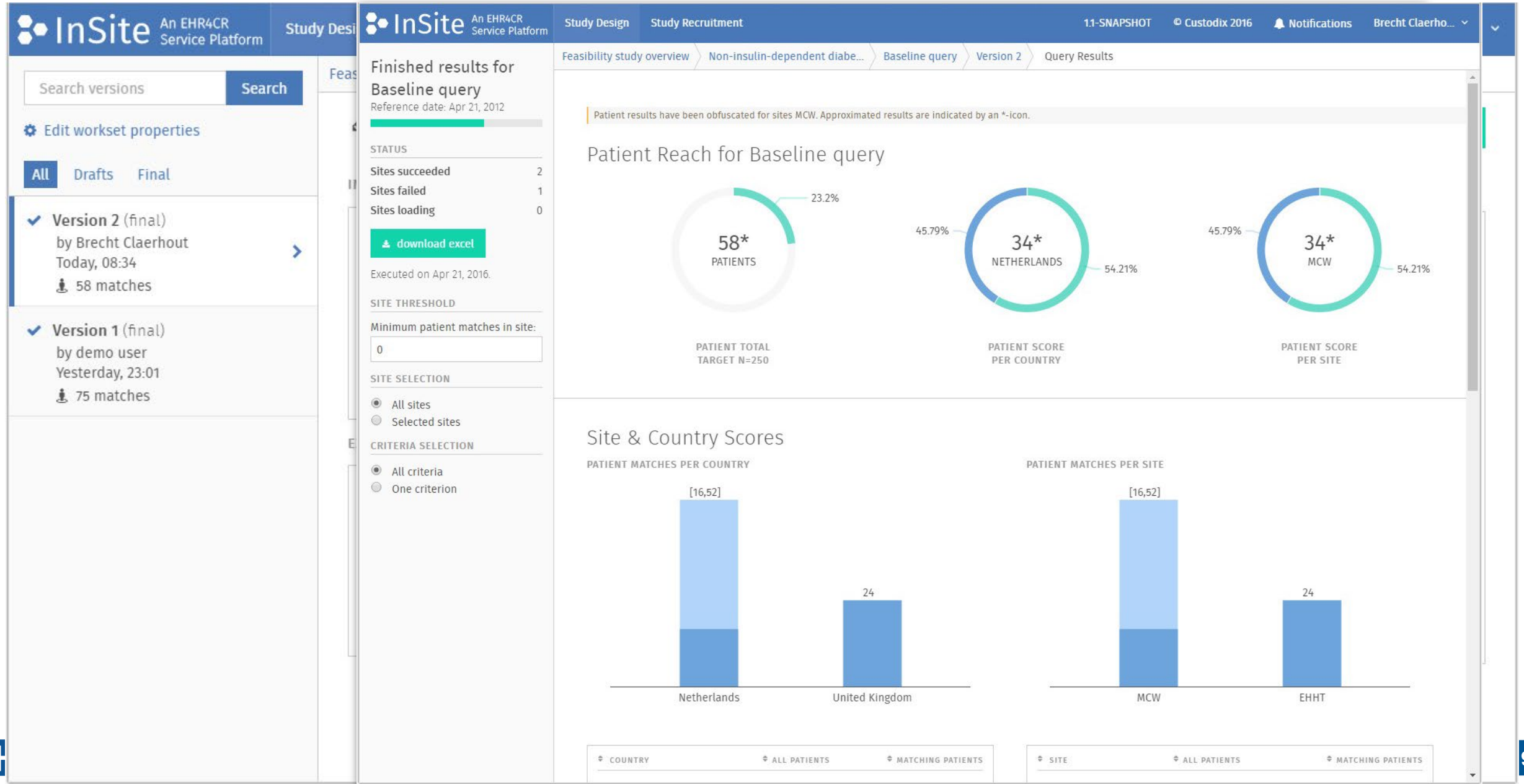
InSite provides expertise and tools to support local sites with mappings

Only aggregated data (patient counts) leave the hospital, only on approval



Protected by Privacy Enhancing Techniques
e.g. suppression of small counts
Full audit trail inside hospital
External governance by i~HD

InSite – Protocol feasibility query



Clinical research platform scale up

InSite

11 **Countries** in which InSite is active

31 **Million** patient lives in the InSite network

50 **Hospitals** in the InSite network

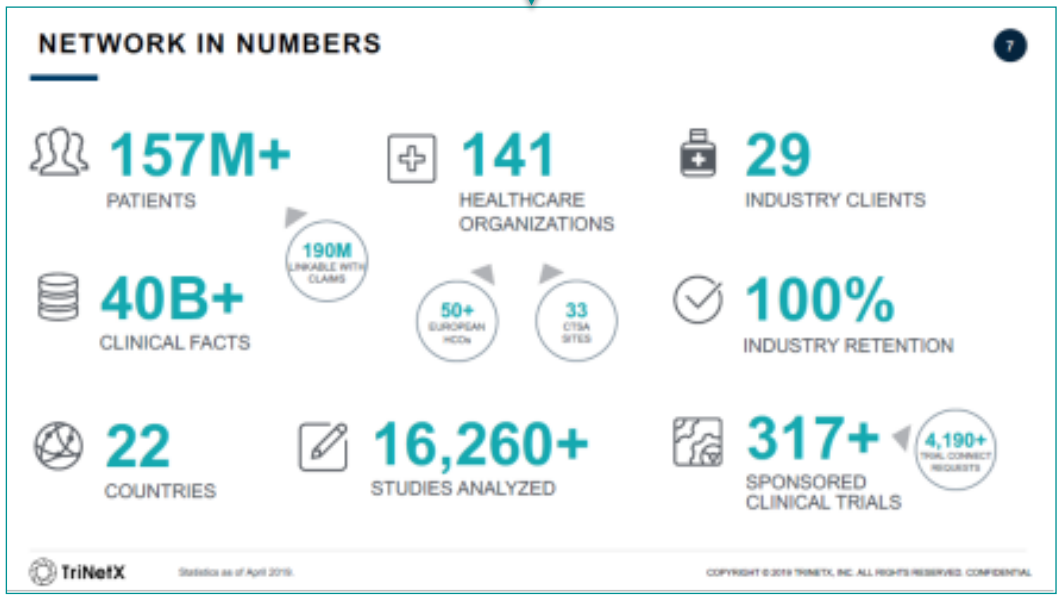
>100 **Additional** actively discussing hospitals

Key hospitals includes

TYKS · Vall d'Hebron Hospital · UZ · Assistance Publique Hôpitaux de Paris · MHH Medizinische Hochschule Hannover · Imperial College Healthcare NHS Trust · Hospital Universitario 12 de Octubre SaludMadrid · Ospedale Niguarda Ca' Granda · Region Örebro län Universitetssjukhuset Örebro · CHUC

Custodix merger with TriNetX

Growth within 5 years



Why some eligibility criteria cannot be converted into EHR queries

- Criteria that could not be formalised, such as
  - conditional events (e.g. medication used for another reason)
  - medical response, treatment response
  - measurements usually taken at home
  - toxicity grades
  - "symptomatic", “may or may not", “treatment naive”
  - “more than one medication” but not specified which ones
  - “must have recovered from all side effects”
  - “uncontrolled"
- Likely willingness of the patient to provide informed consent or to comply with abstinence
- Criteria that should apply at a particular visit or at screening
- Participation in another trial
- Investigator's opinion

Claerhout et al. Federated electronic health records research technology to support clinical trial protocol optimization: Evidence from EHR4CR and the InSite platform
https://doi.org/10.1016/j.jbi.2018.12.004

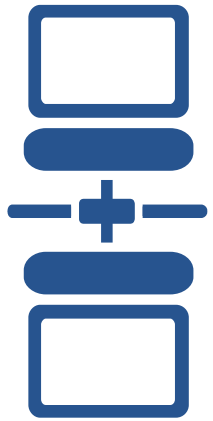
Redundant data entry

- 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]



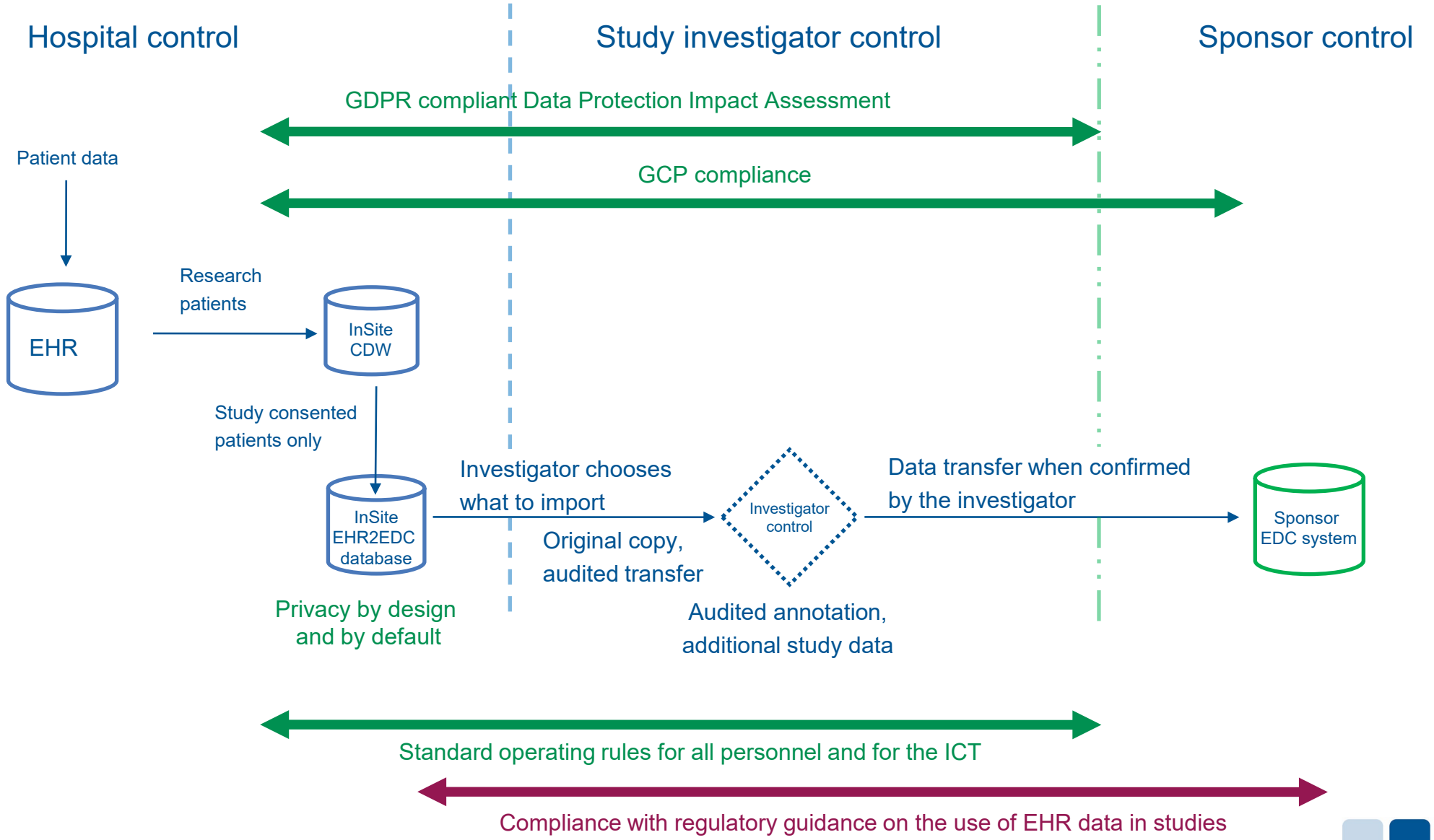
Investigational sites estimate that over

70%

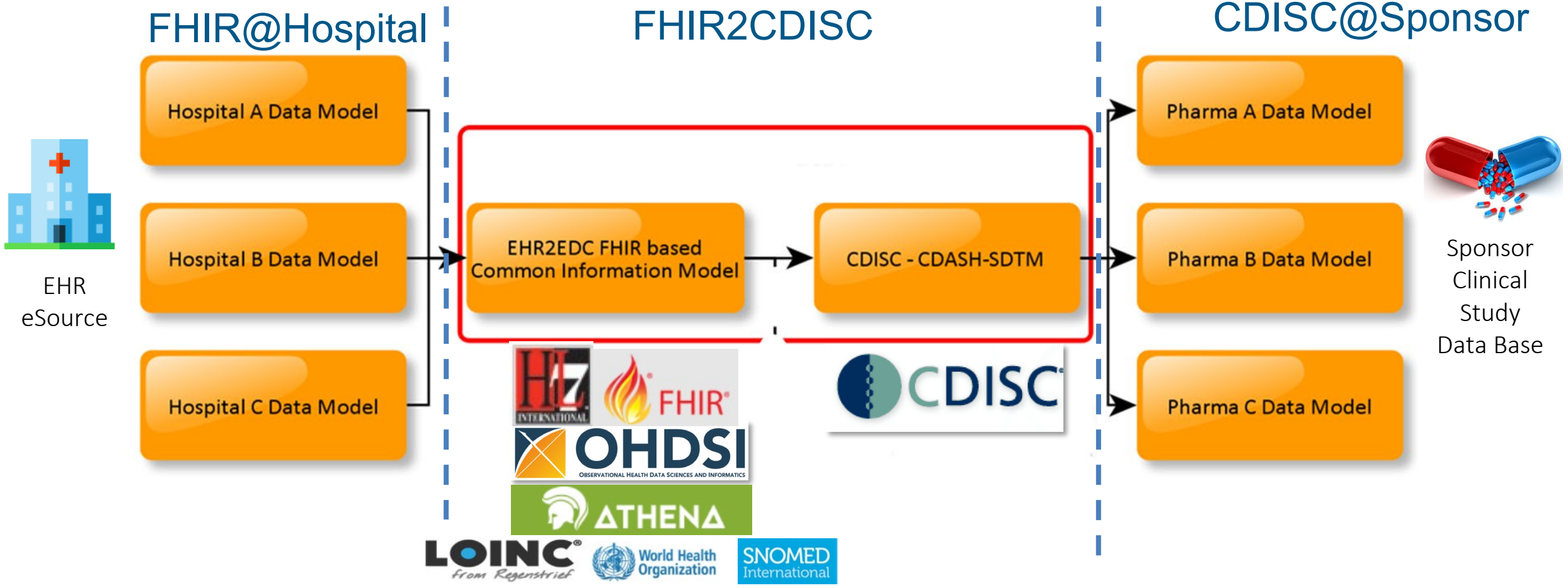
of data are duplicated between EHR and clinical trial systems[2]

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



Mapping eSource EHR Data Standards



The EHR2EDC results in a nutshell

Interoperability mapping

The first validated set of the most commonly collected data in clinical trials was mapped, Common Information Model (CIM) and HL7 Fast Health Interoperability (Resources (FHIR) based interoperability profiles developed

Regulatory

ISO Good Clinical Practice (GCP) and Regulatory compliance for regulated trials

Data governance

Principles, code of practice and Standard Operating Rules to support hospitals to conform to applicable GDPR regulations

Technical module

Tested and validated

Validation study

Multi-centric, multi-sponsor validation study (TransFAIR) successfully completed at the partner sites

- Six protocols from three pharma companies (AstraZeneca, Janssen, Sanofi)
- Four categories of health data (demographics, vital signs, laboratory and medication)
- Hospitals from three countries: AP-HP (France), 12 Octubre (Spain), IRST (Italy)
- >11000 data points automatically transferred
- Covering 37% of the patient data needed for these studies
- Several companies now developing commercial solutions

EU-PEARL

EU PATIENT-CENTRIC CLINICAL TRIAL PLATFORMS

Strategic alliance between the public and private sectors to:

by developing a common framework
for platform clinical trials/Integrated Research Platforms (IRPs)

Platform

To test multiple drugs for a single disease in a continuous manner, with drugs allowed to enter and leave the platform on the basis of a decision algorithm.

EU-PEARL focuses on PLATFORM TRIALS

Basket

To test one drug for multiple diseases or disease subtypes.

Umbrella

To test multiple drugs for a single disease.

BENEFITS OF PLATFORM TRIALS

Relevant for complex and/or rare diseases with high unmet needs.

Drugs are tested in parallel so treatments can be developed faster.

Shared infrastructure can result in trials becoming more efficient.

"Plug and play" system allows for potential drugs to enter and exit the trial according to the results observed.

Less strain in patient recruitment as only one control group is needed to test several drugs.

Outcomes and learnings are shared amongst different companies, researchers, etc, thus advancing science faster.

EU-PEARL

EU PATIENT-CENTRIC CLINICAL TRIAL PLATFORMS

Shared master protocol and methodology.

Scientific, legal, regulatory and ethical requirements.

Network of hospitals, clinicians and researchers.

Data governance policies and procedures.

Regulated access to patient electronic health records and patient cohorts.

Pathway for patients' participation in trials design.

Value to hospitals = value to all health stakeholders

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

Efficient capability to conduct research: income and reputation

Ability to measure health outcomes and improve care

Stronger drive to improve data quality

Example data quality issues from hospitals

Leeds Hospital's 'Own Data' Stopped Surgery

The NHS chief who halted children's heart surgery at Leeds General Hospital says the hospital's faulty data was to blame.

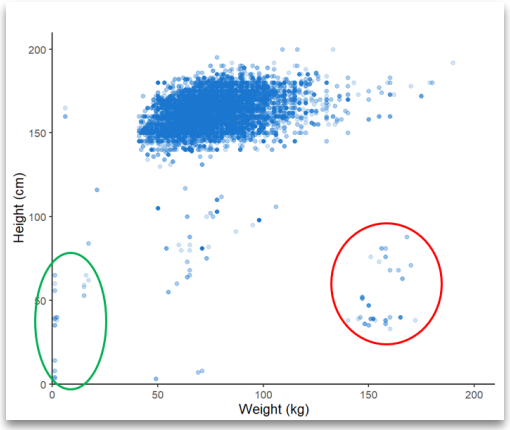
Tuesday 9 April 2013 10:33, UK

Twice as many babies and children seemed to be dying at the unit compared with specialist facilities elsewhere in the country.

Kristin M Hirata [1], Ann H Kang, Gina V Ramirez, Chieko Kimata, Loren G Yamamoto

Affiliations + expand

PMID: 28976456 DOI: 10.1097/PEC.0000000000001277



34% of weight errors led to medication-dosing errors
48% of these patients required additional monitoring, examination or treatment

- Most health is captured by busy junior staff, using various EHR systems
- Staff have no access to training in data quality
- Patients also have no training! (but their data is increasingly important)

Work on data quality dimensions and assessment methods

Methods and dimensions of electronic health record data quality assessment: enabling reuse for clinical research

Nicole Gray Weiskopf, Chunhua Weng

A Harmonized Data Quality Assessment Terminology and Framework for the Secondary Use of Electronic Health Record Data

Michael G. Kahn

A Pragmatic Framework for Single-site and Multisite Data Quality Assessment in Electronic Health Record-based Clinical Research

Michael G. Kahn, MD, PhD,*† Marsha A. Raebel, PharmD,‡§ Jason M. Glanz, PhD, MS,‡‖ Karen Riedlinger, MPH, MT (ASCP),¶ and John F. Steiner, MD, MPH‡

Secondary Use of EHR: Data Quality Issues and Informatics Opportunities

Taxiarchis Botsis[a,b], Gunnar Hartvigsen[a,c], Fei Chen[b], Chunhua Weng[b]

A practical framework for data management processes and their evaluation in population-based medical registries

M. SARIYAR[1], A. BORG[1], O. HEIDINGER[2] & K. POMMERENING[1]

A Data Quality Assessment Guideline for Electronic Health Record Data Reuse

Nicole G. Weiskopf, PhD;[i] Suzanne Bakken, RN, PhD;[ii,iii] George Hripcsak, MD, MS;[ii] Chunhua Weng, PhD[ii]

Applying probabilistic temporal and multisite data quality control methods to a public health mortality registry in Spain: a systematic approach to quality control of repositories

RECEIVED 30 August 2015
REVISED 21 December 2015
ACCEPTED 17 January 2016

AMIA INFORMATICS PROFESSIONALS, LEADING THE WAY.
OXFORD UNIVERSITY PRESS

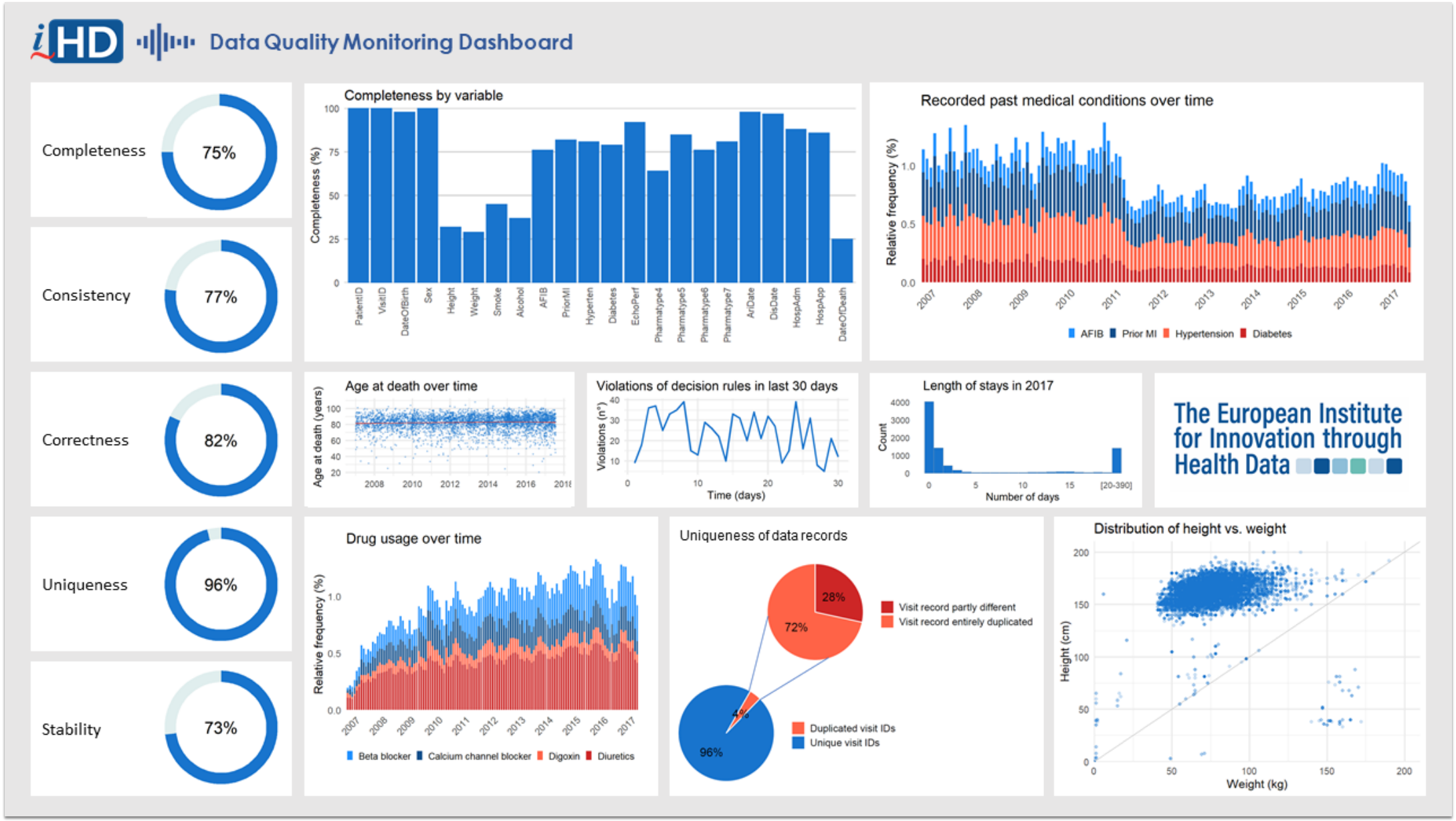
Carlos Sáez[1,2], Oscar Zurriaga[3,4,5], Jordi Pérez-Panadés[3], Inma Melchor[3], Montserrat Robles[1] and Juan M García-Gómez[1,6]

Data quality rules, assessment tools, improvement support

Name	Definition
Completeness	Data values are present
Consistency	Data satisfy constraints (format, allowable ranges and values, domain rules, relations)
Correctness	Values are true and unbiased with respect to their real-world state
Uniqueness	Records representing a single patient are not replicated

Name	Definition
Timeliness	Data is up-to-date to their real world state for the task at hand
Stability	Data inherent concepts and statistics are comparable among sources (hospitals, professionals, etc) and over time
Relevance	Data are useful for their task
Contextualization	Data are annotated with the acquisition context, their meaning and semantics
Trustworthiness	Data can be trusted based on the reputation of the stakeholders involved in their acquisition

Data quality rules, assessment tools, improvement support



Standards and regulations on EHR systems and eSource

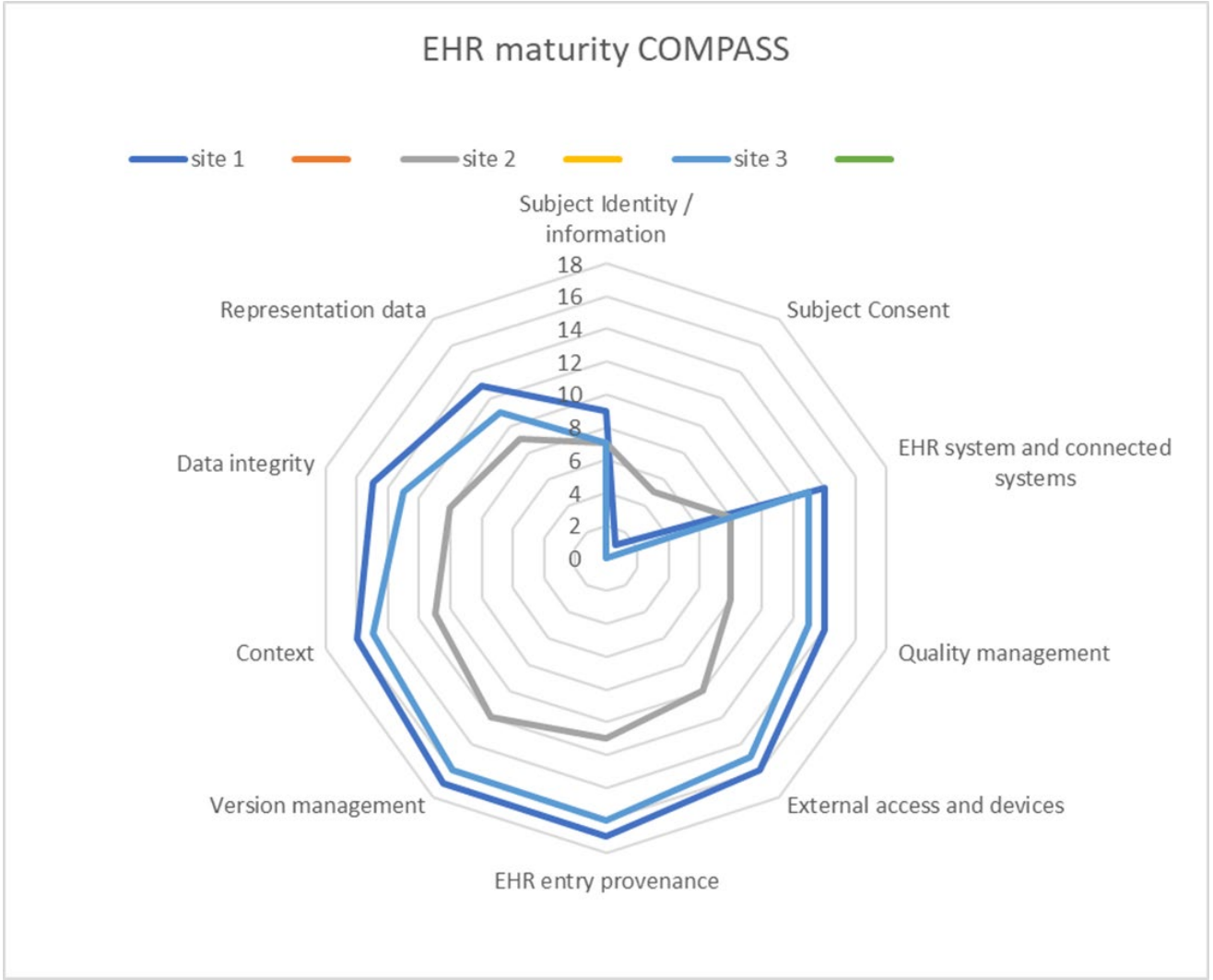
- ISO 18308: Requirements for an electronic health record reference architecture, 2011
- CDISC: Leveraging the CDISC Standards to Facilitate the use of Electronic Source Data within Clinical Trials, Version 1.0, November 2006
- EMA Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials (General-EMA/INS/GCP/454280/2010)
- FDA Guidance for Industry Electronic Source Data in Clinical Investigations, September 2013
- HHS final rule: 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications, October 16, 2015
- FDA Guidance for Industry: Use of Electronic Records and Electronic Signatures on Clinical Investigations Under 21 CFR Part 11- Questions and Answers, Draft guidance, June 2017
- MHRA Position Statement and Guidance Electronic Health Records, Version 1.0, 16 September 15
- ICH Guideline for good clinical practice E6(R2)
- FDA Guidance for industry on the Use of Electronic Health Record Data in Clinical Investigations, July 2018

Growing a Hospital Network of Excellence

Assessment criteria reflect:
- ISO EHR standards
- Regulatory eSource guidelines
- Industry quality frameworks

Two level assessment process
- 1: Online self-assessment
- 2: Optional on site assessment, Certification

Maturity Compass
- EHR Information Governance
- eSource readiness
- Data Quality



Growing a Hospital Network of Excellence

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Maturity Compass
- EHR Information Governance
- eSource readiness
- Data Quality

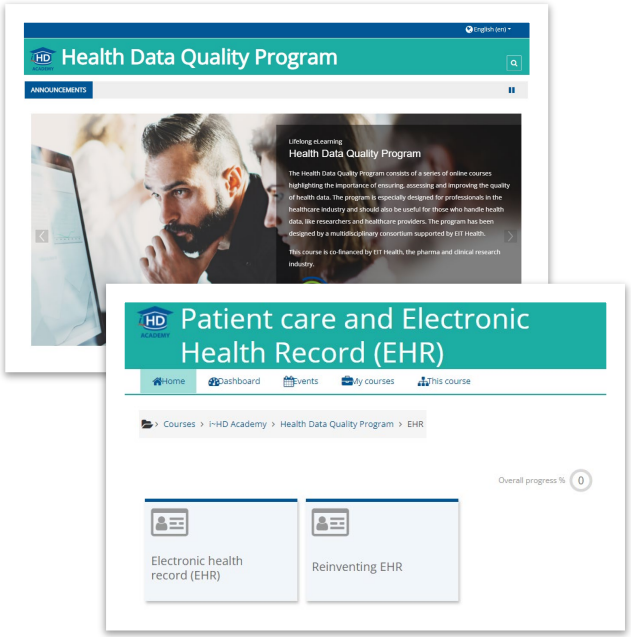
Improvement programmes for these domains

- Compass, dashboards
- Benchmarking intra & inter hospitals of excellence
- Peer learning events
  - Webinars
  - Tutorials
  - Physical workshops
- Sponsored in partnership with industry

Sustainable on-line catalogue
- A searchable & accessible online tool of hospitals of excellence

ACADEMY

- **Quality educational programs to support all stakeholders**
  - Trustworthy use of high-quality health data to continuously improve care and accelerate research
- **"By the i~HD community for the i~HD community"**



Data Quality

Trustworthy health ICT systems

ACADEMY

Data interoperability standards

GDPR and information governance

Videos
Narrated presentations
Assessment tools e.g quiz

The spectrum of data use: from care to research

Individual level health data

EHR systems, apps, sensors, genomics, Clinical Decision Support, AI

Used for:

- Health status monitoring
- Continuity of care (including the patient and caregivers)
- Care pathway tracking, clinical workflow management
- Real-time feedback and guidance to patients and clinicians
- Personalised medicine
- Disease interception, prevention and wellness
- Healthcare provider reimbursement

Population level health data

EHR systems, regional & national eHealth infrastructures

Reused for:

- Healthcare provider performance and planning
- Quality and safety, care pathway optimisation
- Medical device and algorithm refinement
- Pharmacovigilance
- Public health surveillance
- Public health strategy
- Health services and resource planning

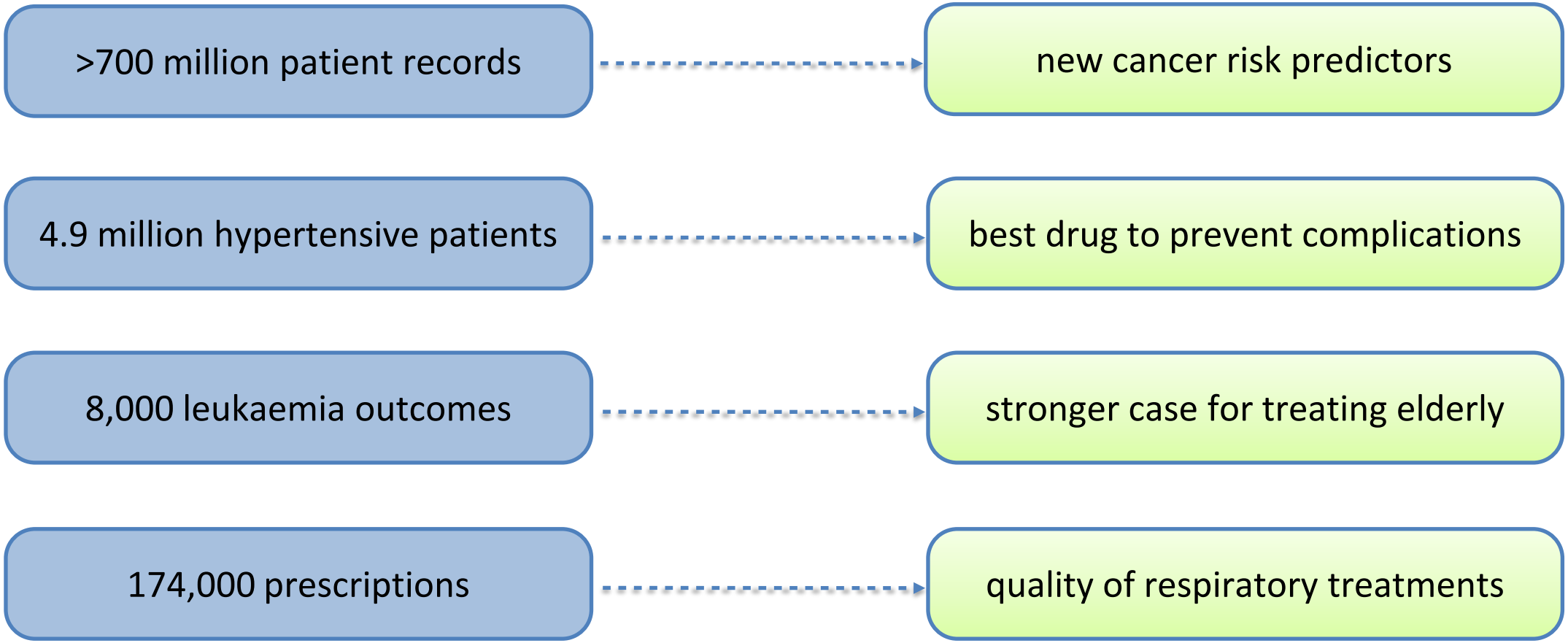
Big health data

national & international research infrastructures, federated query platforms + cross-sectoral services

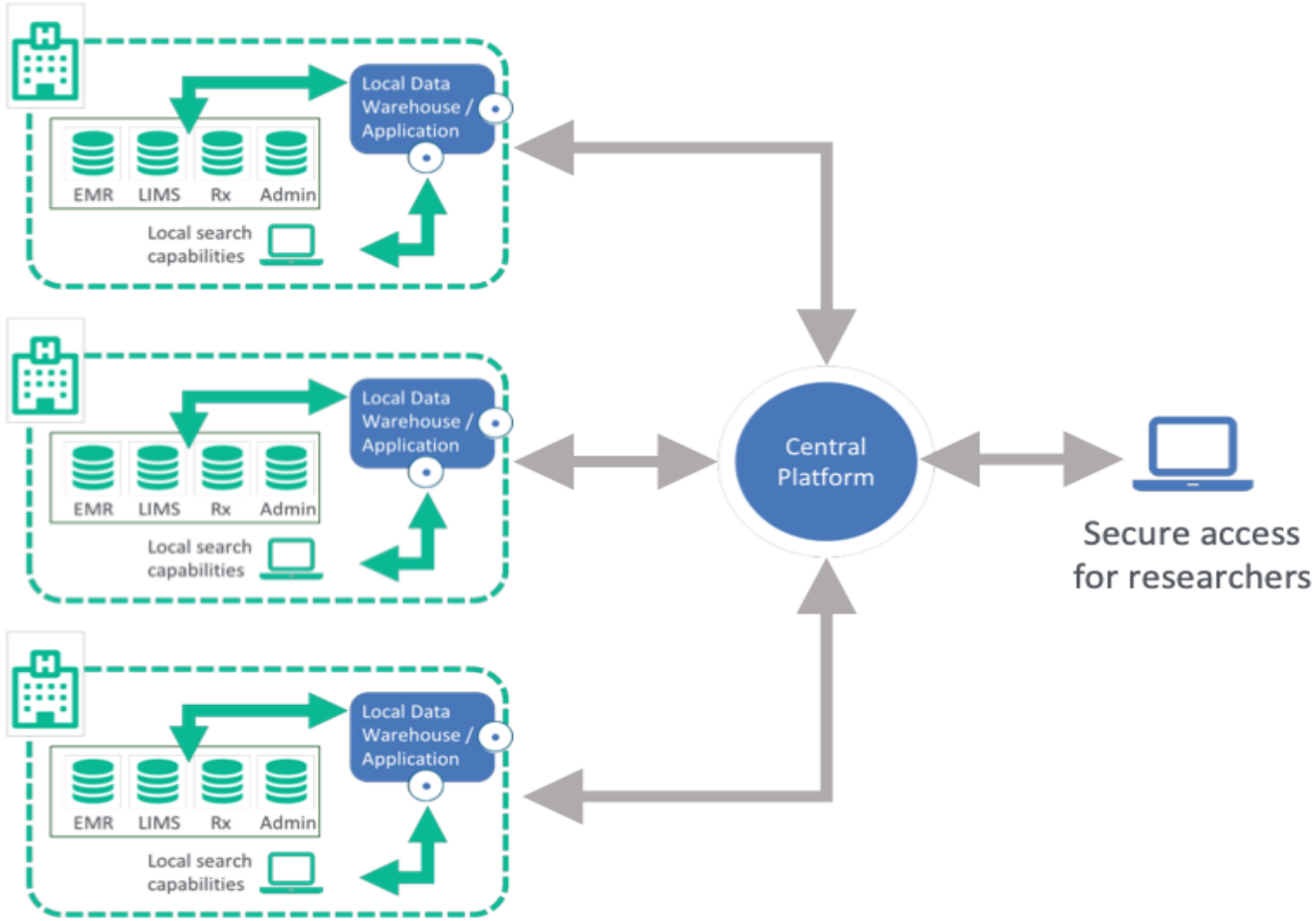
Reused for:

- Epidemiology
- Digital innovation: devices, sensors, apps
- AI development
- Personalised medicine and bio-marker research
- Diagnostics development
- Drug development
- Disease understanding and stratification

Some research findings from "big data"



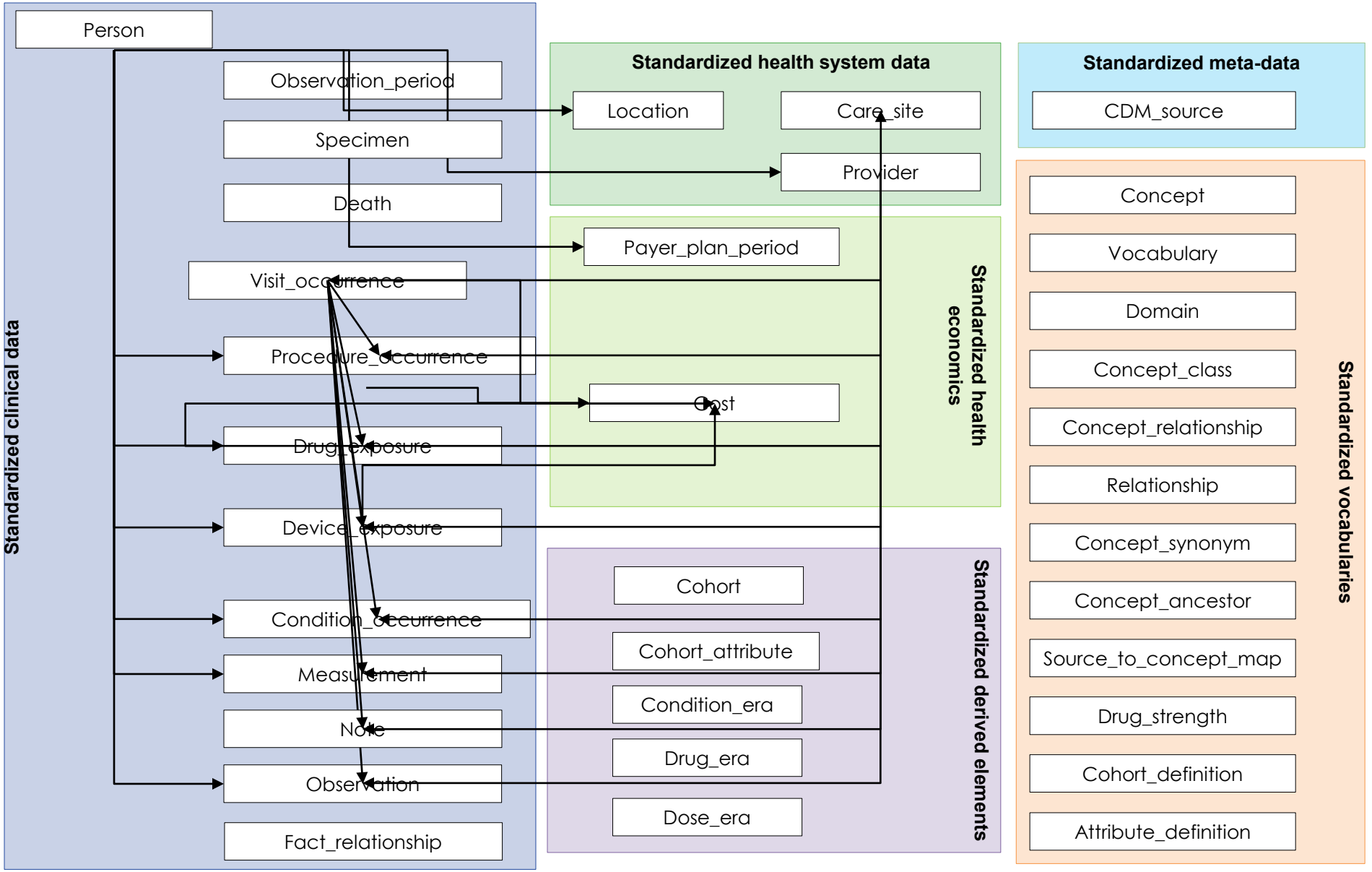
European Health Data & Evidence Network



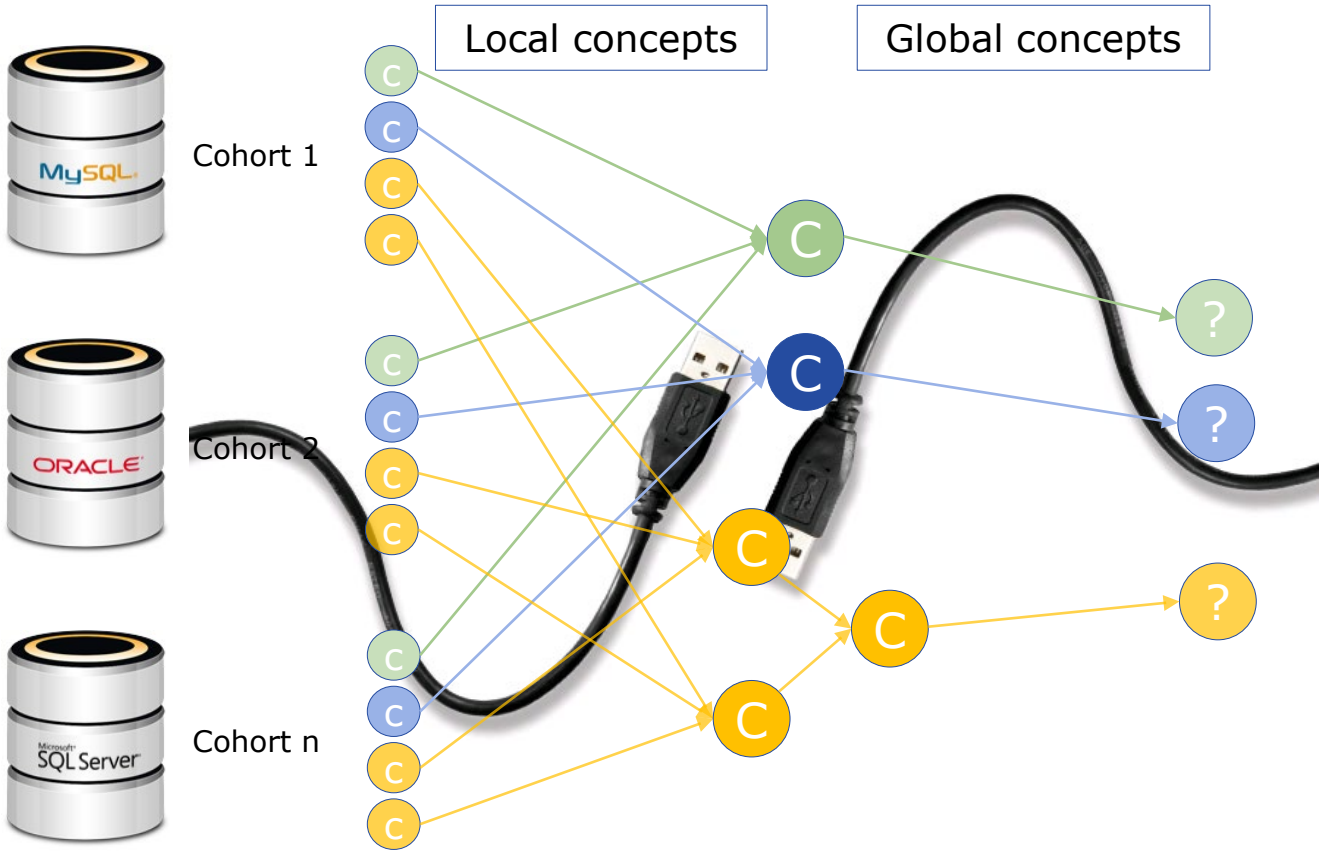
Benefits of federated networks

- 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

The OMOP Common Data Model



Data harmonisation



	C1	C2	...	Cn
V1				
V2				
⋮				
Vn				

Common Data Models

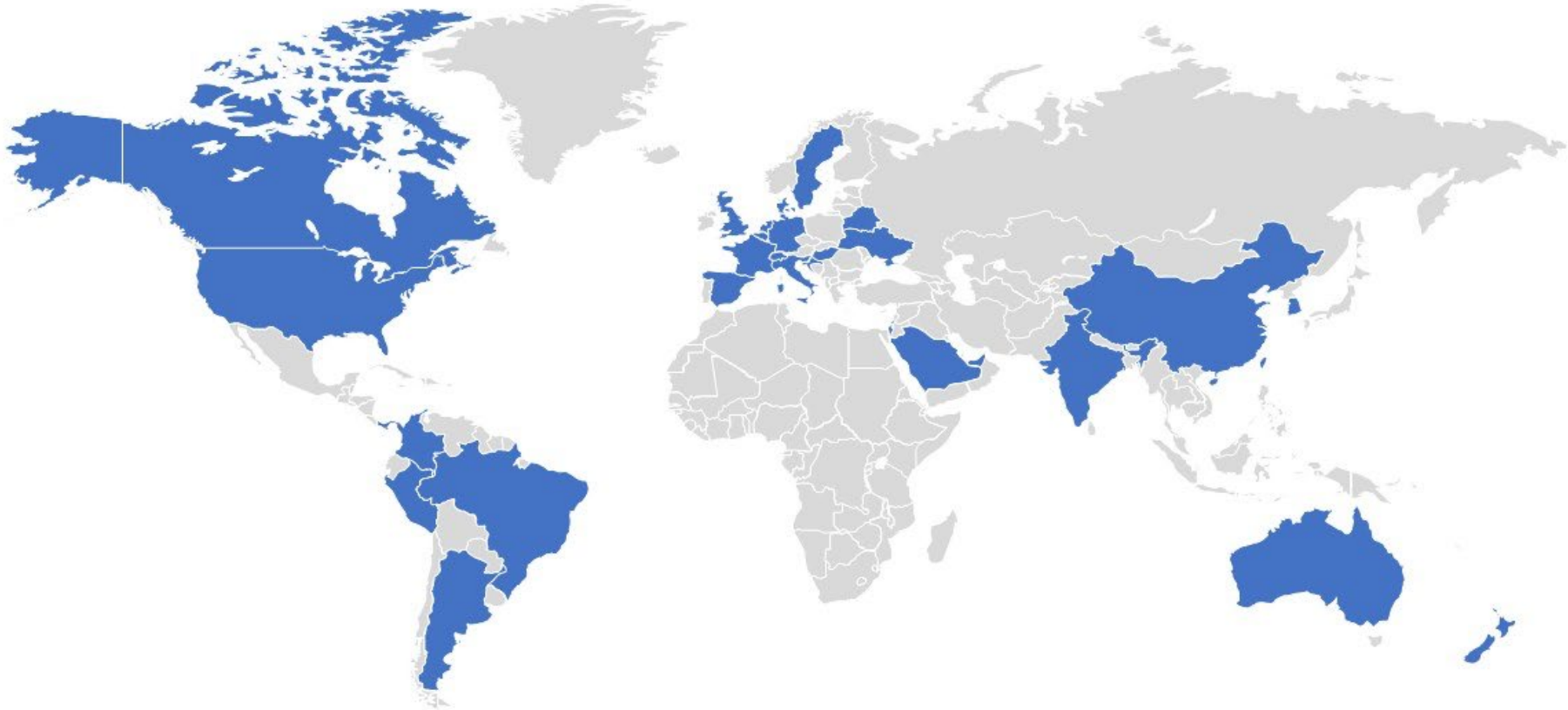
Standardised Clinical Models

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

The OHDSI community, working with EHDEN



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

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

RESEARCH

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]

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.

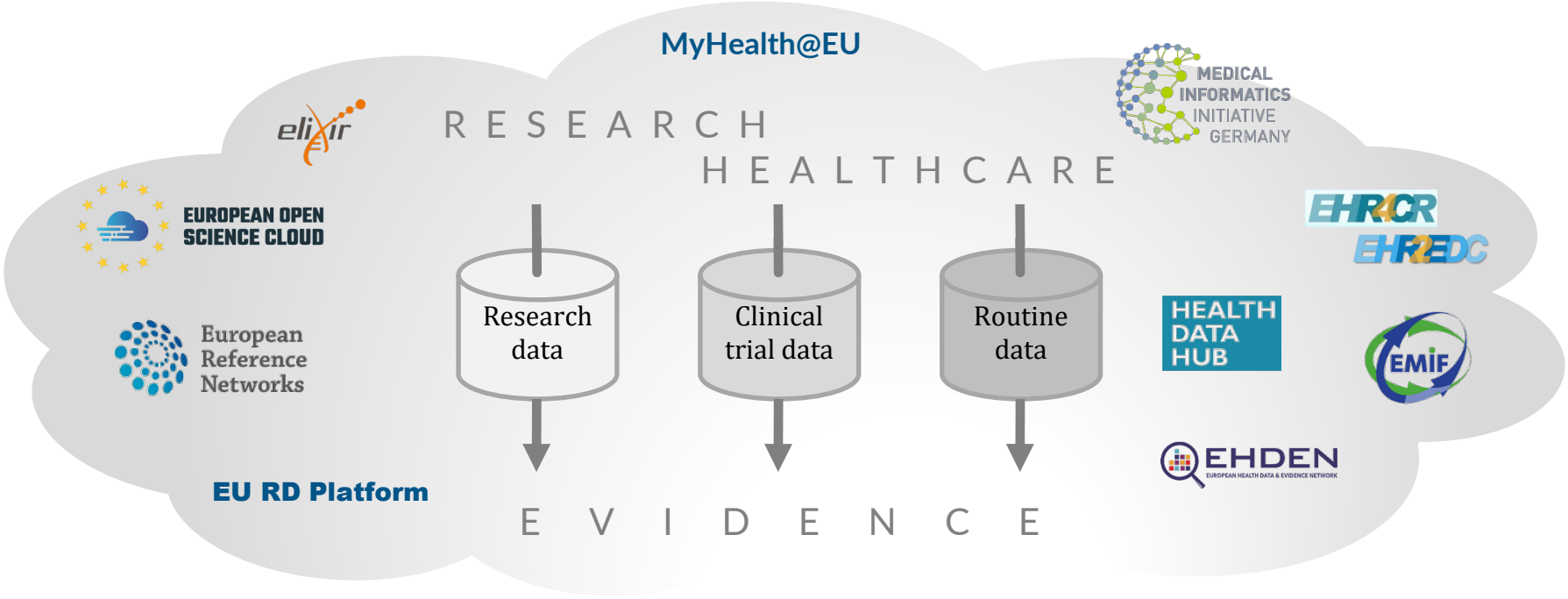
8 330 497 people who received at least one dose of covid-19 vaccines

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

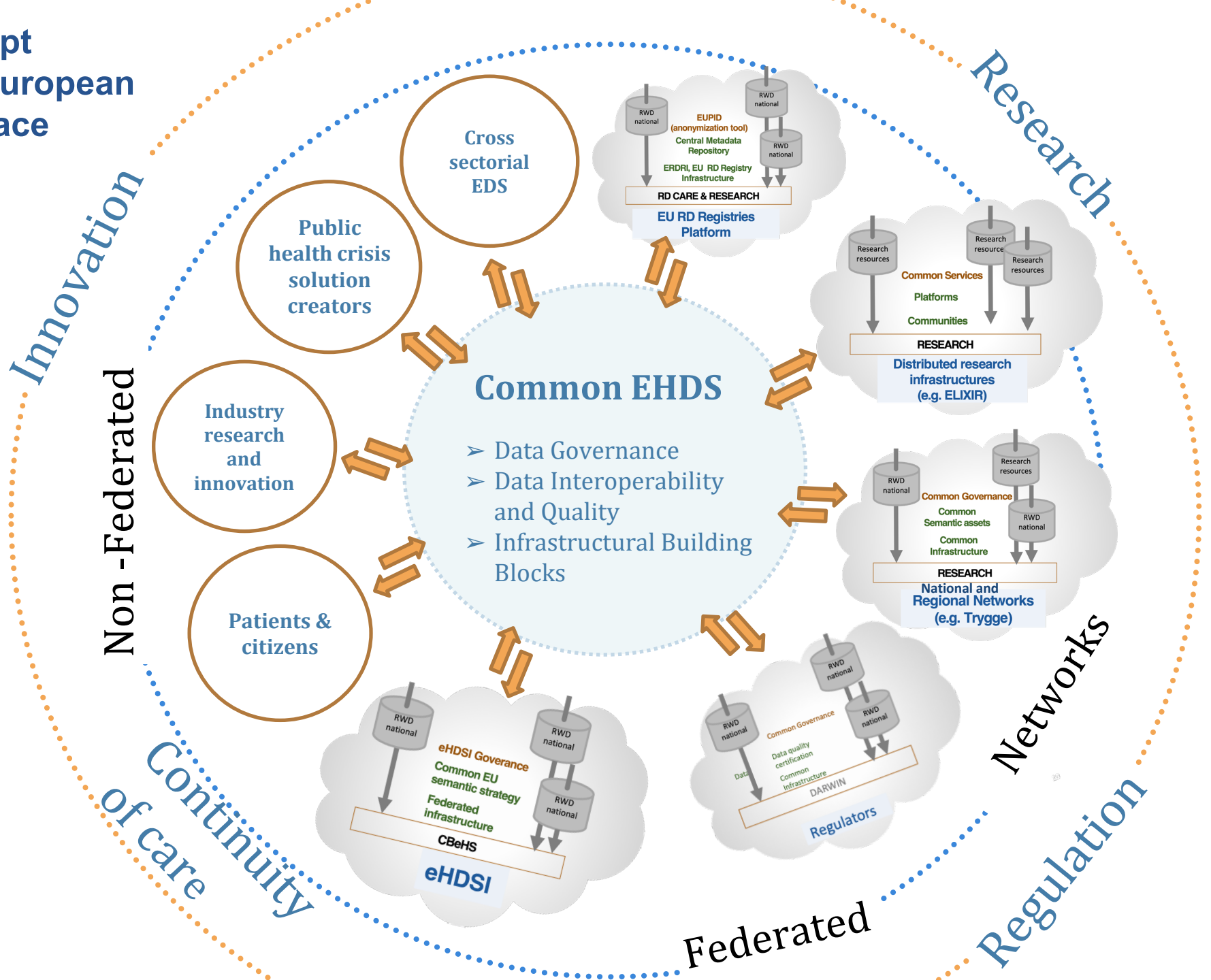
14 330 080 participants from the general population (control group)

Big health data sharing initiatives

- Myriad of initiatives to share health data across jurisdictional, institutional and domain borders:
  - Sharing data for cross-border 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

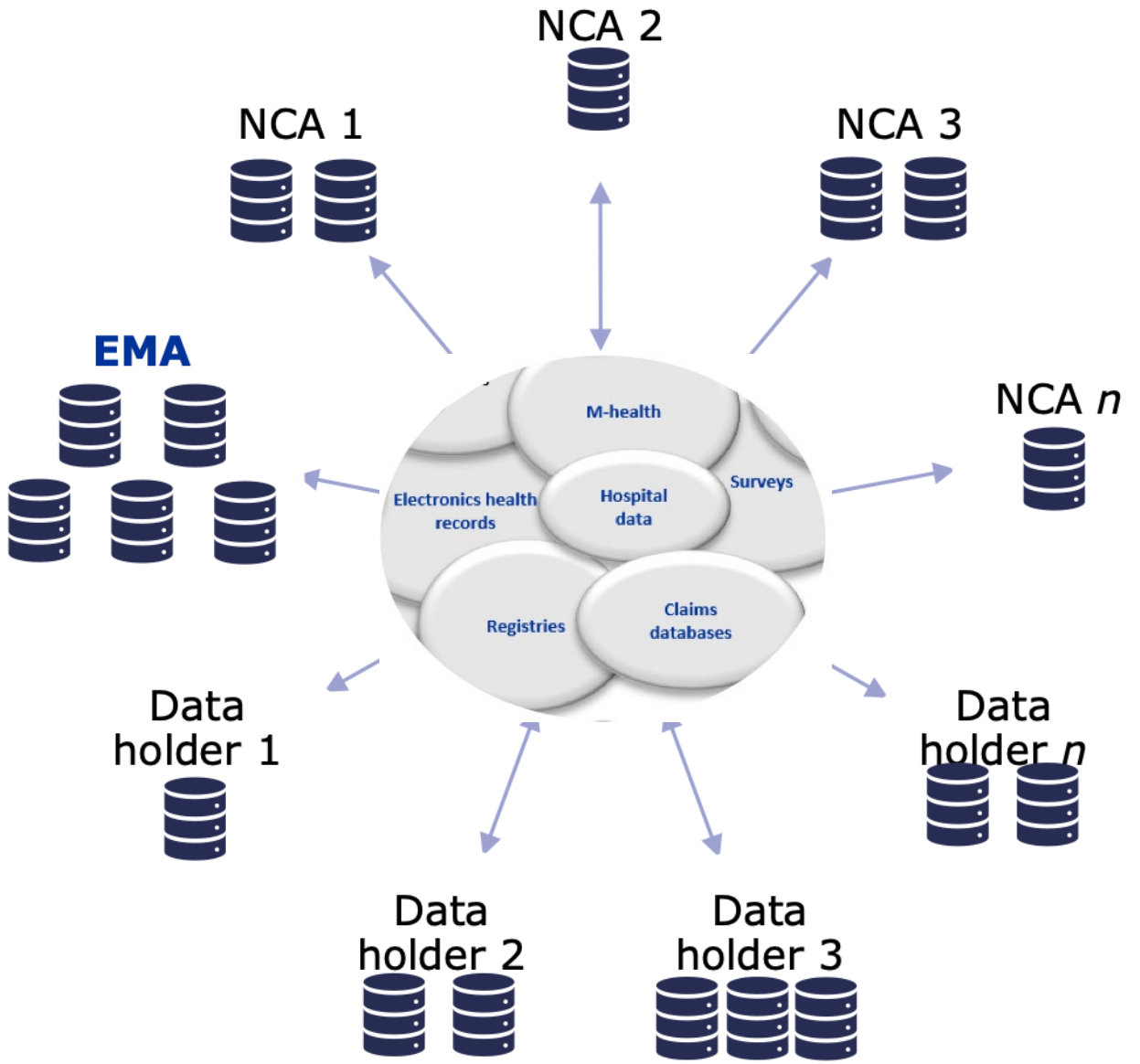


Possible concept model for the European Health Data Space



EMA DARWIN initiative

- EMA's planned network for Real World Evidence generation
- Focus:
  - Drug development – disease epidemiology, unmet need, historical controls, planning
  - Authorisation – contribution to BR, controls, extrapolation to general & special populations
  - On market – benefit risk monitoring, extension of indication



Source: Peter Arlett, EMA, 2021

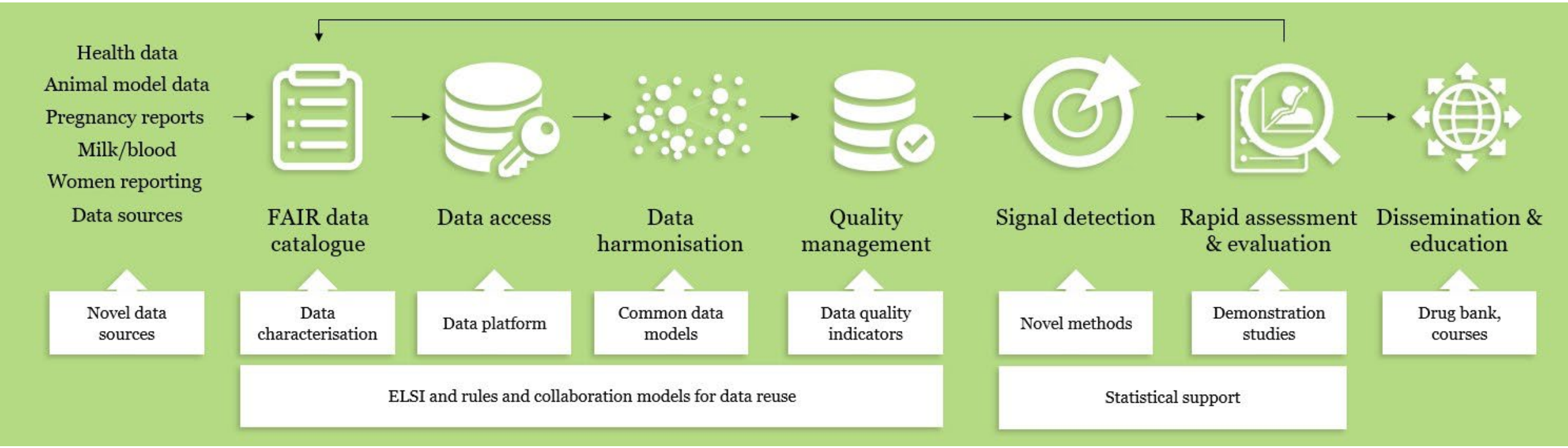
concePTION
SAFETY EVIDENCE ECOSYSTEM

Building an ecosystem for better monitoring and communicating safety of medicines use in pregnancy and breastfeeding: validated and regulatory endorsed workflows for fast, optimised evidence generation

Co-ordinated by Novartis and UMC Utrecht
EMA is a partner

efpia imi innovative medicines initiative
The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking ConcePTION grant n° 821520

IMI Conception



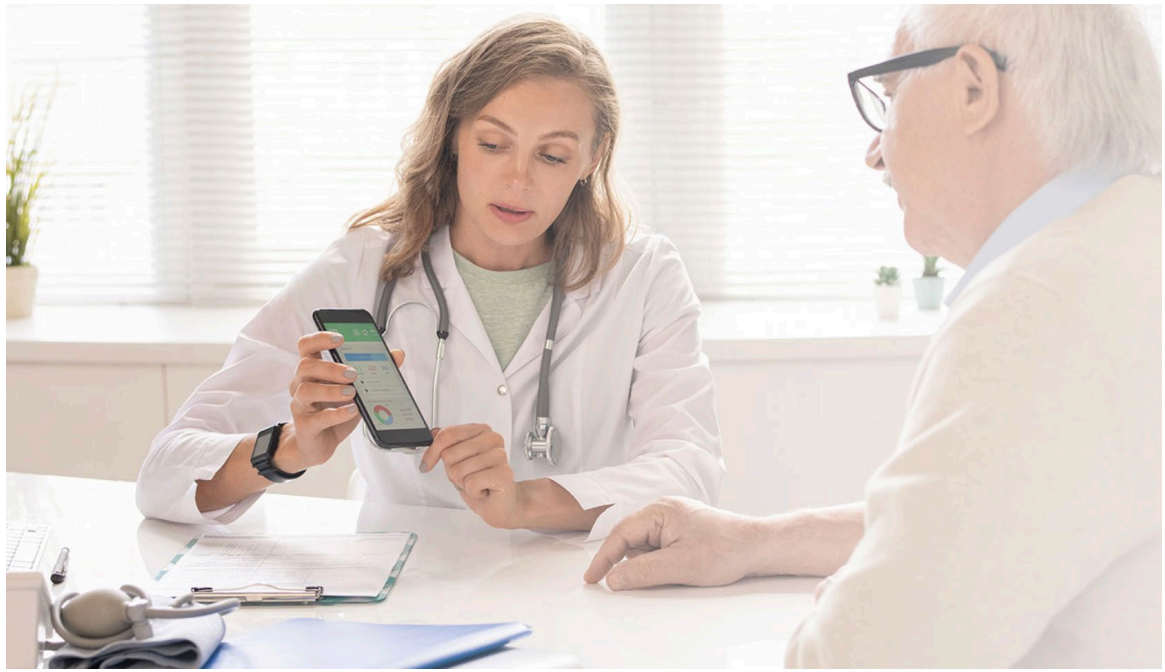
Some areas of RWE generation methodology are being prepared for EMA ITF submission

One or two areas are candidates for EMA Qualification Advice

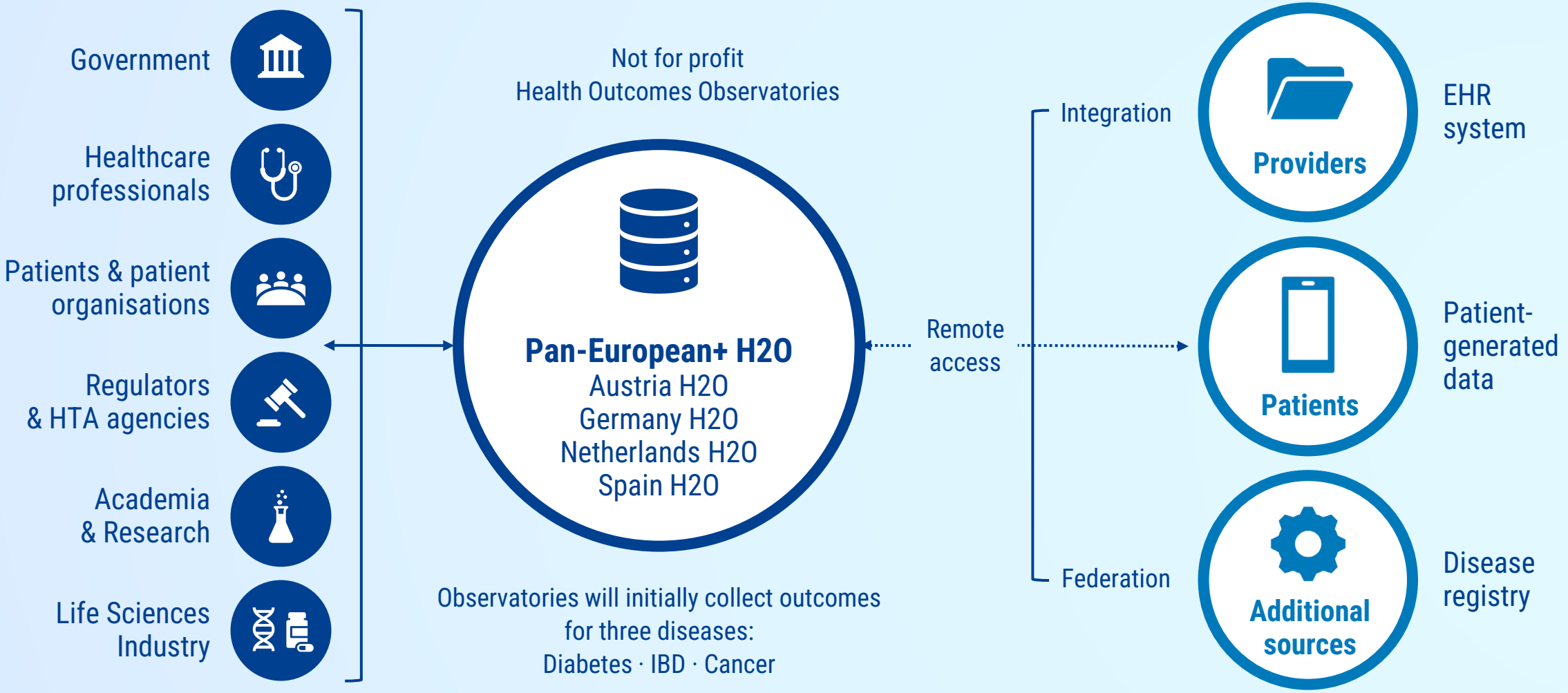
Medicines information for patients

- Equip and empower citizens with digital information tools, the **Gravitate Lens (G-Lens)**
- offering trustworthy, up-to-date and personalised medicines information sourced from the ePI
- targeting
  - safe use of medicines
  - confident, active, and responsive in their patient journey
  - better health outcomes and quality of life

Gravitate Health



H2O | First European scale network for health outcomes data



Source: Stamm et al. (2021). NEJM Catalyst

How do we reach societal acceptability?

- Data protection regulations prioritise the **rights of the individual** to privacy
- Clinical research can bring important benefits **to society**
- Many surveys indicate **patients are in favour** of their data being re-used for research
- The public need **greater transparency** about why and how health data are used, safeguarded, and the benefits of that use

We need to find the right balance between the rights of the individual and the benefits for society

The challenge with gaining public acceptance of health data reuse

Individual level health data

EHR systems, apps, sensors, genomics,
Clinical Decision Support, AI guidance

Used for:
- Health status monitoring
- Continuity of care (including the patient and caregivers)
- Care pathway tracking, clinical workflow management
- Real-time feedback and guidance to patients and clinicians
- Personalised medicine
- Disease interception, prevention and wellness
- Healthcare provider reimbursement

Population level health data

EHR systems, regional & national
eHealth infrastructures

Reused for:
- Healthcare provider performance and planning
- Quality and safety, care pathway optimisation
- Medical device and algorithm refinement
- Pharmacovigilance
- Public health surveillance
- Public health strategy
- Health services and resource planning

Big health data

national & international research infrastructures,
federated query research platforms
+ cross-sectoral infrastructures & services

Reused for:
- Epidemiology
- Digital innovation: devices, sensors, apps
- AI development
- Personalised medicine and bio-marker research
- Diagnostics development
- Drug development
- Disease understanding and stratification

Decreasing public understanding of why and how data are used

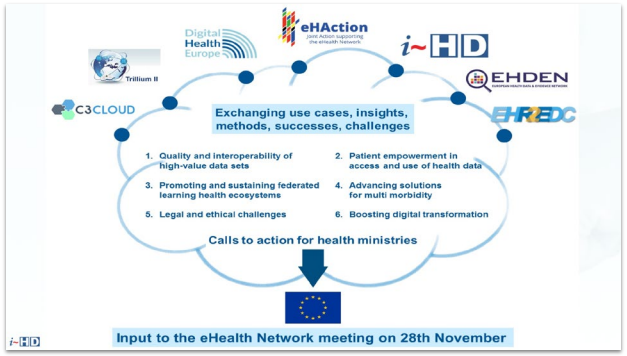
Increasingly unfamiliar data users

Increasing time from data use to demonstrated value

Increasing distance of data results from the patient

Perceived lessening choice and greater cybersecurity risk = harder to trust

Example ecosystem events and reports



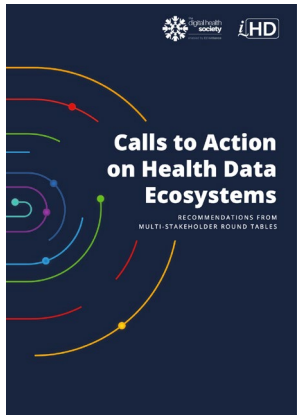
Joining the Dots synergies conference
Nov 2019

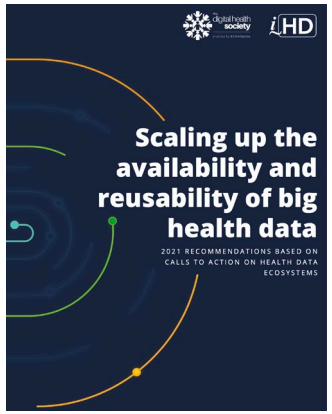
DigitalHealth Europe project:
EHDS: Policy White Paper, industry consultation, patient and citizen consultation 2020

eHealth Stakeholder Group member

TEHDAS Towards European Health Data Space

TEHDAS expert WP8, WP5 (WP6)





Multi-stakeholder consensus events and reports 2020-21, joint with DHS, sponsored by MS, J&J and MSD

Data protection and data altruism

Data Protection

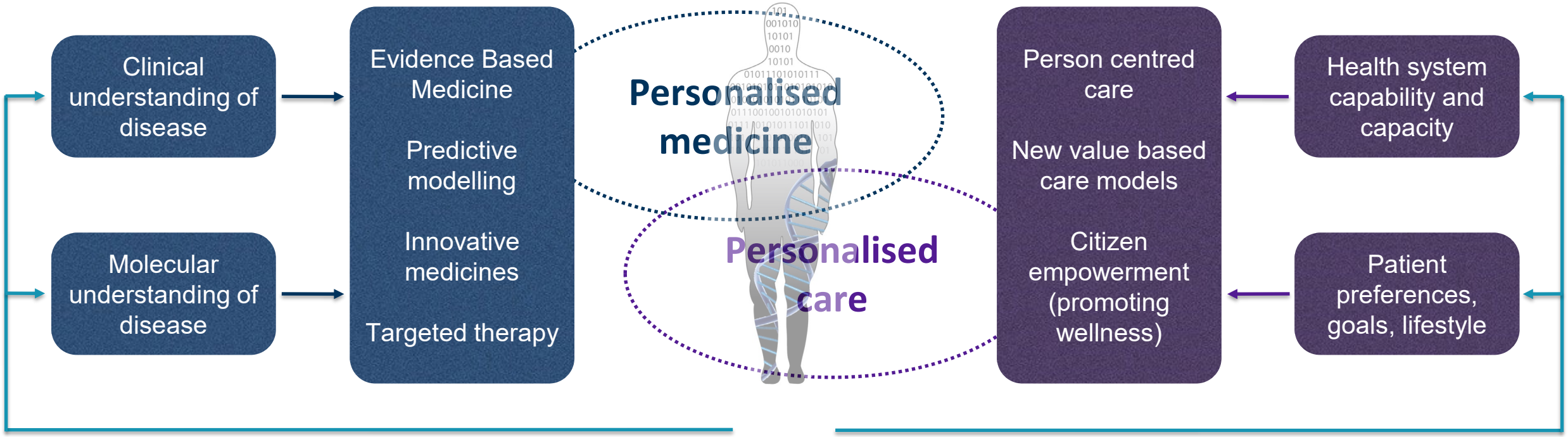
GDPR
HIPAA Privacy Rule

Data Altruism

Data Governance Act
(Health Record Banks)

- Public preferences respected
- Societally acceptable data uses
- Agreed minimum safeguards
- Codes of data conduct widely upheld
- Accountability for use
- Public involvement and transparency
- Visible societal benefits

Personalised Health and Learning Health Systems…



…need all stakeholders to collaborate, to maximise the insights we can gain from health data