The European Institute For Innovation Thr~ugh Health Data

i~HD and i2b2:

THE NEED TO SCALE UP LEARNING FROM HEALTH DATA

Prof Dipak Kalra
President of i~HD

The Digital Patient

Micro-biome

Proteome

The Human Genome

Biobanks

The Quantified Self

HealthKit, ResearchKit

Social media

Virtual communities

Living Labs

Real Word Evidence

Real World Data

The connected patient

Watches

Trackers

Simulation

Mathematical modelling

Virtual Physiological Human

In the last 5 years, more scientific data has been generated than in the entire history of mankind

90% of the data in the world today has been created in the last 2 years

Global electronic health records market expected to reach USD 29.81 billion by 2022

By 2017, 1.7 billion smartphone users will have downloaded health apps

Monitoring services will account for 65% of the global mHealth market by 2017

Big Data

Disease registries

Claims databases

Electronic health and care records

Cohort studies and biobanks

Personal health records

Clinical trials data, electronic case report forms

Mobile health apps

Wearable sensors

Genome

Air quality

Social networks

Lab on a chip

Climate

* This is not a comprehensive list

The Value of Health

Political and policy context

Economic context:

- Legacy of the crisis: high debts and deficits
- Continued increases in public health spending anticipated
- Concerns about how this will be paid for (sustainability of public finances)

Population health:

- Ageing and rising levels of chronic disease and comorbidity
- Public health problems and inequalities

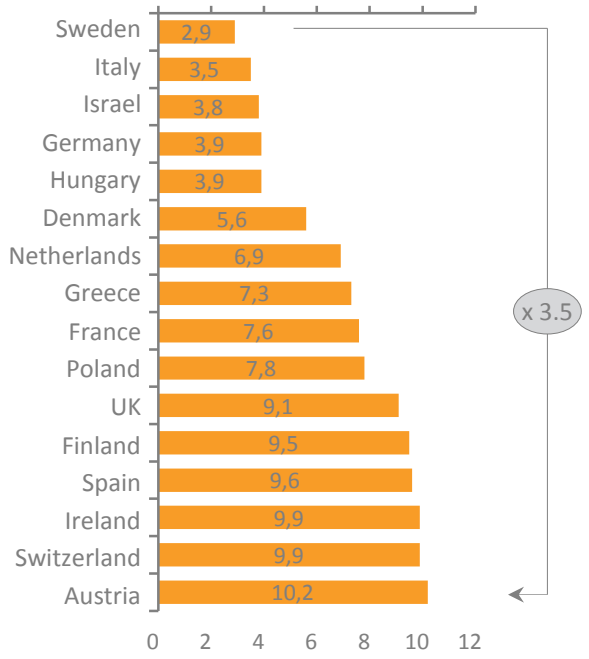
Health systems:

- Challenge of responding to changing population needs
- Need for structural reforms – e.g. integrated care, eHealth
- Evidence of marked variation in clinical practices and significant levels of 'waste'

Slide courtesy of Daniel Furby, FIPRA International

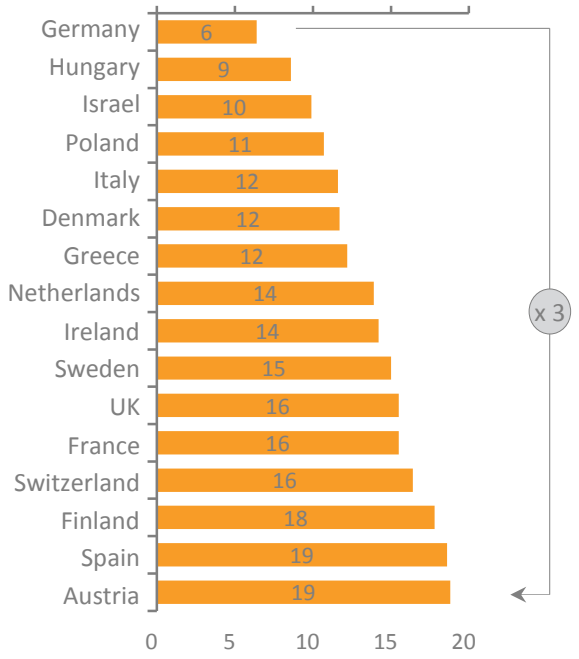
Variation of heart failure outcomes across European countries

> 3x variation in death during first HF admission



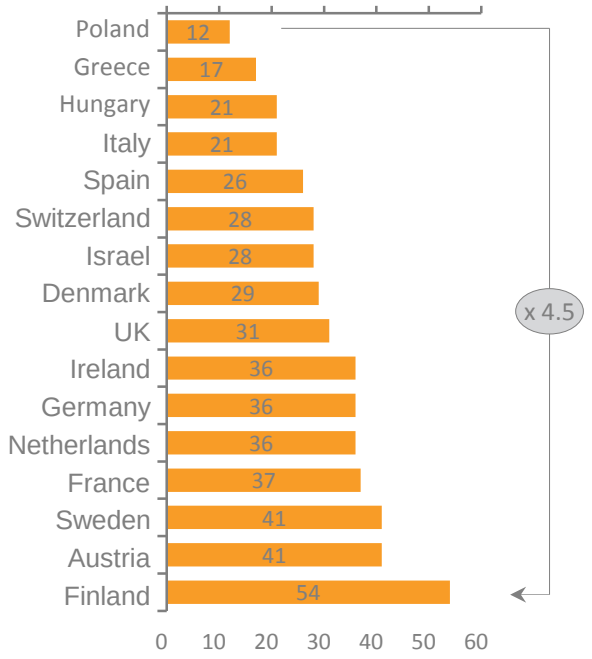
Death during first admission, %

3x variation in 12 week mortality rate for HF



12 week mortality rate, %

>4x variation in 12 week readmission rate for HF

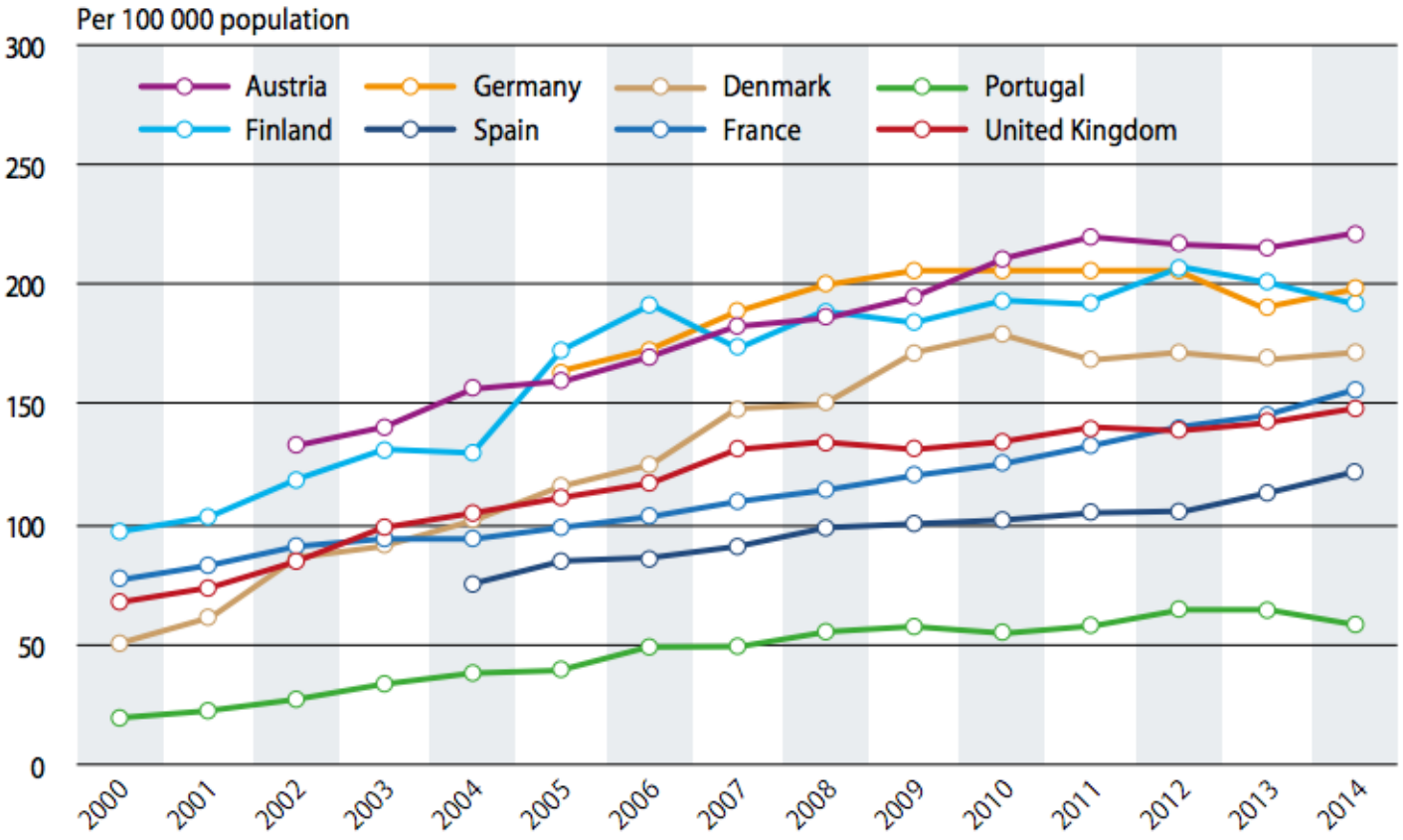


12 week readmission rate, %

Slide courtesy of Thomas Allvin, EFPIA

Huge practice variation between OECD countries

Rates of knee replacement vary hugely across OECD health systems. Is this justified?

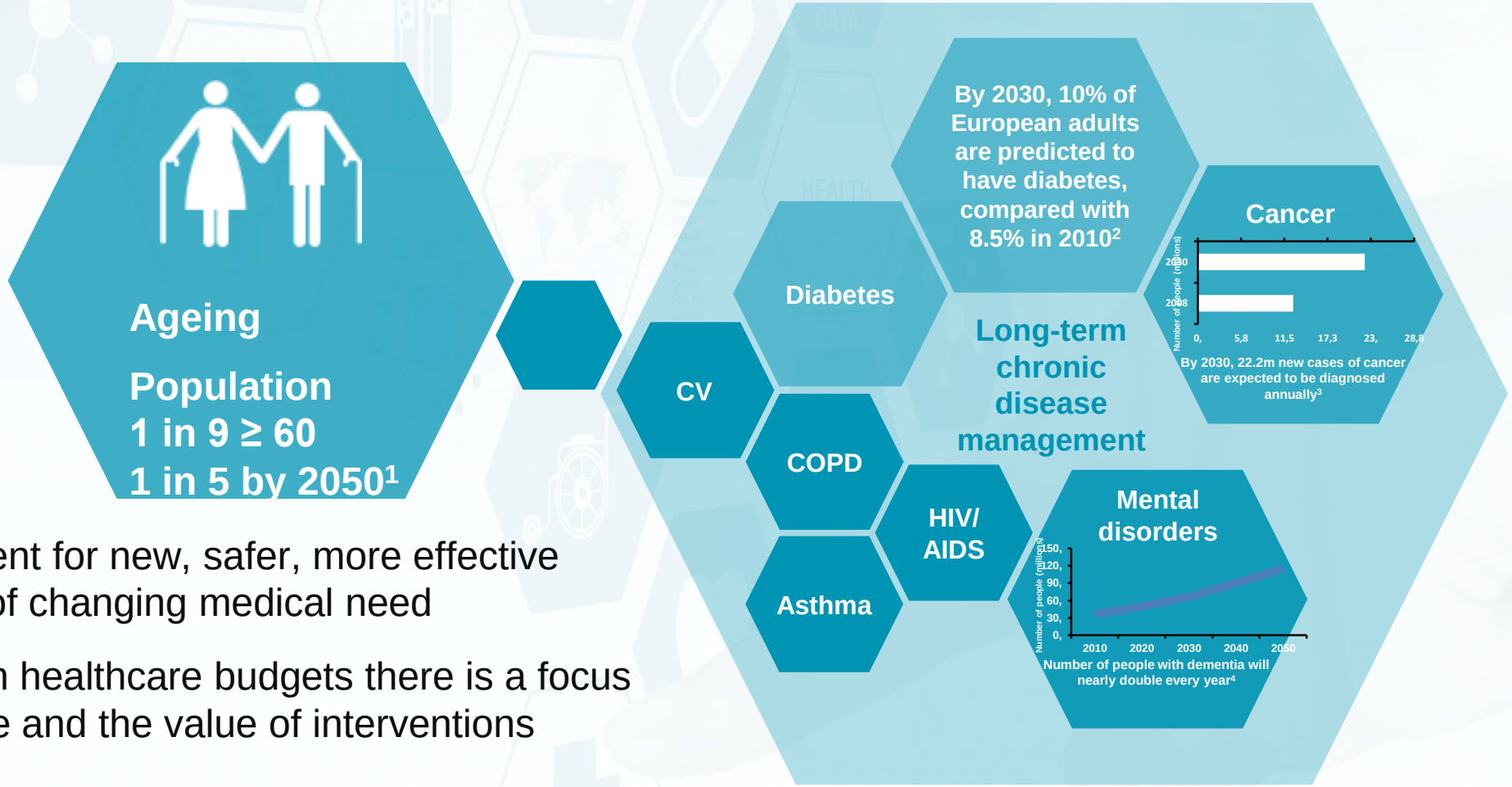


...asking the people who have had the operation is the way to find out.

Source: Trends in knee replacement surgery, 2000–2014, selected countries; OECD Health Statistics, 2016

Slide courtesy of Thomas Allvin, EFPIA

Treatment needs are changing



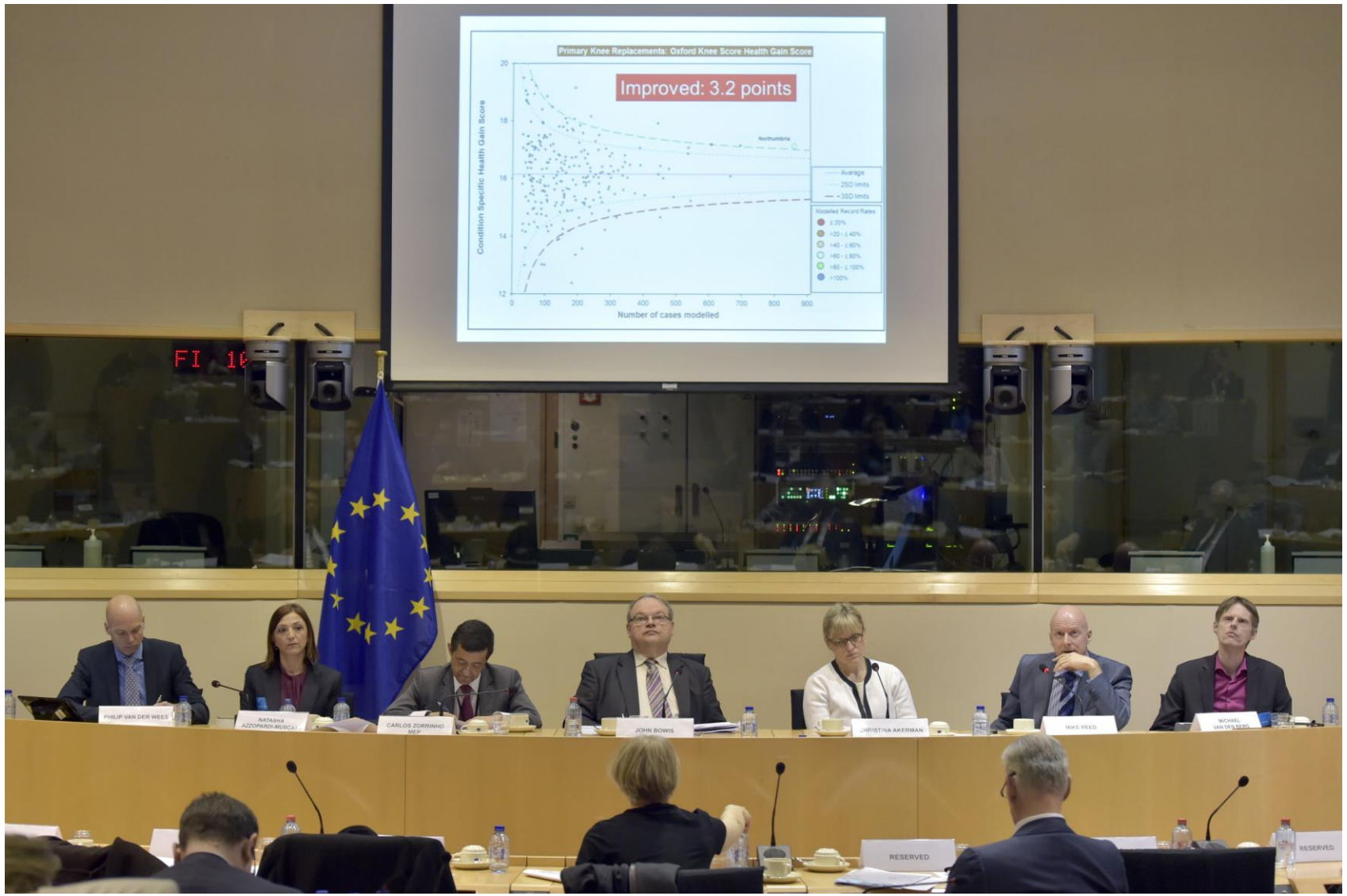
- There is a requirement for new, safer, more effective medicines in areas of changing medical need
- With the pressure on healthcare budgets there is a focus on best practice care and the value of interventions

1.http://www.unfpa.org/webdav/site/global/shared/documents/publications/2012/UNFPA-Exec-Summary.pdf
2.IDF Diabetes Atlas. Fifth edition. http://www.idf.org/diabetesatlas/europe. Last accessed October 2013

3. Bray F, Jemal A, Grey N, et al. Global cancer transitions according to the Human Development Index (2008-2030): a population-based study. Lancet Oncol 2012; 13(8):790-801.
4. Alzheimer's Disease International. http://www.alz.co.uk/research/statistics. Last accessed October 2013

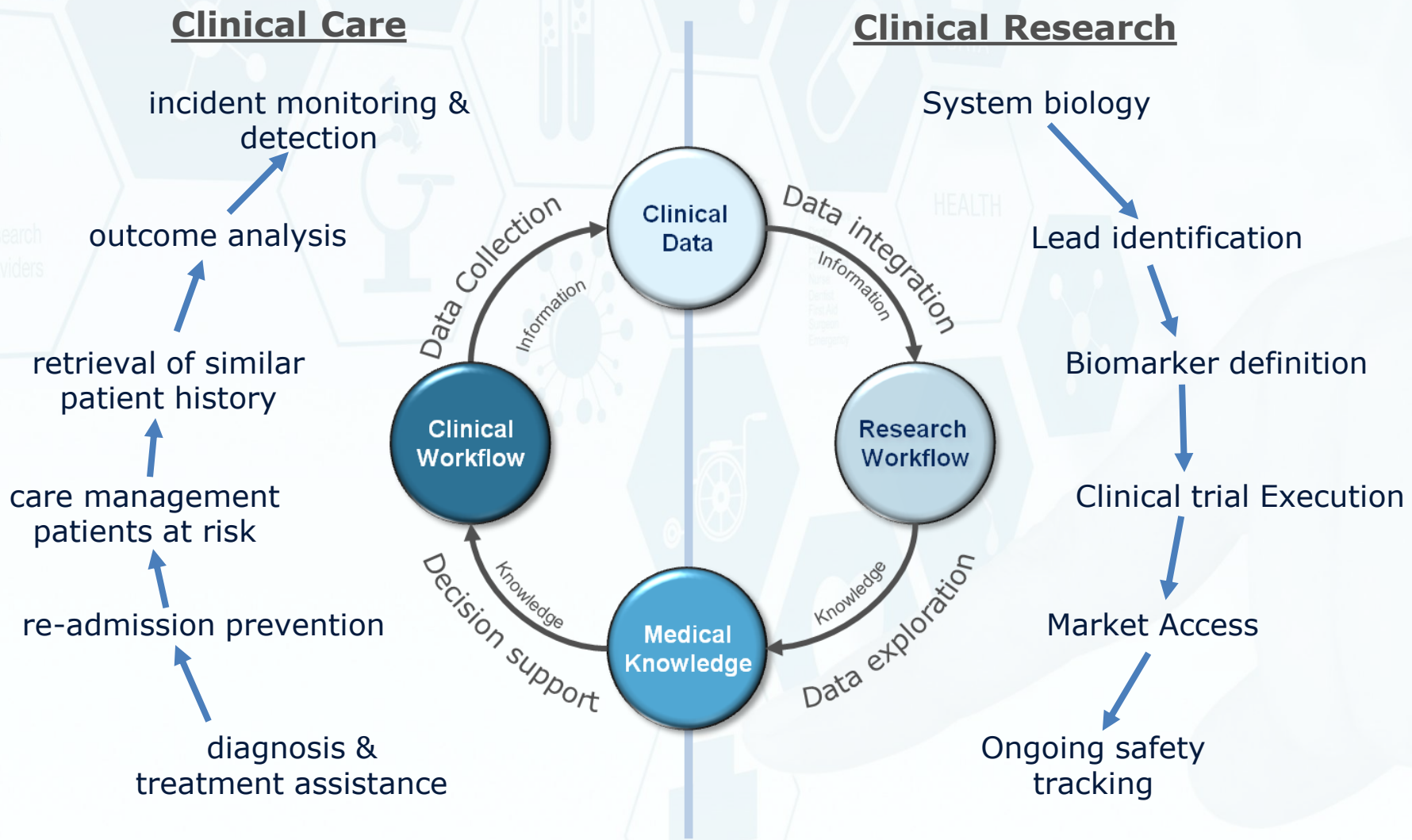
Value based health care as a solution

Focus on health outcomes measurement



Slide courtesy of Daniel Furby, FIPRA International

Learning Health Systems



Slide courtesy of Bart Vannieuwenhuyse, Janssen

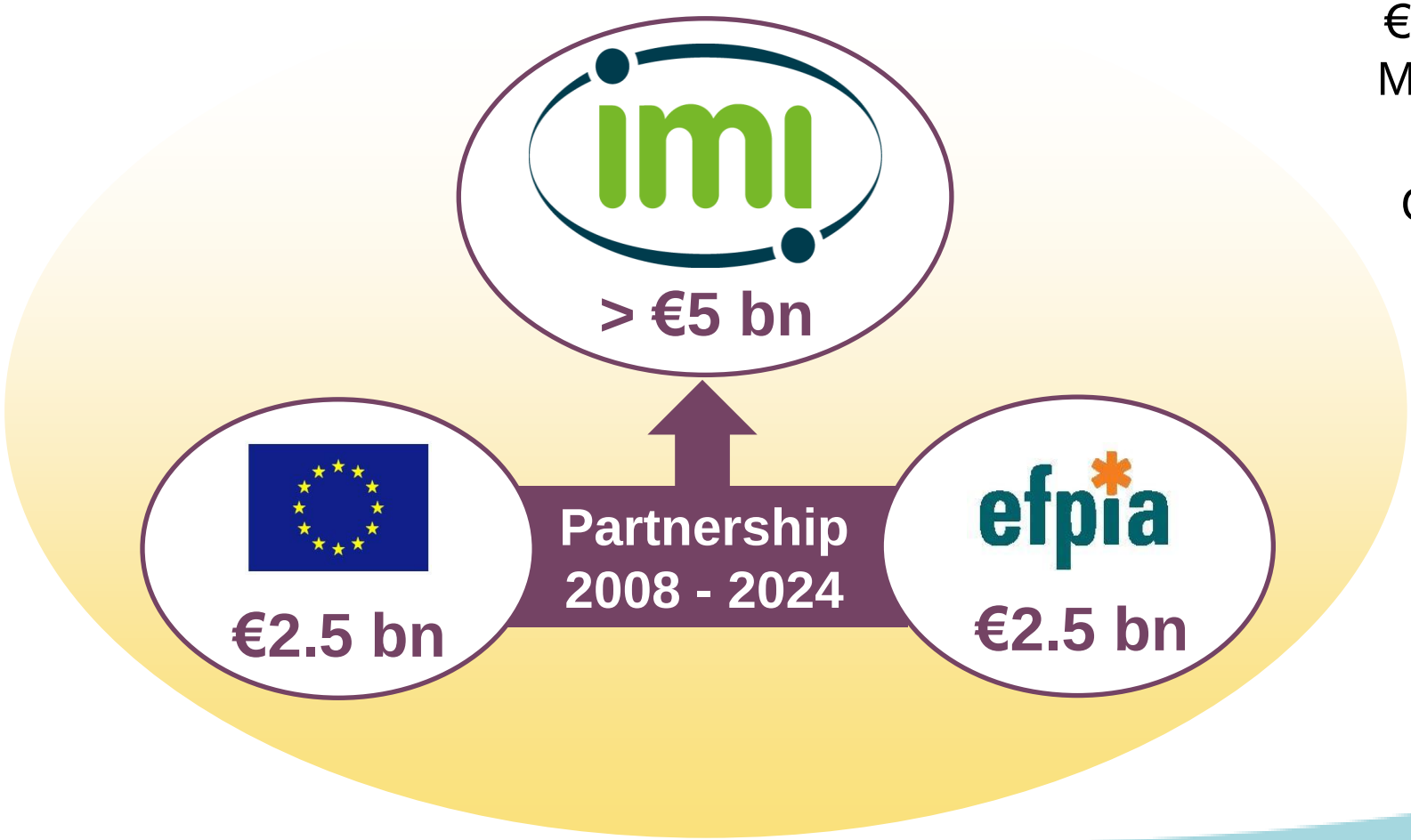
IMI – Europe's partnership for health

IMI1: 2008-2013

€2 bn budget
59 projects

IMI2: 2014-2024

€3.3 bn budget
More ambitious
More open
Greater scope



innovative medicines initiative

Slide courtesy of Pierre Meulien, Executive Director of IMI

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/

Innovative Medicines Initiative

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 results

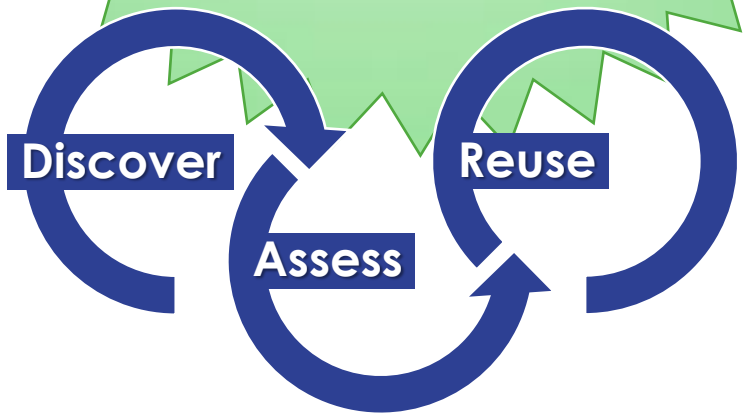
- An innovative platform to enable the trustworthy reuse of health data for research
- The platform can connect securely to the data within multiple hospital EHR systems and clinical data warehouses across Europe
- It enables trial sponsors (e.g. pharma) to
  - predict the number of eligible patients for a candidate clinical trial protocol
  - assess its feasibility and to locate the most relevant hospital sites
- It enables connected hospitals to
  - efficiently identify and contact the patients who may be eligible for particular clinical trials
- Now being deployed commercially: the InSite Platform, by Custodix

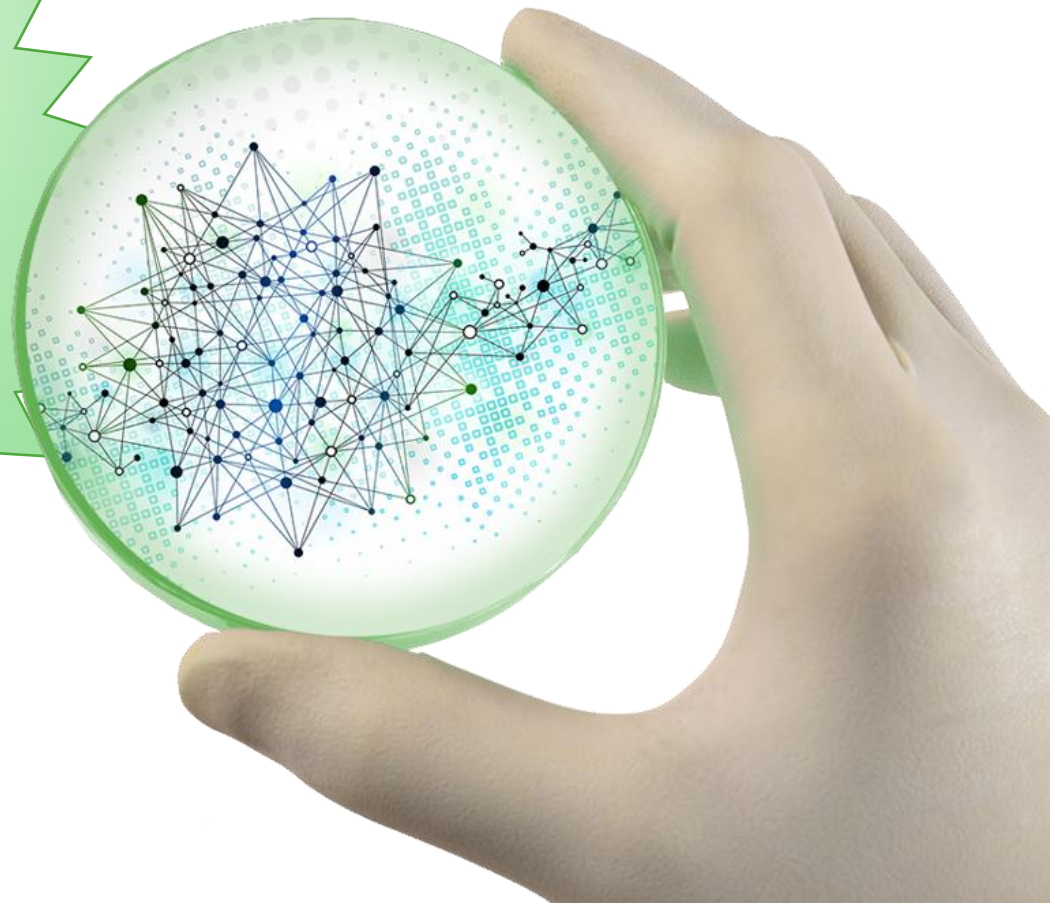
2016 – 2017 Champion Programme

“A multi-stakeholder collaboration aiming to accelerate and ensure the future of clinical research in Europe.”

EMIF vision

To become the trusted European hub for health care data intelligence, enabling new insights into diseases and treatments





Slide courtesy of Bart Vannieuwenhuyse, Janssen

EMIF overview

ACADEMIC PARTNERS 37

SME PARTNERS 9

EFPIA PARTNERS 10

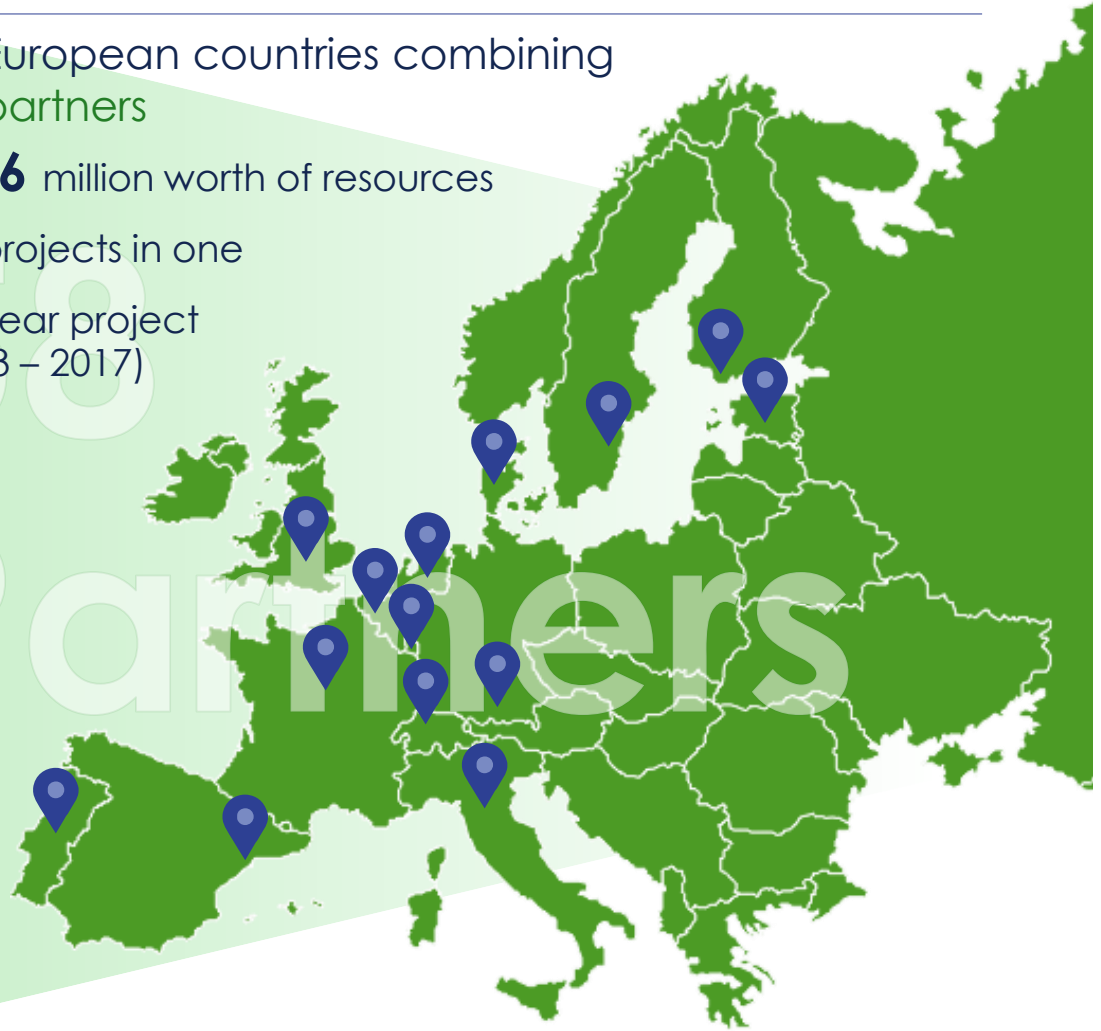
PATIENT ORGANISATION 1

14 European countries combining
57 partners

€56 million worth of resources

3 projects in one

5 year project
(2013 – 2017)



Slide courtesy of Bart Vannieuwenhuyse, Janssen

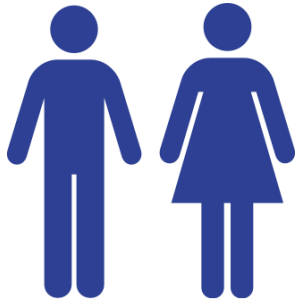
Available data types

Large variety in "types" of data

- Primary care data sets
- Hospital data
- Administrative data
- Regional record-linkage systems
- Registries and cohorts (broad and disease specific)
- Biobanks
- Secondary care data sets
- Paediatric data sets

Data is available from more than 40 million subjects from six EU countries, and in addition:

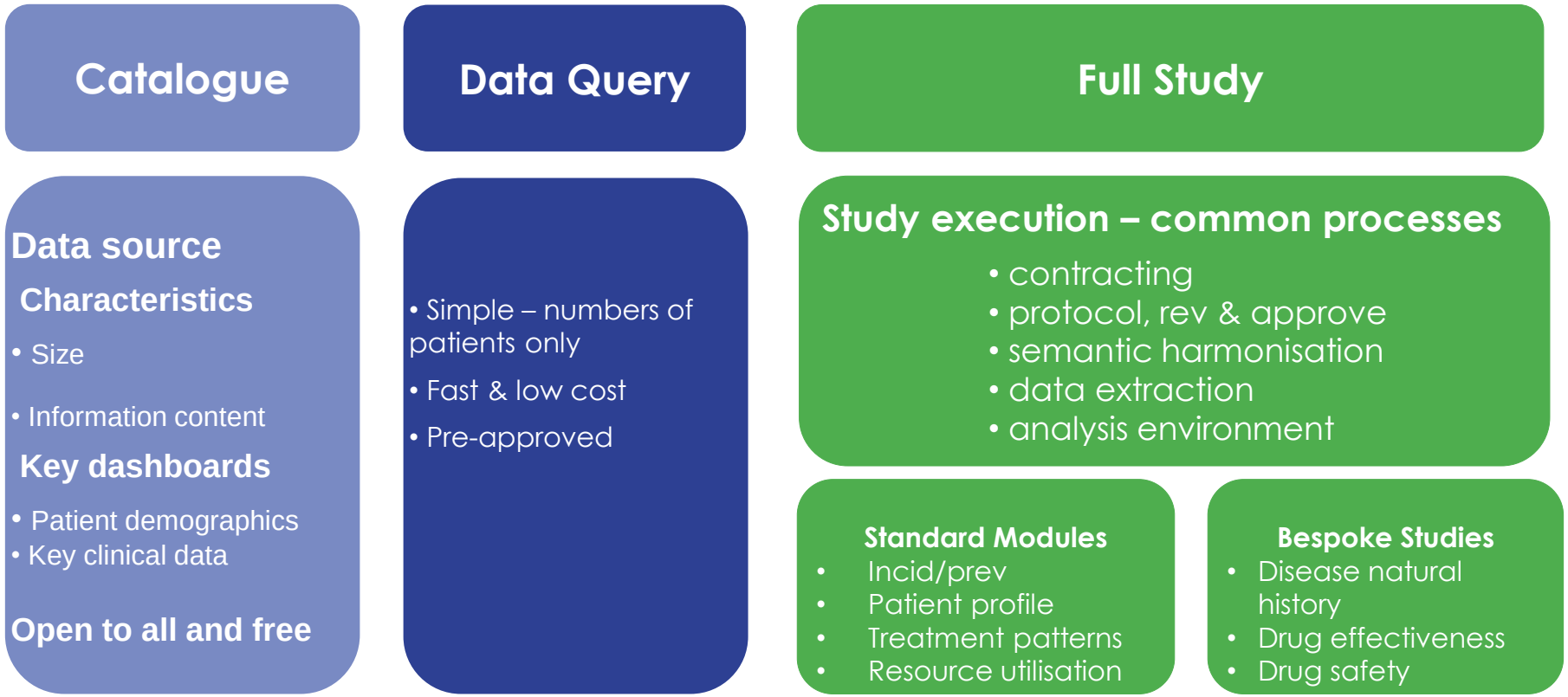
25,000 subjects in AD cohorts



more than **94,000** subjects in metabolic cohorts

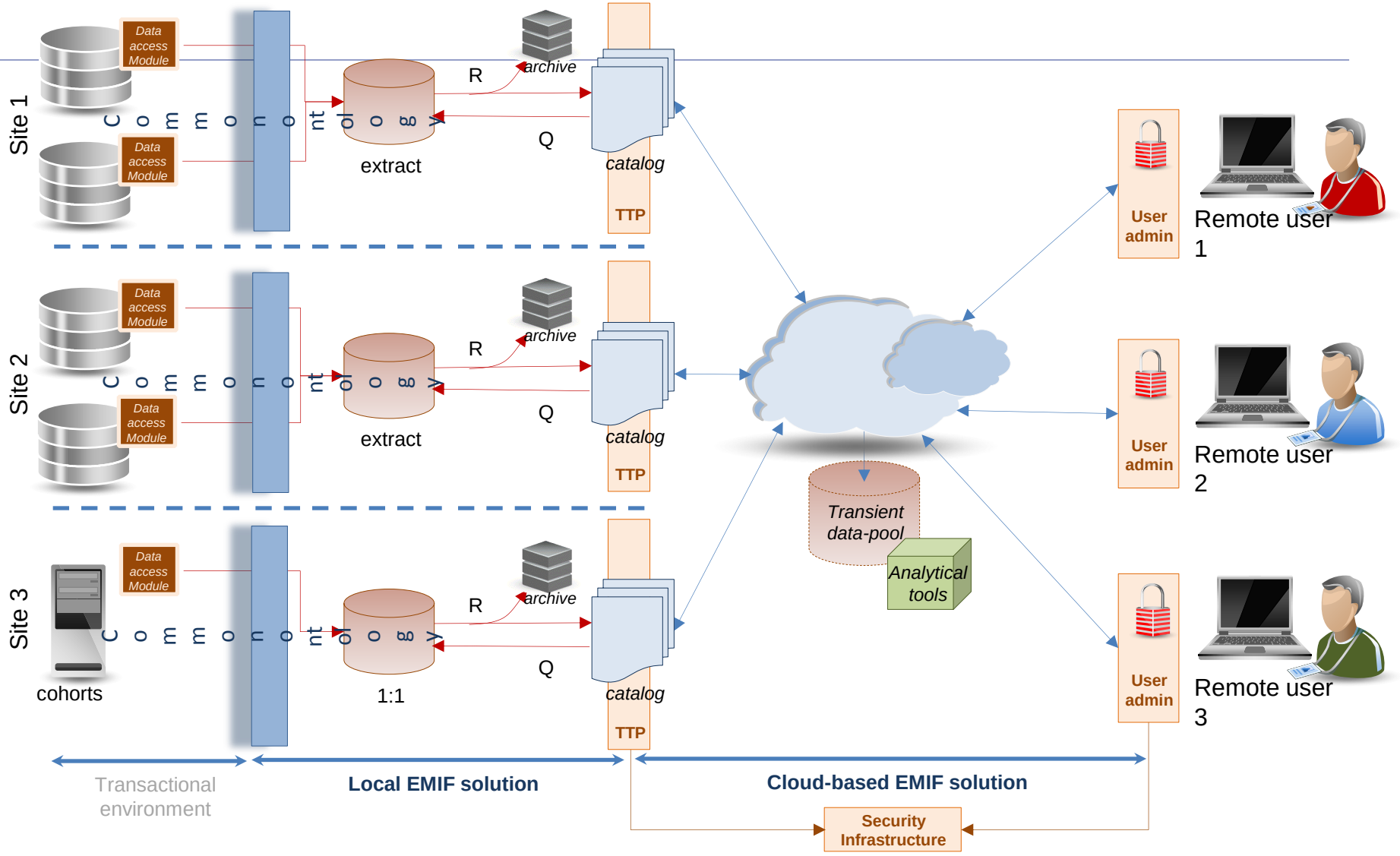
Slide courtesy of Bart Vannieuwenhuyse, Janssen

A Common Environment for the federated data network

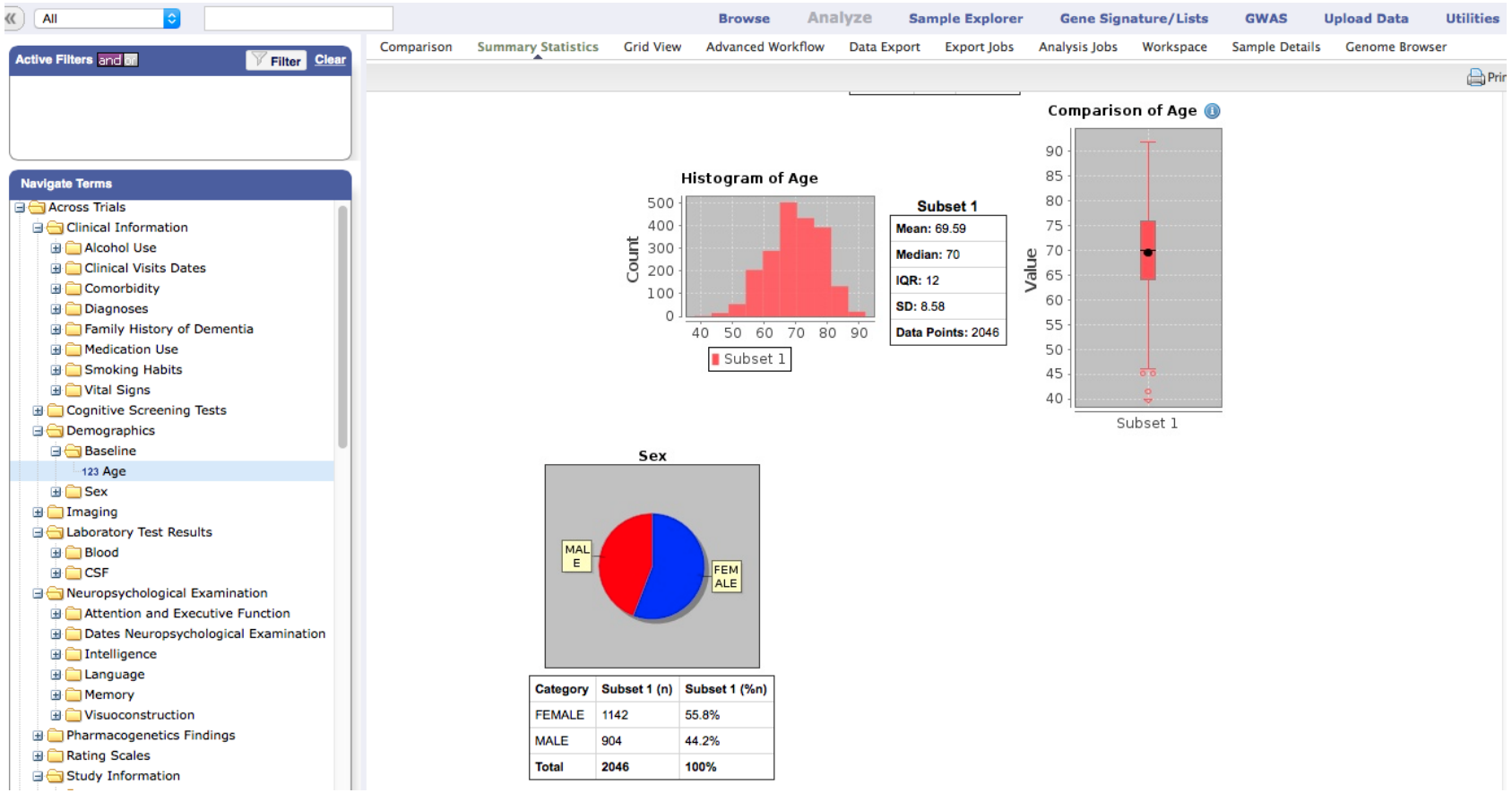


Slide courtesy of Peter Egger, GSK

Data Discovery → Data Access → Data Reuse



EMIF-AD tranSMART dataplatform



Slide courtesy of Peter Egger, GSK

Hunting for biomarkers…

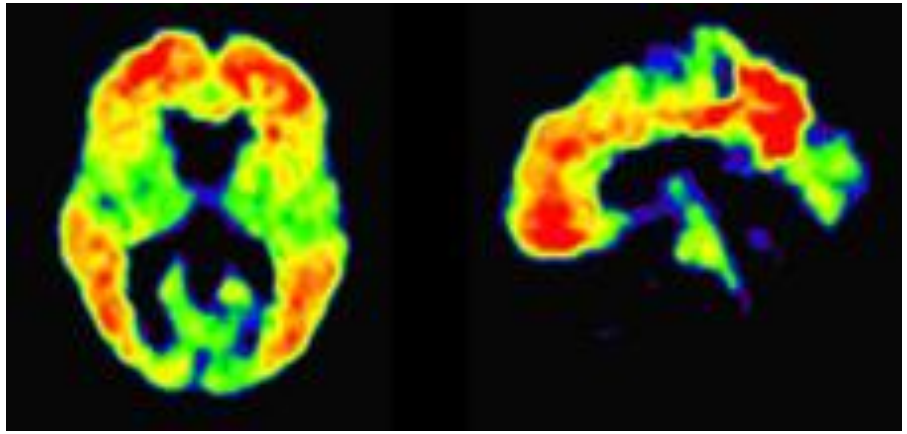
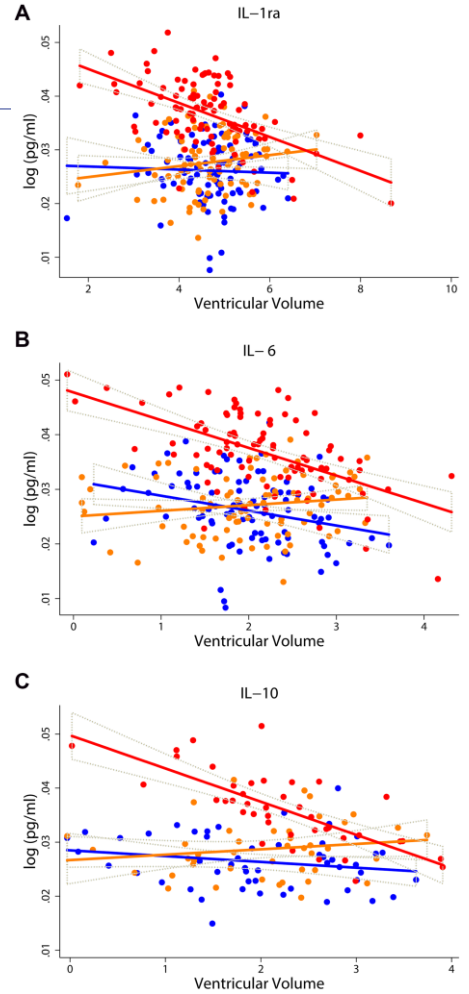


Image courtesy of Pieter Jelle Visser, VU University Medical Centre, University of Maastricht



Leung R, Proitsi P, Simmons A, Lunnon K, Güntert A, Kronenberg D, et al. (2013) Inflammatory Proteins in Plasma Are Associated with Severity of Alzheimer's Disease. PLoS ONE 8(6): e64971

Common challenges to the use of health data for person centred care, and the re-use of health data for clinical research

Privacy protection, ethics and security

accessing data

Quality and interoperability of health data

learning from the data

Demonstrating value

transforming healthcare


To guide and catalyse the best, most efficient and trustworthy uses of health data and interoperability,
for optimising health and knowledge discovery

i~HD was formed because a complementary, neutral and not-for-profit organisation was found to be needed

- **to play a central role in defining governance for,** and expanding, a trustworthy health data driven ecosystem including EHRs and clinical research platforms
- **to promote the adoption of healthcare standards and of data quality**, to enable more effective, safer and better integrated healthcare
- **to act as a connector between health care and clinical research standards**, that are presently developed in silos and impair the interoperability and pooling of health data for research
- **to promote to society the importance of using health data for research**, to improve efficiency through reduced duplications, delays, costs enhance speed and efficiency in clinical studies

i~HD aims to foster multi-stakeholder collaboration

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Goal of i~HD: assuring public trust when reusing EHRs for research

- Compliance with data protection legislation, at a European level and across all European Member States
- Consistent information governance practices and expectations across Europe
  - Societally acceptable codes of good practice for governing many uses of health data
  - Reflect state of the art in privacy protection and information security
  - Greater confidence and reduced risk for those providing data for research use e.g. hospitals, GPs, patients
  - Greater confidence and reduced risk for those performing the research, managing the data or sponsoring the research
- Greater societal endorsement of public health and research uses of health data
- A scaling up of learning from health data, leading to more rapid innovation in treatments, and accelerated health system transformation towards better health outcomes

i~HD Governance Principles for Clinical Research Platforms

Introduction

These principles cover the appropriate operation of clinical research platforms, services, tools and applications by various parties:

- Research Centres (RCs) carrying out feasibility studies and commissioning clinical trials.
- Recruitment Sites/Data Providers, usually hospitals, which make their data available for distributed queries to determine possible numbers of patients matching the eligibility criteria of tentative trial protocols with the aim of participating in subsequently commissioned clinical trials, and make use of supplied applications and services to identify potentially eligible patients within their site.
- Service Providers (SPs) which provide the infrastructure, tools, applications and services to allow the exchange of distributed queries and aggregate statistics between Research Centres and Recruitment Sites, and supply applications for use within a Recruitment Site to locally identify potentially eligible patients.
- The *European Institute for Innovation Through Health Data* (i~HD) which provides oversight and rules for the appropriate governance of the overall Platform

These principles are a high-level articulation of requirements which are further codified in other documents as rules to be followed and standard operating procedures to be implemented.

The principles are grouped as those relating to the design of systems, the operational procedures, and organisational structures.

Organisational

Effective Information Governance: organisations need to pro-actively monitor for possible misuse or accidental breaches, review their processes and procedures, and collaborate with other actors involved in developing, operating and using the clinical research platform, and with i~HD, to ensure that overall approaches are effective.

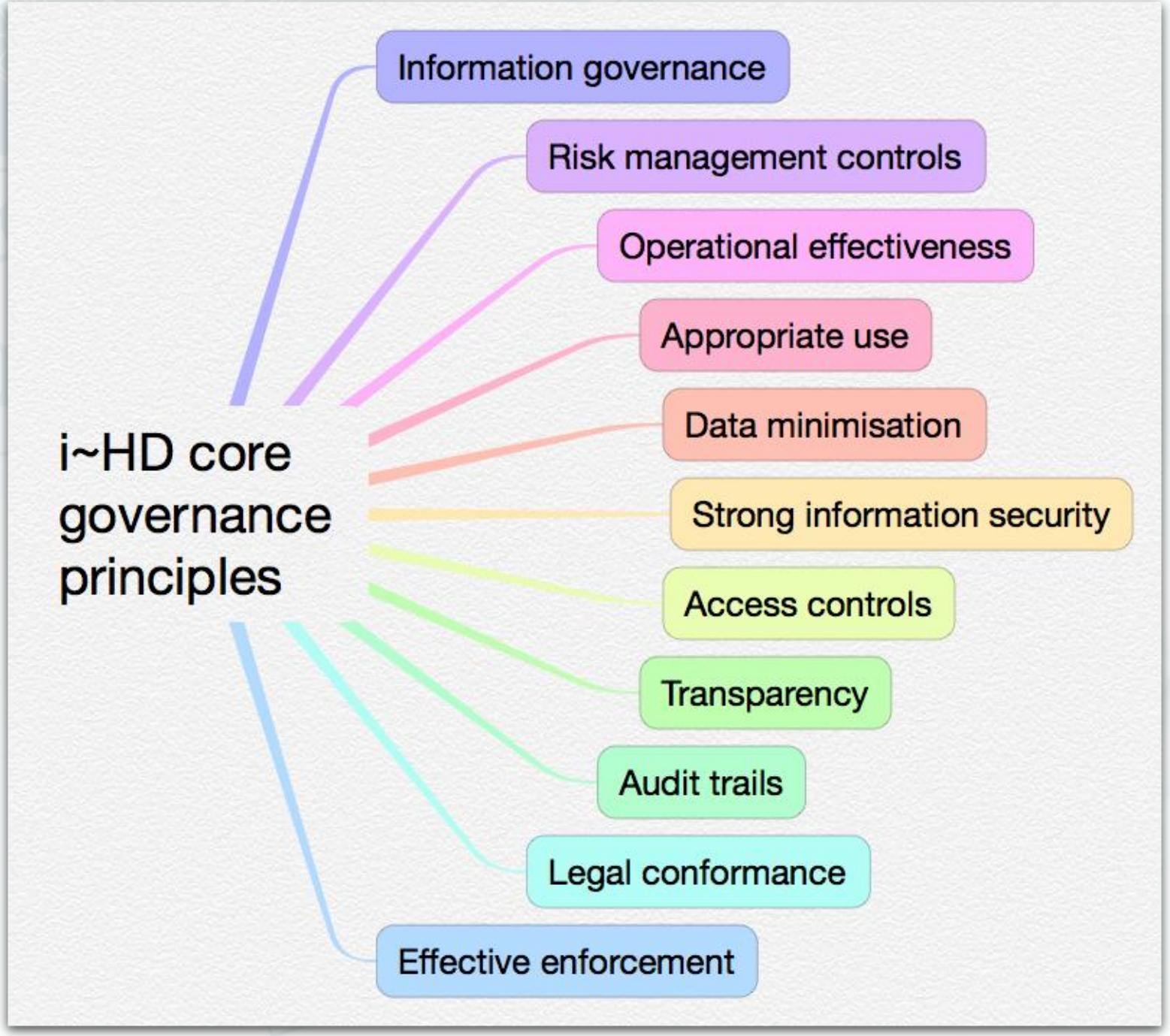
Transparency: organisations need to ensure that their purpose and operations should be overt and comprehensible to all stakeholders, except where this might compromise security and effectiveness – *this includes informing patients and the wider public about the benefits from and controls on the use of their medical information, either directly or through their healthcare providers.*

Adequate Training & Resourcing: organisations need to ensure that they have the necessary skills, knowledge, and resources to provide effective information governance (alongside other organisational obligations) – *this includes ensuring that staff using a clinical research platform are aware of and have been appropriately trained in, relevant areas of information governance, privacy protection, and security practices.*

Effective enforcement: there must be clear contractual obligations so that sanctions can be applied to individuals responsible for any misuse– *data controllers must be able to rapidly suspend accounts or specific processing to prevent further misuse; there need to be effective processes to handle appeals against any sanctions or suspension.*

Clarity of authority: – there must be specified points of contact and levels of authorisation for any decisions that need to be taken to handle an incident or effect a resolution – *this includes have clear instructions for staff as to how to report possible misuse.*

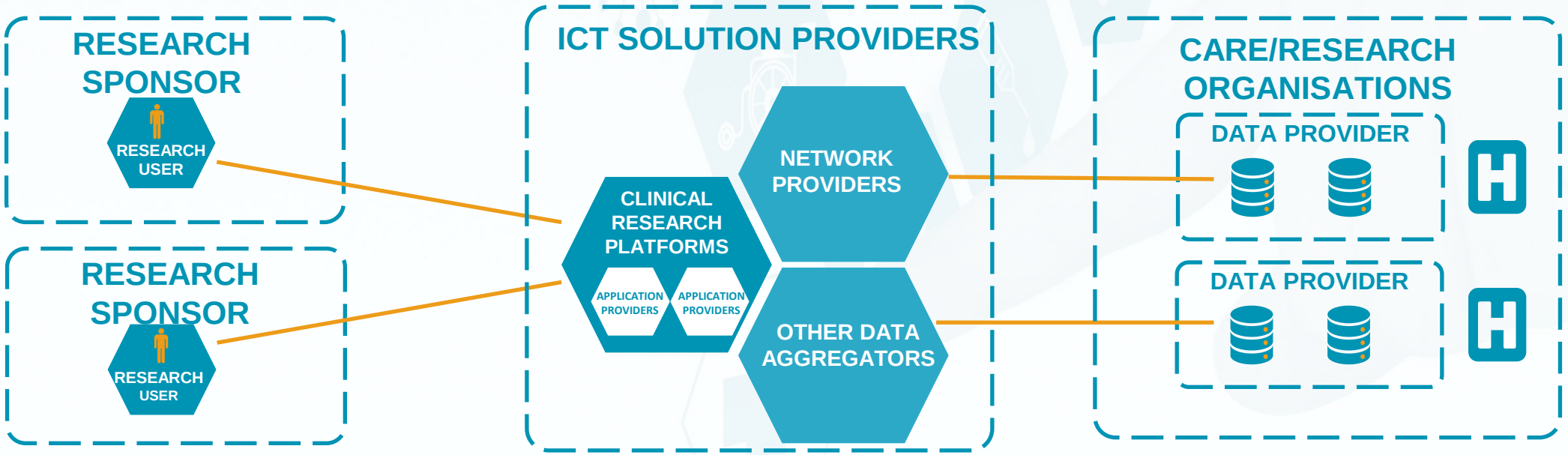
Legal conformance: it is expected that organisations will meet relevant European, national and local data protection and privacy legislation and policies, including health-specific requirements pertinent to the nations in which they operate – *this would include meeting other industry-accepted good practice guidance. Note that this includes the principles of data minimisation and information security.*



i~HD information governance priorities

Best practices and voluntary codes of practice

- Educate and train research and ICT staff
- Accredit staff and organisations
- Certify service providers and EHR systems
- Oversee and audit governance & security



Citizens juries

- https://www.connectedhealthcities.org/get-involved/citizens-juries/

Jury members share their thoughts on the use of health data for purposes beyond their direct care.

Slide courtesy of Mary Tully, Director of Public Engagement
CHC, University of Manchester

CONNECTED HEALTH CITIES
A nhsa project

What can we learn from the CHC Citizens Juries?

- Plans that produced explicit public benefit more acceptable than those that improved "efficiency"
- Particularly concerned about:
  - whether improving efficiency would (once again) lead to inequitable distribution or closure of services
  - whether the lack of funding or political will to implement new services would lead to dissatisfaction due to expectations having been falsely raised
- Potential uses should clearly communicate the possibility for improvements in drugs, treatments, and other healthcare at lower costs for NHS
- Some jurors became more accepting of commercial uses as they understood them better
- Commercial uses that did not produce actual health benefits were unacceptable, regardless of data safeguards
- Commercial gain should be secondary to public benefit

CONNECTED HEALTH CITIES
A nhsa project

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Essential needs for interoperability

- Guideline and decision support systems, notification and alerting components, and analytic tools need to process integrated health data drawn from multiple EHR systems in a consistent manner
- Intelligent personal health guidelines interoperating with PHRs and EHRs need to support the centring of care on patients
- Health services, insurers and public health bodies need fine grained activity and outcome data to inform service planning, commissioning and prevention/wellness programmes
- New generation personalised medicine, underpinned by ‘omics sciences and translational research such as the VPH, needs to integrate EHRs with data from research: fundamental biomedical science, clinical and population health research, and clinical trials

Overview of assets used to represent clinical meaning

Concept representation

- Hierarchical terminology systems
- Post-coordinated terms
- Ontology
- Defined subsets of terms

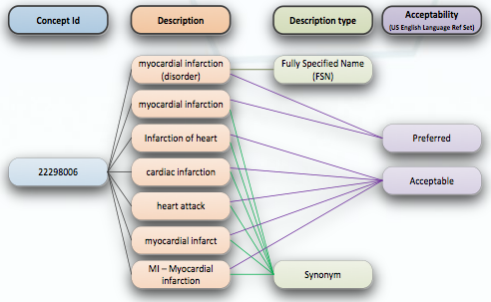
EHR information models

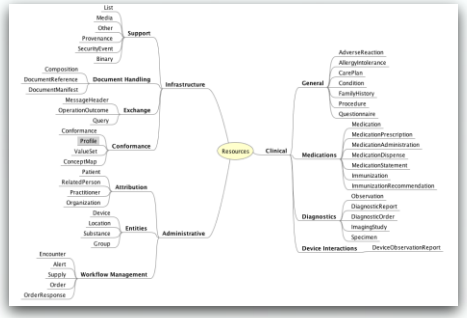
- EHR reference models
- Clinical document registries

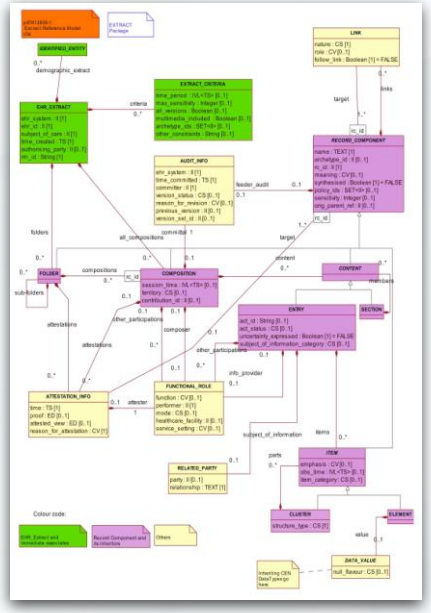
Use Case Driven

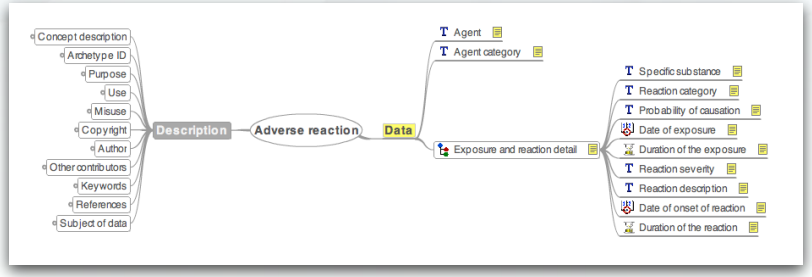
Clinical models

- Archetypes
- Templates
- Datasets
- Data dictionaries

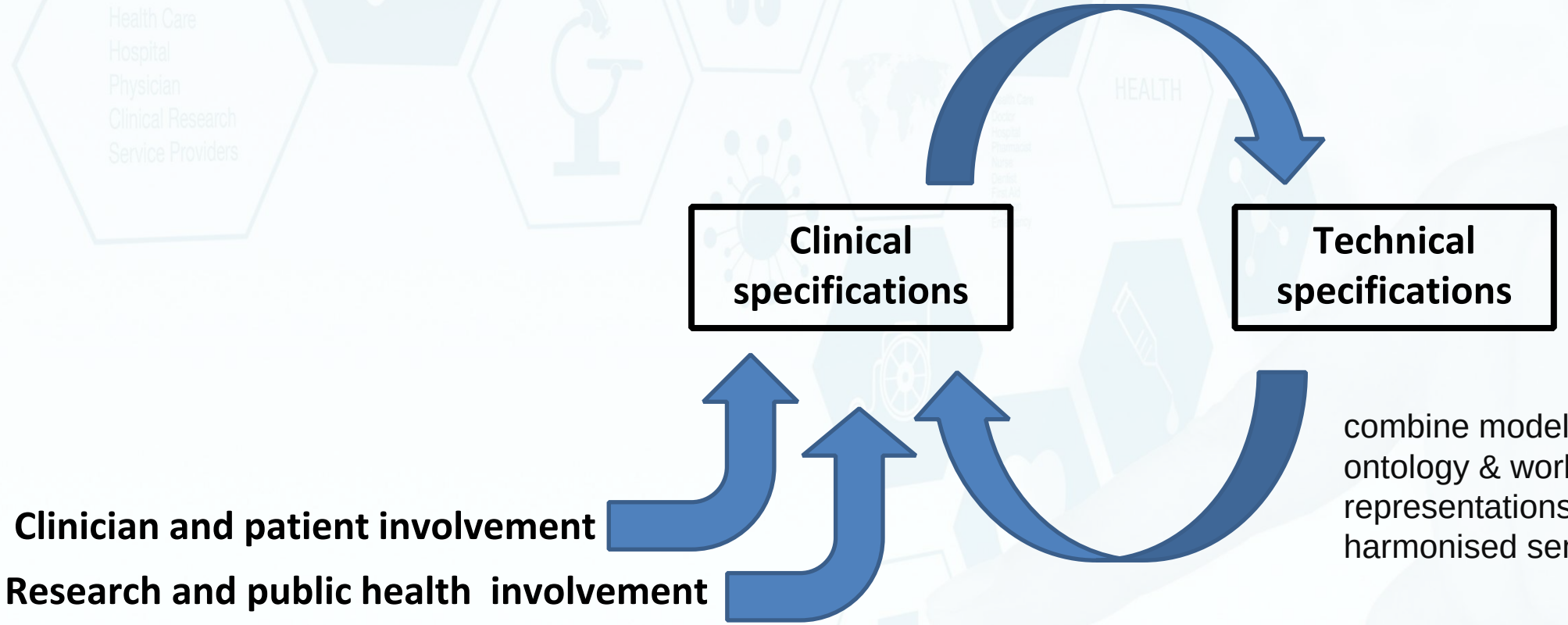








Developing good practices in the collaborative development of standards



combine modelling, terminology, ontology & workflow representations to produce harmonised semantic resources

Slide courtesy of Robert Vander Stichele

i~HD European Network of Excellence for Hospitals Aims:

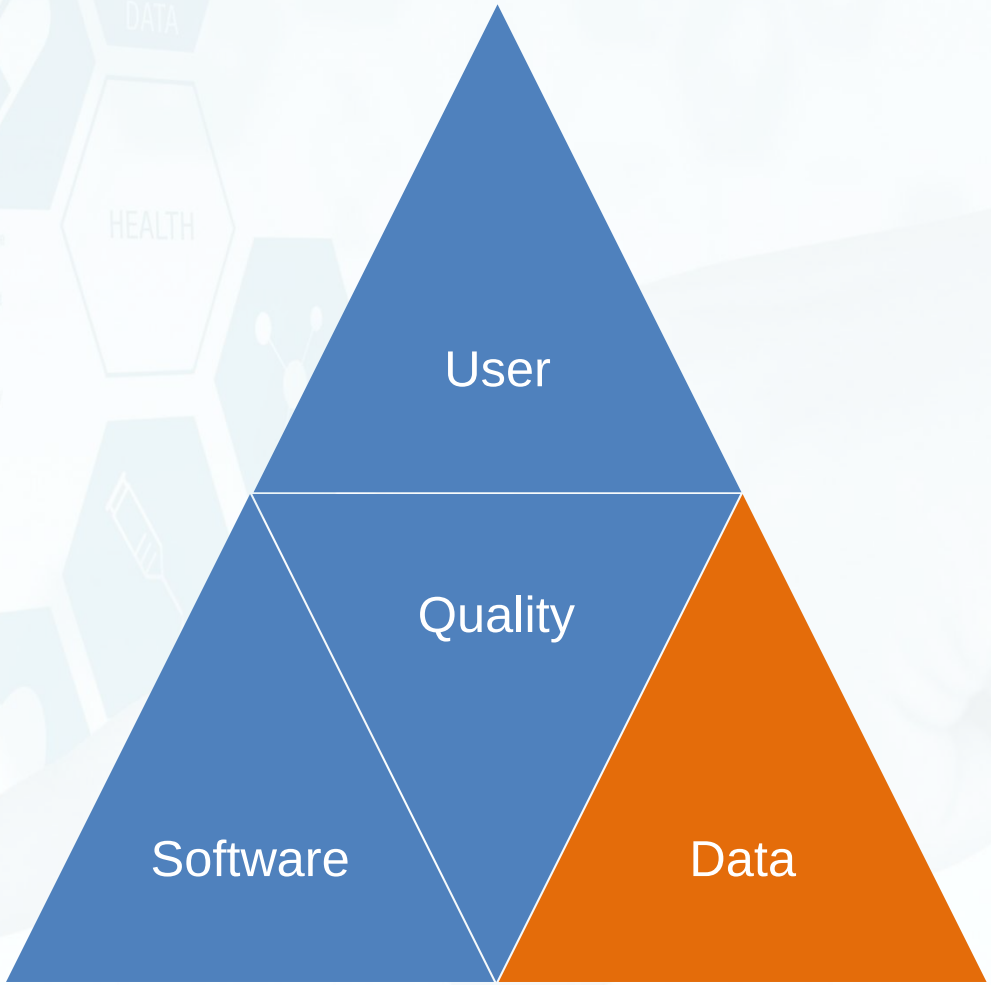
- to support European hospitals (and, later, other care providers such as general practice)
  - to collect health data of the highest possible quality
  - to make the best use of their health data internally (for patient care and for organisational quality improvement)
  - to make the best use of their health data externally (supporting continuity of care, public health strategy and research that is publicly funded and industry sponsored)

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

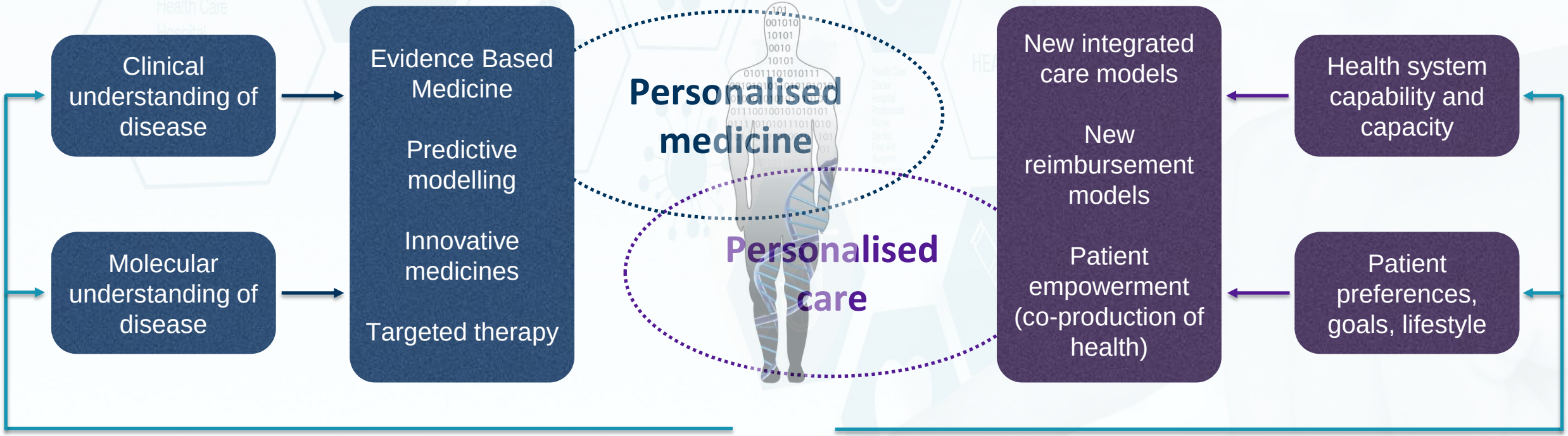
➔Focus on three areas:

- ➔ Healthcare
- ➔ Clinical trials
- ➔ Big data

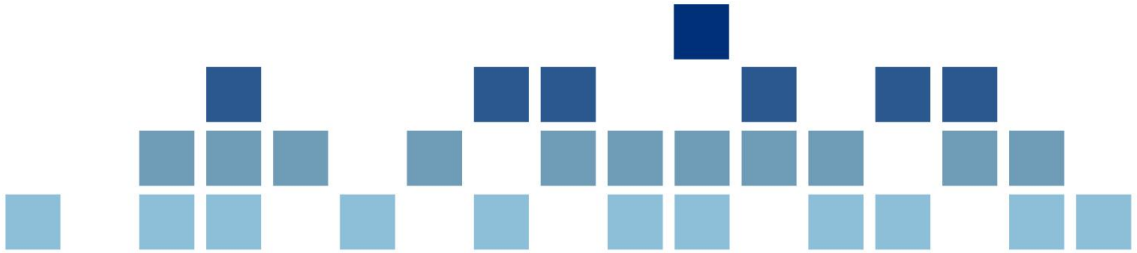


Slide courtesy of Pascal Coorevits, Ghent University & EuroRec and Carlos Sáez, Universitat Politècnica de València

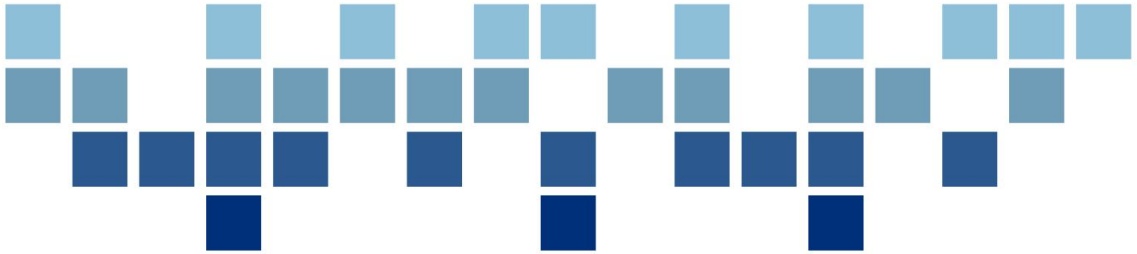
Personalised health……and Learning Health Systems



…are critically dependent on interoperable big health data



The European Institute For Innovation Thr~ugh Health Data



i~HD

Enriching knowledge and enhancing care through health data