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INNOVATIVE HEALTHCARE STRATEGIES

11 > 14 SEPTEMBER 2019

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INNOVATIVE HEALTHCARE STRATEGIES

Workshop 2:
The reuse of electronic health records for Learning Health Systems

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Prof. Dipak Kalra
President of The European Institute for Innovation through Health Data

Welcome by the workshop chair

The importance of good EHRs for Learning Health Systems

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THE IMPORTANCE OF GOOD EHRS FOR LEARNING HEALTH SYSTEMS

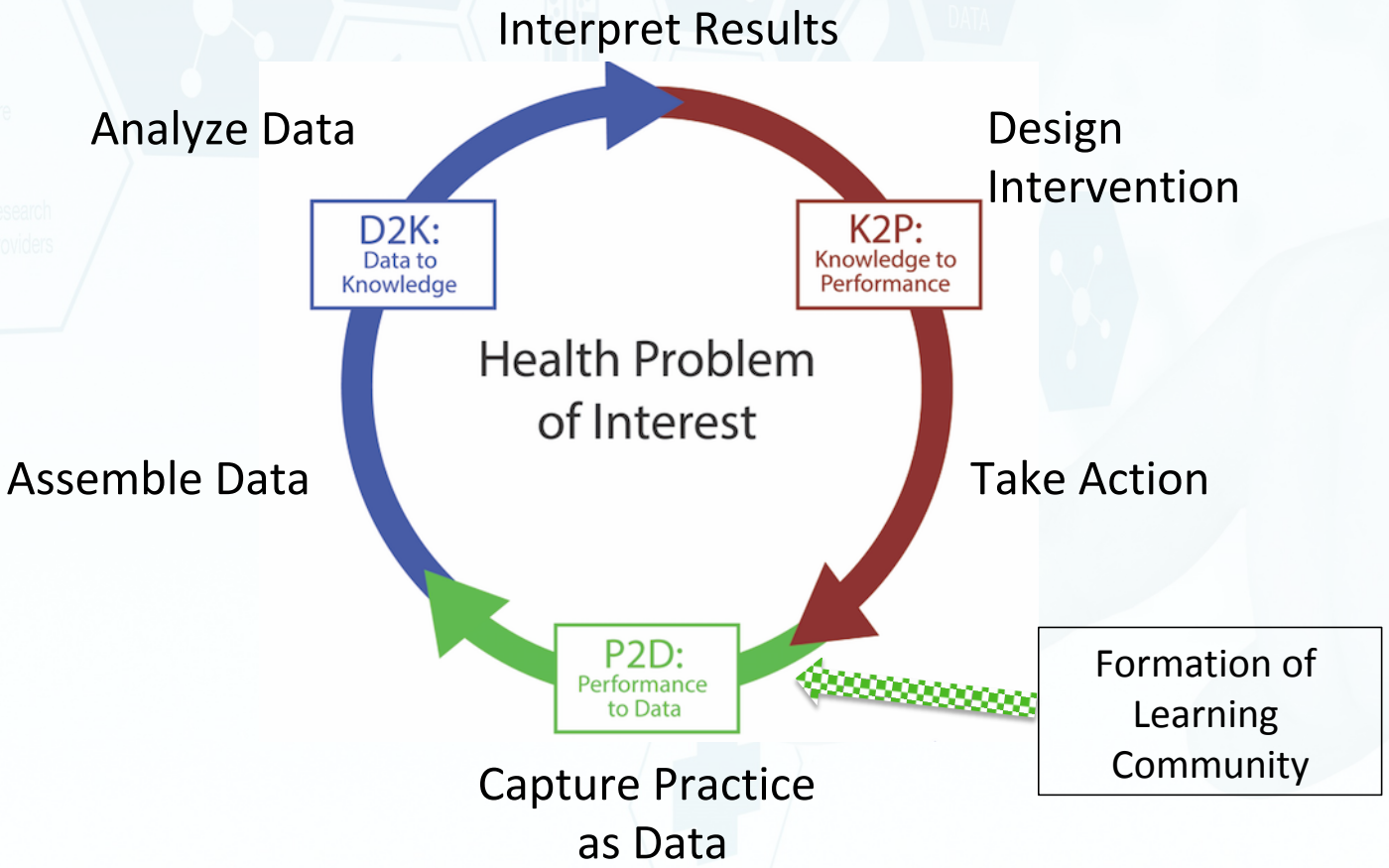
Prof Dipak Kalra
President of i~HD

+

Thomas Allvin
EFPIA Executive Director for Strategy and Healthcare Systems

EAHM Congress, Ghent
13th September 2019

The Learning Health System: "Virtuous Cycles" of Study and Change



Slide courtesy of Prof Charles P. Friedman, Department of Learning Health Sciences, University of Michigan

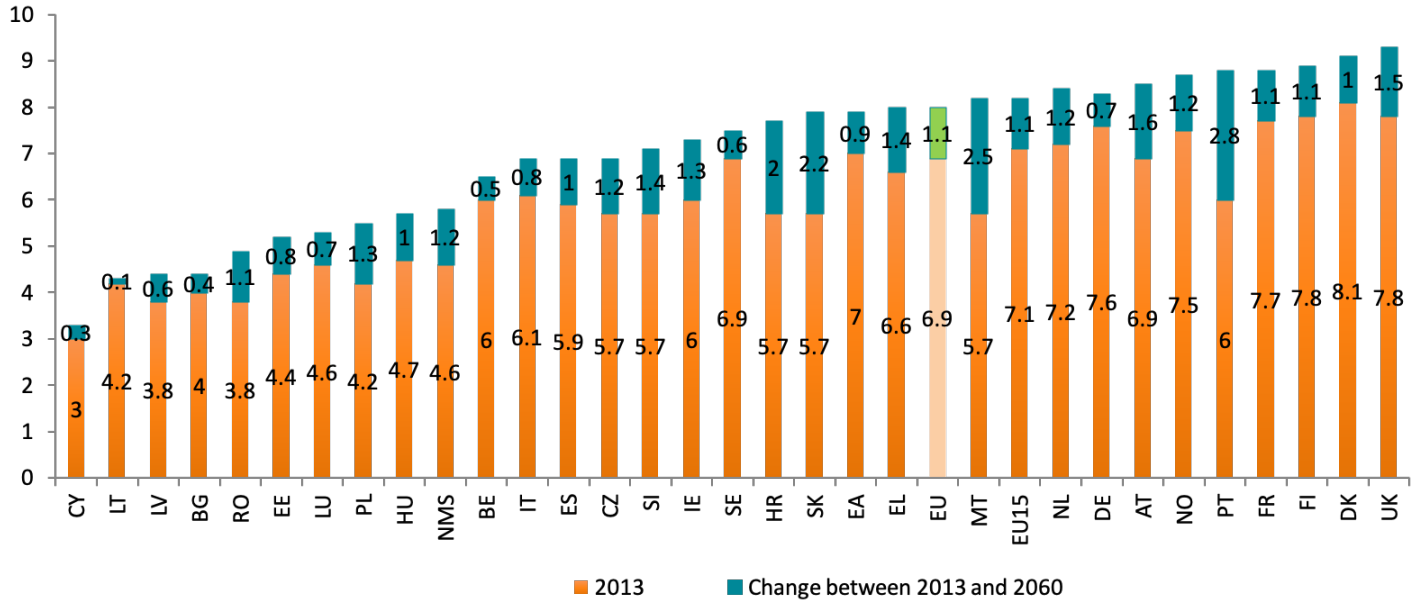
The Learning Health System: Going global

- Initiatives at Varying Scales
  - Single Organisations
  - Networks
  - Regional
  - National
  - International

Slide courtesy of Prof Charles P. Friedman, Department of Learning Health Sciences, University of Michigan

Population ageing creates sustainability challenge for EU health systems

Projected increase in public expenditure in healthcare due to demographic change (2013-2060) (% of GDP)

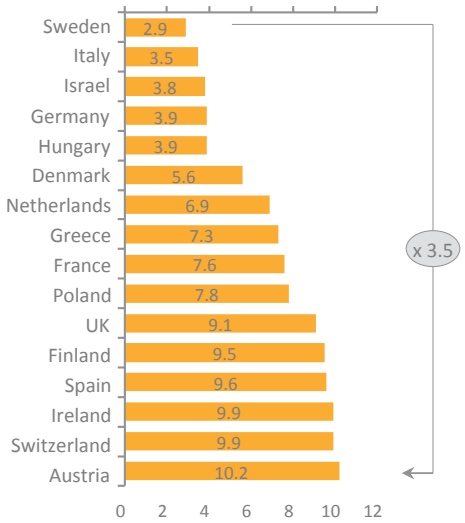


NOTE: FOR THE EU, NMS (NEW MEMBER STATES) AND THE EA (EURO AREA) THE AVERAGE ARE WEIGHTED ACCORDING TO GDP. EUROPEAN COMMISSION (2015). THE AGEING REPORT.

Slide courtesy of Thomas Allvin, EFPIA

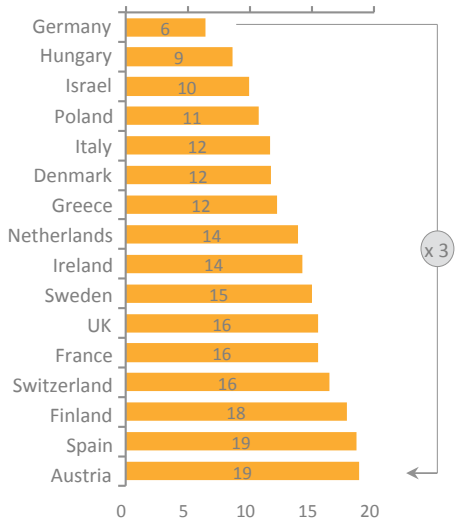
Variation of heart failure outcomes across European countries

> 3x variation in death during first HF admission



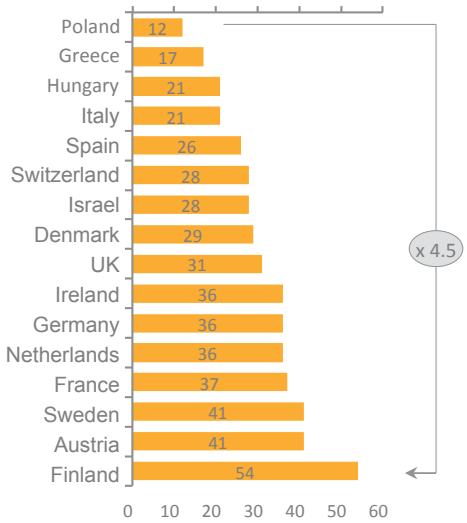
Death during first admission, %

3x variation in 12 week mortality rate for HF



12 week mortality rate, %

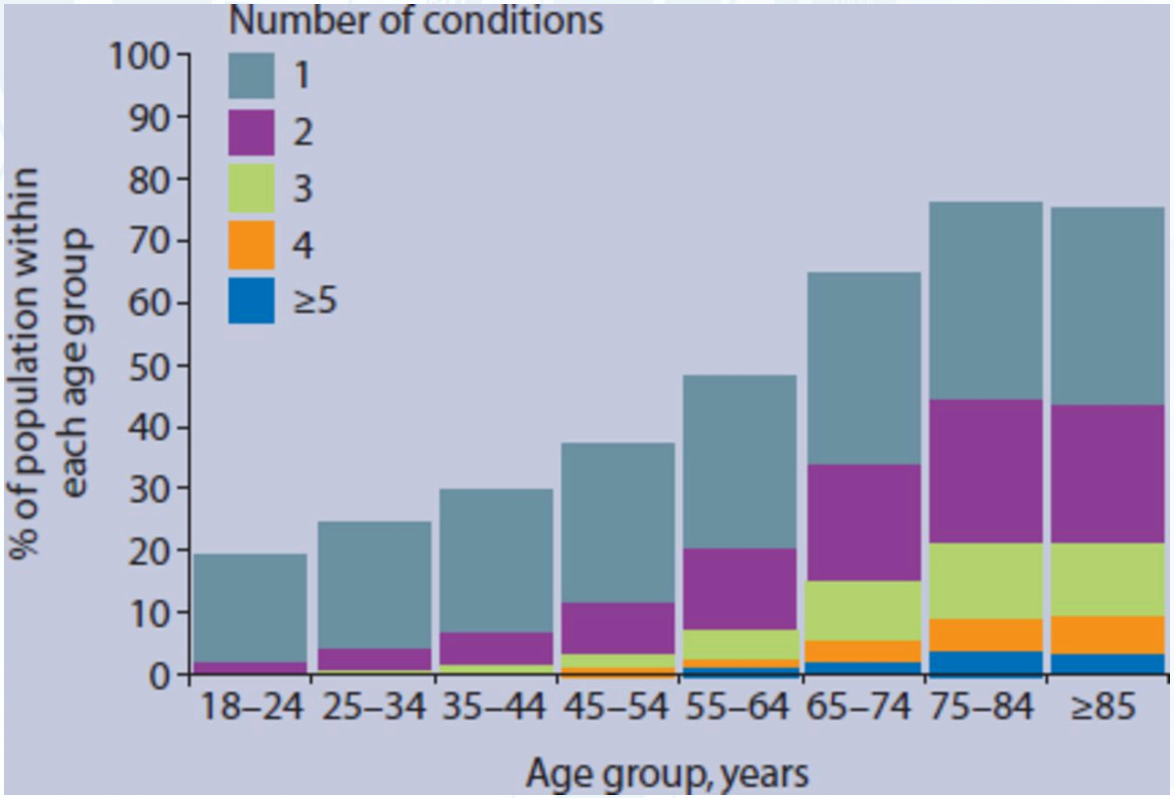
>4x variation in 12 week readmission rate for HF



12 week readmission rate, %

Slide courtesy of Thomas Allvin, EFPIA

Multi-morbidity: the scale of the challenge



Chris Salisbury, Leigh Johnson, Sarah Purdy, Jose M Valderas and Alan A Montgomery
Br J Gen Pract 2011; 61 (582): e12-e21

Estimated 20 – 40 % waste in health systems

- According to a WHO report from 2010, on average 27% of healthcare expenditure is wasted
- There are several sources of waste, but **half** of the total waste is estimated to be due to **practice variation** and use of low-value interventions
- A recent OECD report concludes that around one fifth of healthcare expenditure could be channeled towards better use

Slide courtesy of Thomas Allvin, EFPIA

Value-Based Health Care (VBHC) is helping shift focus from volume of services to value created for patients

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

DECEMBER 23, 2010

What Is Value in Health Care?

Michael E. Porter, Ph.D.

In any field, improving performance and accountability depends on having a shared goal that unites the interests and activities of all stakeholders. In health care, however, stakeholders have myriad, often conflicting goals, including access to services, profitability, high quality, cost containment, safety, convenience, patient-centeredness, and satisfaction. Lack of clarity about goals has led to divergent approaches, gaming of the system, and slow progress in performance improvement.

Achieving high value for patients must become the overarching goal of health care delivery, with value defined as the health outcomes achieved per dollar spent.[1] This goal is what matters for patients and unites the interests of all actors in the system. If value improves, patients, payers, providers, and suppliers can all benefit while the economic sustainability of the health care system increases.

Value — neither an abstract ideal nor a code word for cost reduction — should define the framework for performance improvement in health care. Rigorous, disciplined measurement and improvement of value is the best way to drive system progress. Yet value in health care remains largely unmeasured and misunderstood.

Value should always be defined around the customer, and in a well-functioning health care system, the creation of value for patients should determine the rewards for all other actors in the system. Since value depends on results, not inputs, value in health care is measured by the outcomes achieved, not the volume of services delivered, and shifting focus from volume to value is a central challenge. How is value measured by the process of care used; process measurement and improvement are important tactics but are no substitutes for measuring outcomes and costs.

Since value is defined as outcomes relative to costs, it encompasses efficiency. Cost reduction without regard to the outcomes achieved is dangerous and self-defeating, leading to false "savings" and potentially limiting effective care.

Outcomes, the numerator of the value equation, are inherently condition-specific and multidimensional. For any medical condition, no single outcome captures the results of care. Cost, the equation's denominator, refers to the total costs of the full cycle of care for the patient's medical condition, not the cost of individual services. To reduce cost, the best approach is often to spend more on some services to reduce the need for others.

N ENGL J MED 363;26 NEJM.ORG DECEMBER 23, 2010

2477

The New England Journal of Medicine

Downloaded from nejm.org on September 13, 2017. For personal use only. No other uses without permission.

Source: "What is Value in Health Care"
(Michael Porter, New England Journal of Medicine, 2010)

- The fundamental **goal and purpose** of health care is **to improve value for patients**

$$\textbf{Value} = \frac{\text{Health } \textbf{outcomes} \text{ that matter to patients}}{\textbf{Costs} \text{ of delivering these outcomes}}$$

- Value is the only goal that can **unite the interests** of all system participants
- Value is created in caring for a patient's **medical condition** over the **full cycle of care**

The most powerful single lever for reducing cost and improving value is improving outcomes

Source: ICHOM 2019

Slide courtesy of Thomas Allvin, EFPIA

By learning from its data…

- …Kaiser Permanente is able to track outcomes and develop data driven algorithms embedded within its EHR systems, to achieve:
  - HIV death rate half of national average
  - Decrease in coronary heart disease death rate by a third
  - Decrease in pressure ulcers by two thirds
  - Death due to sepsis reduced by > 50%

The LHS ambitions of many European hospitals

- Shift the focus of performance and reward from acti… comes
- Optimise care pathways to maximise health o… whist making best use of resources
- Respond to payer and public dema… ore integrated and person centred care
- Implement continuous l… nd improvement cycles
- Enhance their cu… capability to undertake research, for reputation a… ess reasons
- Colla… oss hospital networks, and across Europe, to share good prac… and support each other with improvement

Good EHR and reusable data is a critical success factor

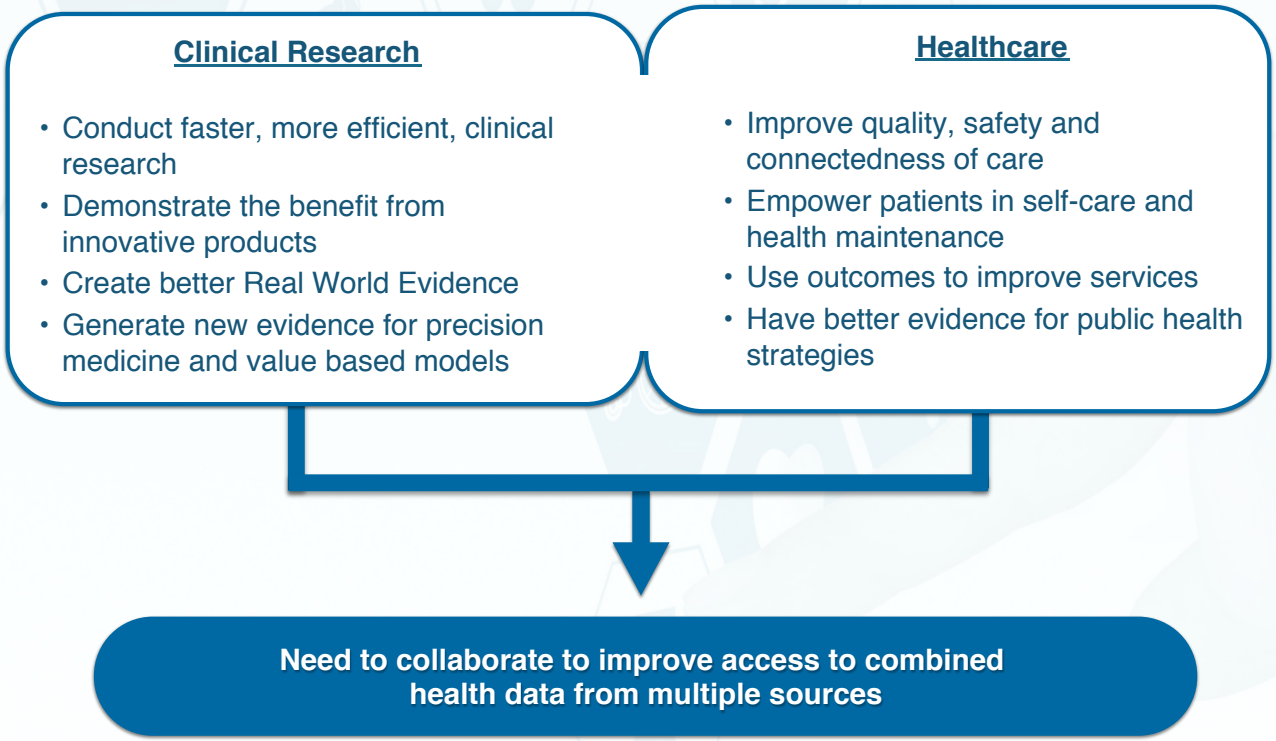
The European Institute for Innovation through Health Data (i~HD)
was created as an outcome of European R&D projects, to address needs confirmed by multiple healthcare and research stakeholders

Developing solutions for improving health data and its trustworthy use

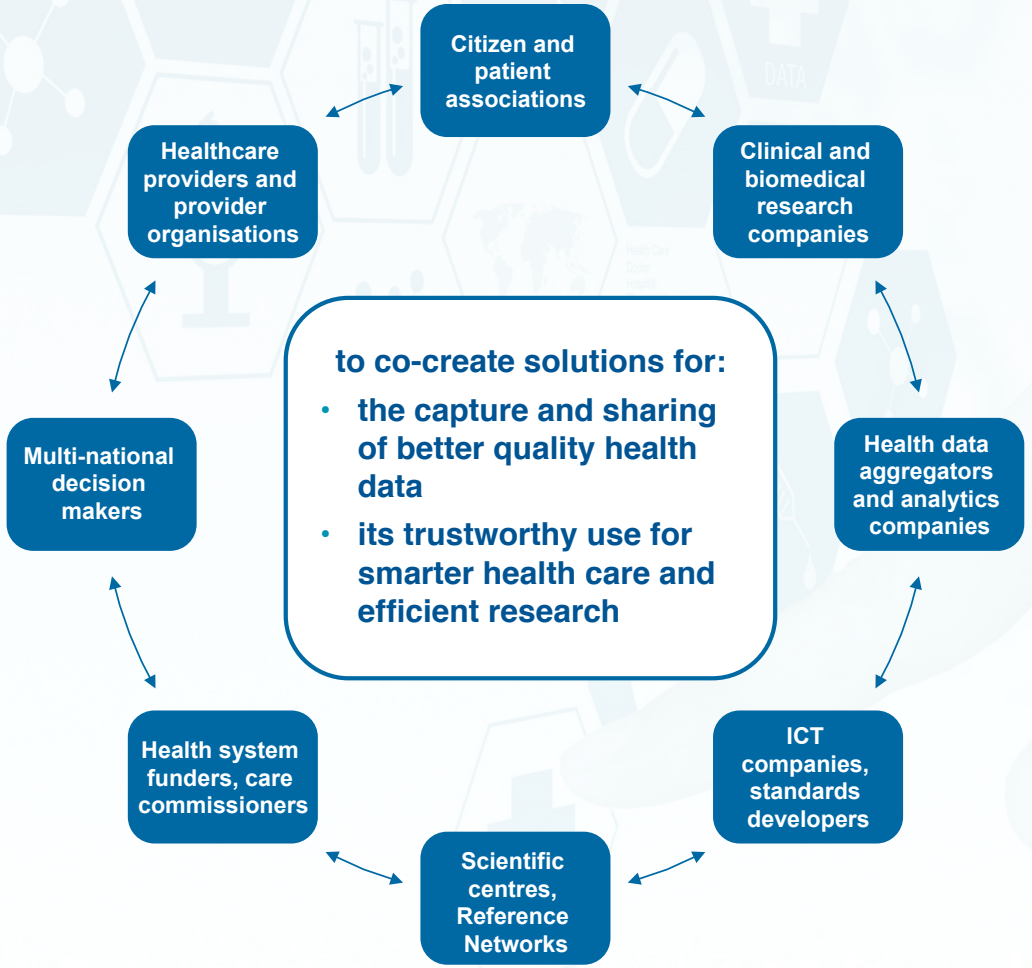
Enriching knowledge and enhancing care through health data

i~HD is registered in Belgium as a not-for-profit organisation
It is financed by membership fees,
by providing services e.g. data quality, certification and governance
and through funded projects

i~HD targets a convergence of opportunity from health data

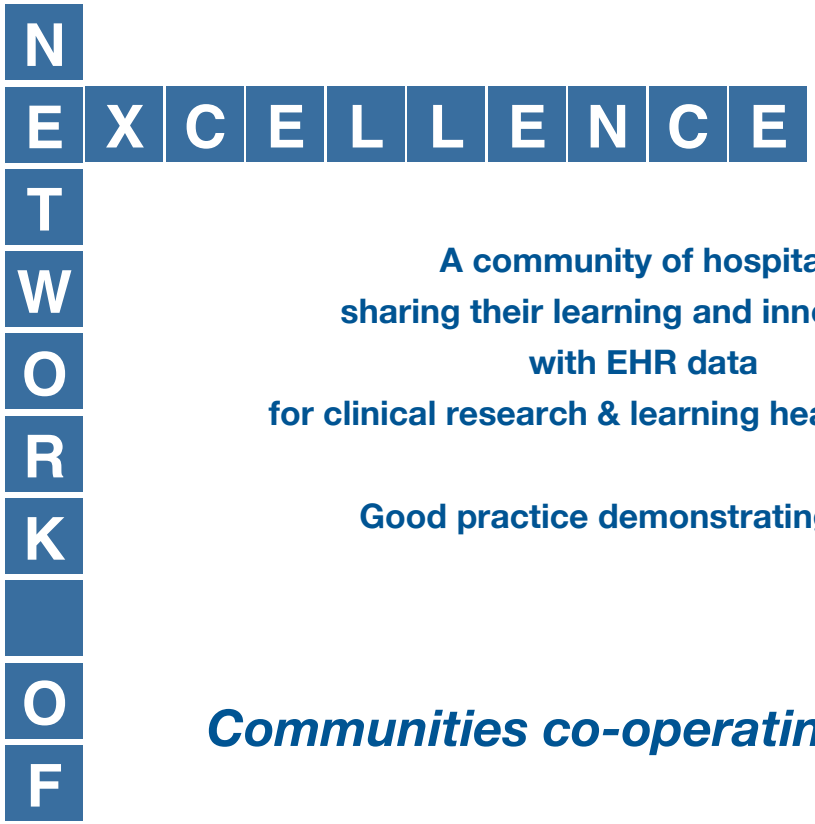


i~HD is a neutral body, bringing stakeholders together



Issues that hospitals have raised with us

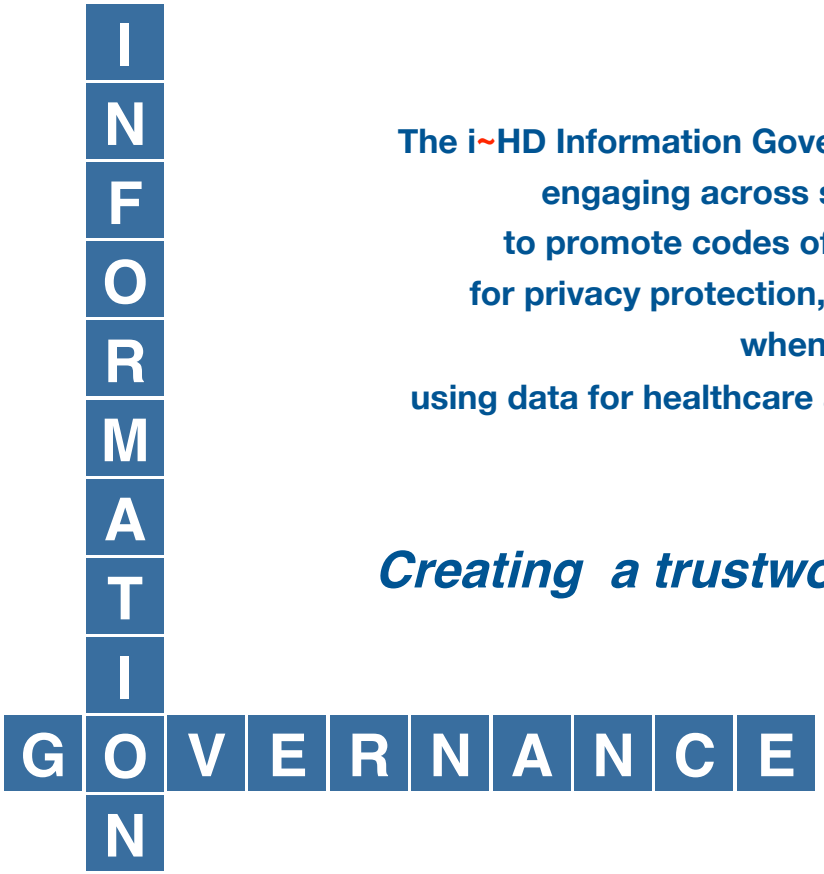
- Limited reuse of their EHR data at present
- Poor EHR data quality, difficulties in improving it
- Concerns about data protection, especially with the GDPR
- Often working to locally-defined outcomes, so impossible to compare or collaborate with other hospitals
- Limited capacity to measure patient reported outcomes



A community of hospitals
sharing their learning and innovations
with EHR data
for clinical research & learning health systems.

Good practice demonstrating value

Communities co-operating and working synergistically



The i~HD Information Governance Task Force is
engaging across stakeholders
to promote codes of good practice
for privacy protection, security & ethics
when
using data for healthcare and clinical research

Creating a trustworthy environment

i~HD information governance initiatives

GDPR

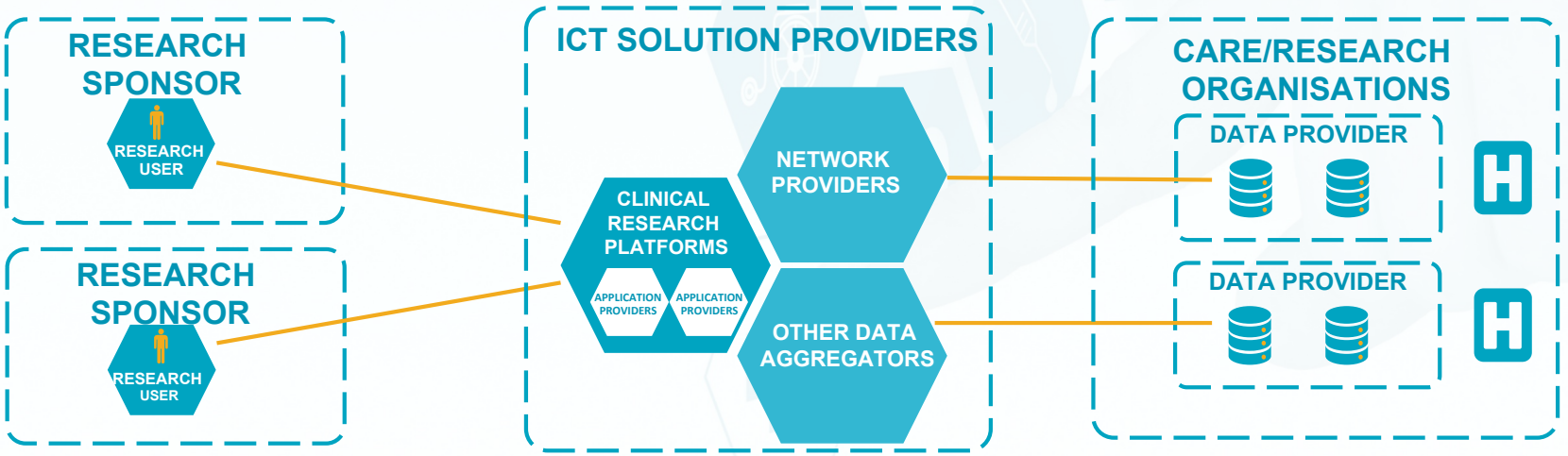
IMI code of practice on secondary use of medical data in scientific research projects, and other codes

Principles and Standard Operating Rules

Educate and train research and ICT staff

Certify research platforms and EHR systems

Promote consistent practices across Europe



GDPR & health data challenges

1. Which **legal basis** is best suited to different scenarios of reusing health data for research?
2. Who are the **data controllers**, **joint controllers** and **processors** in a federated big data & analytics ecosystem?
3. What safeguards would be adequate for **accountability** & **security**?
4. How can **rights** - especially to erasure & portability - be upheld in the health data innovation space?
5. How can we be meaningfully **transparent** with patients & the public about **health data reuse** for research?

i~HD Quality Seal for Research Platforms

- This Seal provides assurance to healthcare organisations, research centres and research sponsors, that ICT products and services used for research using EHRs do so in secure ways that protect data privacy, including GDPR compliance
- Service providers of clinical research platforms can apply for this Seal
- We hope in the future that hospitals and other organisations will insist on only connecting to platforms with this Seal

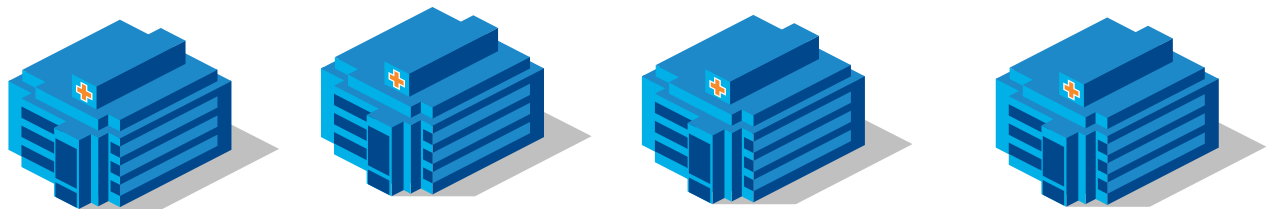
Assessment methods to improve data quality,
promoting the importance of data quality,
scaling this up across Europe

to enable the best quality data
for learning health systems
& clinical research

Having great data to use & making great use of data

Do European healthcare providers have the right data for value-based healthcare?

EFPIA is working with i-HD to assess the data readiness in a number of European hospitals, using the ICHOM standard set for Heart Failure



Slide courtesy of Thomas Allvin, EFPIA

Key components of project

- Agree the ICHOM heart failure indicators that are most relevant for an outcomes-based approach.
- Re-formulate the indicators as EHR variables
- Compile a list of approximately ten hospitals and confirm willingness to participate via a collaboration agreement, with assurance about data protection and GDPR compliance
- Conduct data item assessment and data quality assessment
- Draw overall conclusions including common areas for improvement

Slide courtesy of Thomas Allvin, EFPIA

EPF European Patients Forum

i~HD

Datasaveslives.eu

Prof. Pascal Coorevits

Certification and Labelling Adviser, EuroRec Representative

Assessing the data quality of hospital EHRs

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Assessing the data quality in hospital EHRs

Pascal Coorevits

Professor of Medical Informatics and Statistics, Ghent University
Vice-President for Research, the EuroRec Institute
Data Quality Task Force Lead, i~HD

GHENT UNIVERSITY

The European Institute For Innovation Thr~ugh Health Data

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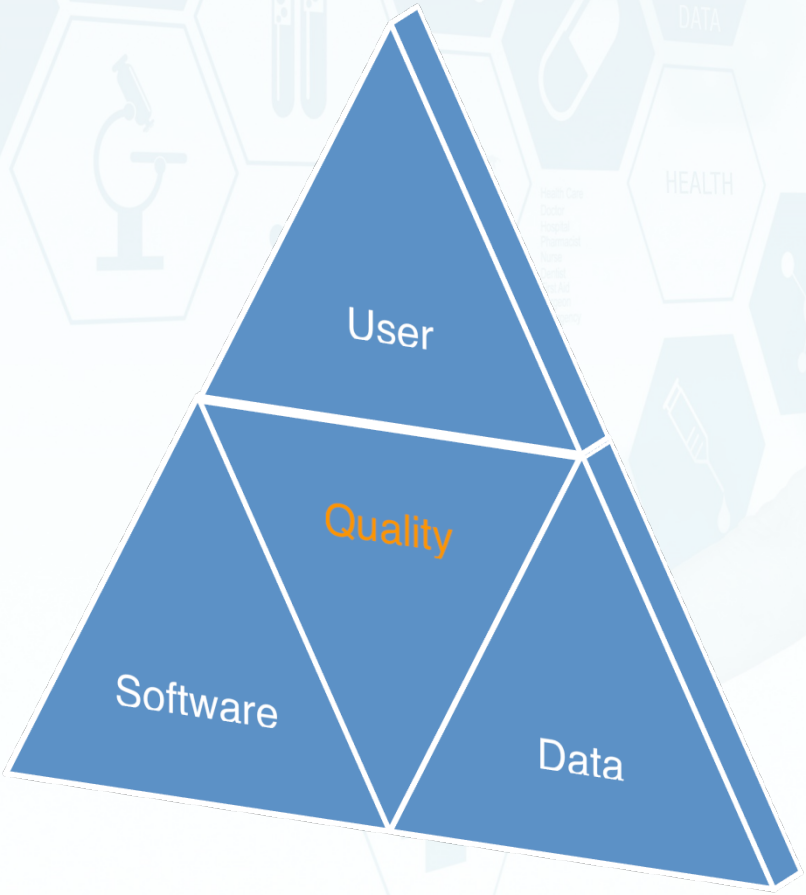
Quality of health data is vital

- Patients and clinicians want health data to be safe, rapid and evidence based
- Healthcare managers also want to use resources efficiently and need insights for strategic planning
- Public health agencies need reliable data to guide healthcare and prevention programmes
- Healthcare funders need good quality data to reward high-quality and value-based care
- Pharma wants to re-use EHRs to accelerate clinical research
- Regulators and HTA agencies want to be able to trust Real World Evidence in decision making
- Everyone wants to achieve the best patient outcomes and they all know that good data is a critical success factor


User
Quality
Software
Data

Electronic Health Records

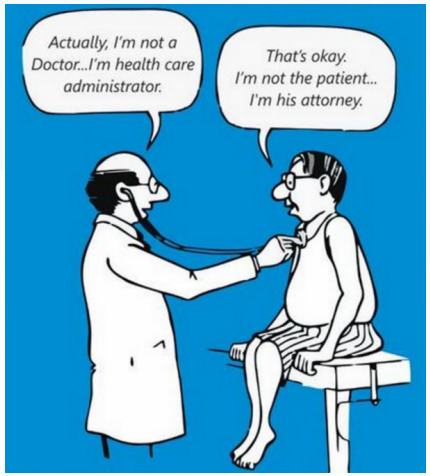
- Electronic Health Records offer enormous potential to improve the safety, quality and efficiency of healthcare
- Empirical evidence for the beneficial impacts of most eHealth technologies on the quality and safety of healthcare are often lacking, or at best, only modest
- Some of the reported issues: lacking of key EHR features, not using EHRs to their full potential, poor interoperability, low usability, low EHR (data) quality, etc…

Quality of EHRs and EHR data

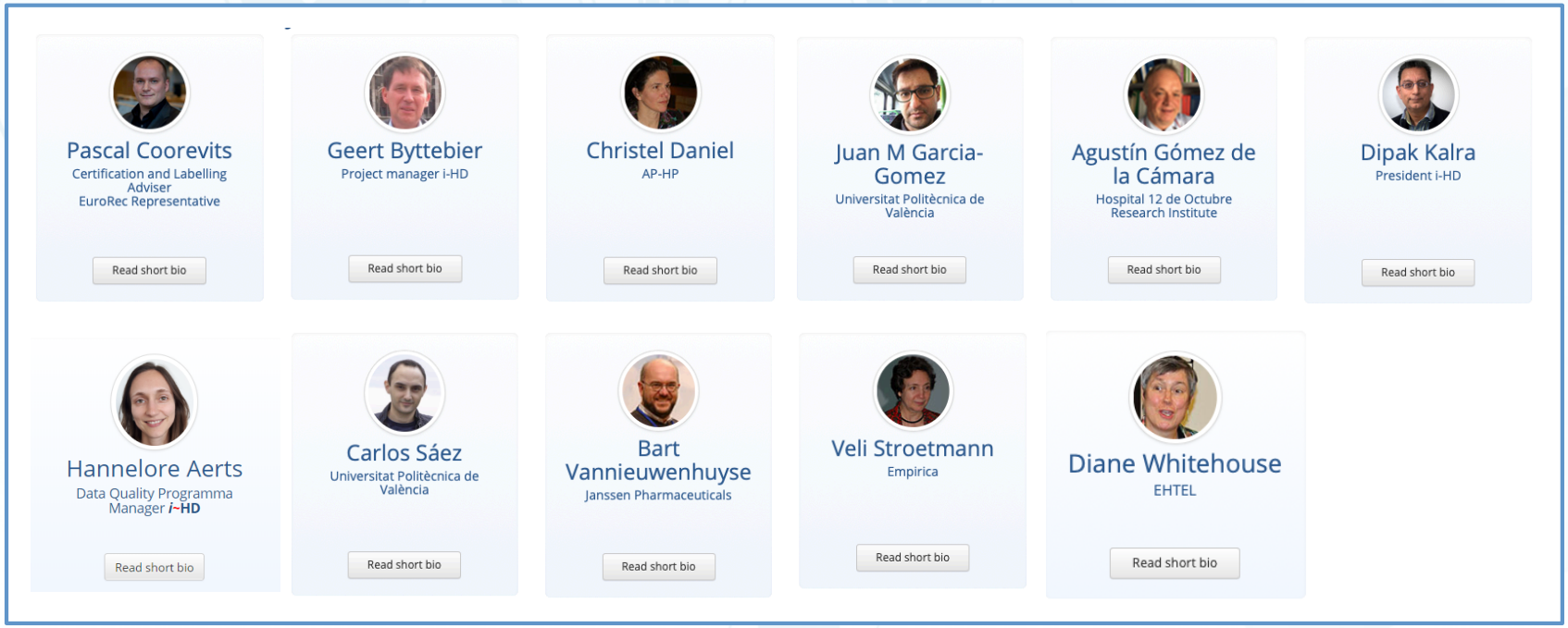
- To use EHRs efficiently for daily routine care, for clinical research, for big data analytics, … a number of functionalities are needed (e.g. security, confidentiality, trustworthiness, …)
- Mechanisms are required to ensure e.g. data correctness, completeness, consistency, …

Quality assurance is essential

Quality labelling & certification are needed



i~HD Data Quality Taskforce



i~HD Data Quality Taskforce aims

- Develop data quality assessment methods, tools and improvement strategies to maximise quality of health data
- Promote the importance of data quality
- Guidance in assessing and improving data quality
- Scale up a multi-stakeholder understanding and commitment to increase data quality

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;[iii] Chunhua Weng, PhD[iii]

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

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

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]

Work on data quality dimensions and assessment methods

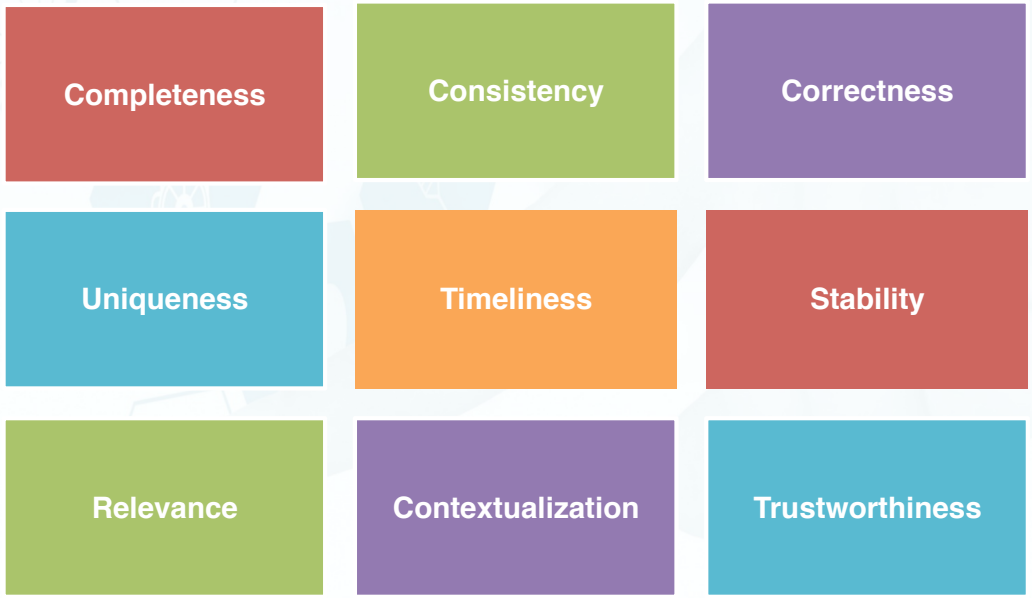
i~HD

Work on data quality dimensions and assessment methods

- Several data quality indicators used
- Several definitions for the same concept
- No universal approach

→ mapping exercise

→9 quality dimensions



Completeness – "data values are present"

Data Group	Data Item	Avg. usage	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7	Site 9	Site 9
Demographics	Gender	100%	100,00%	100,00%	100,00%	100,00%	100,00%	100%	100%	100,0%	100,00%
Demographics	Case Status	96%	99,87%	100,00%	60,00%	100,00%	100,00%	100,00%	100%	100,0%	100,00%
Demographics	Date of Birth	89%	100,00%	100,00%	99,00%	NA	100,00%	100%	100%	100,0%	100,00%
Demographics	Admission date	84%	100,00%	100,00%	100,00%	NA	100,00%	99,53%	58%	100,0%	100,00%
Diagnosis	Diagnosis Text	81%	50,46%	84,02%	100,00%	100,00%	98,05%	100,00%	14%	100,0%	80,98%
Diagnosis	Diagnosis Code	81%	50,46%	84,02%	100,00%	100,00%	98,05%	100,00%	14%	100,0%	80,98%
Demographics	Discharge date	75%	100,00%	100,00%	100,00%	NA	100,00%	100,00%	58%	100,0%	14,18%
Diagnosis	Diagnosis Date	70%	50,46%	84,02%	100,00%	100,00%	100,00%	NA	13%	100,0%	80,98%
Medication	Dosage	25%	20,36%	0,00%	NA	NA	94,43%	95%	NA	NA	12,21%
Findings	Weight	25%	29,56%	18,24%	NA	NA	89,17%	27,20%	36%	7,5%	13,82%
Laboratory Findings	Platelets Blood	48%	52,78%	33,14%	63,73%	NA	100,00%	100%	45%	NA	33,88%
Laboratory Findings	SGPT (ALT) in serum	47%	33,61%	22,29%	100,00%	NA	100,00%	100%	47%	NA	21,86%
Laboratory Findings	Total Protein in serum	46%	52,37%	14,96%	86,53%	NA	100,00%	100%	47%	NA	16,34%
Laboratory Findings	Total Bilirubin in serum	46%	33,03%	16,99%	100,00%	NA	100,00%	100%	47%	NA	19,58%

Variables such as Weight are quite frequently not present

Doods *et al. Trials* 2014, **15**:18
http://www.trialsjournal.com/content/15/1/18

TRIALS

RESEARCH Open Access

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

Justin Doods[1], Florence Botteri[2], Martin Dugas[1], Fleur Fritz[1*] and on behalf of EHR4CR WP7

i~HD

- Data quality issues found in a survival analysis of pancreatic cancer patients (Columbia University Medical Center, New York)

➢ Information inconsistency between different EHR data sources:

- In a few cases, pancreatitis was **diagnosed as being chronic in the pathology reports** but it was **reported as being only acute in the clinical notes**

➢ Information inconsistency within the same data sources :

- Some patients received **simultaneously two different ICD-9-CM codes** for their diagnoses of diabetes, both **250.01 and 250.02 for type-1 and type-2 respectively**

Consistency – "Data satisfies constraints"

Summit on Translat Bioinforma. 2010; 2010: 1–5. PMCID: PMC3041534
Published online 2010 Mar 1.

Secondary Use of EHR: Data Quality Issues and Informatics Opportunities

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

Osteoporos Int
DOI 10.1007/s00198-016-3635-2

ORIGINAL ARTICLE

Clinical height measurements are unreliable: a call for improvement

A. L. Mikula[1] · S. J. Hetzel[2] · N. Binkley[3] · P. A. Anderson[4]

"Fifty percent of staff reported they on occassion enter patient reported height into the EHR rather than performing a measurement"

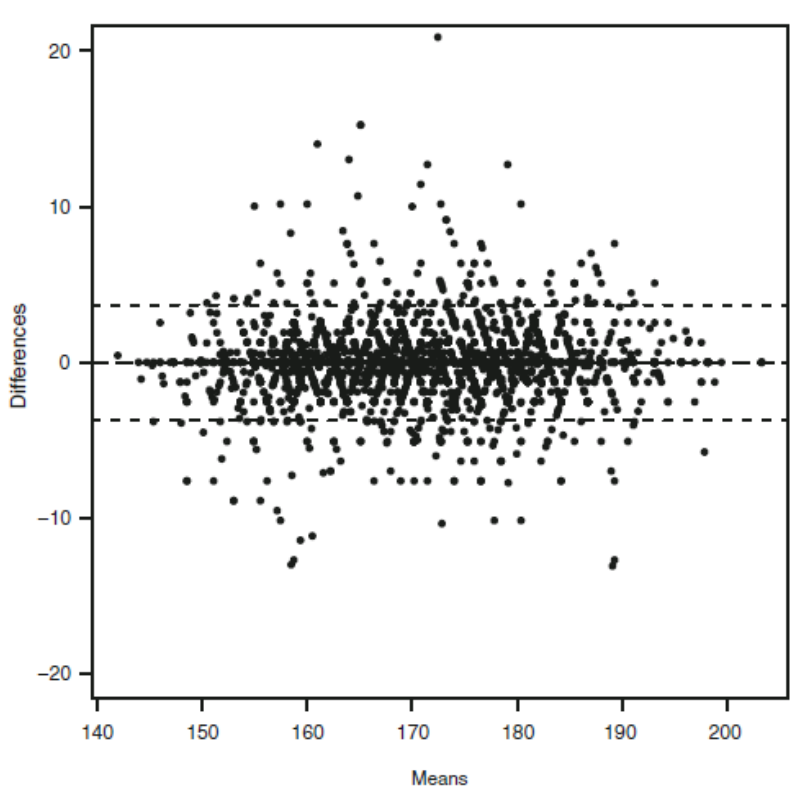


Fig. 4 Bland-Altman plot for height measurements of subjects. Each data point represents a single patient. *X axis* represent mean patient height in centimeters. *Y axis* represents difference between the first and the last height measurement for the individual patients in centimeters. The *dotted lines* represent 95 % CI

i~HD Slide courtesy of Carlos Saez and Juan M. García Gómez, Universitat Politècnica de València

i~HD Hospital Network of Excellence Data Quality Workshop

Towards better data quality in hospitals

Tuesday 23rd May 2017 - Wednesday 24th May 2017

i~HD

PARIS, 5 - 6 MARCH 2018

A two-day workshop run by the **i~HD**
Hospital Network of Excellence and Data Quality Task Force,
in collaboration with

Gaining the Benefits of Improved Health Data Quality

ICHOM International Consortium for Health Outcomes Measurement

EPF European Patients Forum

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MAY 15 - 16, 2019
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i~HD @ VITALIS
21 - 23 May 2019
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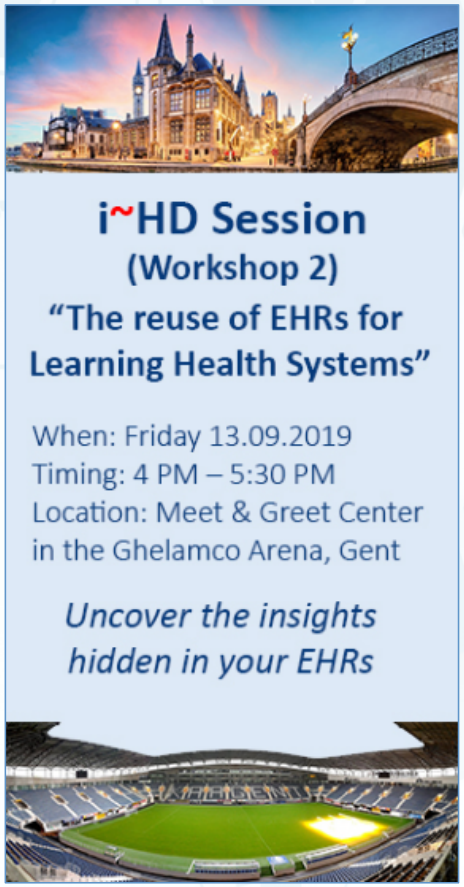
i~HD Session
(Workshop 2)
"The reuse of EHRs for Learning Health Systems"
When: Friday 13.09.2019
Timing: 4 PM – 5:30 PM
Location: Meet & Greet Center in the Ghelamco Arena, Gent
Uncover the insights hidden in your EHRs


Joining the Dots Conference - 27 & 28 November - Brussels
Trillium II
Digital Health Europe
i~HD
EHR4EDC
C3CLOUD
EHDEN
Exchanging use cases, insights, methods, successes, challenges
Quality and interoperability of high-value data sets
Promoting and sustaining federated learning health ecosystems
Patient empowerment in access and use of health data
Advancing solutions for multi morbidity
Calls to action for health ministries
Joint meeting with the eHealth Network on 28th November
Save the date - registration opens soon

Assessing the Quality of Congestive Heart Failure outcomes data at the Hospital del Mar Barcelona

Pascal Coorevits
Geert Byttebier
Dipak Kalra
Geert Thienpont
Carlos Sáez
Juan M. García Gómez
Marta Durá-Hernández
Juan-Manuel Ramírez Anguita
Miguel-Angel Mayer

The European Institute For Innovation Thr~ugh Health Data

GRIB RESEARCH PROGRAMME ON BIOMEDICAL INFORMATICS

upf. Universitat Pompeu Fabra Barcelona

IMIM Parc de Salut MAR Barcelona
Institut Hospital del Mar d'Investigacions Mèdiques

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BDSLab BIOMEDICAL DATA SCIENCE LAB

i~HD

Pilot DQA

- Scoping of the DQA
- Congestive Heart Failure
- 146.602 patient visits with diagnosis of CHF
- ICHOM “Heart Failure” outcome variables basis for selection of variables for DQA ➔ 22 variables (out of 72 ICHOM variables) were selected
- Data Quality Dimensions: Completeness, Correctness, Consistency, Uniqueness & Stability

Congestive Heart Failure (CHF) – ICD9 codes

428 Heart failure
Code, if applicable, heart failure due to hypertension first (402.0-402.9, with fifth-digit 1 or 404.0-404.9 with fifth-digit 1 or 3)
Excludes:
rheumatic (398.91)
that complicating:
abortion (634-638 with .7, 639.8)
ectopic or molar pregnancy (639.8)
labor or delivery (668.1, 669.4)

428.0 Congestive heart failure, unspecified
Congestive heart disease
Right heart failure (secondary to left heart failure)
Excludes:
fluid overload NOS (276.6)

428.1 Left heart failure
Acute edema of lung with heart disease NOS or heart failure
Acute pulmonary edema with heart disease NOS or heart failure
Cardiac asthma
Left ventricular failure

428.2 Systolic heart failure
Excludes:
combined systolic and diastolic heart failure (428.40-428.43)

428.3 Diastolic heart failure
Excludes:
combined systolic and diastolic heart failure (428.40-428.43)

428.4 Combined systolic and diastolic heart failure

428.9 Heart failure, unspecified
Cardiac failure NOS
Heart failure NOS
Myocardial failure NOS
Weak heart

?

402 Hypertensive heart disease
402.0 Malignant
402.00 Without heart failure
402.01 With heart failure

R package: automated pdf & html DQ reporting

Data and configuration files

main_config.csv

DQ analysis parameters, including paths to:

dataset.csv

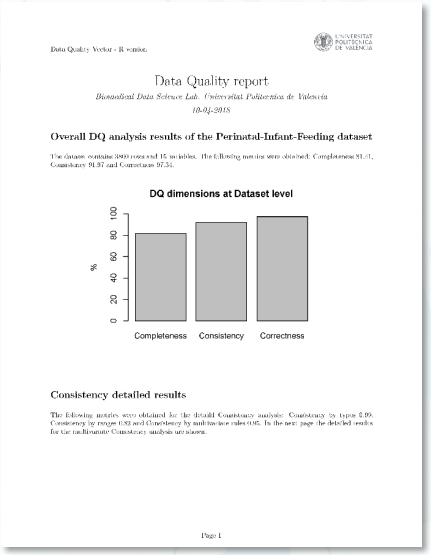
The dataset to be analyzed

dictionary_types.csv

dictionary_ranges.csv

dictionary_rules.R

Data dictionary files with semantics about data types, ranges and multivariate rules


Data Quality Vector - R version

Data Quality report

Biomedical Data Science Lab. Universitat Politècnica de Valencia

16-11-2018

Overall DQ analysis results of the Perinatal-Infant-Feeding dataset

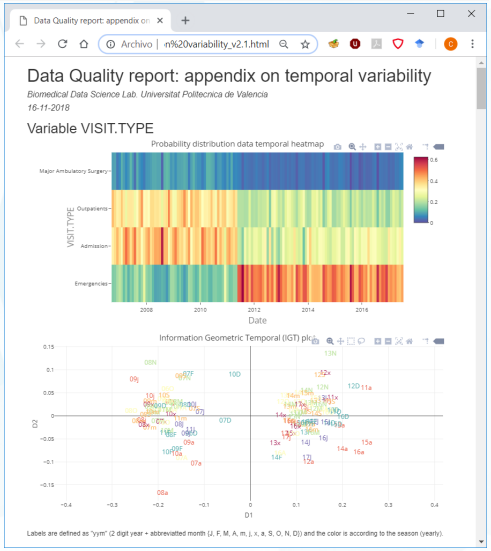
The dataset contains 3969 rows and 15 variables. The following metrics were obtained: Completeness 81.41, Consistency 94.97 and Correctness 97.54.

DQ dimensions at Dataset level

Consistency detailed results

The following metrics were obtained for the detailed Consistency analysis: Consistency by types 0.99, Consistency by ranges 0.93 and Consistency by multivariate rules 0.95. In the next page the detailed results for the multivariate Consistency analysis are shown.

Page 1


Data Quality report: appendix on temporal variability

Biomedical Data Science Lab. Universitat Politecnica de Valencia

16-11-2018

Variable VISIT.TYPE

Probability distribution data temporal heatmap

VISIT.TYPE

Major Ambulatory Surgery

Outpatients

Admission

Emergencies

2008
2010
2012
2014
2016

Date

Information Geometric Temporal (IGT) plot

D2

D1

Labels are defined as "yym" (2 digit year + abbreviated month (J, F, M, A, m, j, x, a, S, O, N, D)) and the color is according to the season (yearly).

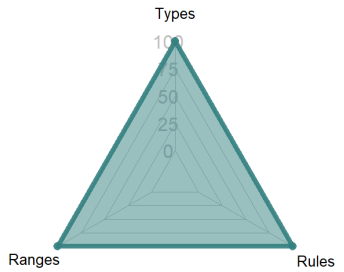
Types → dictionary_types.csv

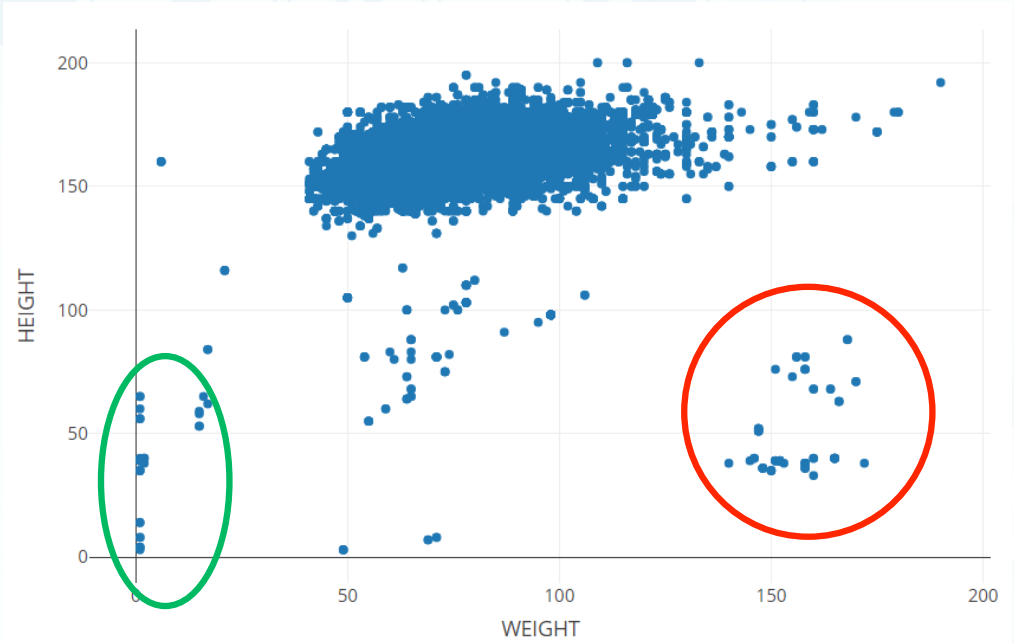
Ranges → dictionary_ranges.csv

Multivariate rule	Comment	Error.sum
ARIDATE <= DISDATE	Arrival date <= Discharge date	0
DATEofBIRTH <= DEATHDATE	Birth date <= Death date	0
DISDATE <= DEATHDATE	Discharge date <= Death date	0
DATEofBIRTH <= ARIDATE	Birth date <= Arrival date	0
(WEIGHT/(HEIGHT/100)^2) <= 70	BMI under 70	180
(WEIGHT/(HEIGHT/100)^2) >= 10	BMI over 10	15

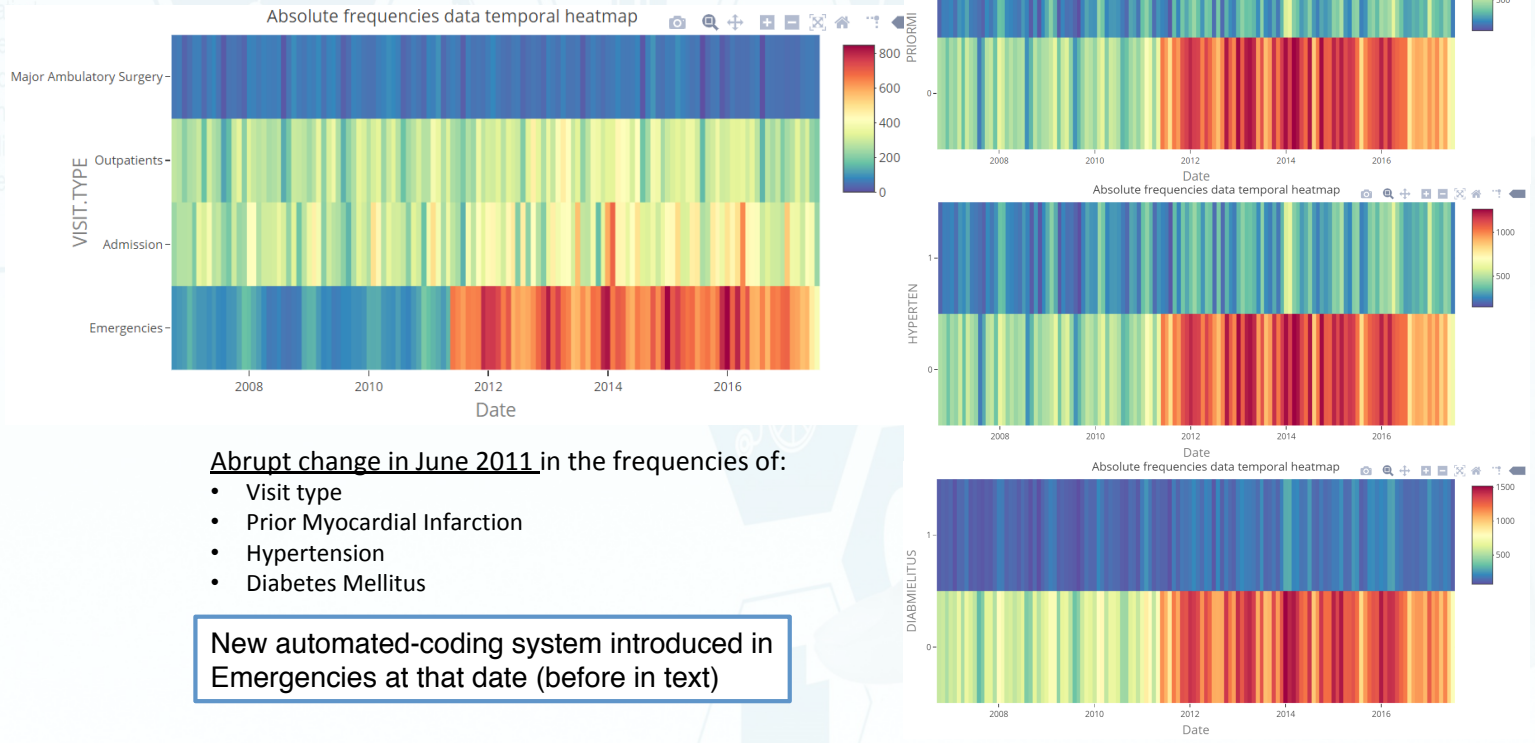
By Types: 99,99 %
By Ranges: 100 %
By Multivariate rules: 99,98 %

Consistency results by types, ranges and rules





Slide courtesy of Carlos Saez and Juan M. García Gómez, Universitat Politècnica de València



Abrupt change in June 2011 in the frequencies of:

- Visit type
- Prior Myocardial Infarction
- Hypertension
- Diabetes Mellitus

New automated-coding system introduced in Emergencies at that date (before in text)

The European Institute For Innovation Thr~ugh Health Data

Report - Pilot Project - Hospital Parc de Salut Mar Barcelona, Catalonia, Spain

DQS4H

Data Quality Service for Hospitals

i~HD

Table of content

- It is essential to have **considerable knowledge of the EHR** (types of data available, how the data were collected or who collected it)
- The **assessment** of the data is the very first step to improve the quality of your data
- Once you know about the quality of your data, it is important to **monitor it regularly**
- **Multidisciplinary** approach is highly recommended
- Thinking of using EHR for different purposes such as research, EHR data models would need to be **expanded and redesigned** and data quality assessment can assist in doing these tasks
- It is of value that an **external assessment** of the data quality is performed by an independent organization
- High-quality data **enhance the validity and reliability** of study findings
- It is critical to ensure that **the metrics** are feasible, valid, and meaningful for a specific EHR and purpose and its quality improvement

Do you want to make better use of your electronic health record?

Do you want to improve the quality of your health data?

DQS4H

Data Quality Service for Hospitals

www.i-hd.eu

i~HD

Preparation and planning

- Webinar on data quality
- Needs and objectives
- Define the scope and domain(s)
- Scope the data sets
- Partnership and confidentiality agreements, GDPR
- Assign roles, timelines
- Contracts

Dataset generation

- Onsite visit
- Prioritise the DQ dimensions
- Select the EHR variables
- Prioritise and localise the i~HD DQ rule library
- Pre-assessment of the data set extract
- Fine tuning the data set
- Final data set for assessment

Assessment

- Validation of the data set
- Tools based analysis of the variables for agreed dimension
- Graphical outputs + descriptive interpretation by i~HD medical and statistical experts
- Preliminary findings discussed with the hospital, to exchange insights on causative factors

Outcome

- Final written report
- Presentation to the team
- Discussion of recommendations
- Improvement strategy planning
- Workshops, online tutorials
- Issue successful hospitals with a **Data Quality Seal**

i~HD

Wat makes the i~HD DQS4H unique?

Pragmatic: minimally invasive to hospital operations

Evidence based: well researched, published, assessment methodology

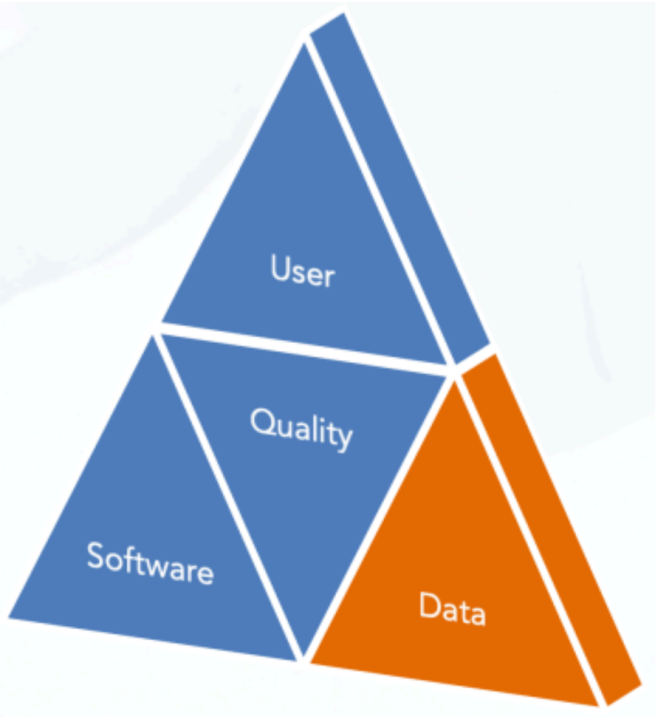
Flexible: can be tailored to your data quality drivers

Focussed: we can help you choose the most suitable dimensions and EHR data variables

Staged: clear sequence of steps with regular interactions and feedback loops

Holistic: we consider quality in the context of your user workflows and your EHR system

Extendable: data sets can be added incrementally, to chart out a data quality improvement journey



i~HD

Frank Staelens
OLV Hospital Aalst

i~HD@iHD_HealthData . Oct 9

i~HD member,@fstaelens, OLV Hospital Aalst: *My vision is that medical data is an important vehicle to measure and improve quality of care in our hospital. i~HD supports us in analysing and visualising our health data and its quality. This helps in providing high quality care."*

- i~HD@iHD_HealthData . Oct 15
- @Joanxcomella, Director of @VHIR_: *Given #iHD mission in health data quality, it was quite obvious for us to select i~HD as a preferred partner for our hospital data quality strategy. It will make us an even more attractive partner for European research activities."* #healthdata

Joan Comella
Director of Vall d'Hebron Institut de Recerca

Miguel Angel Mayer
Hospital del Mar

Dipak Kalra@DipakKalra . Oct 17

Dr Miguel Angel Mayer, from Hospital del MAr and i~HD Member, explains to the SCOPe audience how integrating clinical data, and assessing its quality, has enabled them to accelerate their bio-informatics research. #Datasaveslives

i~HD

Thank you!

pascal.coorevits@ugent.be

www.linkedin.com/pascalcoorevits

Mr. Bart Vannieuwenhuyse
Data Sciences Lead Benelux campus

The value of Real World Evidence to Pharma

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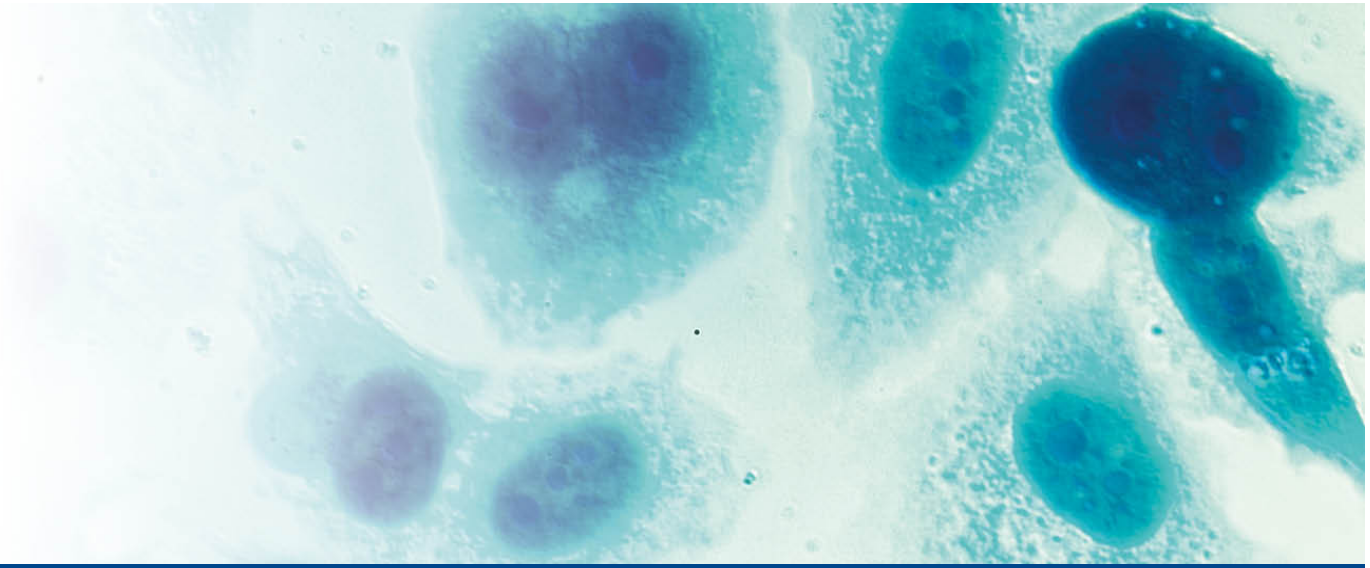


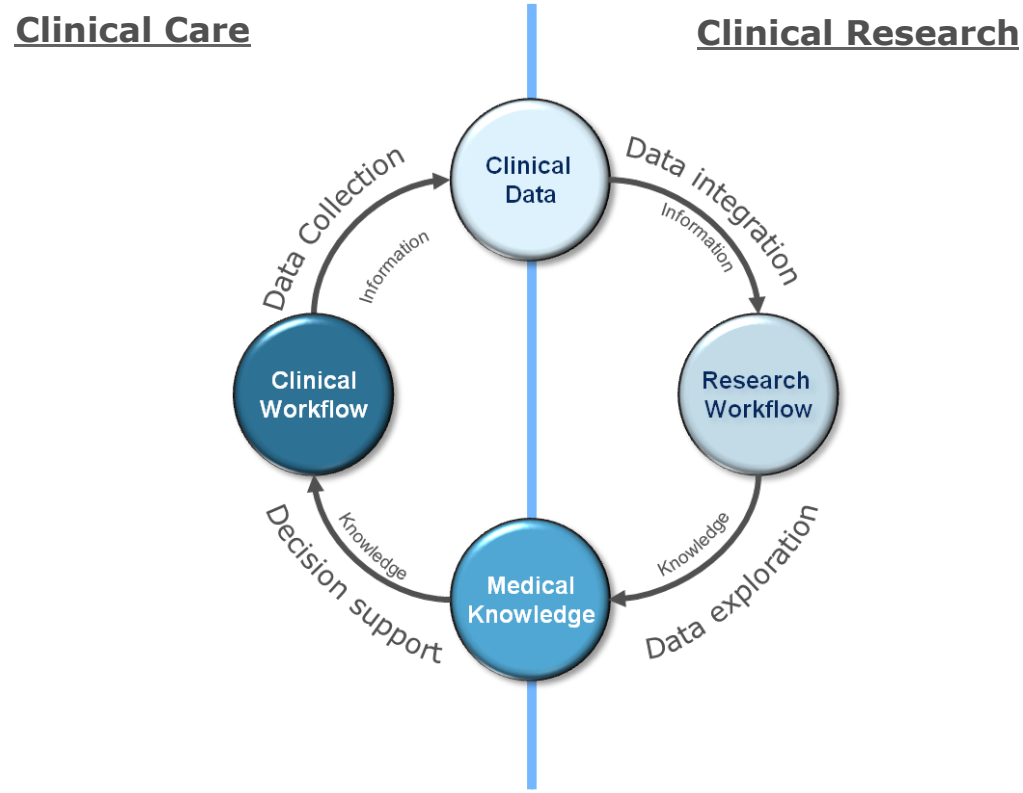
Value of Real World Data to pharma

A data-driven pharmaceutical perspective

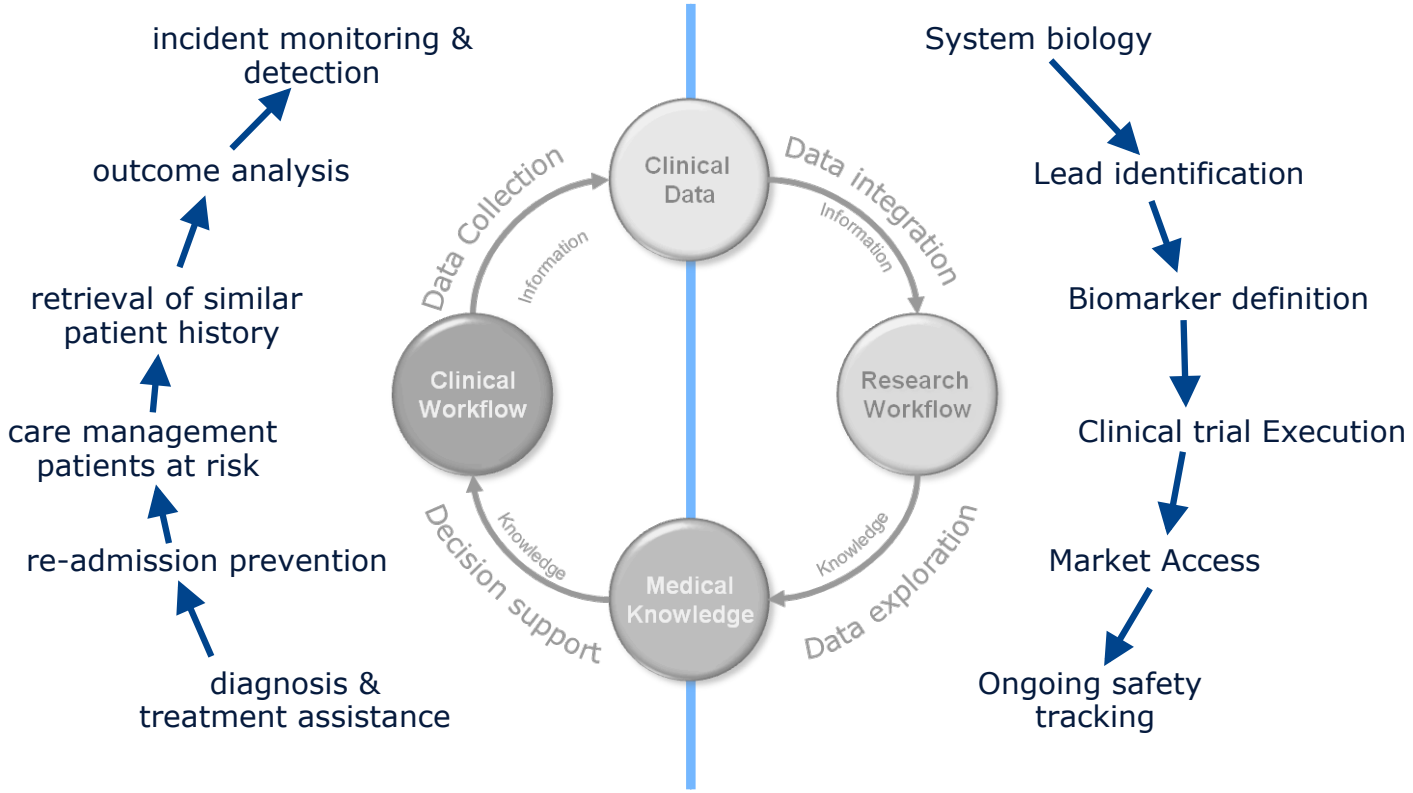
Pictured above: Ulcerative Colitis

Bart Vannieuwenhuyse
September 2019 | Janssen Clinical Innovation

Framework for RWD



Framework for RWD

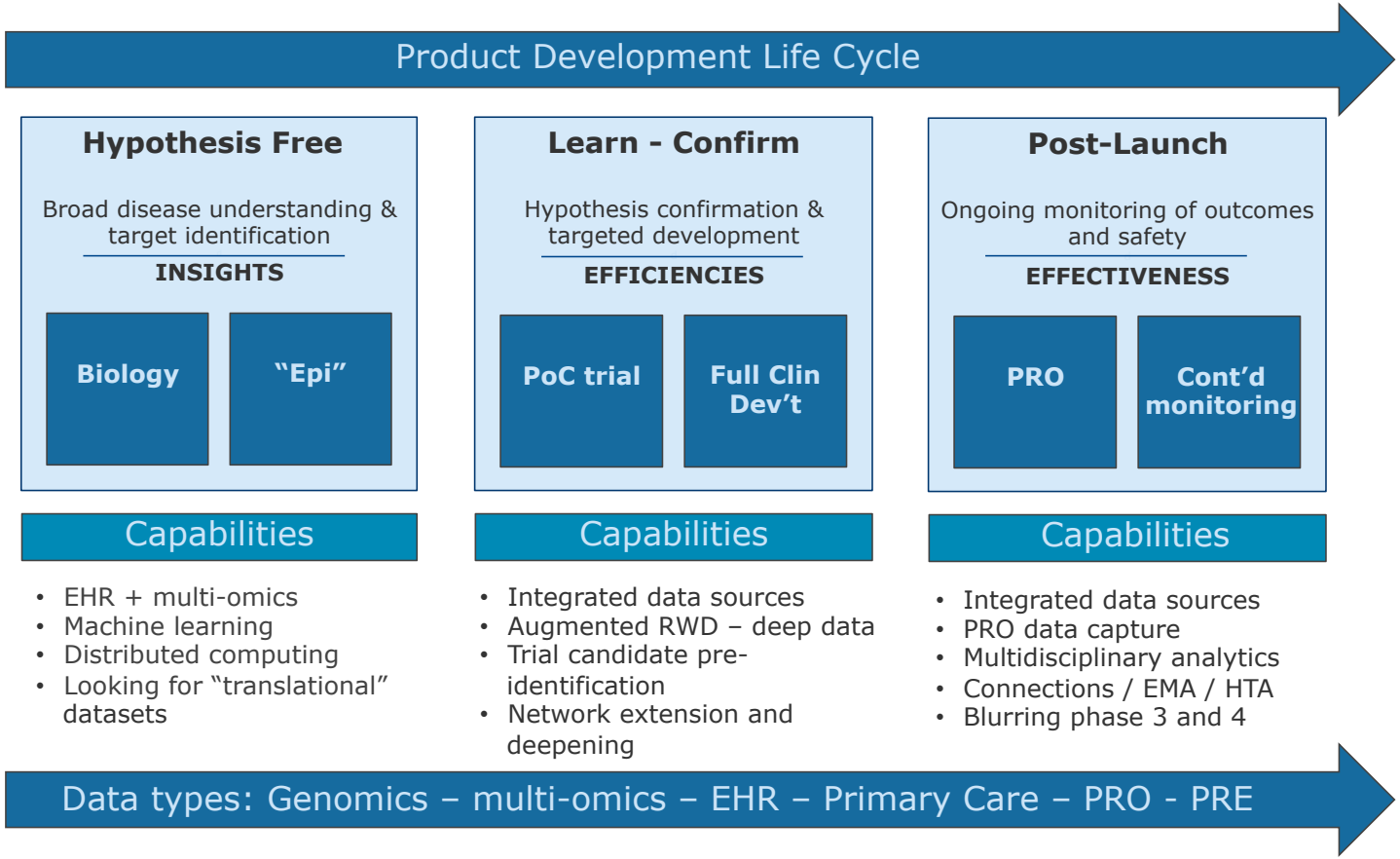


RWD defined

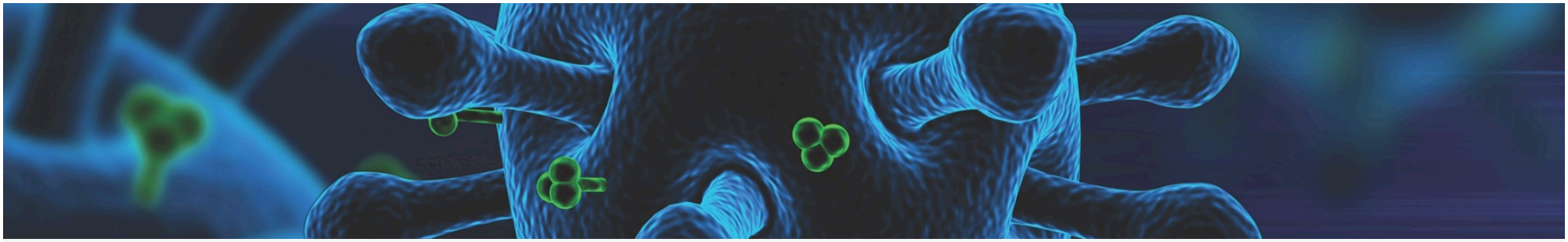
- RWE is generated using data typically collected in **usual health care settings**. RWE is most commonly **generated using a range of non-interventional (observational) studies**, including:
  - **Primary data** collections such as **registries** collecting prospective and/or retrospective data, or **surveys** collecting cross-sectional or retrospective information.
  - Analyses of **secondary data that includes (electronic) medical records, insurance claims data, and government databases** which provide data typically used for retrospective analyses.

RWD is the **"by-product"** of **routine care**

Overview – data driven innovation opportunities



Mobilizing data - challenges



Privacy, legal and ethical issues

Ownership – right to use

Data in silos

Semantic chaos – need for practical solutions on interoperability

Data quality – "horses for courses"

Contractual barriers

Digital pipelines for sharing

Building **trust** among stakeholders

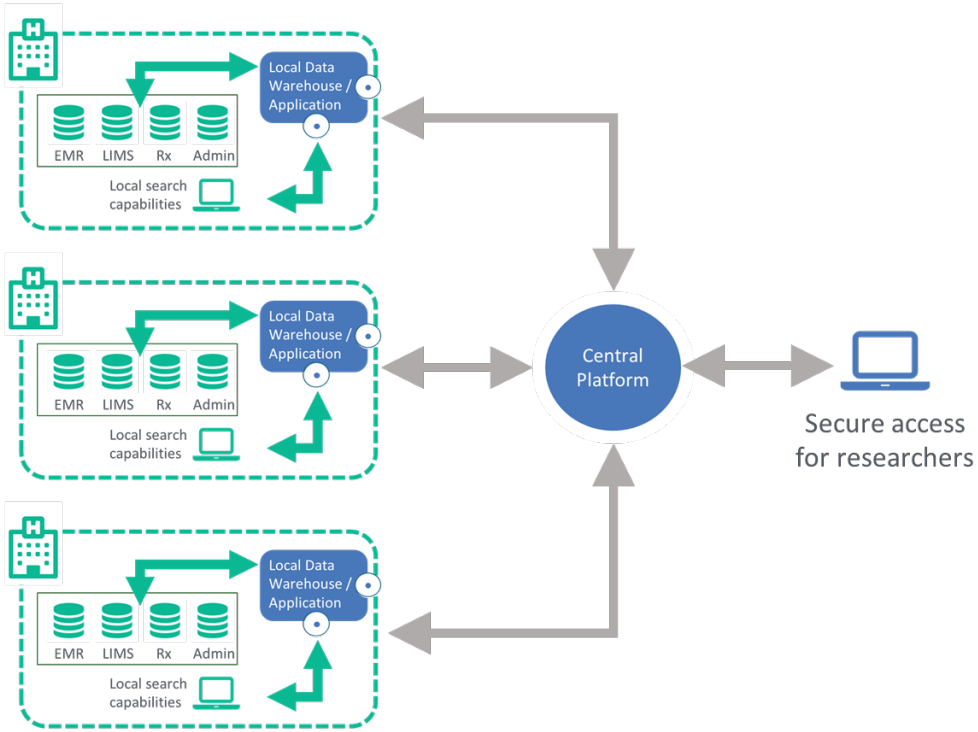
Innovative Medicines Initiative

The IMI is a unique Public-Private Partnership (PPP) between the pharmaceutical industry represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Union represented by the European Commission.

Multiple great examples ---

- Federated approach
- Multi-stakeholder involvement/commitment
- Public-private collaborations
- Need for open-minded innovative approaches, look for long term benefits & potential

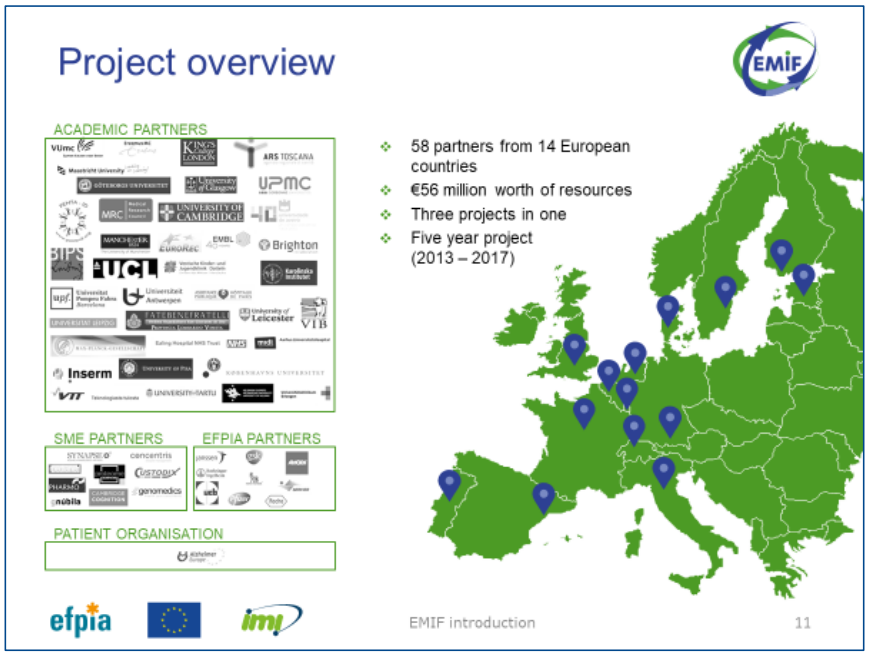
Stimulating the flow of data through federated networks

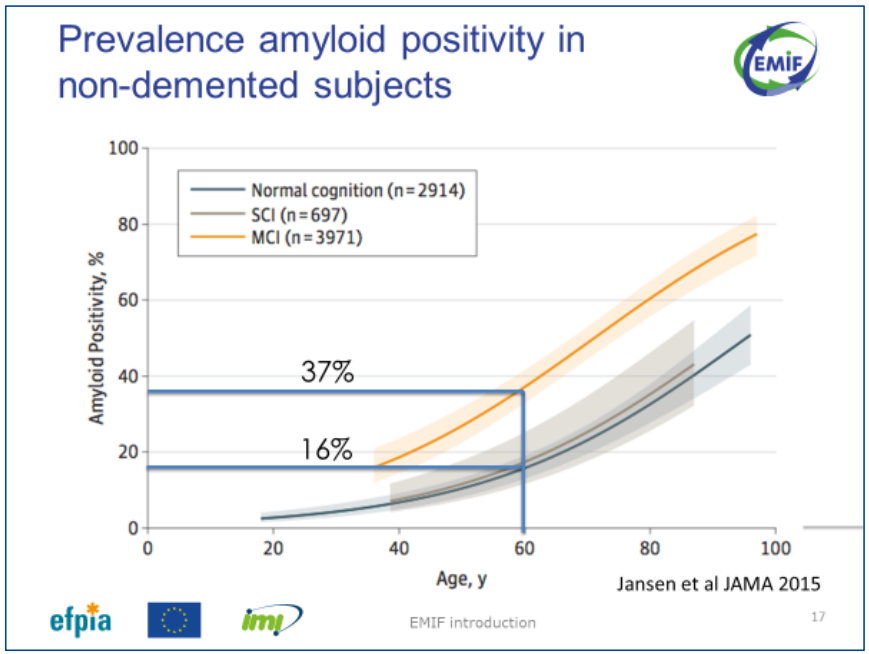


Benefits of federated networks

- 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

Leveraging power of data – EMIF

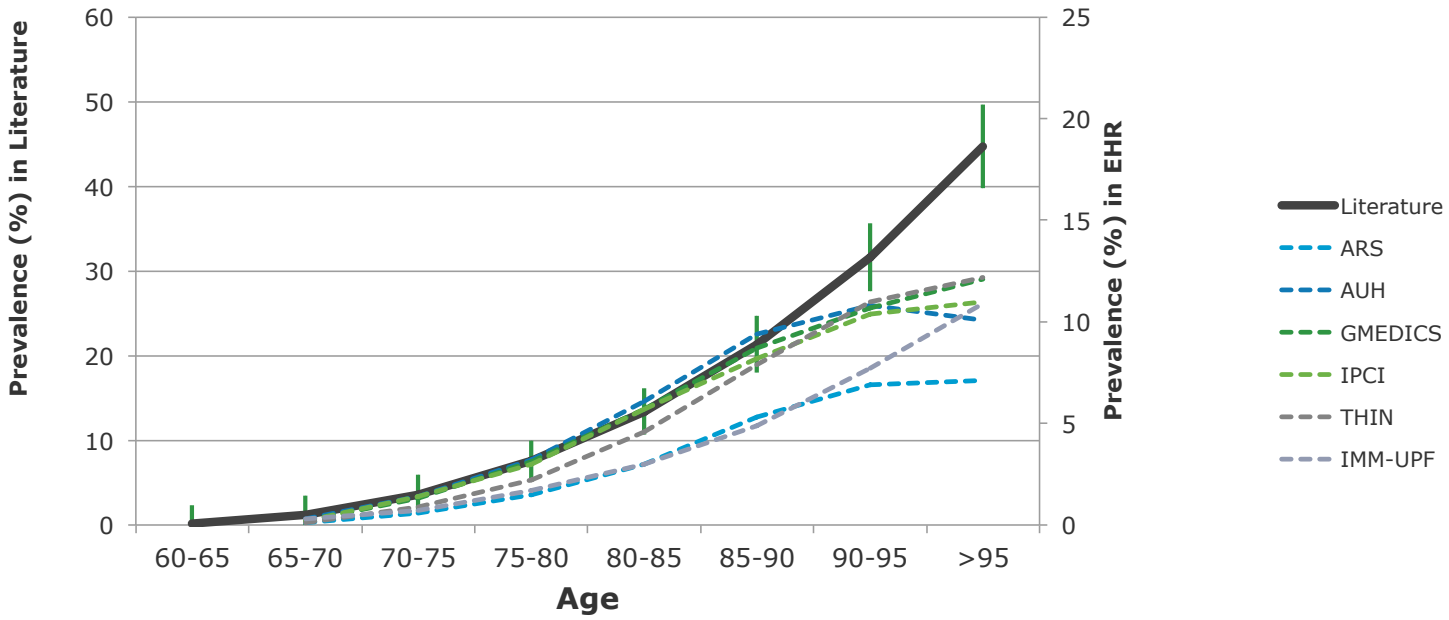




European Medical Information Framework (EMIF)

EMIF-Alzheimer Disease research

Age-stratified prevalence of dementia in Europe from the literature and from electronic health records



Alexander et al, JAD 2014;48:355. Systematic literature analysis of 26 EU studies reveals continuously ↑ing prevalence of dementia from 60 years, reaching 44.7% at >95 years **(left axis)**

Stewart et al (submitted, AAIC 2016). Based on EHR in 6 population databases, prevalence of dementia ↑ed at a similar relative rate by age stratum, but was ~50% of that in Alexander et al's review **(right axis).**

New IMI project

EHDEN
EUROPEAN HEALTH DATA & EVIDENCE NETWORK

- Harmonised 100 million records, mapped to the OMOP common data model
- Ecosystem of certified/qualified SMEs harmonising data sources, supported by €17mio fund via open series of calls
- Federated analytics via OHDSI tooling, ARACHNE and EMIF platforms
- Impact: Improving trust and reusability of real world data for key stakeholders

EHR4CR

The EHR4CR project

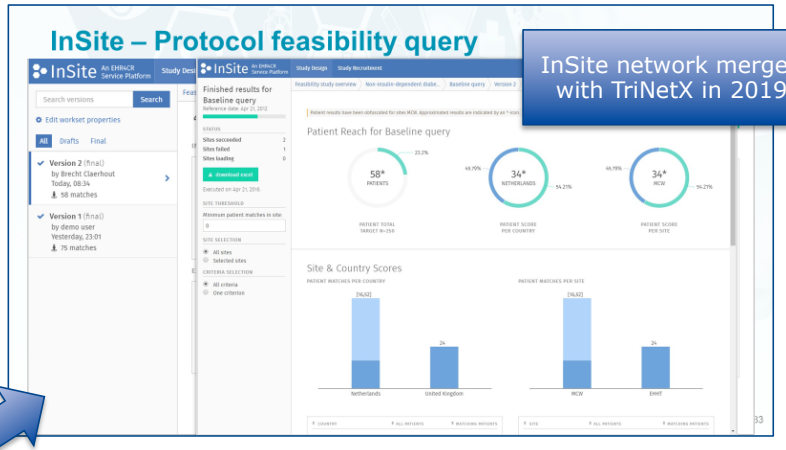
- EHR4CR – Electronic Health Records for Clinical Research
  - 4+1 year project (2011-2016), 35 partners, budget >17M€
- Objectives & Scope
  - Provide a platform for **trustworthy re-use of EHR data** to support innovation in clinical research and healthcare operations.
  - Securely reusing **health 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/

i~HD 25

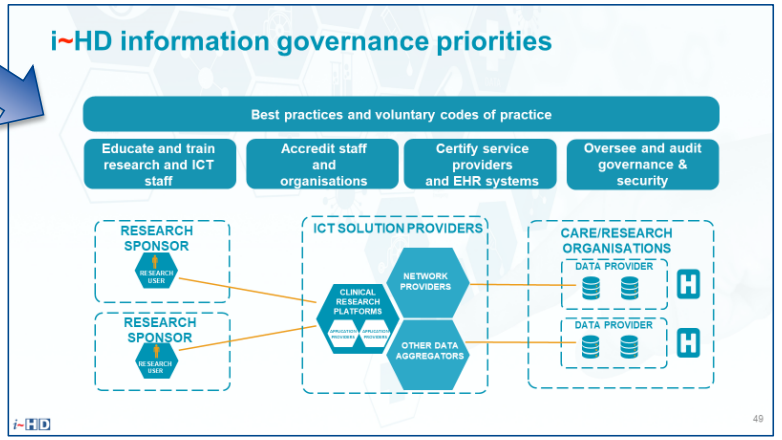
InSite – Protocol feasibility query

InSite network merged with TriNetX in 2019



For profit – InSite platform

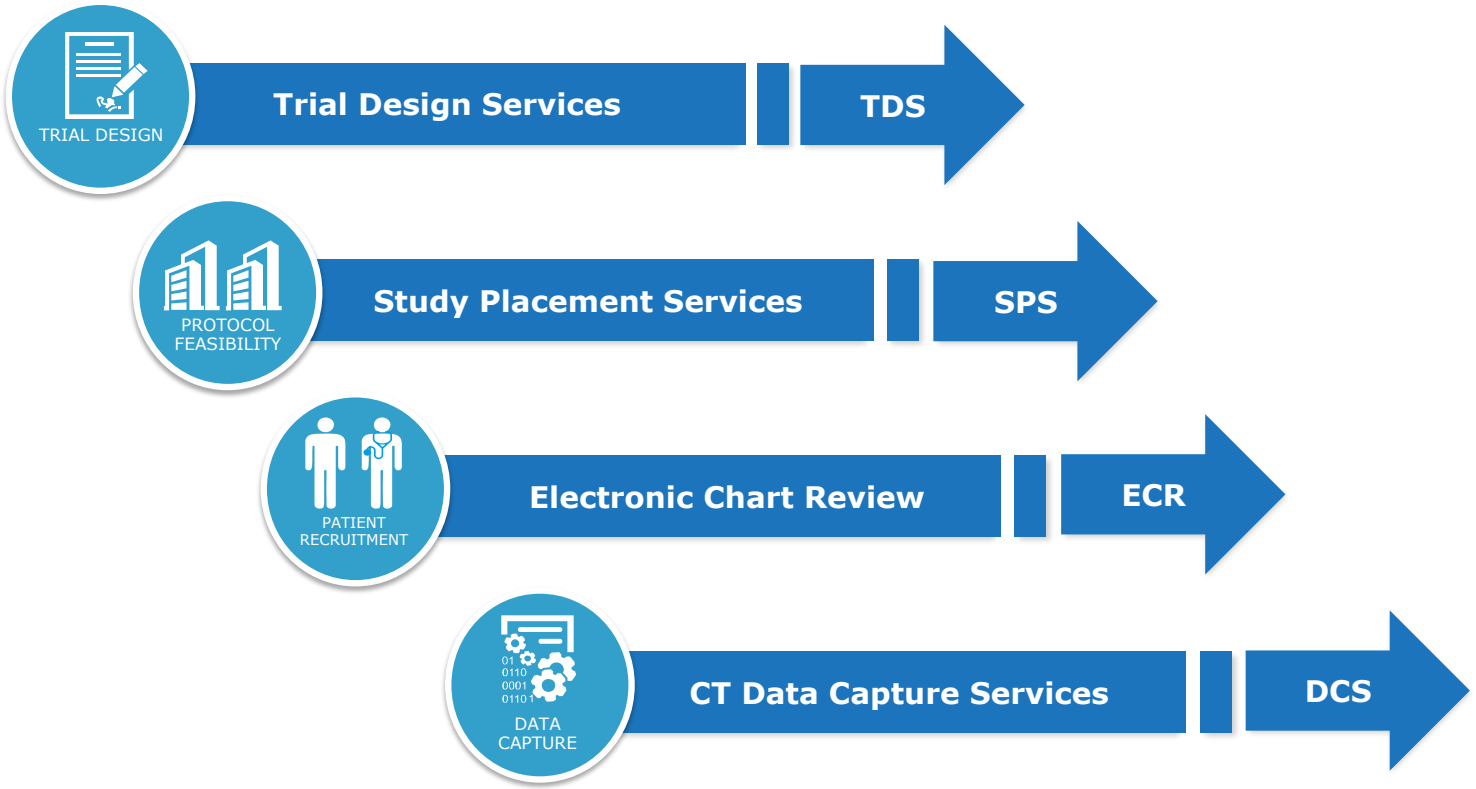
i~HD information governance priorities



Non-profit – iHD institute

Source: presentation Prof Dipak Kalra

Using federated data in clinical research



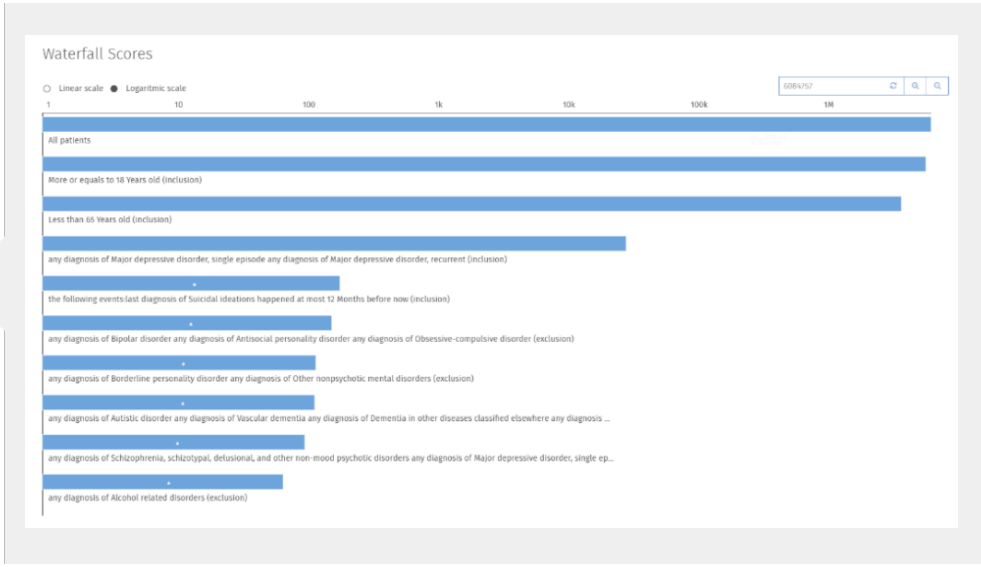
Early protocol design (example InSite)

Trial Design

Understanding impact of eligibility criteria on recruitability of study

Protocol Formalization

Impact on
trial design♪
♪
esketamine trial in major depressive disorders (54135419SUI3001)♪



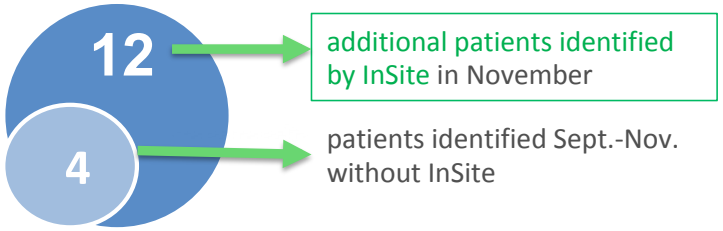
eChart Review / patient enrollment InSite (prospective)

Patricio Molero, MD, PhD
Study PI

Clínica Universidad
de Navarra, Spain

Clínica Universidad de Navarra

InSite recruitment in esketamine trial in major depressive disorders (54135419SUI3001)

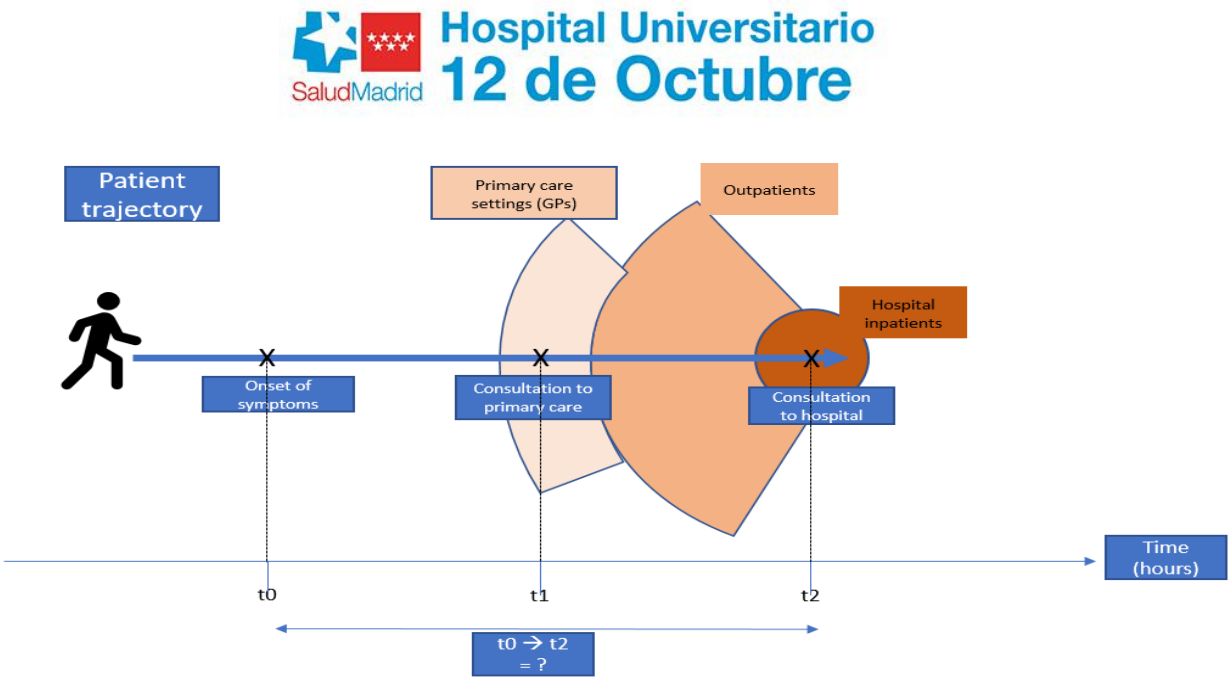


"Fast, powerful tool for the identification of potential candidates"

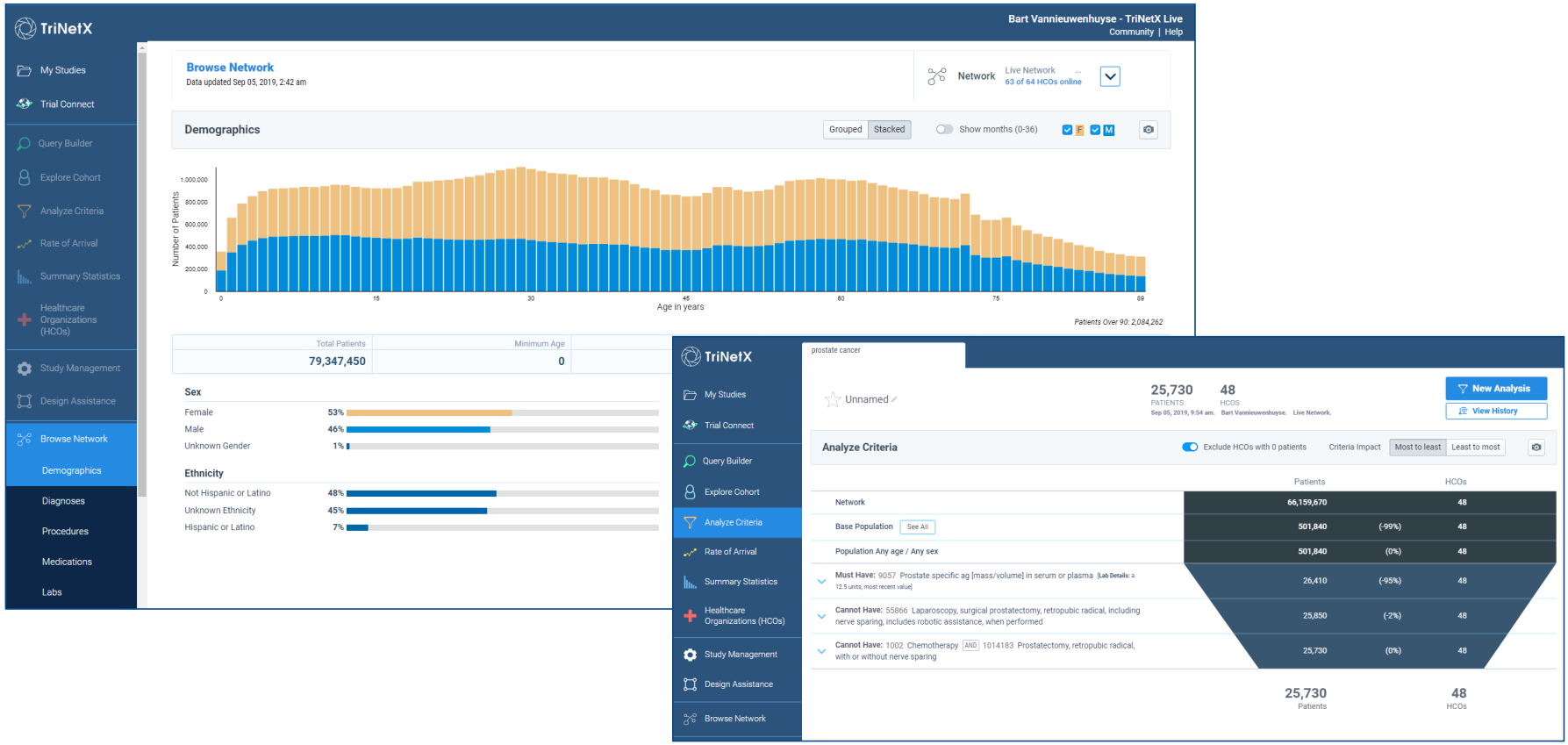
"12 new patients which we otherwise would have missed"

Influenza A infection:
Linking primary care data and hospital EHR data

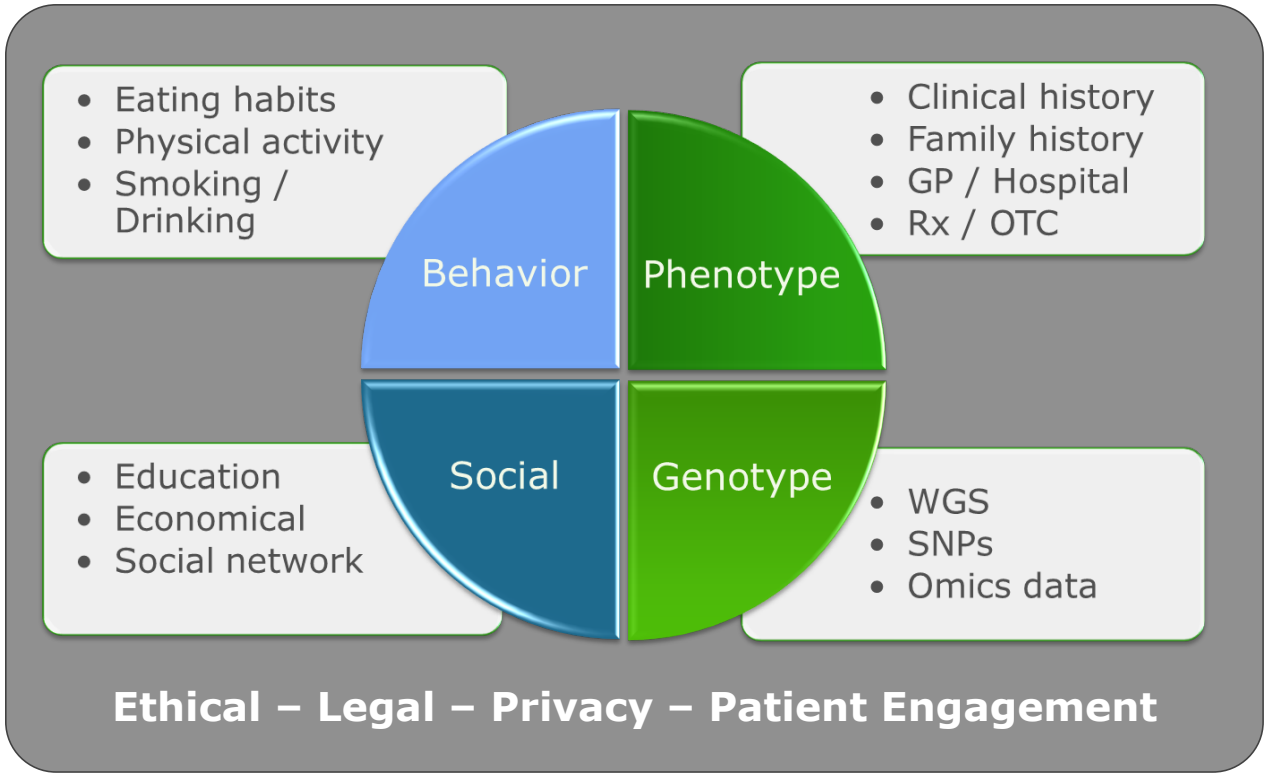
The aim of this pilot project was to define the time lapse between onset of flu symptoms and hospital admission within a cohort of Influenza A patients, by analyzing both hospital electronic health records and primary care (outpatients) data.



Federated data network for clinical research



Future view – “holistic data”



Bart Vannieuwenhuyse
bvannieu@its.jnj.com

Mr. Brecht Claerhout

Managing Director Europe TriNetX Inc.

A case study example of a successfully deployed clinical research platform that reuses EHR data to support research

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Mr. Geert Thienpont

Director of the European Institute for Innovation through Health Data

Moderator

Panel discussion: the business case for hospital investment in high quality EHR data

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THANK YOU FOR YOUR ATTENTION