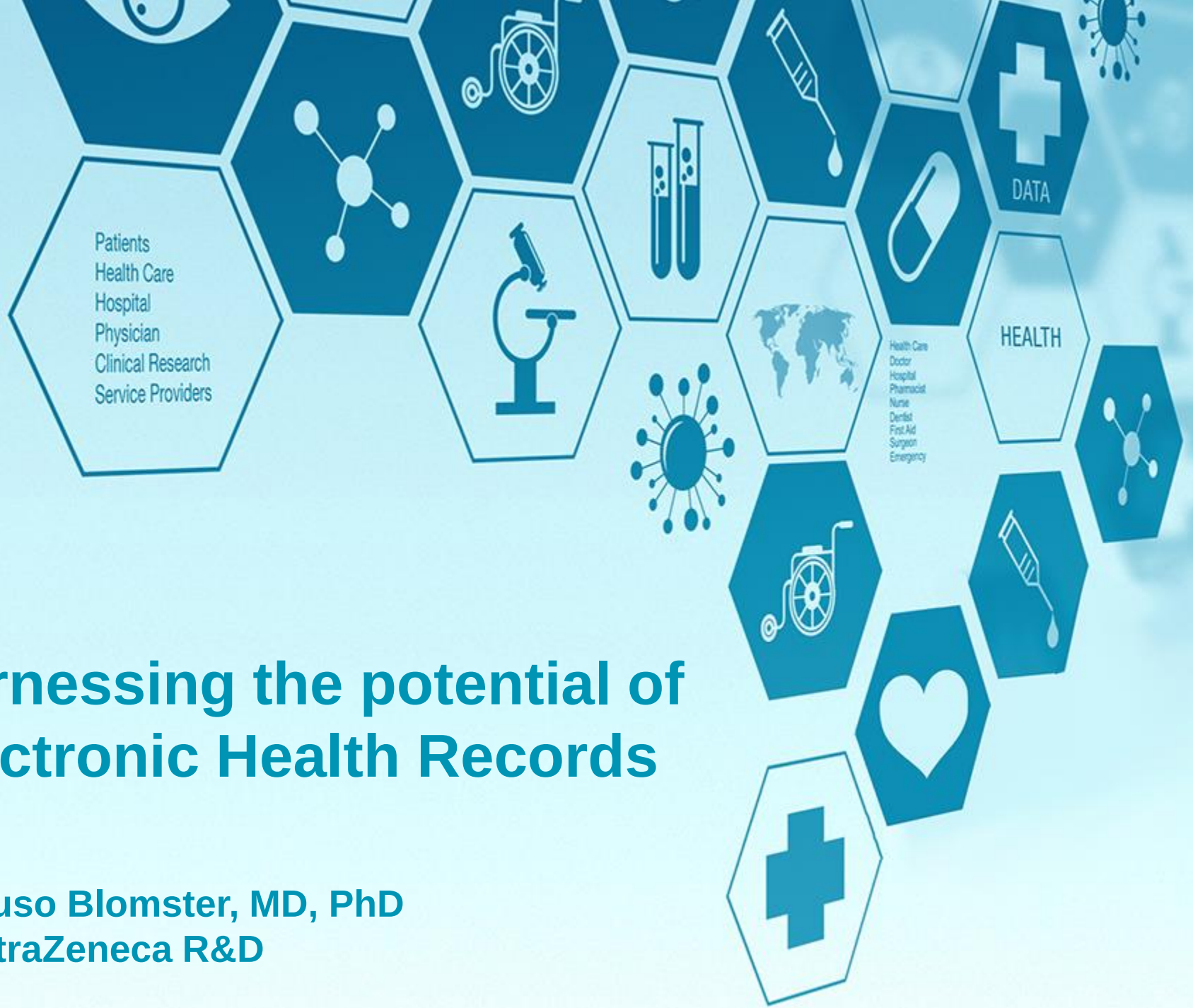

Harnessing the potential of Electronic Health Records

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The framework for Electoric health records (EHR)

- The primary aim for electronic health records is to serve and enable planing and execution of treatment of patients. Besides this they can be untilized for secondary purposes, such as:
- Research and innovation
- Improvement of services and management
- Improvement of treatment pathways and outcome

The challenges in clinical research
- high costs, time delays and ineffectiveness

- Current drug development cost are > 2.5 billion USD
- Less than 20% of clinical trials in EU enroll in time
- 50% of trials miss target recruitment causing delays
- Manual input of data in study electronic health records takes time, resources and is prone to errors
- > 70% of study data is estimated to be duplicated in electronic health records
- Monitoring costs may build up to 1/3 of total trial costs
- A large phase 3 trial (>10 000 patients) may cost up to 300 – 600 million USD.
- Global clinical trial market, both institutional and industry – ~22,000 clinical trials annually worldwide, 5,000 in Europe

The Electronic Health Records (EHR) project

- Objectives & Scope
  - Provide a platform capable of mapping and connecting different hospital records together for **trustworthy re-use of hospital EHR data**
  - Enable innovation in clinical research and healthcare operations.
  - Unlocking **Real World Data** for optimising clinical trials and assessment of health care productivity – something for all: industry, academia and health care official (government / payer organization)
- Status
  - The platform is fully functional – expanding to new hospitals in progress
  - The **European Institute for Innovation through Health Data** – a fully independent governance body.

efpia

imi
Innovative Medicines Initiative

Project (ELECTRONIC HEALTH RECORDS FOR CLINICAL RESEARCH)

2011-2016 (project completed) 2017

PLANNED → 4 YEARS + 1 → **DELIVERED**

EHR4CR R&D platform:
Interoperable system connected to several hospitals

Business model:
New ecosystem to leverage emergence of such practice

Governance:
An institute to regulate and manage the ecosystem

A **InSite clinical platform:**
Interoperable scalable platform connected to hospitals offering services (researchers/industry and hospitals)

B **Champion Industry Program:**
- Post project deployment in real life, connecting *NEW* hospitals to the InSite platform
- Building up experience with sponsoring Efpia companies and hospitals for feasibility & recruitment services

C **The European Institute for Innovation through Health Data (i-HD):**
As an independent governance body

Challenges for the re-use of health data for clinical research addressed

Interoperability

- **Infrastructure & Syntax**
  - Harmonisation in a **Clinical Data Warehouse** partially through ETL (Extract Transform and Load) and partially through query mapping in the platform connectors.
- **Semantic**
  - Eligibility criteria formalisation using **coding-system agnostic query languages** for representing eligibility criteria.
  - Use of a Common Information Model.
  - CIM to site specific **information models transformation services** provide terminology conversion (e.g. PathLex, ICD-10, SNOMED, LOINC, ATC, …), unit conversion, concept expansion, etc.

Scalability & Maintainability

- The platform is a **loosely coupled Service Oriented Architecture**, use of industry standards is maximised. This architecture ensures scalability and maintainability through modularity.

Security & Privacy

- Security relying on CIAM, an **advanced SOA security framework** designed for healthcare environments.
- Governing pinciple: **no data leaves the site**

Confidence in data

- Data quality monitoring can be built in the site node software based on the EHR4CR query technology.

Value for hospitals

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

Better patient care

More patients will get **access to trial drugs and innovative care** pathways **at no additional cost** to the hospital.

Physicians participating in clinical trial are in general more up to date with medical science.

Increased income

Cutting cost will no longer be sufficient to deal with the overall healthcare budget decrease. Hospitals need to search for **new revenue streams**, the clinical trial platform will help them to **attract more trials** and thus income.

Access to tools

Participation to the clinical trial platform includes free access to a **set of tools to explore and analyze patient data**.

Anyone familiar with the cost of clinical IT systems understands the value of this benefit.

Better quality data

The clinical trial platform stimulates hospitals to **focus on the quality** of their data. Improved monitoring, performance benchmarking, reporting and management (e.g. reimbursement coding) drives **optimization of patient care and improved internal management**.

Enhanced reputation

Hospitals and their physicians participating in more clinical trials will get **greater visibility in scientific community**. Which on its turn will attract more research (trials), top-class physicians and more patients (once reputation gets picked up by the media).

Value for 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

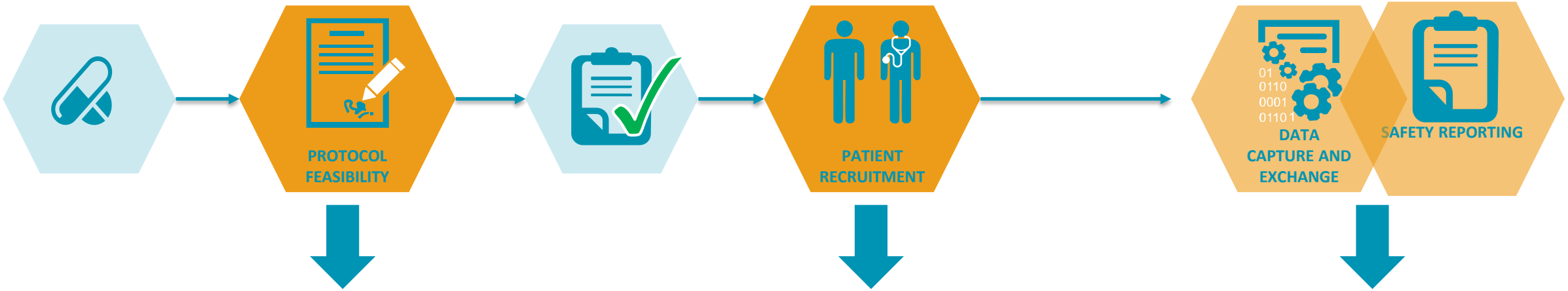
- Less manual work, less corrective measures, etc. lead automatically to a decrease in total trial cost. Pharma will also avoid the expense and time and effort of opening trial sites which will not yield enough patients.

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).

The EHR objective – The full Potential

- A **full service platform able to unlock clinical information stored in EHRs**
- Direct & near real time access to source data redefining the need for queries, SDV etc

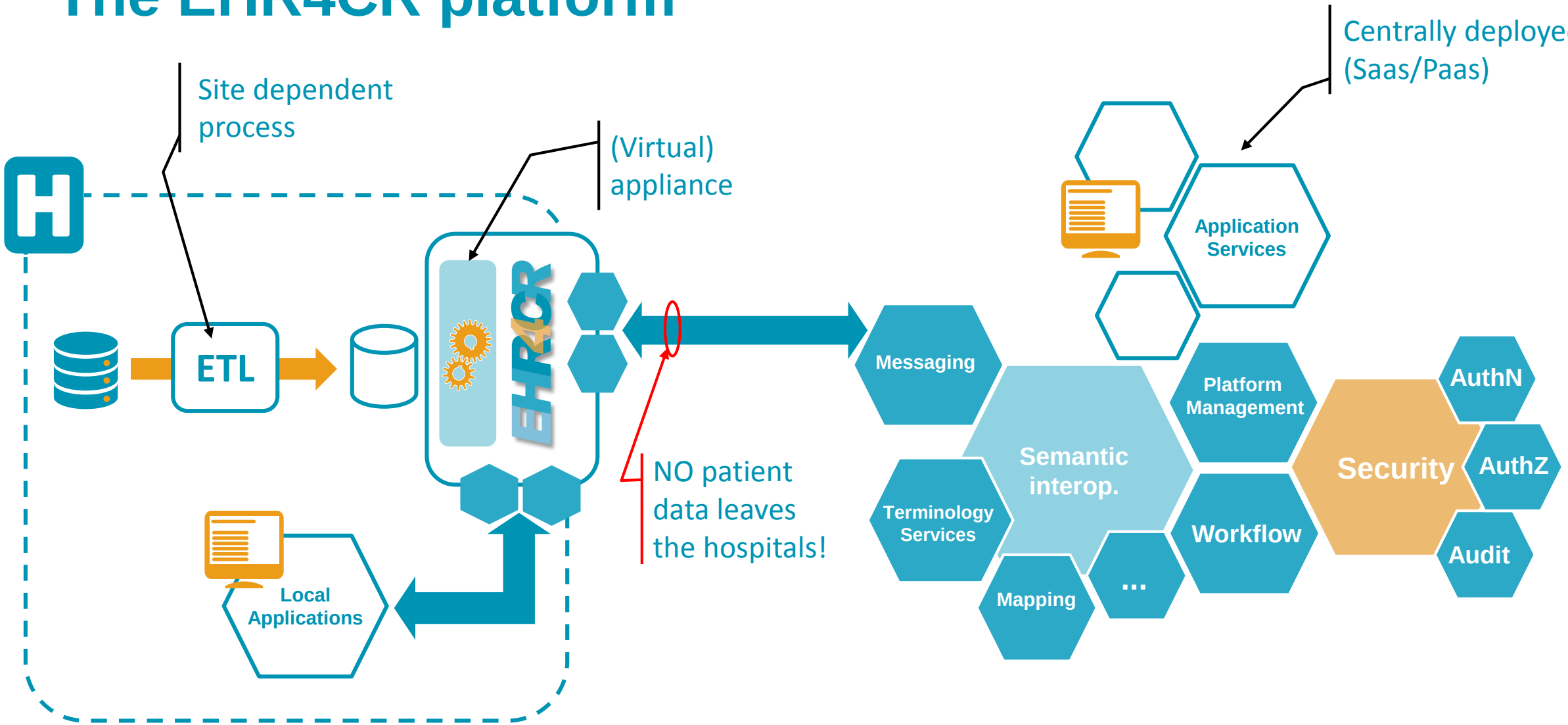


Enabling **protocol testing with real world data** in potential trial sites rather than with guestimates.

Speeding up recruitment by making EHR data **searchable for investigators** and establishing a **unified communication path** between sponsors and sites.

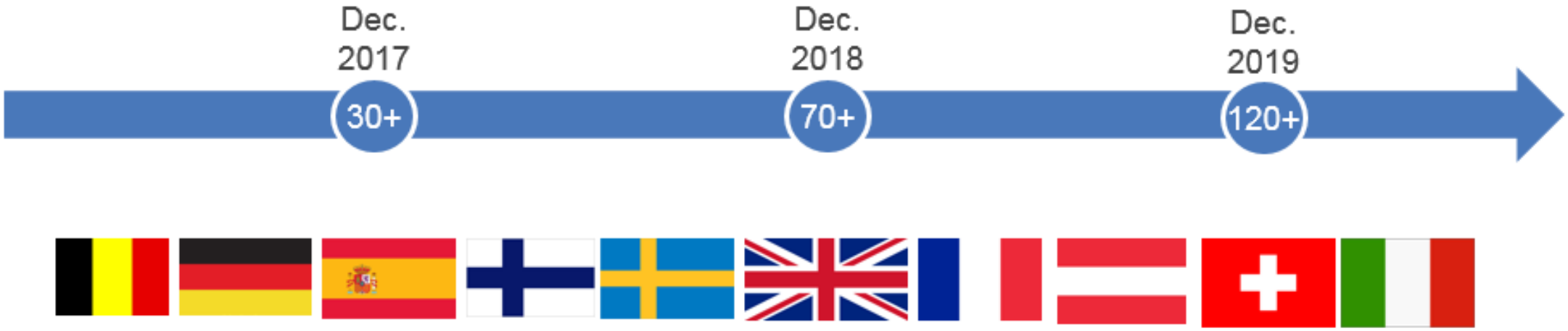
Facilitating **EHR data extraction** for applications used during trial execution (e.g. prefilling of CRFs and of SAE reports).

The EHR4CR platform



EHR4CR CUSTODIX InSite An EHR4CR Service Platform

The InSite Network



The EHR landscape

InSite

(Epic)

TriNetX

Epic

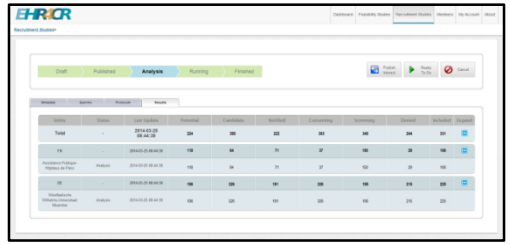
Initial services

Starting with a simple service offering for Research Organisations

- Initial focus is on building the network and introducing the technology in hospitals
- The two services should be able to demonstrate the value of this initiative to all stakeholders
- Piloting new services will be done as the need arises
- The service offering will be expanding as the technology matures

Protocol feasibility services

- **Optimise** protocol eligibility criteria by **instantaneously** testing them out in multiple sites in various countries
- Directly **identify the countries and specific sites** to approach for participation



Trial recruitment services

- **Distribute trial protocols** over multiple sites in a uniform way
- **Track recruitment progress** in real time
- **Optimal recruitment due to tools** provided to hospitals

"Protocol Feasibility services" cover a broader application domain than expected from the name. The service allows patient populations, hospitals and databases to be remotely and securely clinically assessed (distributed query). These services are invaluable ***for trial design, site selection, pharmaco-economics, etc.***

Long term objective

- Establish a **network of clinical sites**
  - **Permanently connected** to the clinical platform giving access to millions of patients in close to real time
  - Each **empowered to support clinical trial processes** through locally provided technology
    - Computer assisted recruitment, extraction of EHR-data for reporting (eCRF, SAE, …), cohort analysis, etc.
- Provide a **multitude of services** to research organisations to optimise the clinical trial process through data re-use
  - Initial services: protocol feasibility, patient recruitment
  - Pre-filling services (eCRF, SAE reporting)
  - Data extraction, analytics
  - Site Benchmarking
  - …

Value = a network of data sources

- Focus on **building connectivity** in Europe
- Engage with **the major European hospitals**
- **Reach out** to similar initiatives in the rest of the world, building a network of networks.