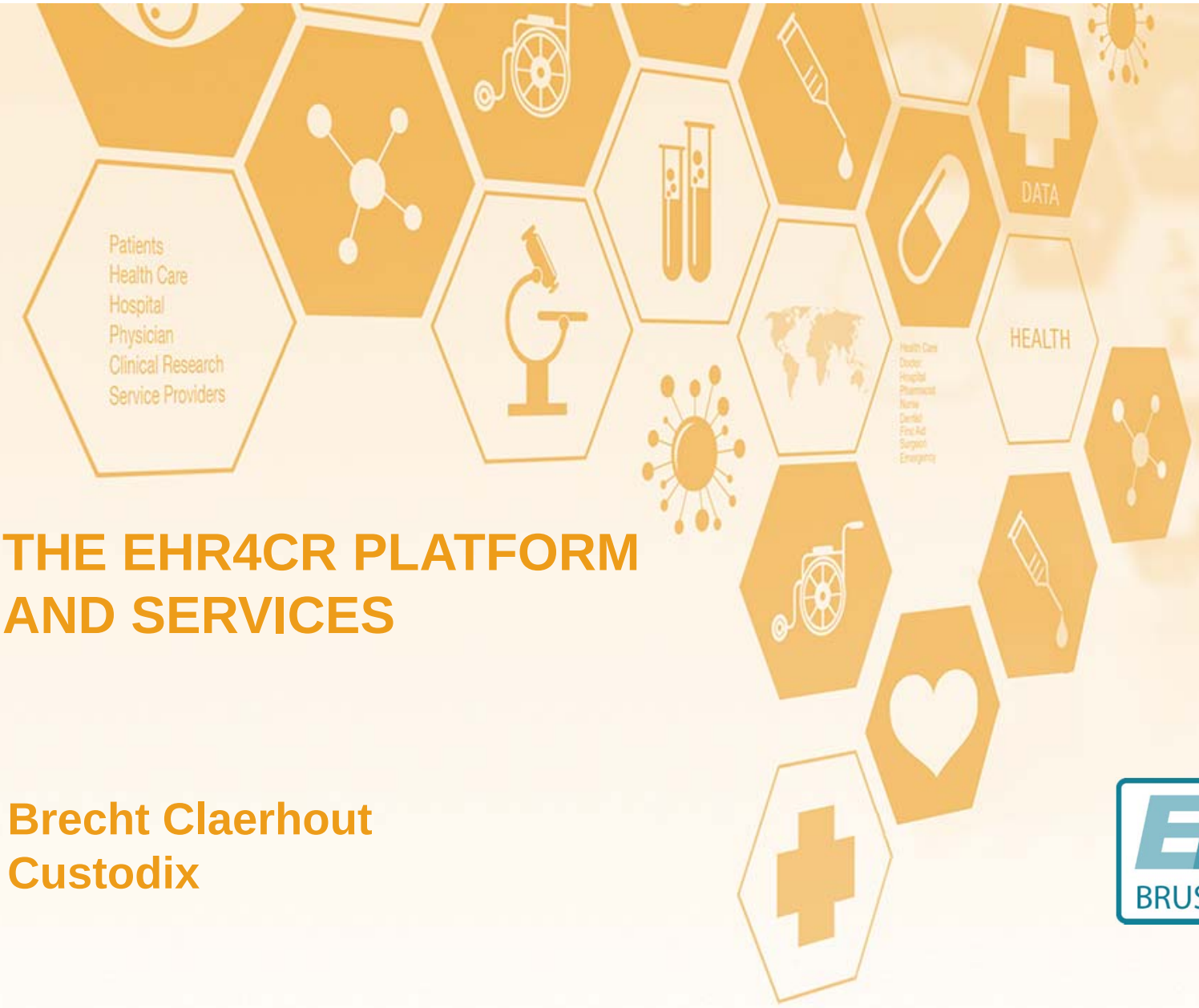
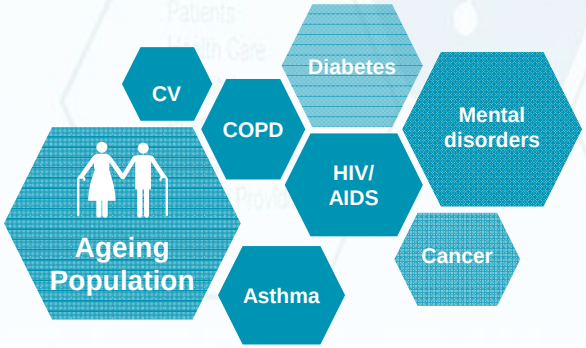


THE EHR4CR PLATFORM AND SERVICES

Brecht Claerhout
Custodix

EHR4CR
BRUSSELS - 9 APRIL 2014

Background



The need for new medicines is real…

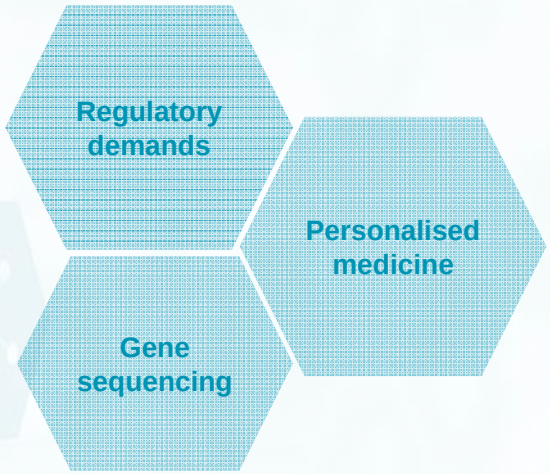
1993 - 1997

90
New drugs on market

2008 - 2012

55
New drugs on market

Drug innovation is slowing down…



Trials become more complex

- R&D cost for new chemical / biological entity ~ €1.17 billion (2012)
- Research shifts away from Europe to Asia

Moving forward

Huge potential in the use of
Real World Data

The percentage of studies that complete enrolment on time:

18% in Europe,

7% in the US

1/3 of protocol amendments are avoidable, at a cost of

$0.5m

Almost

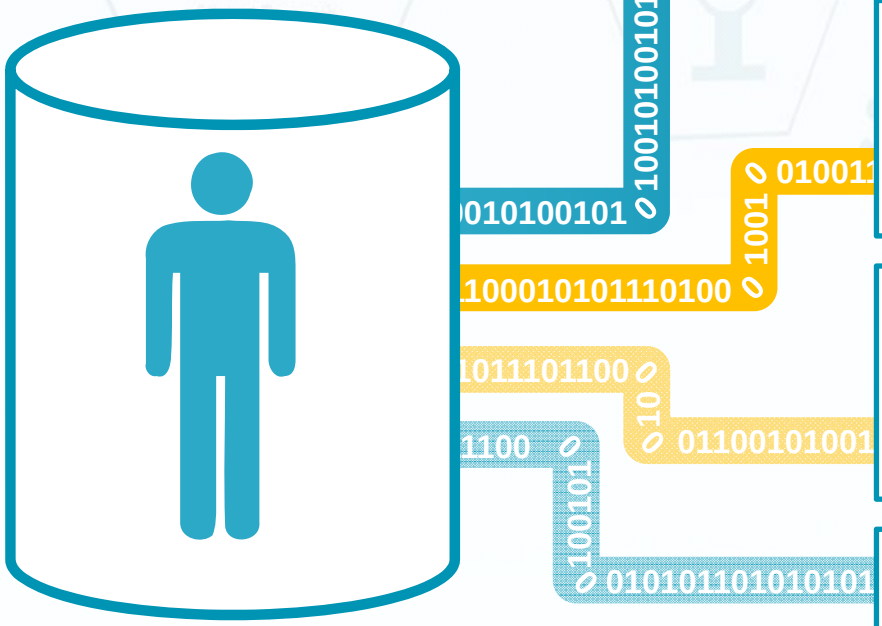
half of all trial delays caused by patient recruitment problems

Only **1/3** of the sites engaged in a multicentre study manage to enrol the requisite number of patients

50%

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

Speeding up protocol design, patient recruitment, data capture & exchange



- Evaluate patient populations in study set up
  - Query EHR database to establish number of potential candidates
  - Improve and validate study designs
- Accelerate patient identification and recruitment
  - Query EHR database to select sites and identify and recruit patients
  - Implement study screening parameters into patient registration and scheduling
  - Researchers obtain key health information before patients arrive for a screening visit (after consent)
- Capture clinical trial data
  - Incorporate study-specific data capture as part of routine clinical care
  - Auto-populate study data elements into case report forms from other parts of EHR database
  - Minimise duplication of data collection
- Exchange clinical trial data
  - Facilitate Serious Adverse Event reporting
  - Efficient patient data collection for study conduct

The EHR4CR platform – unlocking the EHR

- Service platform able to unlock clinical information stored in EHRs for improving clinical research
- Create a trustworthy environment connecting trial sponsors and data providers

The big challenges

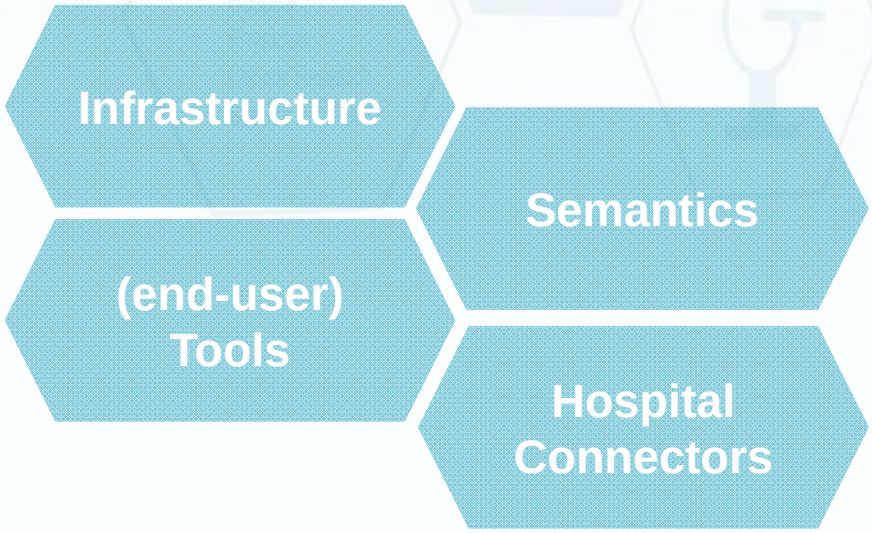
- Connectivity & Interoperability
  - Heterogeneity in technology
  - Heterogeneity information models and terminology

- Security & Privacy
  - Compliance across borders
  - Trust

- Data Quality
  - Structured & unstructured data
  - Completeness
  - Trustworthiness

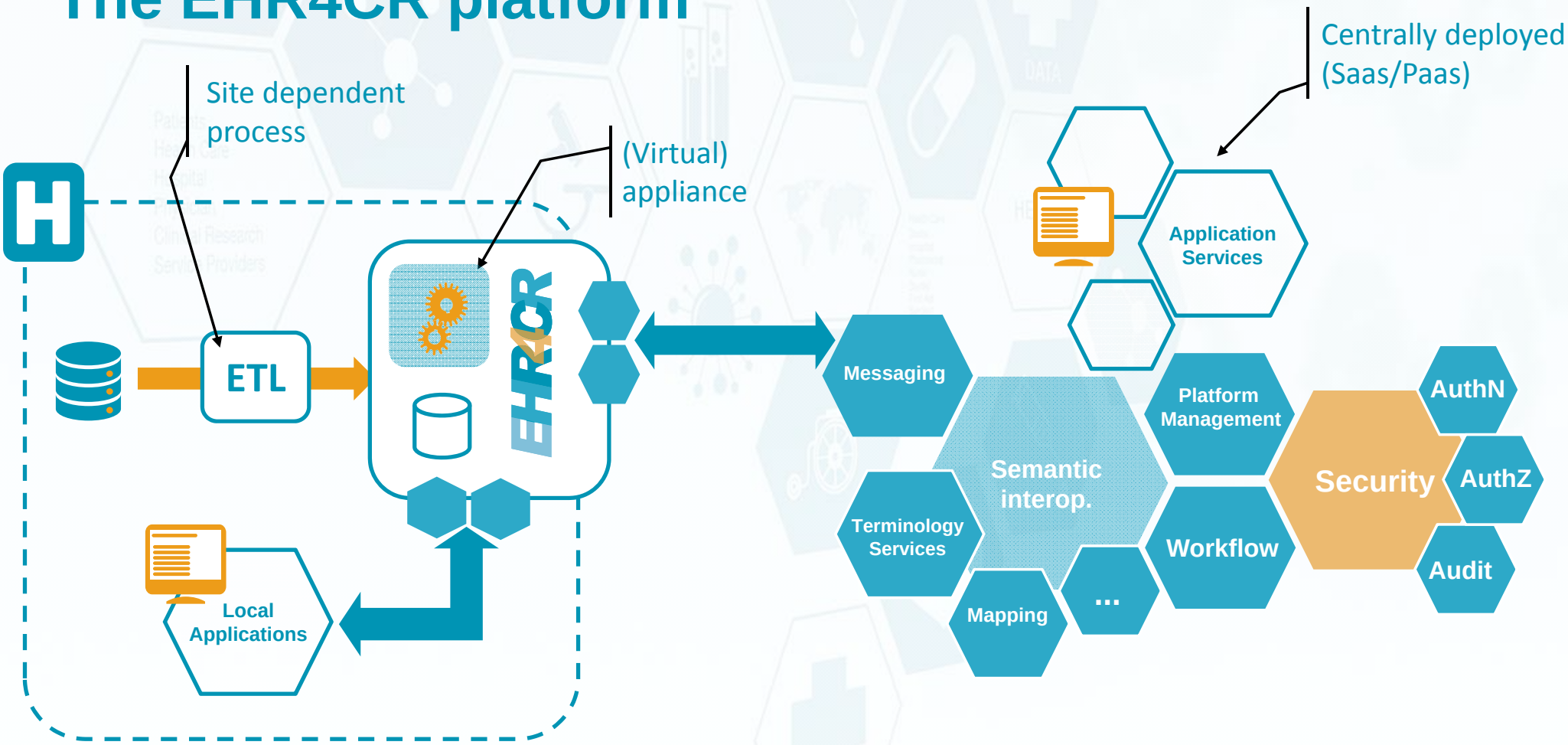
- Operations
  - Service level
  - Operational procedures (intake, …)
  - Maintenance (technical & information modelling)

The EHR4CR platform – an open architecture



- Open platform
  - Service Oriented Architecture
  - Standards based
  - Maximal service decoupling
- Objectives
  - Avoid vendor lock-in
  - Stimulate alternative tool development
  - Open to different semantic interoperability approaches
  - Create added-value by enabling service re-use beyond EHR4CR

The EHR4CR platform



Protocol feasibility

Where will we find sufficient numbers of the right patients?

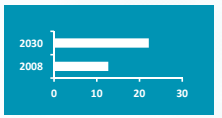
How long will the trial take?

Will we be able to recruit the necessary volume of patients in order to collect data with sufficient statistical power?

Do the inclusion/exclusion criteria make sense?

Aggregate data

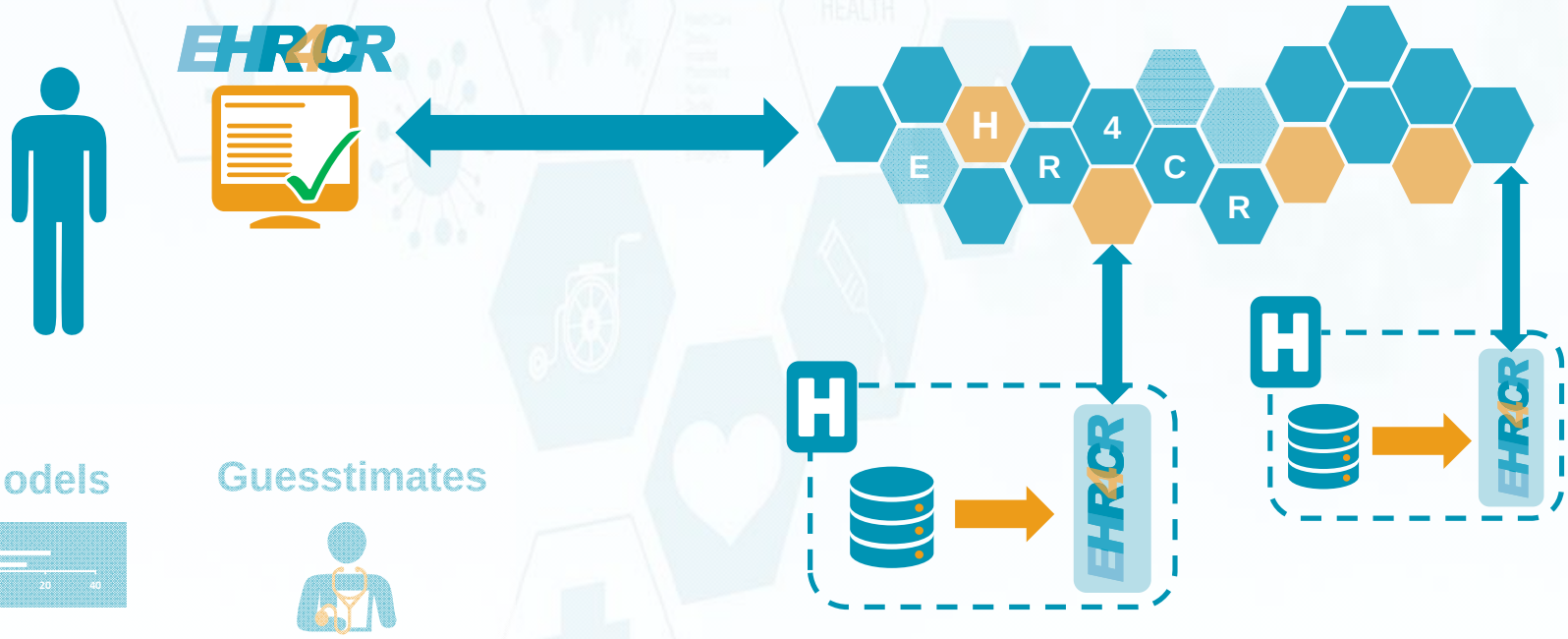
Models



Guesstimates

Protocol feasibility

Let's test this protocol with real world data in potential trial sites!

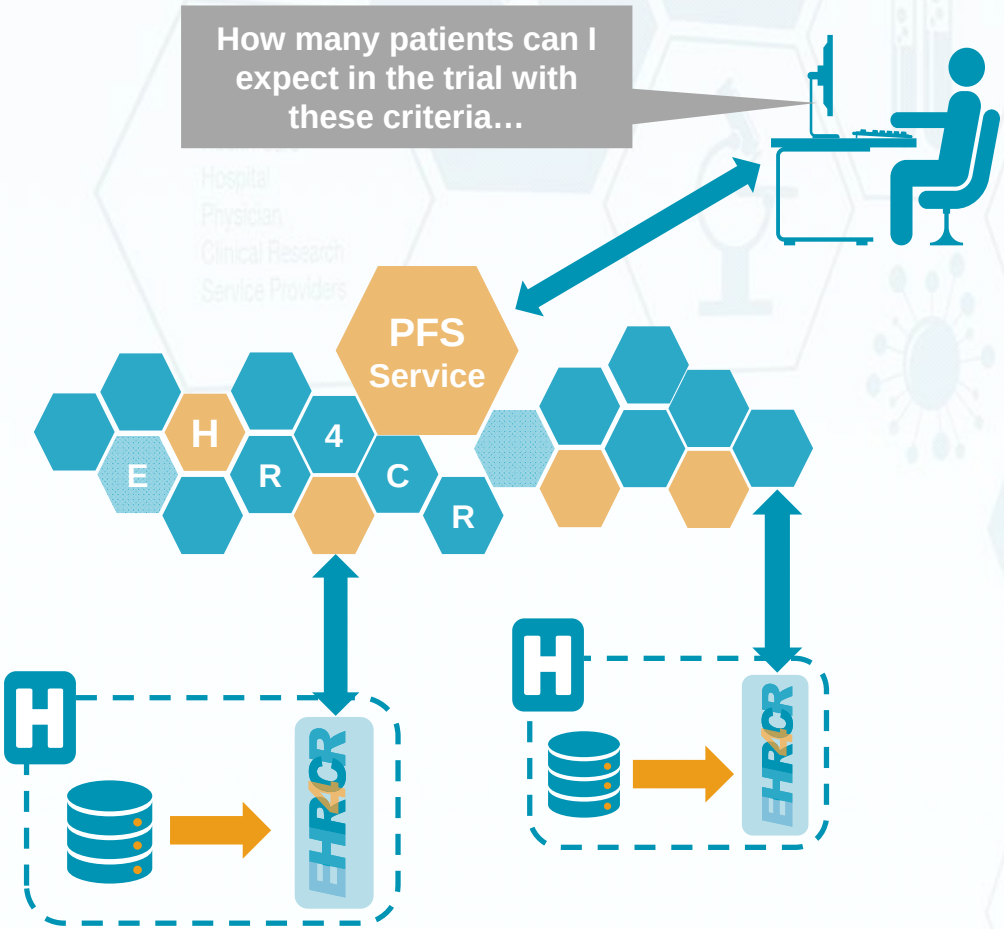


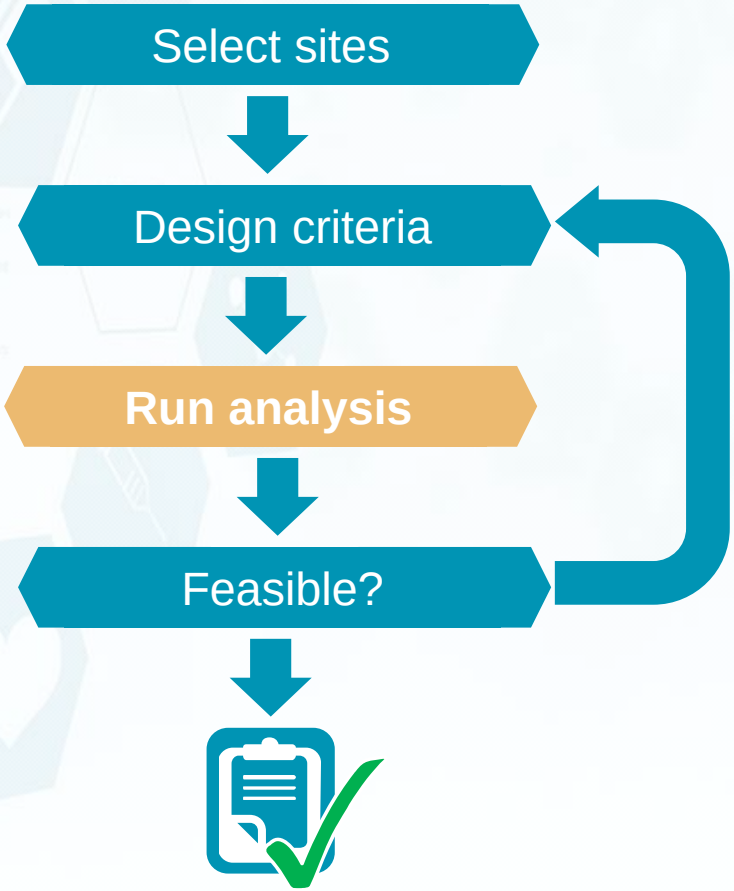
Aggregate data

Models

Guesstimates

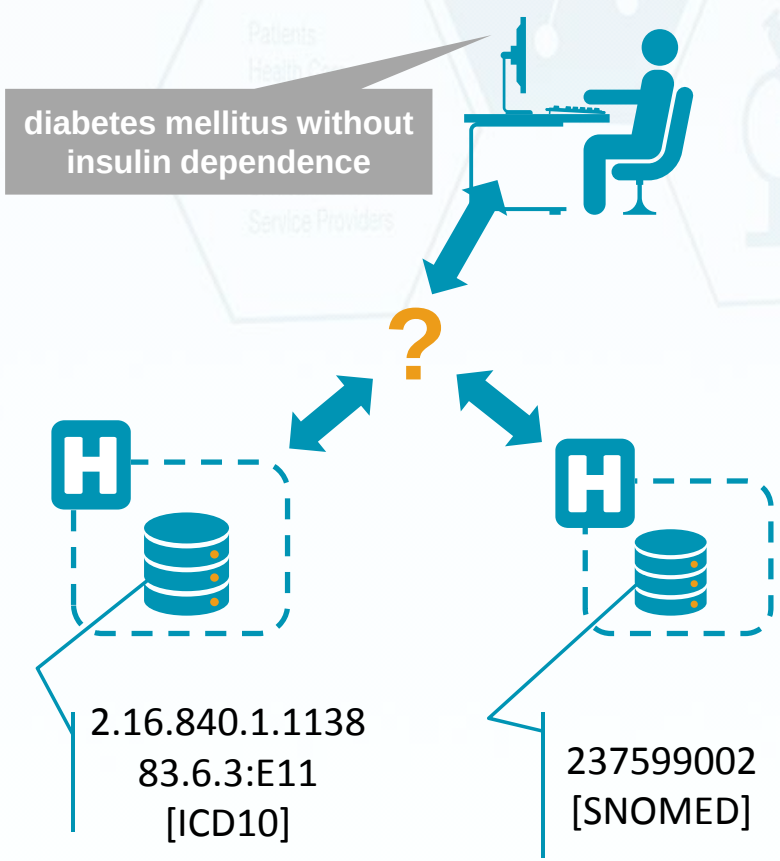
Protocol feasibility



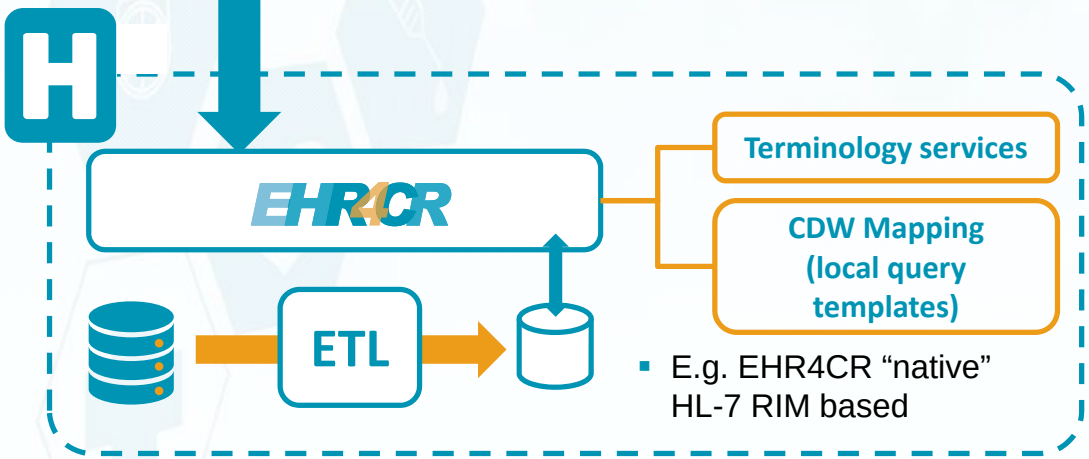


Semantic integration

TECH INFO SEMANTIC INTERGATION



- EHR4CR Information Model
  - Terminology: subsets of PathLex, ICD-10, SNOMED, LOINC, ATC
  - Common Data Elements
  - Using ISO 21090 harmonized data types
  - Concept expansion (central)



Semantic Integration - Querying

TECH INFO SEMANTIC INTERGATION

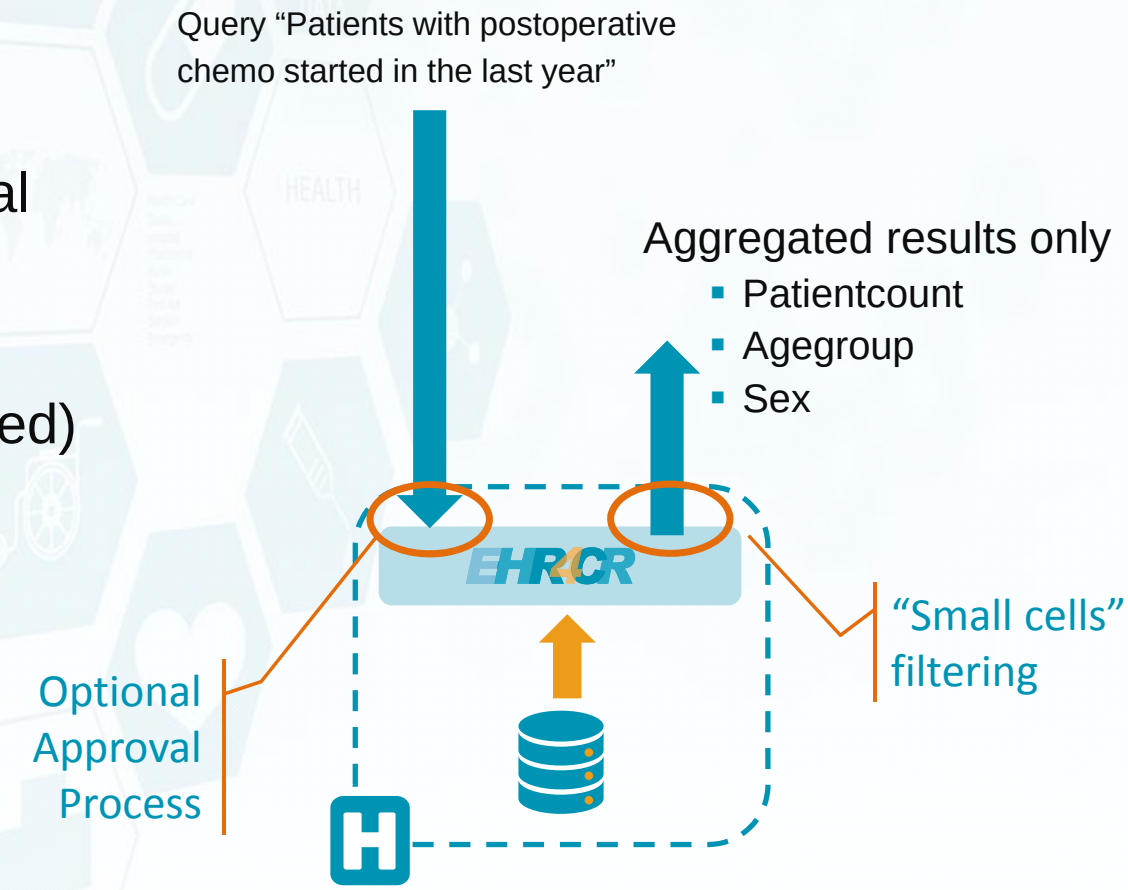
- Criteria more complex than “atomic” database queries
  - Cross-criterion temporal constraints
- “Blue Model”
  - Computable, site representation-independent model
  - General, extensible and expressive language
  - Coding-system agnostic
  - Clinician readable representation (ECLECTIC)

```
1 born() at least 18 year before now and
2 not deceased() and
3 last diagnosis([ICD10:E11,"Diabetes mellitus type 2"]) and
4 last result([LOINC:17856-6,"HBA1c"]) in range(>=6.5,<=10.0)
         unit([UCUM:%,"Percent"])
```

Security & Privacy

TECH INFO SECURITY & PRIVACY

- Privacy by design
  - No patient data leaves the hospital
- Safeguards in workflows
  - Approval process (if locally required)
- Privacy protection monitoring
  - E.g. small cell filtering

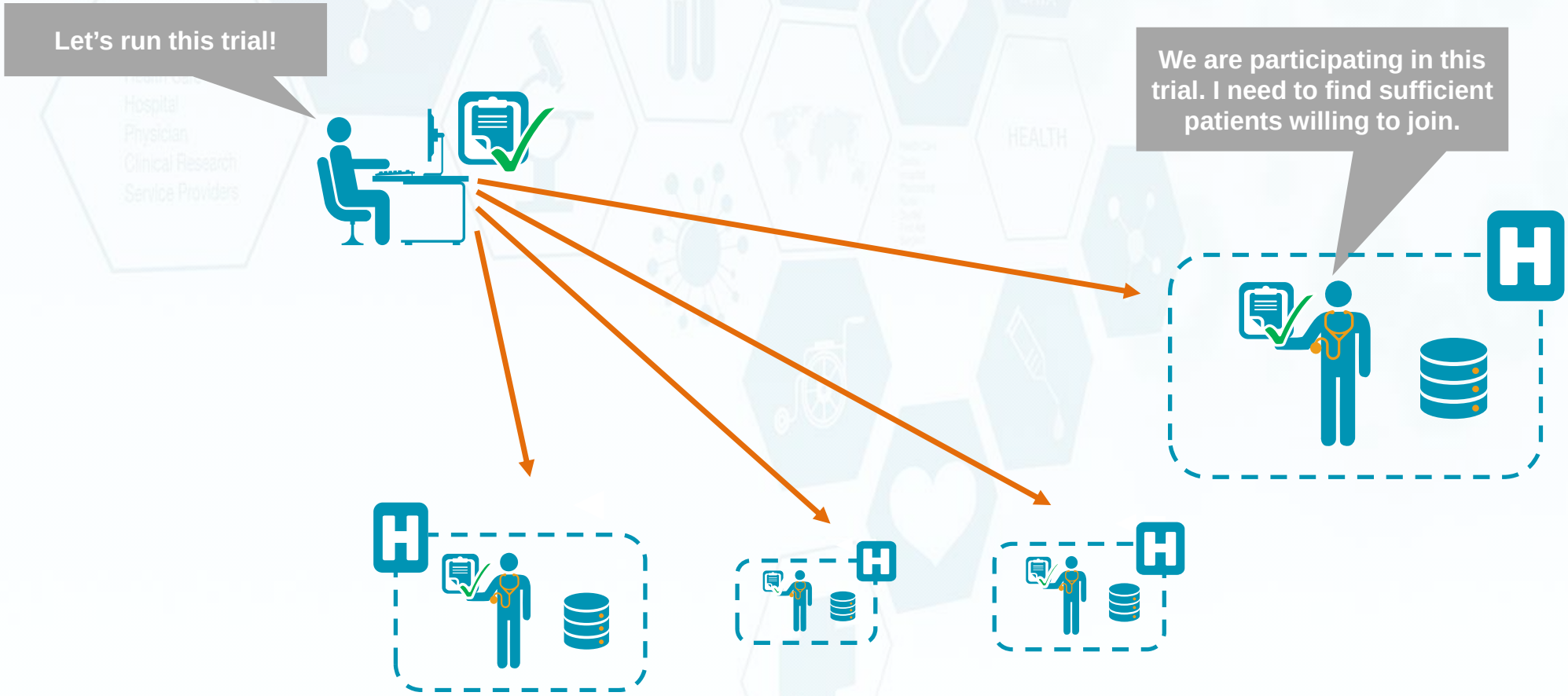


Security & Privacy

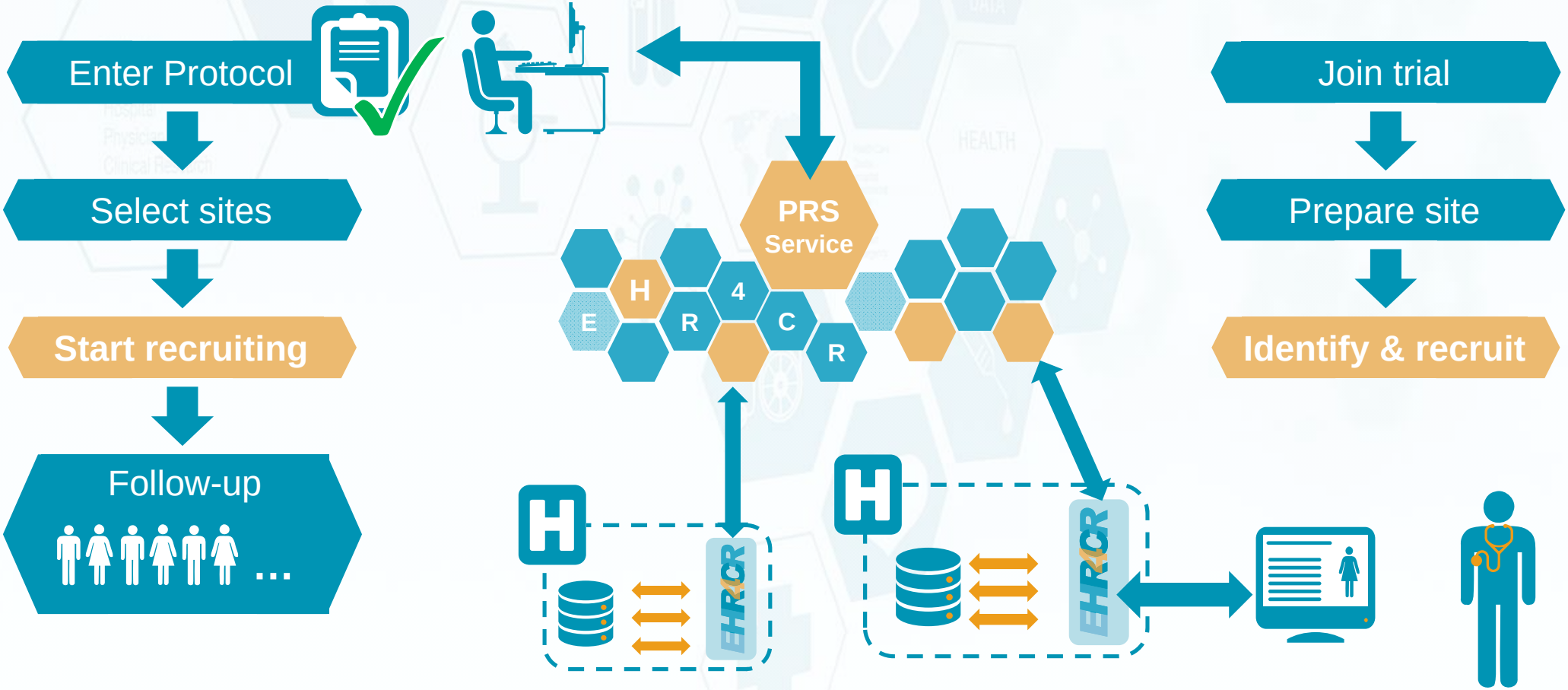
TECH INFO SECURITY & PRIVACY

- EHR4CR Security Framework
  - Advanced SOA security framework (cross-organisation Web Services)
- Key points
  - All operations fully (end-user) authenticated through credential delegation
    - Seamless SSO between websites & services
  - Central Identity & Access Management (IAM)
    - Enforces platform-wide policies (e.g. contractual agreements)
    - Fully complementary to local access control (federates)
  - Unified platform audit trail

Patient identification & recruitment



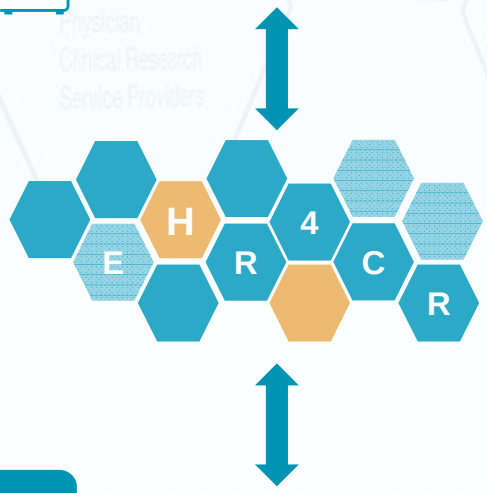
Patient identification & recruitment



Workflow

TECH INFO WORKFLOW

- Study Managers



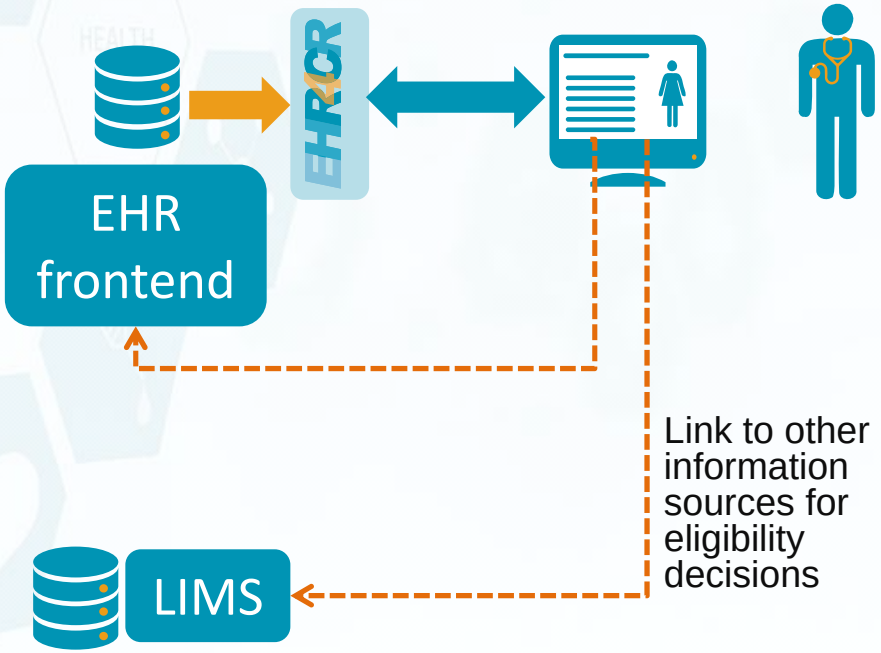
- Site data managers
- (Principal) Investigators
- Treating physicians

- EHR4CR supported workflows simplify clinical trial management process
- Workflows facilitate communication and streamline task assignment between actors
  - Intra- and cross-organisation

Computer aided recruitment

TECH INFO
SEMANTIC
INTERGATION

- EHR4CR based tools enable faster identification (automated filtering)
- Combine power of automated querying with manual lookup in local sources
- Open platform
  - Other recruitment tools can integrated with the EHR4CR hospital connector



Join us!

Operational pan-European platform

Project graduation

EHR4CR - IMI research project

- Project pilot hospitals
- Partner hospitals
  - Technology champions
  - EHR - structured data
  - Venture together into deployment, operations engineering
- Early adopters
  - EHR - structured data
  - Scaling up

Don’t miss out on what’s to come

- Moving towards sustainability in 2015
- Help shape the future of clinical trials
  - Share you visions and ideas!
  - Join the community as an early adopter!

Visit us at the booth for more information

For now… enjoy the demo