EHR4CR – Hur arbetar man med forskningsfrågorna? - från ett industriperspektiv!

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sfmi | SVENSK FÖRENING FÖR MEDICINSK INFORMATIK

Svenska Läkaresällskapet

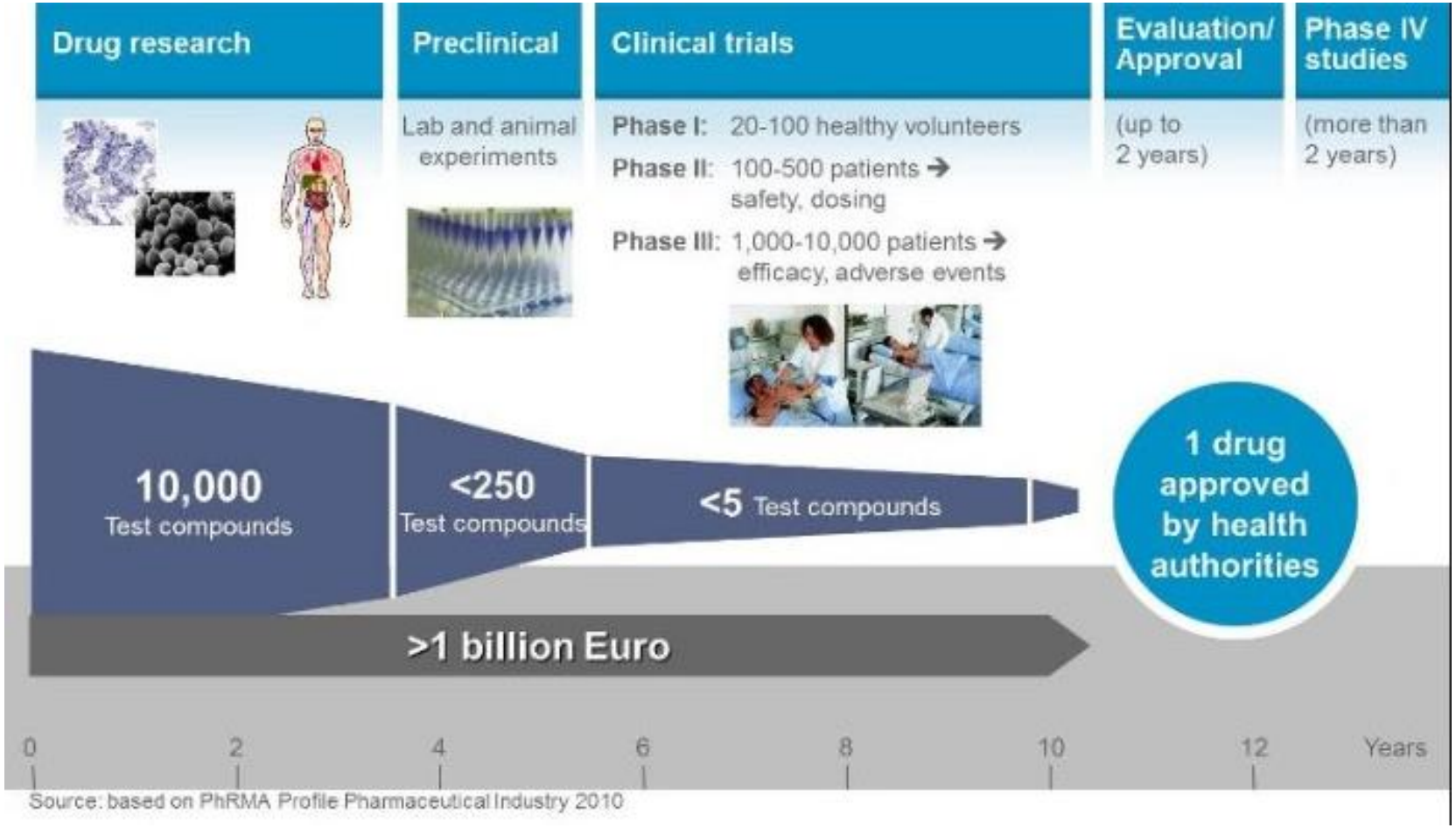
Outline

- Ett industriperspektiv
  - Kort om läkemedelsutveckling
  - Kliniska prövningar och dess utmaningar
- Betydelsen av extern hälsodata för klinisk forskning
- Konkret exempel på hur elektroniska patient journalsinformation kan stödja klinisk forskning: fallet EHR4CR projektet
  - EHR4CR (Electronic Health Records for Clinical Research) projektet
  - Implementering av EHR4CR genom Champion Programmet tillsamans med industri och sjukhus i Europa 2016-2017
  - Diskussion

Industry perspektiv

Läkemedelsutveckling

- **Recognized as a long, costly, and risky process**
  - **Average time to market of 12 to15 years**
  - **Approximate – 2.5 B USD (2016) to bring a new drug to market**
  - **High attrition rate, only 2-4 per cent of early Discovery projects end up as products**



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Problems with clinical trials

- Incomplete and delayed clinical trials are a sore spot of drug development

The percentage of studies that complete enrolment on time:

18% in Europe,

7% in the US[1]

50%

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

Almost

50% **of all trial delays caused by patient recruitment problems[2]**

1/3 **of protocol amendments are avoidable, at a cost of $0.5m**

Each day a drug is delayed from market, sponsors lose[3] up to

$8m

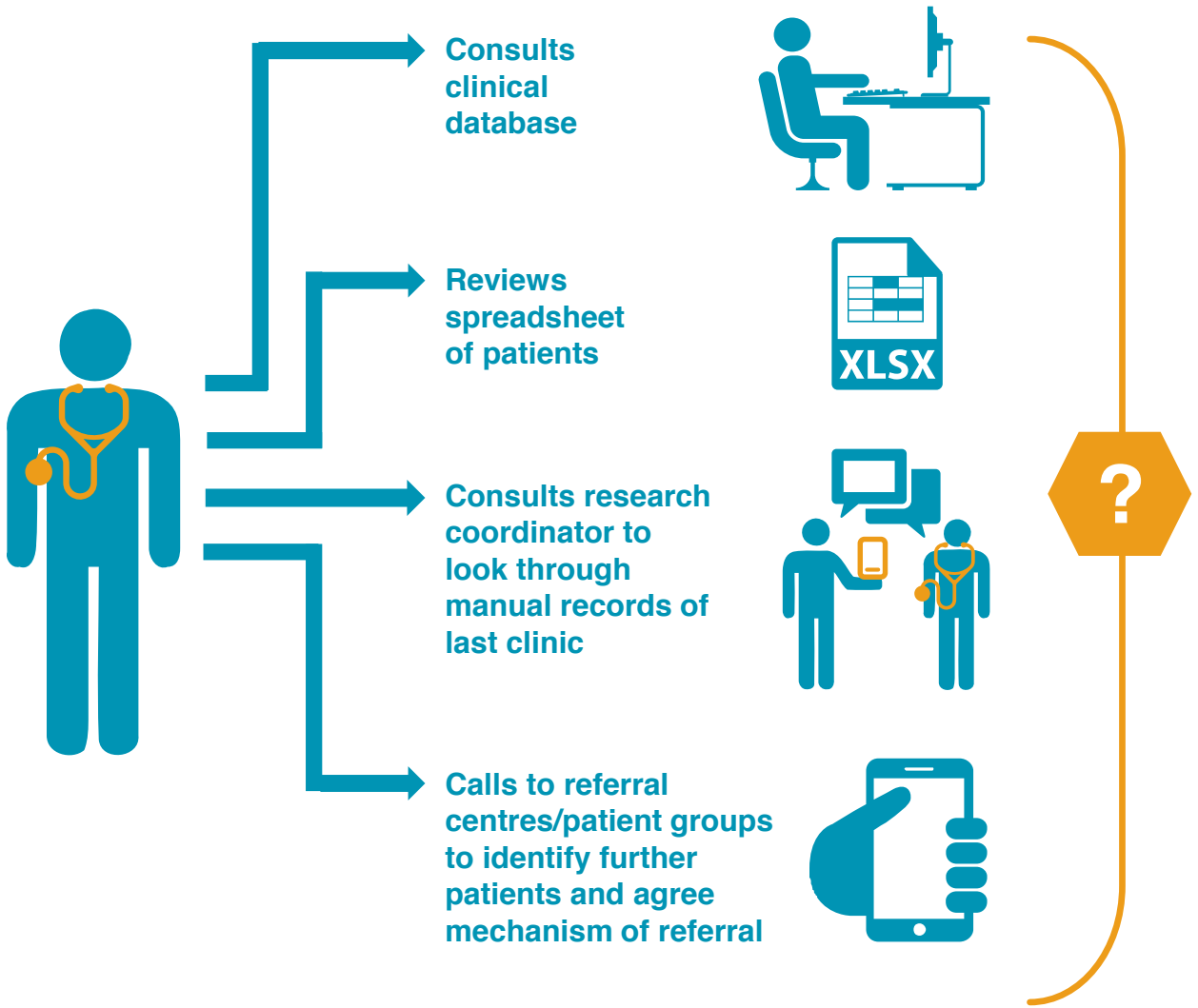
1. State of the Clinical Trials Industry: A Sourcebook of Charts and Statistics, Center Watch, 2008.
2. Study Participant Recruitment and Retention in Clinical Trials: Emerging strategies in Europe, the US and Asia, Business Insights, June 2007.
3. Beasley, "Recruiting" 2008
4. Tufts -http://clinicalperformancepartners.com/wp-content/uploads/2012/07/Fixing-Feasi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

Detailed Feasibility – hospital perspective

If your hospital is approached to take part in a clinical trial…

An investigator completes questionnaire or meets team to assess interest and potential pool of eligible patients

More robust patient numbers, recruitment plan and operational capability then assessed

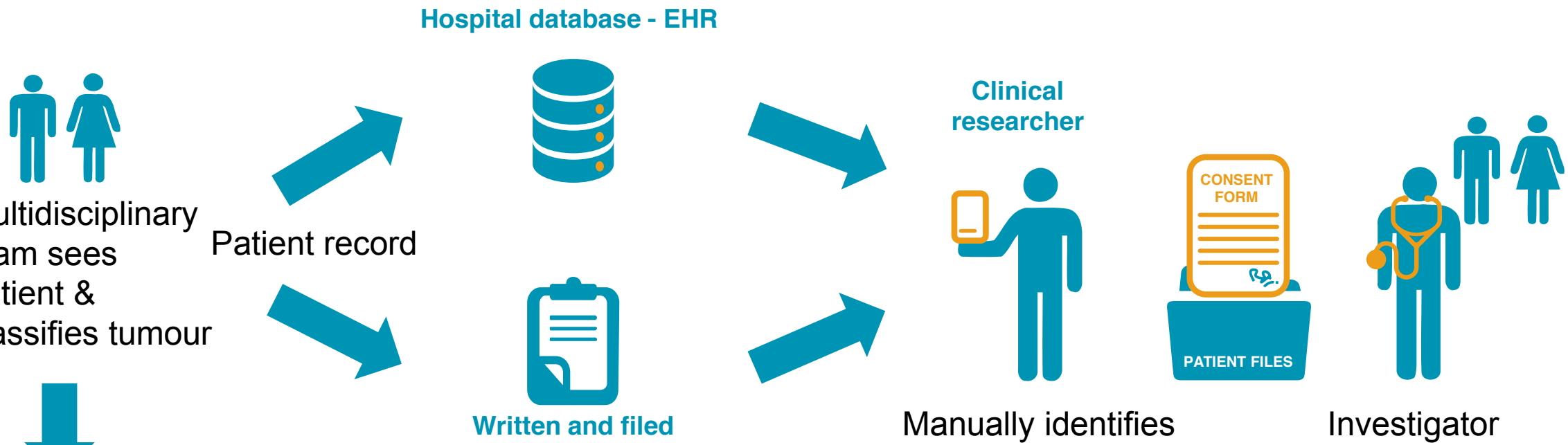


Based on these estimates, this trial has a

50% chance of achieving achieving the target recruitment rate

- **Patient number agreed**
- **Payment agreed**
- **Contract drawn up**

Identifying an eligible patient – an example



Clinician may note down this patient as one that could be suitable in study they recall

Clinician may remember to alert investigator or research nurse about a potential patient that was reviewed at this clinic…

Manually identifies patients against inclusion/exclusion criteria

Investigator validates information and consents patient during first visit

Betydelsen av extern hälso data för klinisk forskning

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

In 2010, OECD Health Ministers met in Paris to discuss how to improve value in health care. In their final communiqué, they underlined the importance of better health information systems and called for more and effective use of health data that has already been collected

OECD, 2013

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

Improved access to health record data…

…will speed up protocol design, patient recruitment, data capture & safety reporting

PATIENTS PROTECTED BY LEGAL AND PRIVACY PROTECTION STANDARDS & REGULATIONS

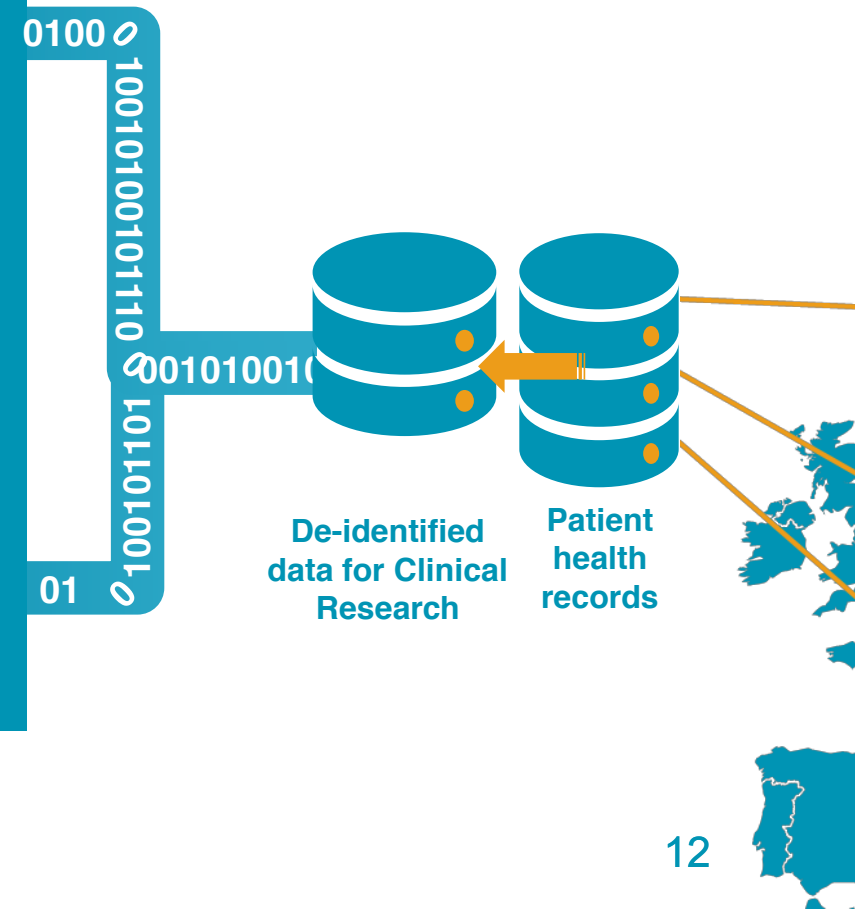
What is the impact of protocol criteria on the size of the patient population for the trial?

Which countries and sites offer the best chance of success?

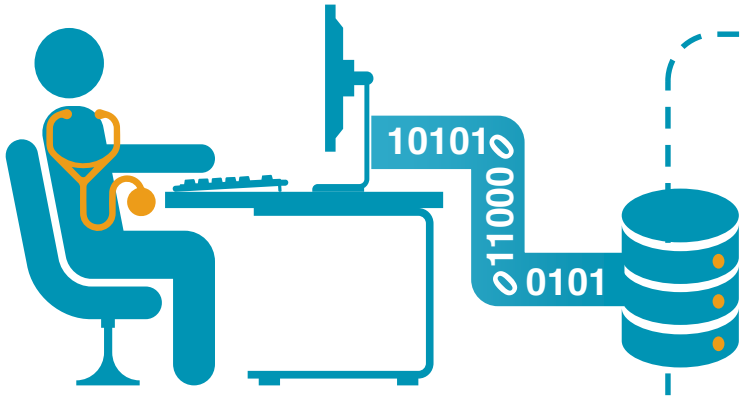
Where are patient candidates and who is the treating physician?

What patient data can be pre-populated into the clinical trial records?

What are the safety issues and have they been reported?



A streamlined process for protocol feasibility…



De-identified data for Clinical Research

- Disease & diagnosis
- Demographics
- Treatment regime
- Co-morbidities

Accurate patient numbers

Clinician uses information to proactively approach clinical trial sponsors

Sponsor uses inclusion/exclusion criteria to search EHR4CR database and identify eligible patient population

Clinician uses this information to better design study protocols for academic research

✓ Payments and contracts based on realistic patient targets

✓ Higher probability of reaching recruitment target

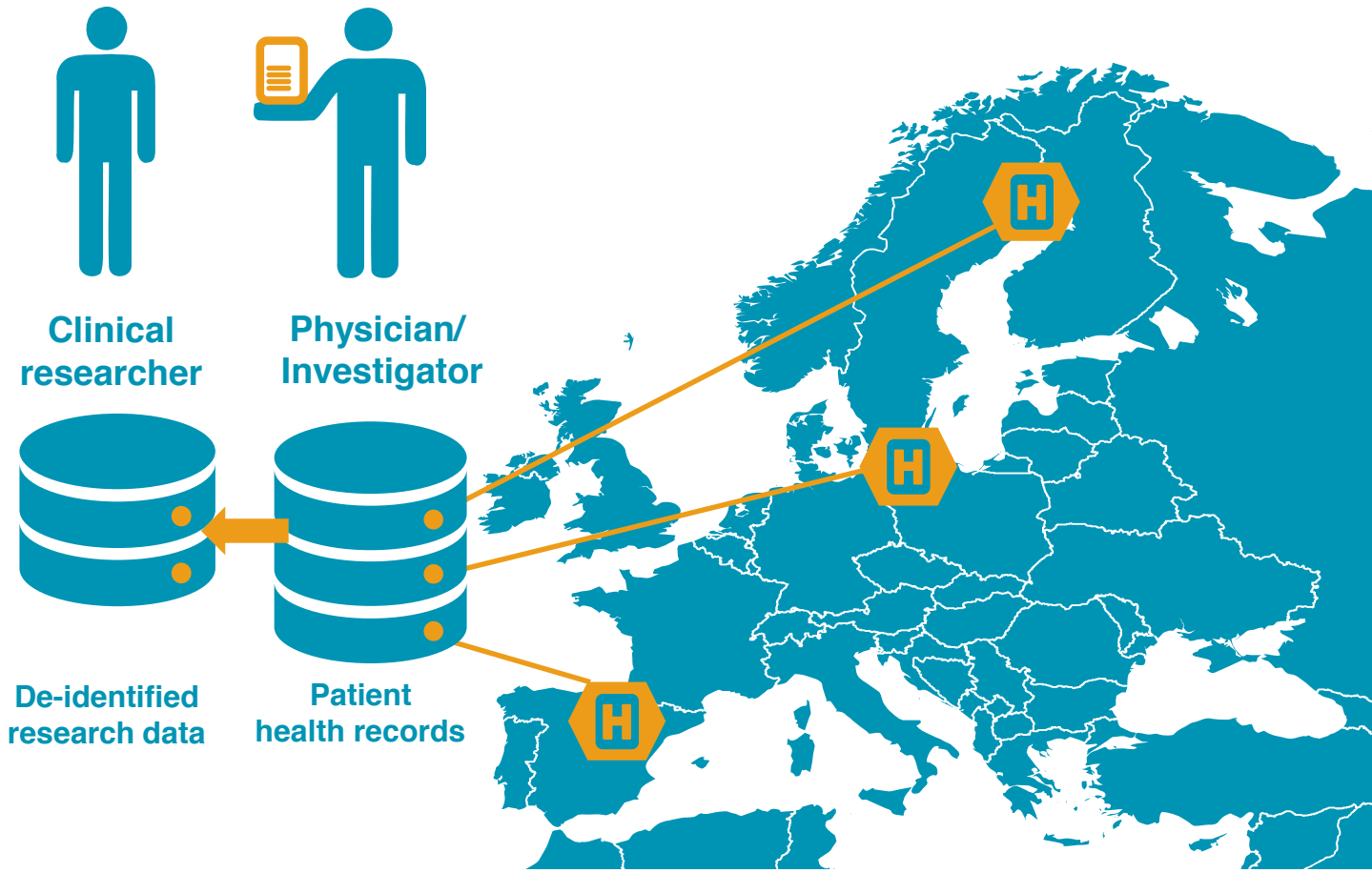
✓ Revenue stream more predictable

Clinician interrogates EHR data (EHR4CR platform) to accurately assess hospital patient population

1. Drug Information Journal, Vol 45, 2011
2. Industry Standard Research, 2010

Proactive partnership in conducting clinical research

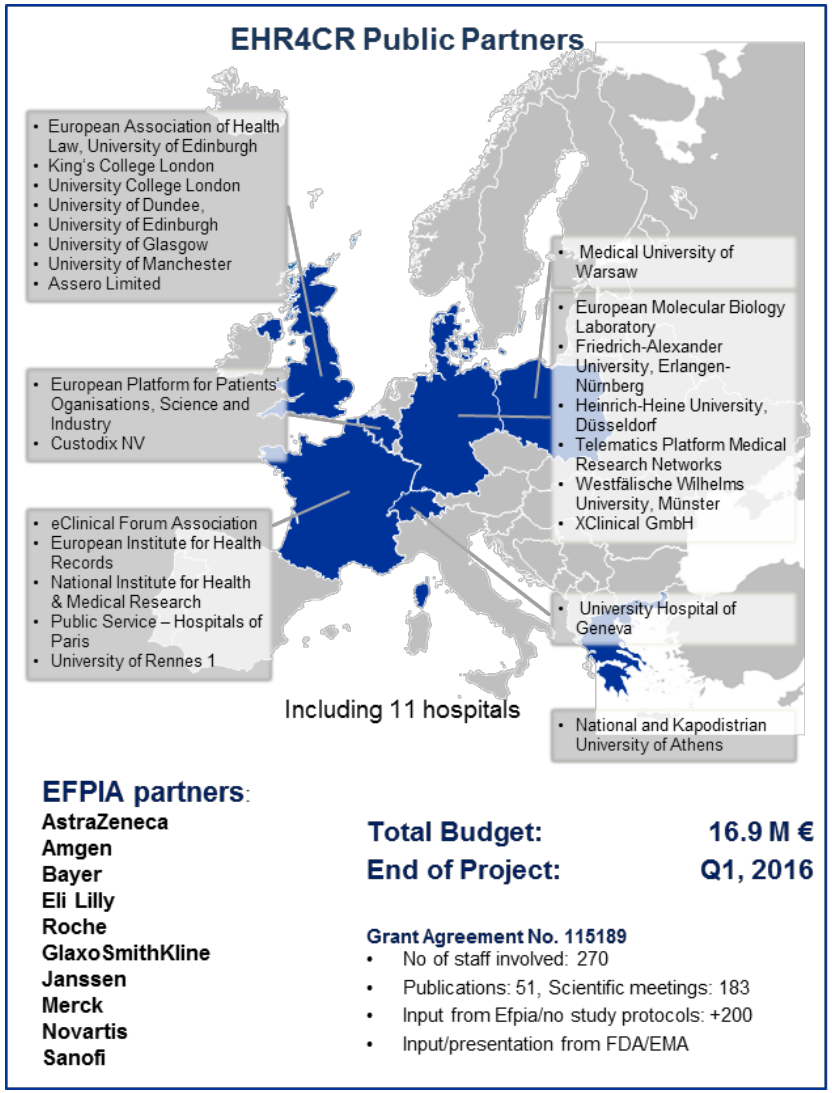
- With research and healthcare systems siting on the same spine and conforming to the same data exchange standards, the re-use of EHR information is possible on a large and scalable way – across:
  - organisations
  - regions and
  - countries



EHR4CR projektet

The EHR4CR project

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

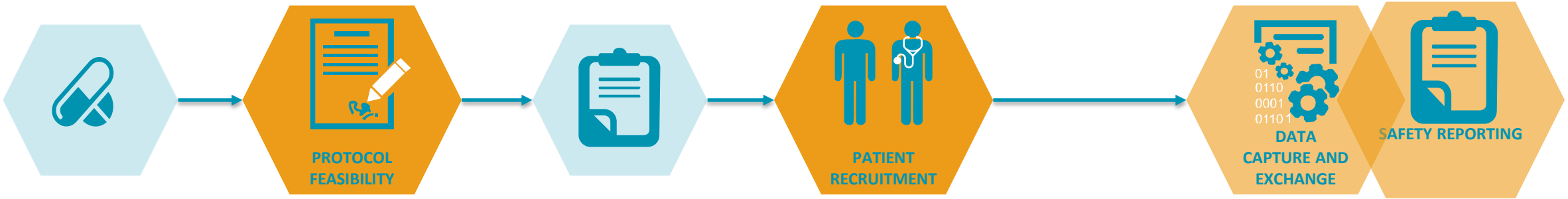


efpia

imi innovative medicines initiative

The EHR4CR objective

- Research and develop a **trustworthy service platform able to unlock clinical information stored in EHRs** for improving clinical research
  - Clear focus on three (3) relevant use cases



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.

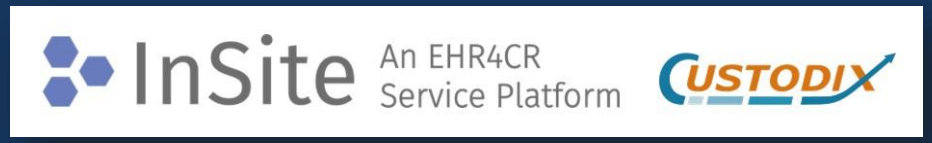
Facilitating **EHR data extraction** for applications used during trial execution (e.g. prefilling of CRFs and of SAE reports).

The EHR4CR project output

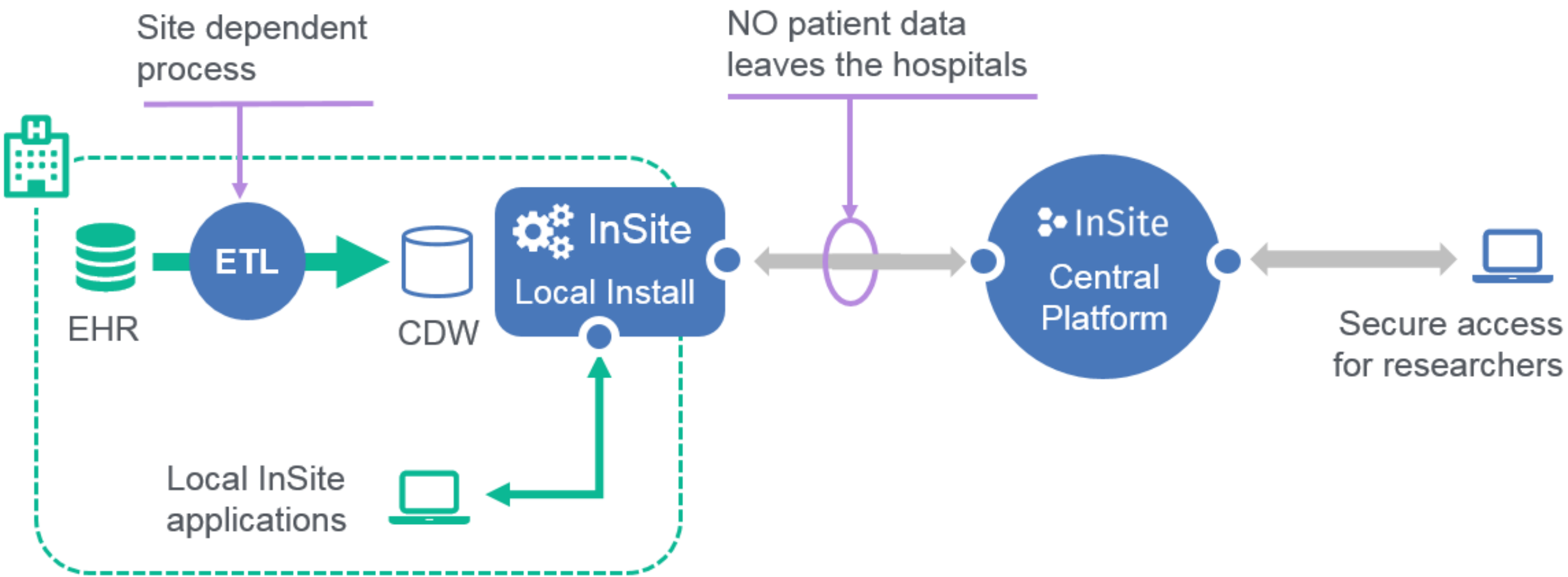
Extended into 2015 (year 5 without public funding) for making the transition to a sustainable platform

- **New commercial stable platform in place** (InSite) by Custodix
- **Established a contractual framework for post project deployment** among interested Efpia/Industry partners (i.e. Amgen, AZ, Bayer, GSK, Janssen, Roche, Sanofi, Boehringer-Ingelheim and ICON
- **Established the European Institute for Innovation through Health Data (i-HD)** as an independent governance body
- **Initiating a post-project early adopter program Champion Program** by connecting new hospitals to the InSite platform, building up experience with sponsoring Efpia companies

The InSite platform



InSite – Technical Overview



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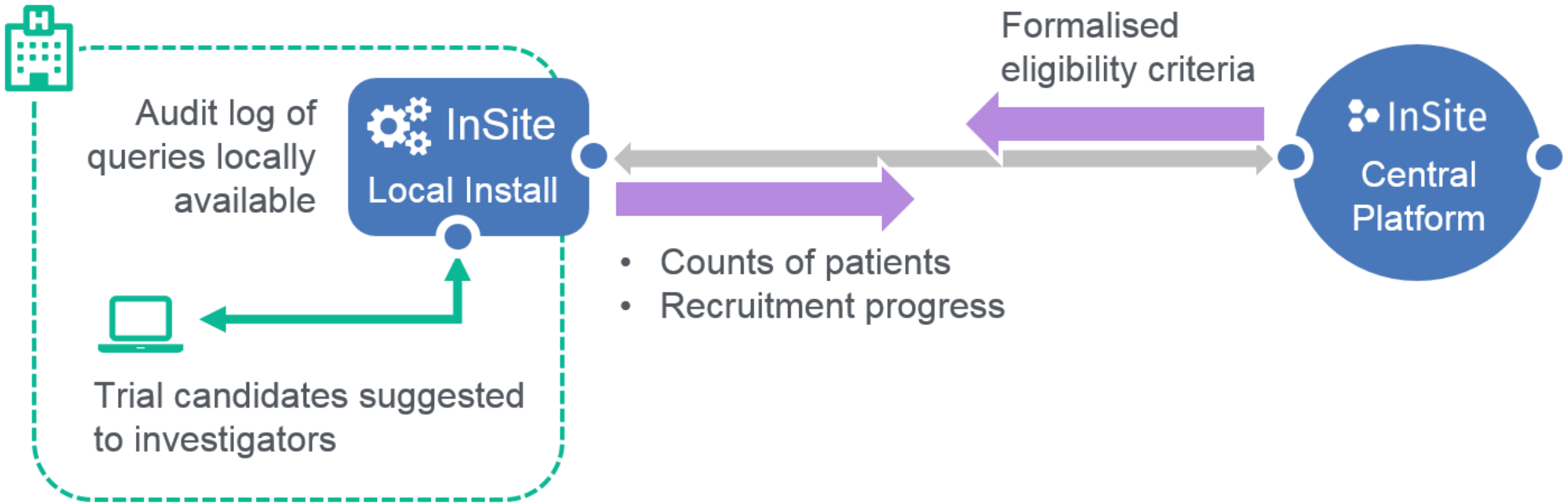
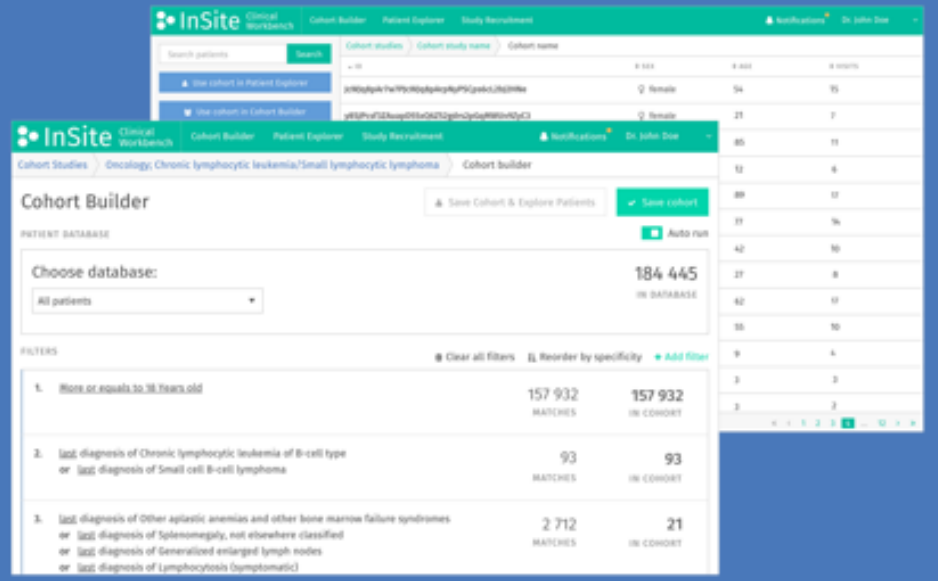


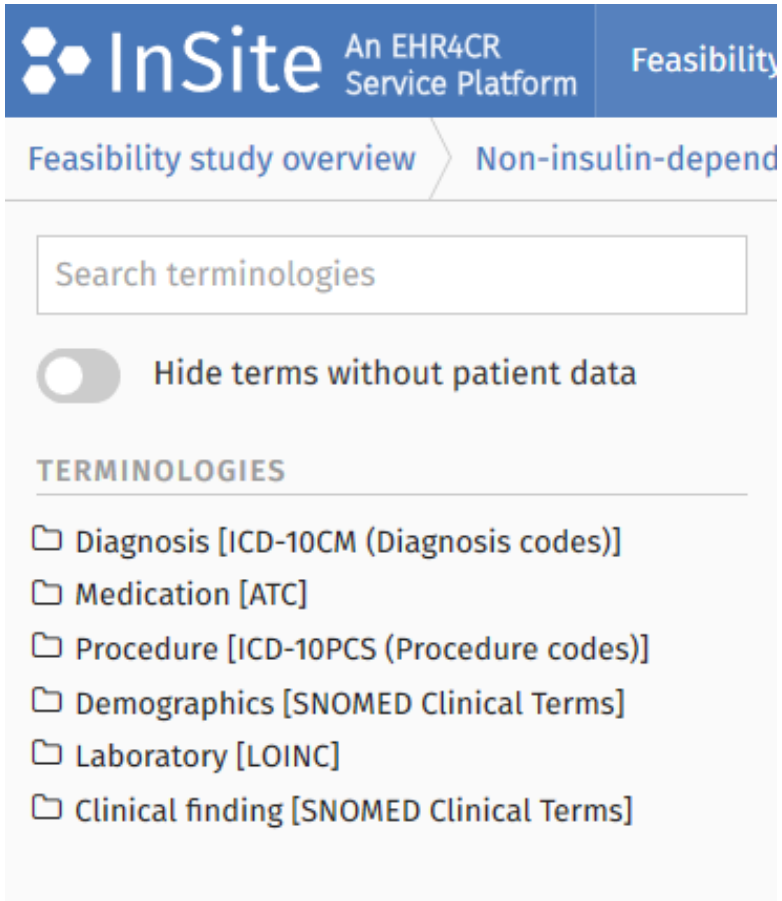
InSite Central Platform – aggregated information for conducting research

InSite

InSite Clinical Site – detailed data exploration for healthcare professionals



Data of Interest



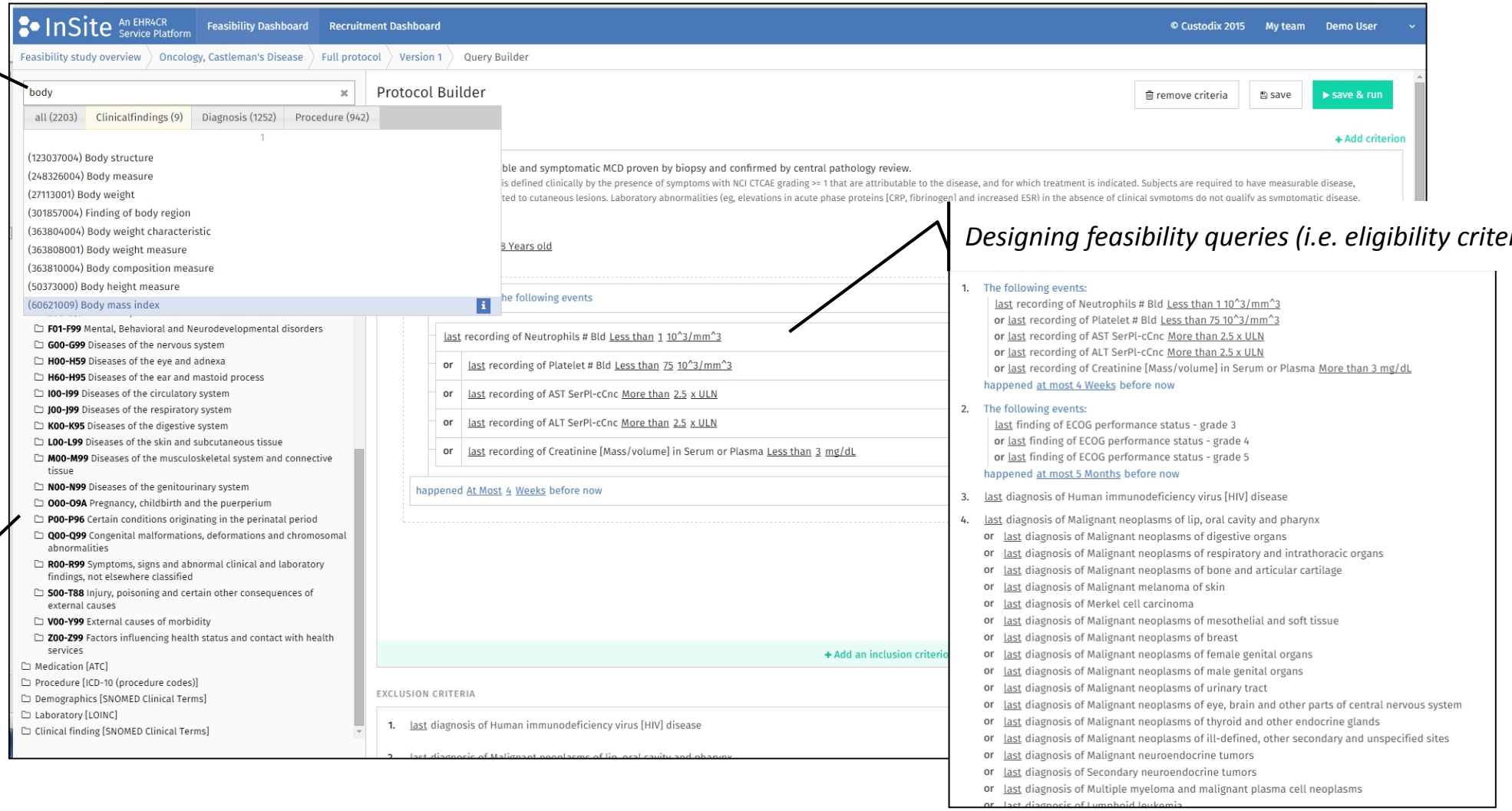
- Data of Interest
  - Demographics, diagnosis, procedures, medication, laboratory
- Local terminology/vocabulary is mapped to **reference terminologies**
- Clinical findings
  - **Fixed list of clinical concepts**
    - Base list originates from the EHR4CR project, will be further curated
  - “Catch-it-all” and Incremental Mapping approach
    - Whatever is easily available
    - Whatever was needed for a specific project

InSite central platform screenshot

PFS Authoring criteria (queries)

Clinical concept quick search

Clinical concepts to design queries with (ICD, LOINC, SNOMED, etc.)



Designing feasibility queries (i.e. eligibility criteria)

1. The following events:
   - last recording of Neutrophils # Bld Less than 1 10^3/mm^3
   - or last recording of Platelet # Bld Less than 75 10^3/mm^3
   - or last recording of AST SerPl-cCnc More than 2.5 x ULN
   - or last recording of ALT SerPl-cCnc More than 2.5 x ULN
   - or last recording of Creatinine [Mass/volume] in Serum or Plasma More than 3 mg/dL

   happened at most 4 Weeks before now
2. The following events:
   - last finding of ECOG performance status - grade 3
   - or last finding of ECOG performance status - grade 4
   - or last finding of ECOG performance status - grade 5

   happened at most 5 Months before now
3. last diagnosis of Human immunodeficiency virus [HIV] disease
4. last diagnosis of Malignant neoplasms of lip, oral cavity and pharynx
   - or last diagnosis of Malignant neoplasms of digestive organs
   - or last diagnosis of Malignant neoplasms of respiratory and intrathoracic organs
   - or last diagnosis of Malignant neoplasms of bone and articular cartilage
   - or last diagnosis of Malignant melanoma of skin
   - or last diagnosis of Merkel cell carcinoma
   - or last diagnosis of Malignant neoplasms of mesothelial and soft tissue
   - or last diagnosis of Malignant neoplasms of breast
   - or last diagnosis of Malignant neoplasms of female genital organs
   - or last diagnosis of Malignant neoplasms of male genital organs
   - or last diagnosis of Malignant neoplasms of urinary tract
   - or last diagnosis of Malignant neoplasms of eye, brain and other parts of central nervous system
   - or last diagnosis of Malignant neoplasms of thyroid and other endocrine glands
   - or last diagnosis of Malignant neoplasms of ill-defined, other secondary and unspecified sites
   - or last diagnosis of Malignant neuroendocrine tumors
   - or last diagnosis of Secondary neuroendocrine tumors
   - or last diagnosis of Multiple myeloma and malignant plasma cell neoplasms

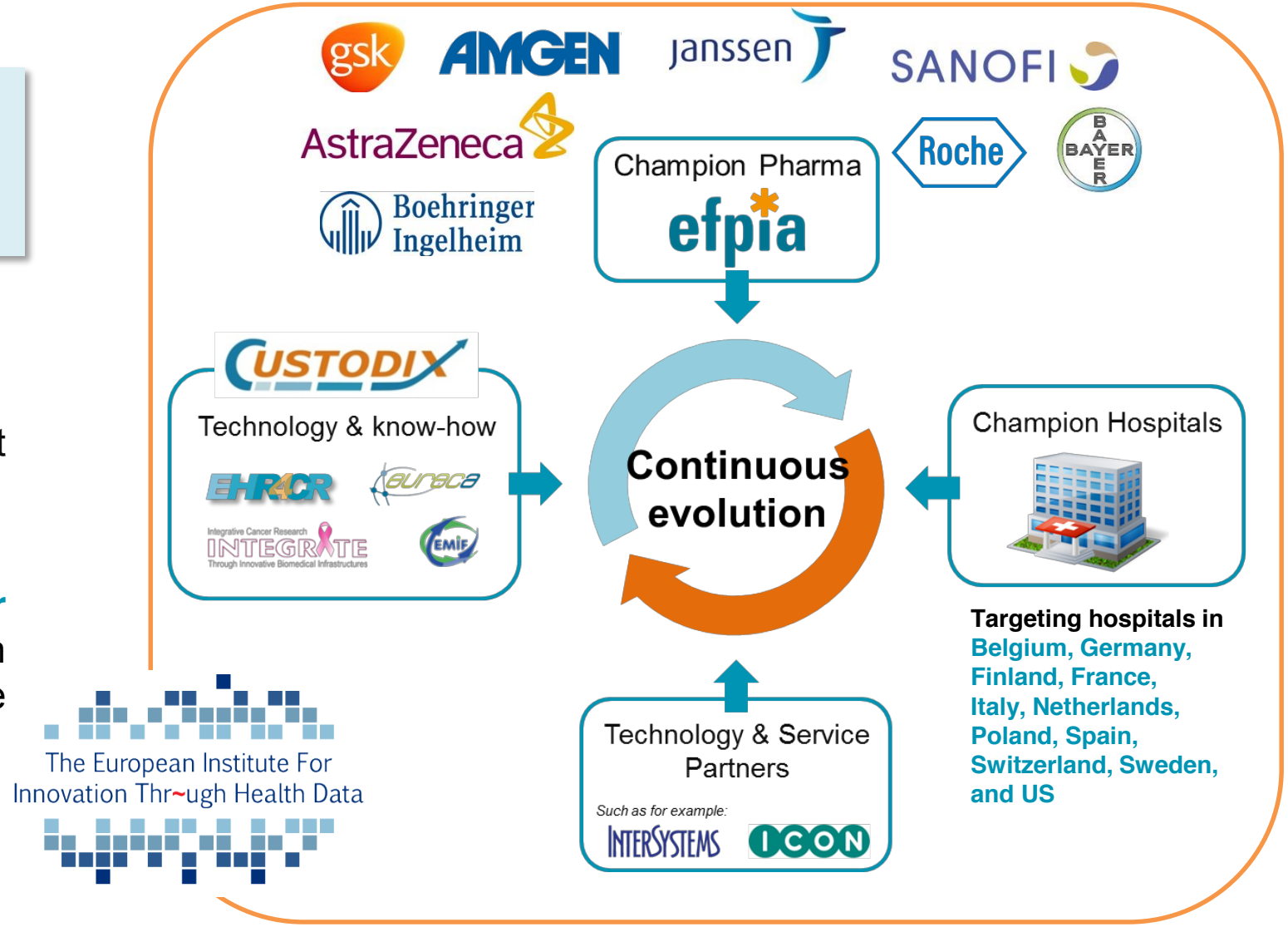
EHR4CR Champion Program

2016 – 2017 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** which aims to govern the EU data re-use ecosystem



Benefits for Hospitals

Attract More Clinical Research

Resulting in:

- Better patient care
- New revenue streams

Get Free Access to Software

- Participating sites get access to software for local use
- Champions will get premium versions for free

Remain in Control

Be part of an EU community:

- Steer the future of EHR data reuse
- Always determine how your data is used

Value for pharma & research organisations

Clear value proposition for research organisations

Better trial design

- Optimising clinical protocol design will reduce costly corrective measures such as protocol amendments, late addition of new trial countries or sites.

Quicker achieved recruitment targets

- Computer assisted patient identification tools result in accelerated identification, fewer patients missed,…

Overall increased efficiency

- Further automation and optimisation of the clinical trial process by use of a central platform result in an overall increased efficiency.

Improve trial success rate

- The number of trials failed due to failure to recruit will be reduced.

Reduce cost

- Less manual work, less corrective measures, etc. lead automatically to a decrease in total trial cost. Pharma will also avoid the expense and time and effort of opening trial sites which will not yield enough patients.

Increase revenue

- The platform will reduce the elapsed clinical trial time, which in the end translates into a quicker time to market and thus additional revenue (increased time on market under patent protection).

Novel Business Model

- InSite is a matchmaker between researchers and data providers
- InSite does not interfere with agreements between sponsors and sites participating in trials

Governing the EHR4CR Ecosystem

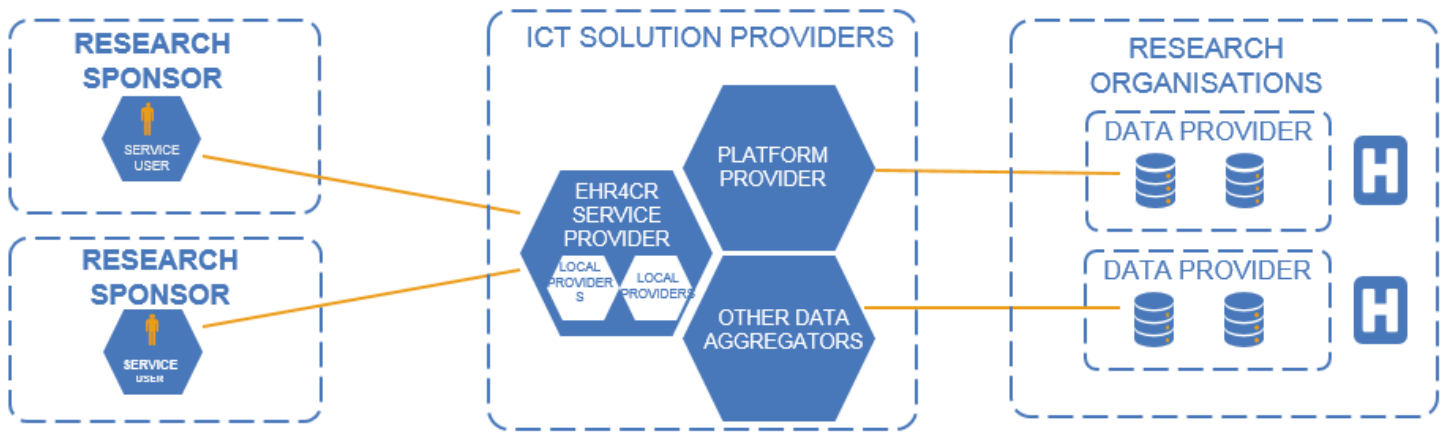
The needs…

Educate and train research and ICT staff

Accredit staff and organisations

Certify service providers and EHR systems

Oversee and audit governance & security



The European Institute For Innovation Thr~ugh Health Data

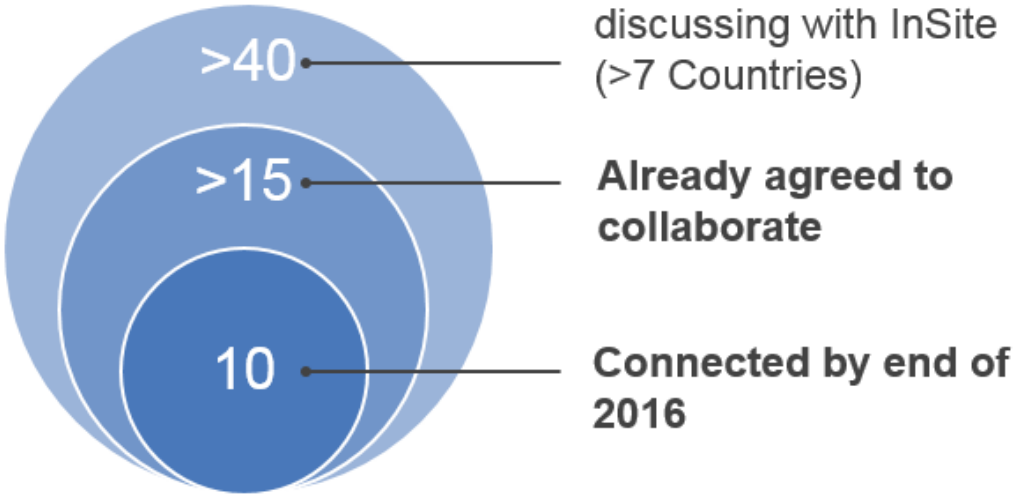
i~HD has been formed because a complementary, neutral and not-for-profit organisation is needed

- **to play a central role in governing** and expanding a trustworthy health data driven ecosystem including EHRs and EHR4CR platform services
- **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

The European Institute For Innovation Thr~ugh Health Data

Champion Programme 2016 – 2017

InSite Champion Hospitals



Building a scalable pan-European network

Slutsatser från ett Svenskt perspektiv

- EHR4CR InSite plattform och tjänster har validerats och tillmötesgår EU krav om data säkerhet (Data Protection Directive 95/46/EC)
- Champion Program och InSite visar på potentialen hur nytta kan göras möjligt för både industri perspektiv, klinisk forskning och för sjukvård.
- I det implementationsarbete som pågår nu har Sverige en möjlighet att ta en ledande position för att medverka till att stärka klinisk forskning
- Där EHR4CR InSite medverkan för svenska sjukhus vara ett exempel för att stödja visionen för att Sveriges e-hälsoarbetet: Bäst i världen 2025

The EHR4CR project has been an important journey which would have been difficult without the IMI private/public setting…

…but NOW the exciting time begins!

Thank you for your attention

InSite wins award in EU SME eHealth Competition 2016

2ND

CATEGORY : CHAMPION

eHealth Solution EU SME Competition 2016

- The InSite platform (www.insiteplatform.com) was **voted 2nd in the EU eHealth Competition 2016** in Amsterdam in the Champions category.
- The eHealth Competition is an initiative that rewards the **best eHealth/mHealth solutions** produced by SMEs (http://www.ehealthcompetition.eu/).
- The competition has the **endorsement of the European Commission**. In the 2016 edition year there were 112 entries, of which 16 finalists competed in Amsterdam in front of an international jury.