

The European Institute For
Innovation Through Health Data



Patients
Health Care
Hospital
Physician
Clinical Research
Service Providers

THE INCREASING OPPORTUNITIES FOR USING HEALTH DATA AS A TOOL FOR CLINICAL RESEARCH

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President of i~HD

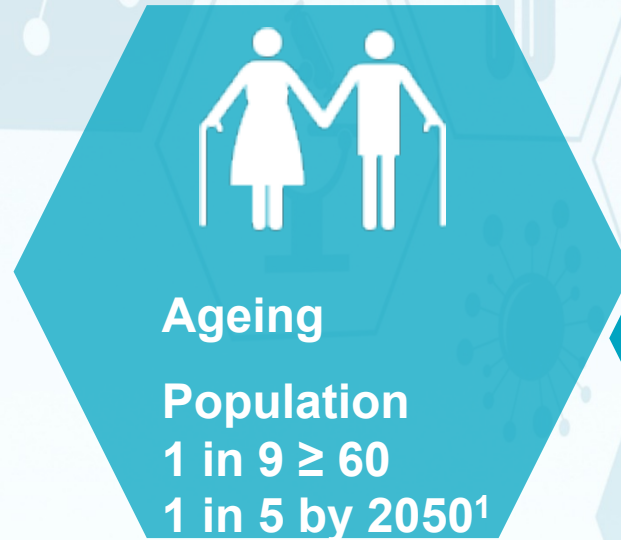
DATA

HEALTH

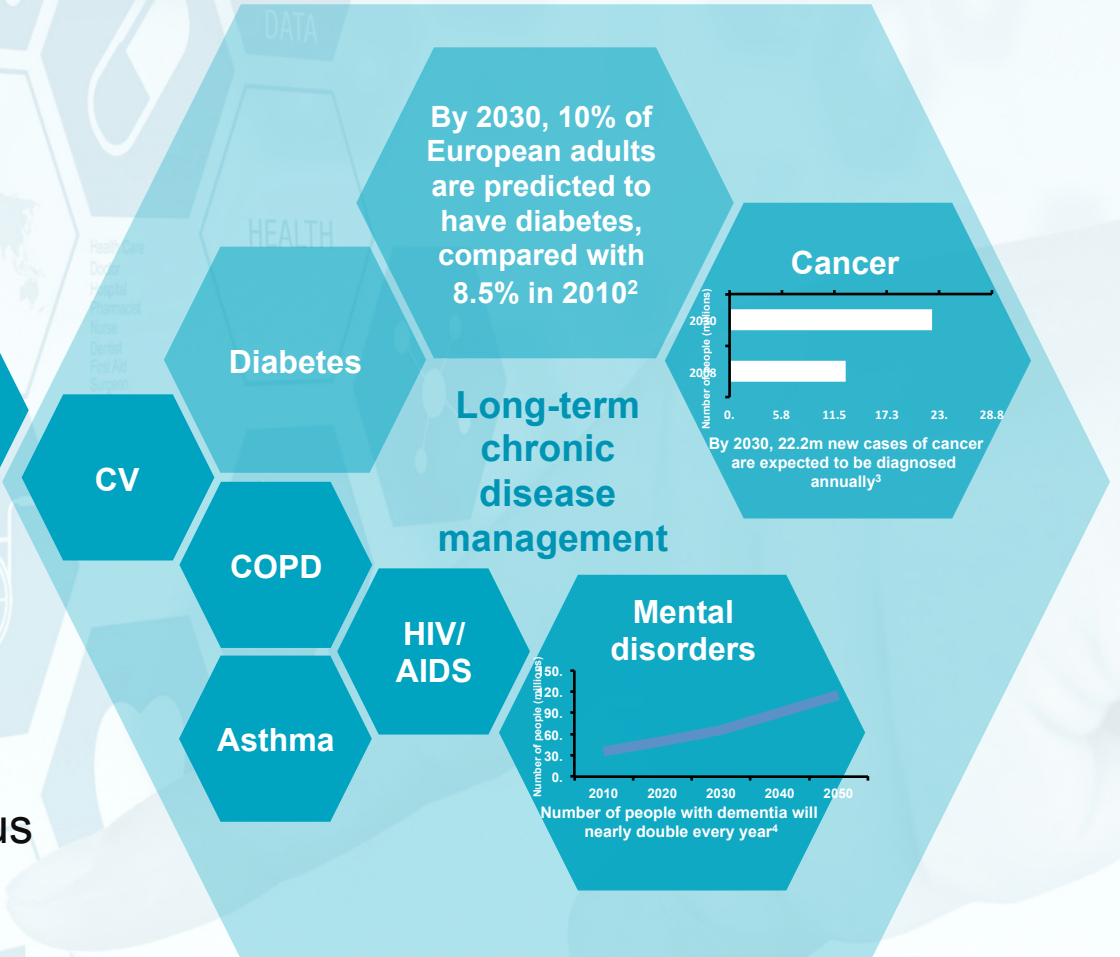
Health Care
Doctor
Hospital
Pharmacist
Nurse
Dentist
First Aid
Surgeon
Emergency

Treatment needs are changing

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- 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

We need to accelerate Life Science innovation

A large number of medicines are in development in order to...

- leverage new science
- expand treatment options
- improve quality of life
- provide value for money

Medicines in Development in 2012

Alzheimer's Disease 72	Cancer 948	Colorectal Cancer 85
Cardiovascular Disorders 252	Arthritis 76	Lung Cancer 141
HIV/AIDS 88	Diabetes Mellitus 212	Leukemia 139
Parkinson's Disease 24	Mental Disorders 255	Skin Cancer 85
Rare Diseases* 460	Respiratory Disorders 398	Breast Cancer 132

Source: PhRMA 2012 Profile of the Pharmaceutical Industry


personalised
medicine


Sequencing of the
Human Genome

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 US¹



Almost

half of all trial delays caused by patient recruitment problems²



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

\$8m³



50%

of today's clinical trials fail to achieve the target recruitment rate⁴

1. State of the Clinical Trials Industry: A Sourcebook of Charts and Statistics, Center Watch, 2008.

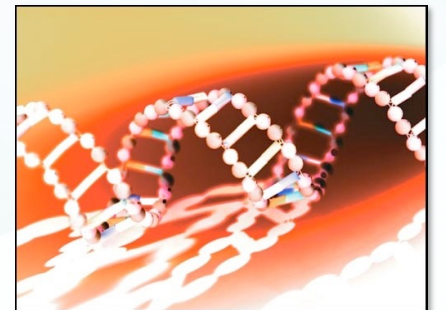
2. Study Participant Recruitment and Retention in Clinical Trials: Emerging strategies in Europe, the US and Asia, Business Insights, June 2007.

3. Beasley, "Recruiting" 2008

4. Tufts -<http://clinicalperformancepartners.com/wp-content/uploads/2012/07/Fixing-Feasibility-Final-Jan-2012.pdf>

Trends in healthcare and EHRs

- Patient-centered, life long records
- Multi-disciplinary / multi-professional
- Transmural, distributed and virtual
- Structured and coded (cf. semantic interoperability)
- More metadata and coding at a granular level!
- Intelligent (cf. decision support), clinical pathways...
- Predictive (e.g. genetic data, physiological models)
- More sensitive content (privacy protection)
- Integrative
- Personalised



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/>



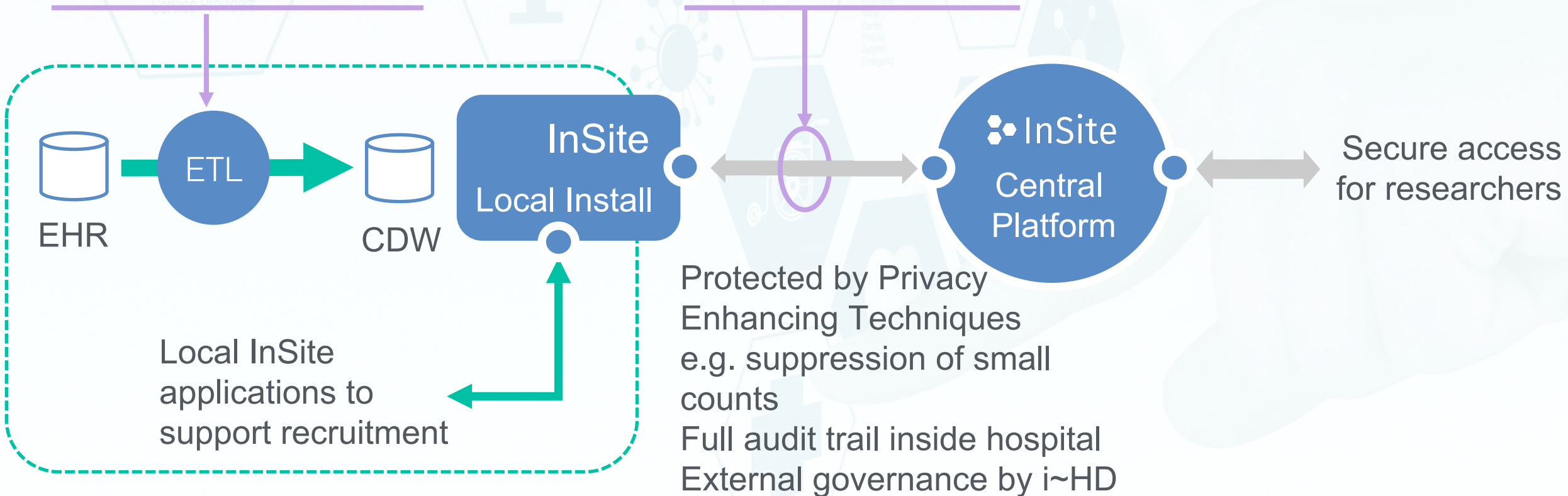
Electronic Health Records for Clinical Research

- EHR4CR has developed 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

InSite – Technical Overview, for Protocol feasibility

Custodix provides expertise and tools to support local sites with mappings

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



InSite – Protocol feasibility query

InSite An EHR4CR Service Platform
Study Design Study Recruitment
1.1-SNAPSHOT Custodix 2016 Notifications Brecht Claerho...

Search

⚙️ Edit workset properties

All Drafts Final

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

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

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

STATUS

Sites succeeded: 2
Sites failed: 1
Sites loading: 0

download excel

Executed on Apr 21, 2016.

SITE THRESHOLD

Minimum patient matches in site:

SITE SELECTION

All sites
 Selected sites

CRITERIA SELECTION

All criteria
 One criterion

Feasibility study overview > Non-insulin-dependent diab... > Baseline query > Version 2 > Query Results

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

Patient Reach for Baseline query

58*
PATIENTS

23.2%

PATIENT TOTAL
TARGET N=250

34*
NETHERLANDS

45.79%

PATIENT SCORE
PER COUNTRY

34*
MCW

45.79%

PATIENT SCORE
PER SITE

Site & Country Scores

PATIENT MATCHES PER COUNTRY

Netherlands United Kingdom

PATIENT MATCHES PER SITE

MCW EHHT

⌵ COUNTRY ⌵ ALL PATIENTS ⌵ MATCHING PATIENTS

⌵ SITE ⌵ ALL PATIENTS ⌵ MATCHING PATIENTS

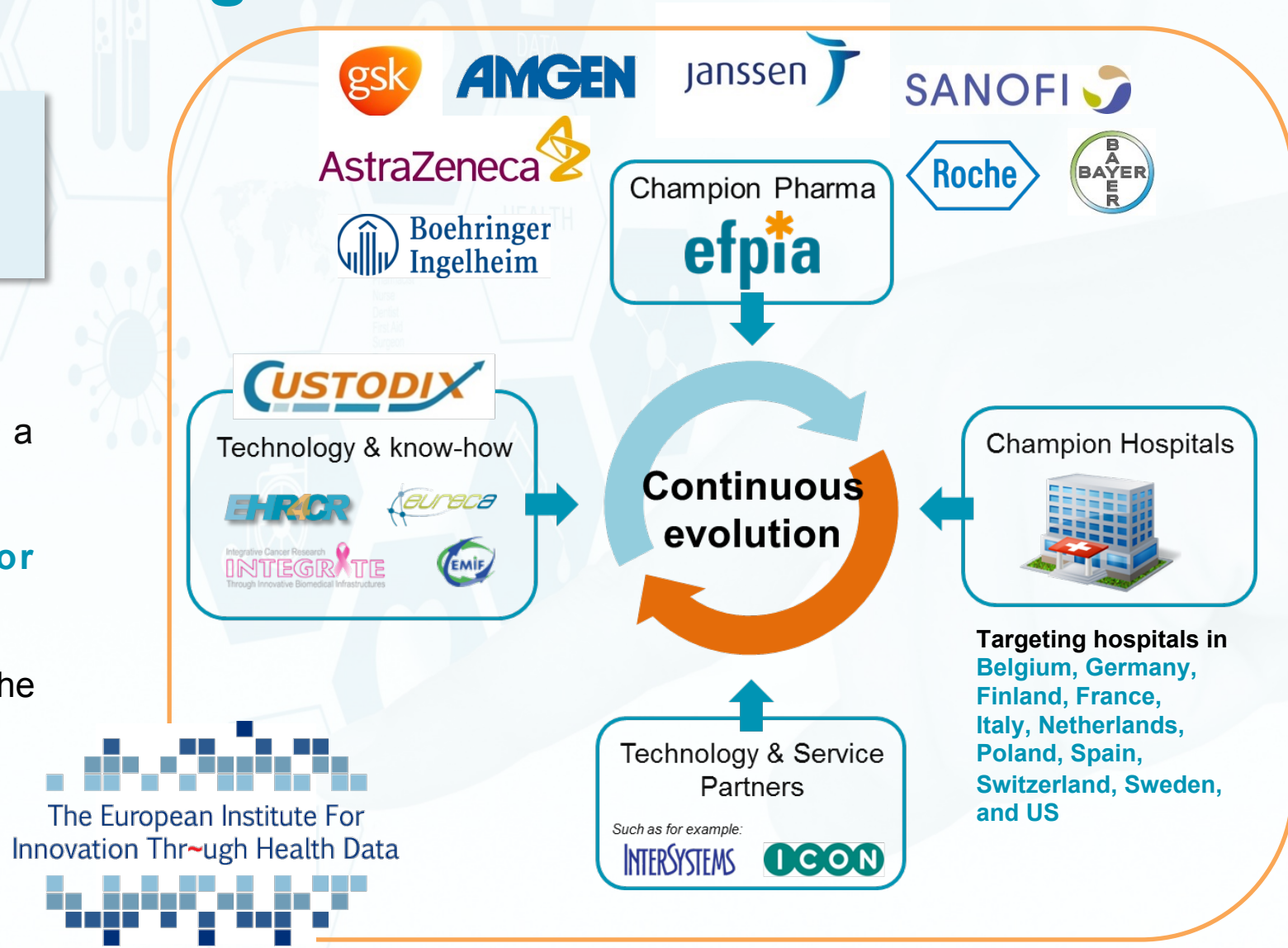


2015 – 2016 Champion Programme

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

The Champion Programme serves to:

- Further **validate and improve** technology
- Define (refine) the rules of engagement for a **sustainable ecosystem**
- Start building a **network of hospitals**
- Engage with **European Institute for Innovation through Health Data**
 - an European not-for-profit entity
 - providing independent governance of the EU data re-use ecosystem
 - promoting best practices



Value for hospitals

Value generated at multiple levels: clinical research, overall care provision and revenue



Free access to tools

- explore and analyse patient data
- derive business intelligence
- conduct own research
- collaborate with other European hospitals in new trials



Better quality data

- stimulate a focus on data quality
- improve monitoring, performance benchmarking, reporting and management (e.g. reimbursement coding)



Better patient care

- optimise patient care
- more patients will access trial drugs and innovative care pathways
- physicians more up to date with medical science



Enhanced reputation

- greater visibility in scientific community
- attract more research
- attract top-class physicians
- attract patients



Increased income

- greater income from trials
- new revenue streams

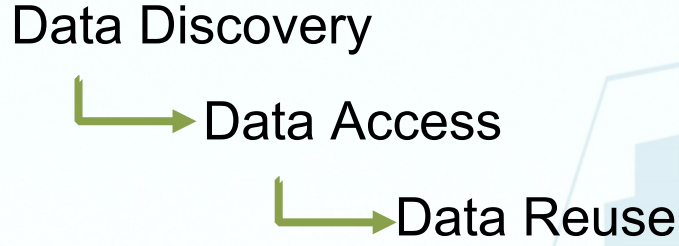
EMIF - the vision



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

EMIF supports flow from:



Data available through consortium

- Large variety in “types” of data



Primary care data sets



Hospital data



Administrative data



Regional record-linkage systems



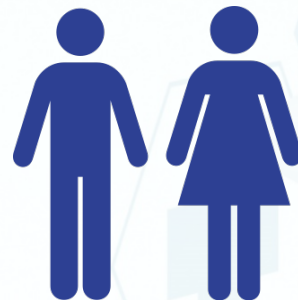
Registries and cohorts (broad and disease specific)



Biobanks

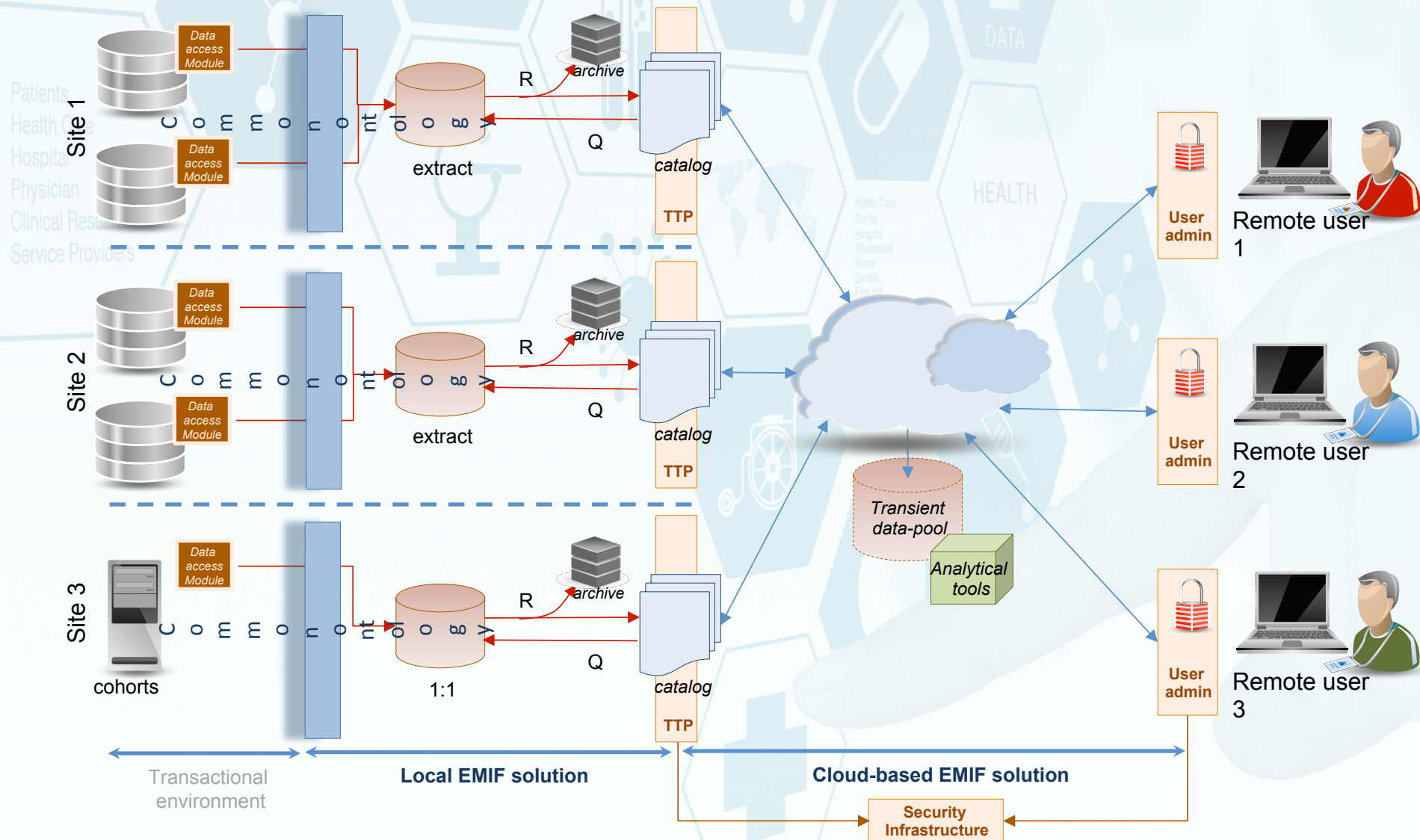
- Data is available from more than 53 million subjects from seven EU countries, including

25,000
subjects in
AD cohorts



more than
94,000
subjects in
metabolic cohorts

Data Discovery → Data Access → Data Reuse



Targeting therapies to the right patients



Group of patients with the same syndrome



Personalised healthcare

- Identifying clinically significant patient subgroups is a key element of any personalisation strategy, helping to:
 - better understand disease diversity
 - identify differences between patients
 - identify the best drug targets
 - develop new biomarkers and diagnostic tests
- bringing clearly defined benefits for patients

Responding to a convergence of needs

Patients
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Clinical Research needs

Optimise clinical research processes

- achieve faster and more accurate patient identification
- identify sites that have access to the most suitable patients
- reduce protocol amendments

Enhance access to Real World Data

- study the use of new medicines in real populations
- conduct comparative effectiveness studies
- monitor long term safety
- gather evidence for adaptive licensing

Healthcare needs

Improve quality and safety of care

- enhance care co-ordination
- increase adherence to clinical evidence
- reduce medical errors and treatment delays

Support patients in self-care and health maintenance

Improve efficiency of care

- optimise care pathways to improve outcomes
- collate evidence for public health strategy and decision-making

Need to remove the bottlenecks to accessing and combining health data from diverse sources across Europe

i~HD has been formed because a complementary, neutral and not-for-profit organisation is needed

- **to play a central role in governing** 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

Clinical Research needs

Healthcare needs

Best practices in information governance

Harmonised health information and standards

The European Institute For
Innovation Through Health Data

Solutions for better quality health data, and legitimate uses of data

Intelligence derived from health data e.g. research, outcomes

Quality assessments, certification and audit

Value Assessment programmes

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DATA

HEALTH

Health Care
Doctor
Hospital
Pharmaceutical

Promoting value from the use of health data

**Value
to healthcare**

Physician
Clinical Research
Service Providers

**Value to patients and
to society**

Health Care
Doctor

**Value
to research**

HEALTH

**Grow a Network
of Excellence**



**Develop value assessment programmes,
to demonstrate:**

- outcomes evidence to improve care
- faster and more efficient clinical research
- better information for public health decisions
- improved quality of EHR data
- good practice in privacy protection
- positive patient and societal acceptance

**towards
a more value-driven outcomes-focused
learning health ecosystem**

**Promote and
collaborate
globally**





The European Institute For Innovation Th~ugh Health Data



Enriching knowledge and enhancing care through health data