The EHR4CR project: the case of federated EHR research technology to support clinical research & trials

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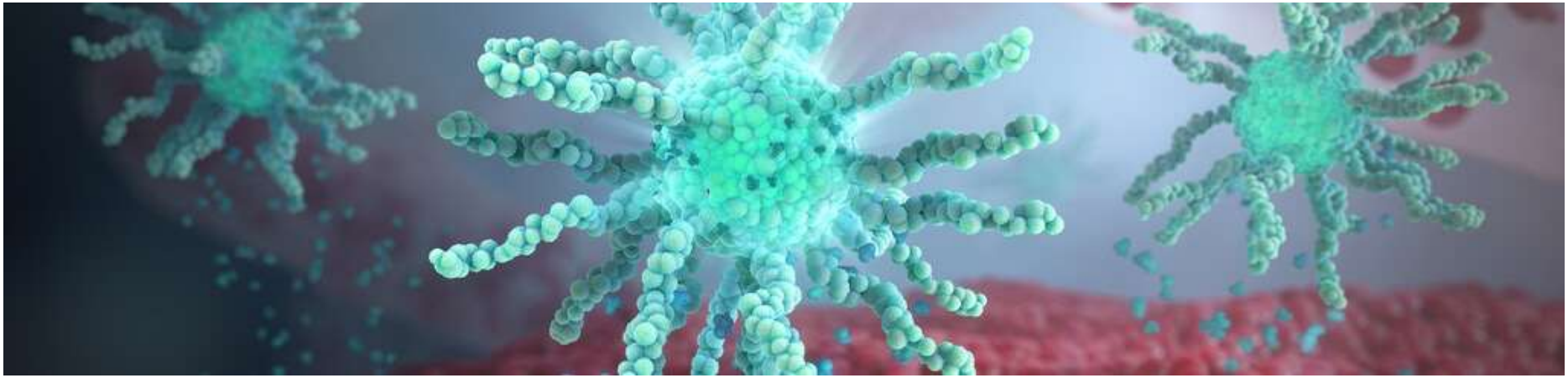


Outline

- The EHR4CR project & scale up activities
- How does FED EHR technology works?
- Examples of using FED EHR services in AstraZeneca
- Outlook for FED EHR technology

2009 call topic

Research problem R&D a trustworthy and scalable platform technology & business model for re-using electronic Health Data (EHR) across system, countries and regions for supporting clinical research process in Europe

2011-2016

EHR4CR

imi innovative medicines initiative

2017-2019 deployment of InSite in Europe

Emerging Federated EHR Research platform technology vendors

with growing hospital networks in Europe, US and beyond

InSite

TriNetX

CLINERION Real World Data Solutions

flatiron

DEEP 6

FED EHR technology is:

- unlocking new opportunities to enhance clinical research;
- enable new collaborations between sponsor, health care organisations and investigational sites;
- providing a new gateway for trustworthy use RWD, which can transform the way we do clinical trials

Key enabler for success is **win-win services** for sponsors and HCOs.

Setting the scene

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

EHR4CR

innovative medicines initiative

2011-2016

Electronic Health Records for Clinical Research

Vision

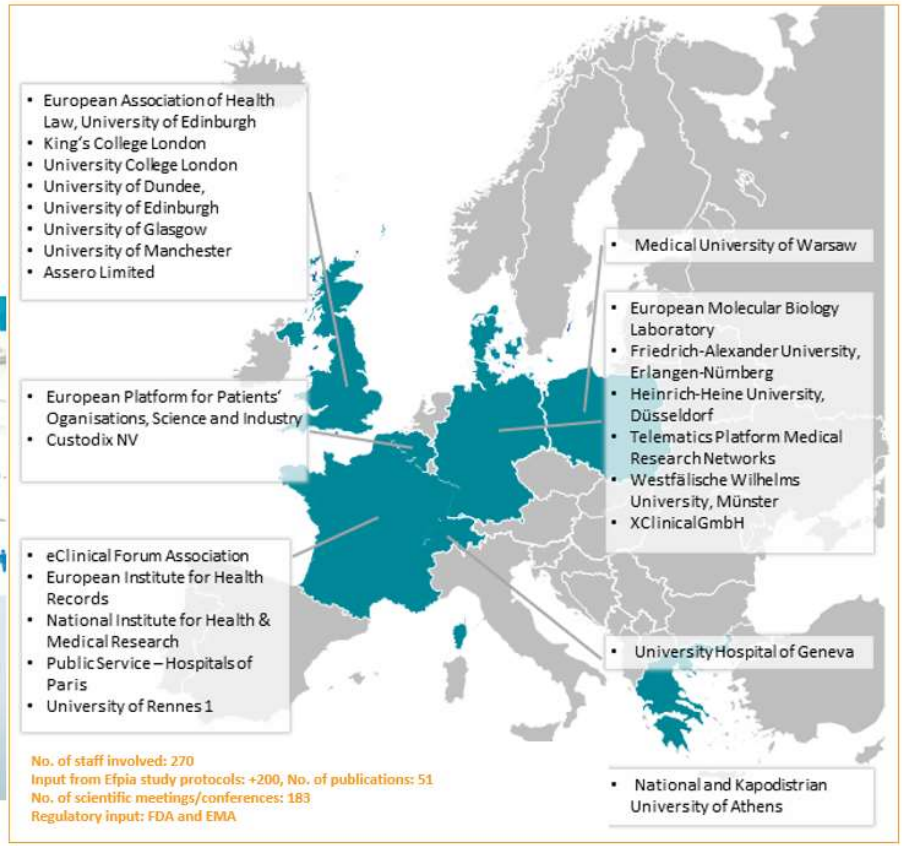
To be the trusted gateway to eHealth information for research and knowledge discovery to transform healthcare worldwide.

Mission

Delivering sustainable value-added solutions for the trustworthy re-use of eHealth data and information to improve global clinical research.

Values

- Provide flexible, scalable and interoperable solutions
- Ensure full compliance with relevant ethical, legal, regulatory, and privacy protection standards and policies
- Deliver innovative, customer-focused and sustainable value-added services
- Optimize healthcare connectivity by enabling adoption, collaboration, accountability and transparency



No. of staff involved: 270
Input from Efpia study protocols: +200, No. of publications: 51
No. of scientific meetings/conferences: 183
Regulatory input: FDA and EMA

efpia AstraZeneca, Amgen, Bayer, Eli Lilly, GSK, Janssen, Merck, Novartis, Roche, Sanofi

Coordinator: Mats Sundgren, AstraZeneca

efpia 4

Electronic Health Records for Clinical Research

Impact on Industry

Clinical Trial impact

InSite

WINNER EUROPEAN INNOVATIONS AWARDS 2018

InSite platform is accessible under a license, with access to EHR4CR partner on better condition and privileged relation with CUSTODIX (https://www.insiteplatform.com)

- **Improved accuracy in trial design from start and protocol assessment with use of de-identified EHR data in real time in the largest European network of interconnected hospital with access to more that 30mio EHRs**
- **Increase speed, quality & reduce cost/time**
  - Data driven study design. Reduce 2-3 months industry standard turn around time per protocol to less than 2-3 days (including multiple iterations of I/E criteria) using less resources
  - Reduce amendments (e.g. 4-5 months time saved per amendment)
  - Faster recruitment by making EHR data searchable for investigators and establishing a unified communication path between sponsors and sites
    - On going pilots with AZ and Efpia companies demonstrate significant enhanced recruitment

Societal impact

The European Institute For Innovation Thr~ugh Health Data

- Institute of innovation through Heath Data (i-HD) has been created to promote quality of data (https://www.i-hd.eu)
- Quality Labelling of Clinical Research Platforms and accreditation mechanism for service provider of EHRs and RWD providers
- Governing the Reuse of Health Data for Research

Sustainability

- Champion program for the expansion for the network (completed in December 2017) resulting in an European hospital network of +50 hospitals
- Efpia Champion partners continue collaborate on influence the growth of the network
- EIT Health EHR2EDC project (https://www.eithealth.eu/ehr2edc)

efpia

Today

Capabilities of new health data-collection/re-use technologies including EHRs will have a huge impact to support clinical research and trial execution over the next years

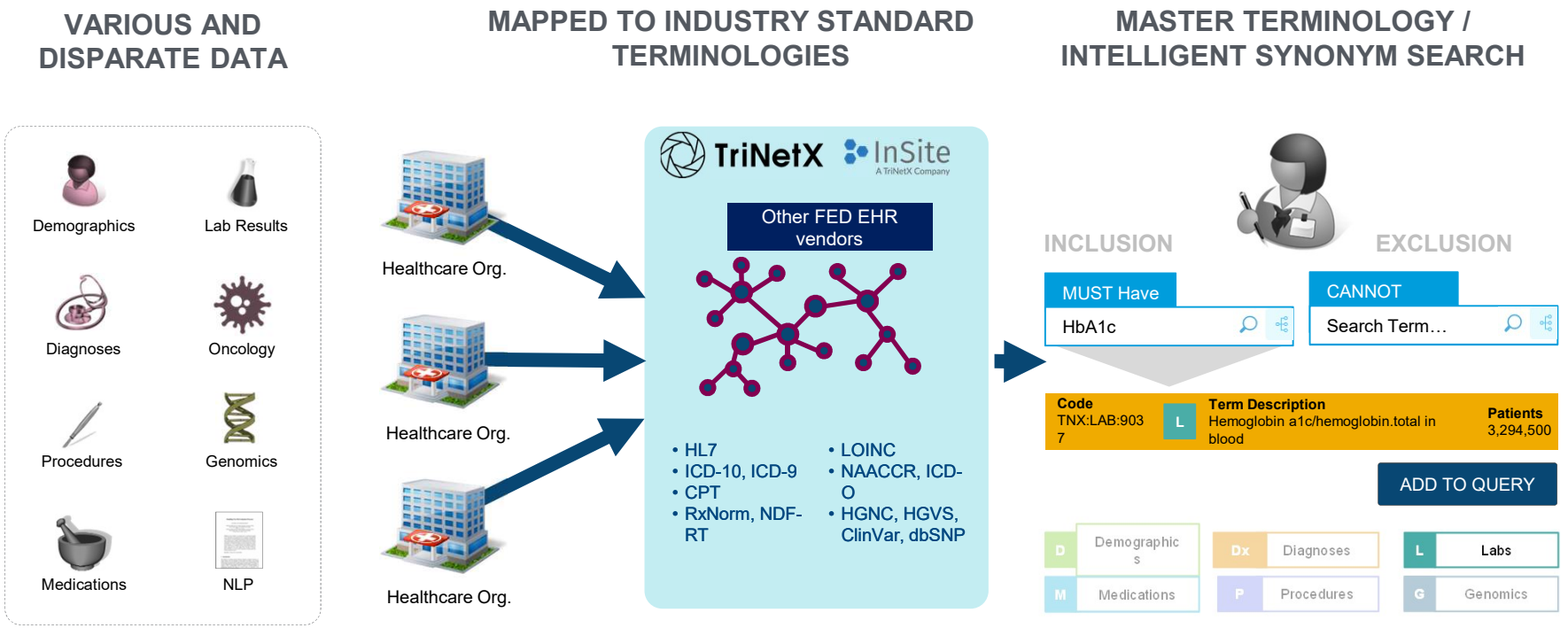
The foundation of this federated EHR platform technology is there, processes are in place and regulators are supportive. The technology is disruptive to the current Business Models by collaborating directly with HCOs

EHR4CR has paved the way for the establishment of Federated EHR technology services with new vendors and HCO networks, and a foundational project for other IMI projects e.g., EMIF, EHEDEN and PEARL & EIT Health EHR2EDC

How federated EHR platforms works

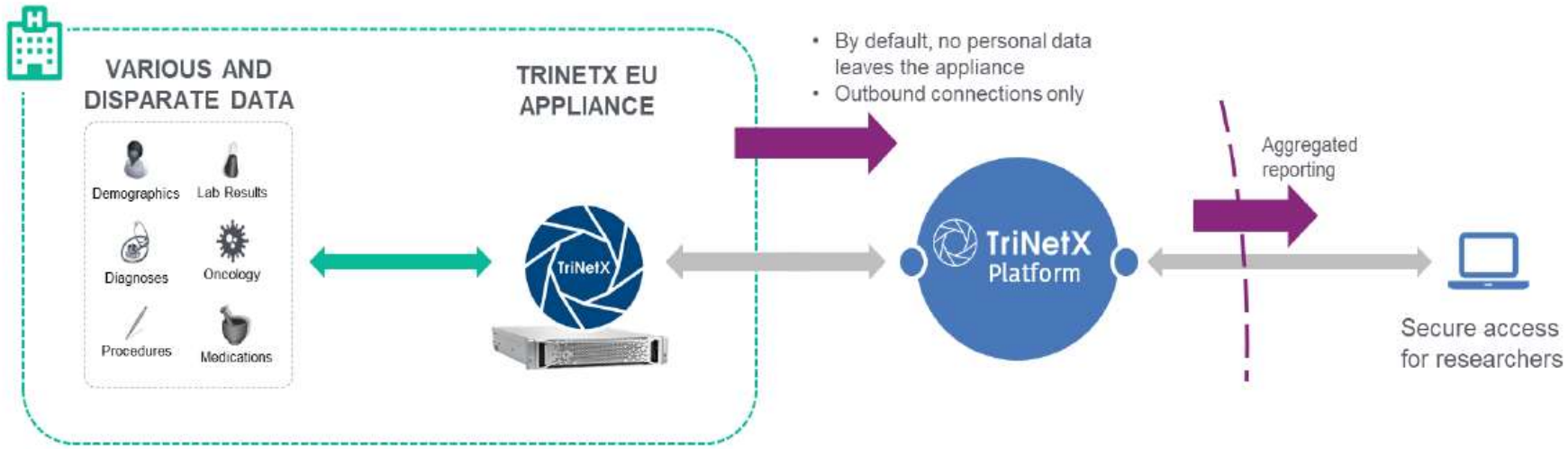
FED EHR research platforms: TriNetX & InSite

combine and standardize disparate patient level data across HCOs



FED HER: How it works

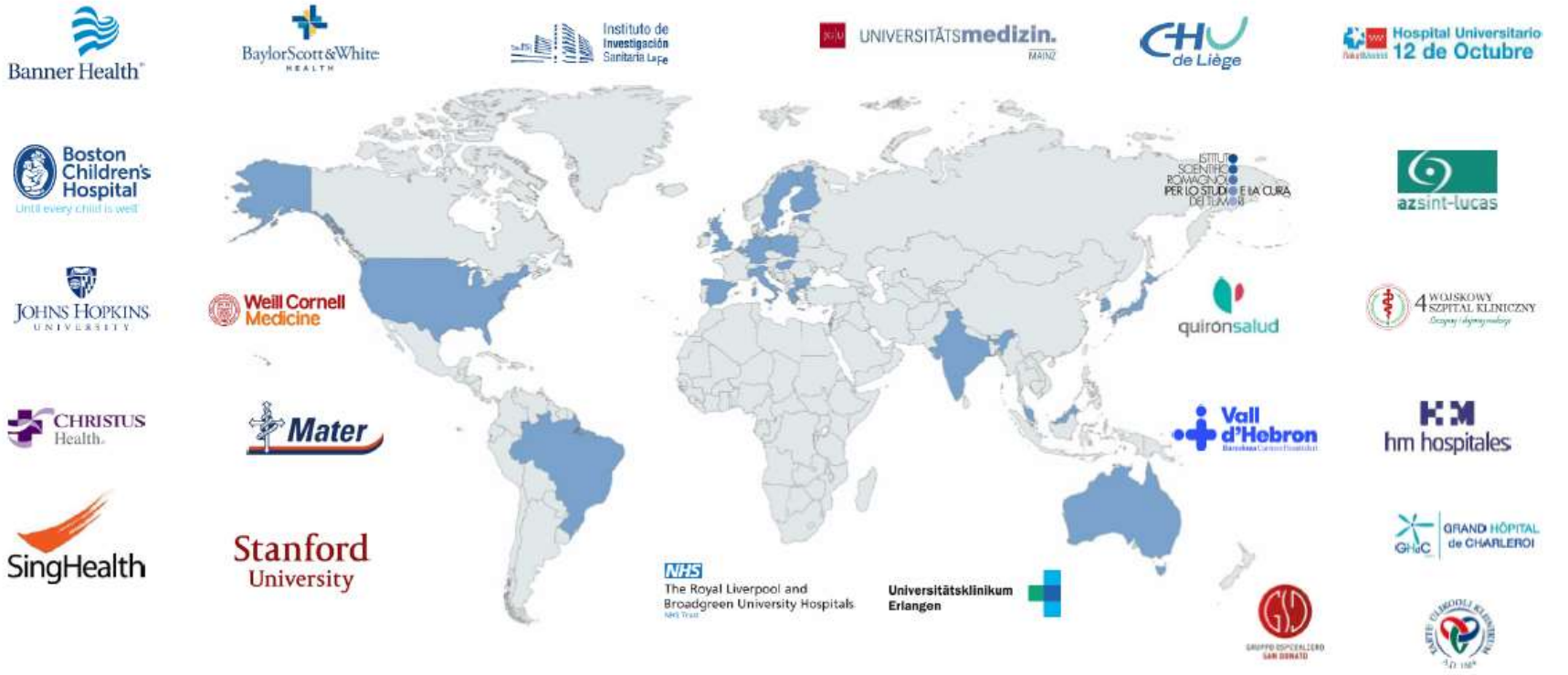
HIGH-LEVEL DATA SECURITY – Data stays where it has been created at HCOs



Inside HCO/Hospital

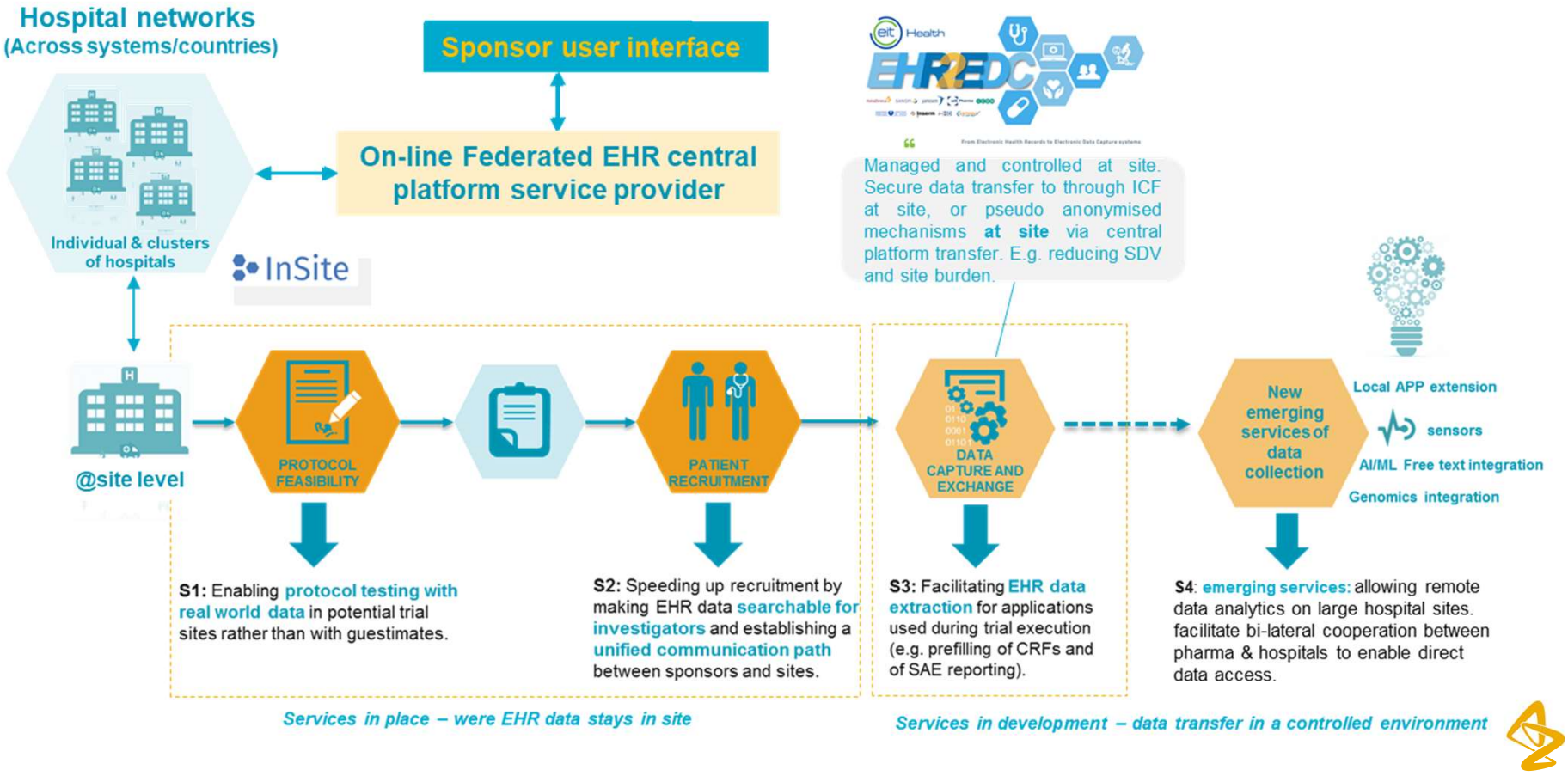
TriNetX Global Network of HCOs

Live FED EHR network span +130 connect HCOs (+1200 sites) and +120 M patient lives



TriNetX InSite A TriNetX Company

What can Federated EHR technology?

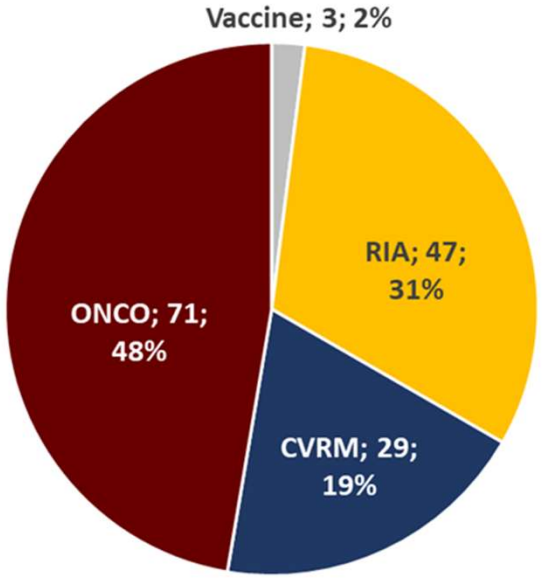


Examples from AstraZeneca

FED EHR support for >150 studies delivers performance benefit in AZ

- **Design Support.**
  - **Site engagement**/confirming study interest with results in <7-day average response and >50% response rate overall
- **Exploratory assessment**
  - of patient demographics and disease risk factors mapped against potential and current sites
- **EHR-driven patient journeys & advanced analytic services**
  - across clinical programs

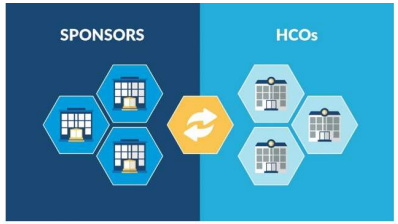
Electronic Health Record supported studies since launch in 2019



Milestone reached – Sep 2020

FED EHR enabled services in 2021 – *early & late-stage portfolio using real time EHR data*

- ✓ **Design support**
- ✓ **Feasability support**
- ✓ **Trial Connect for recruitment support**
- ✓ **Treatment Pathways & Compare Outcomes**
- ✓ Site EHR enabled recruitment pilots in Europe and US on-going



Trial Connect accelerates study site selection and investigator engagement

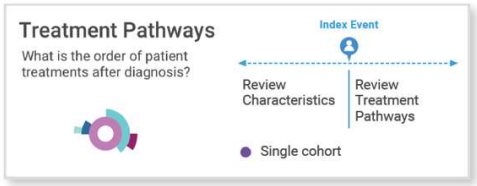
- Directly engage with the right sites quickly and easily
- Centrally monitor site acceptances, declines and pending responses.

Trial Connect

- The industry average for site identification is **six weeks** (42 days)
- The TriNetX average for site identification is **two weeks** (14.4 days)

Compare Outcomes
Conduct comparative effectiveness research with propensity score matching, stratification, and Kaplan-Meier analyses.

- Conduct retrospective observational analysis
- Compare cohorts' baseline characteristics
- Compare risk of outcomes across cohorts
- Perform time-to-event analysis

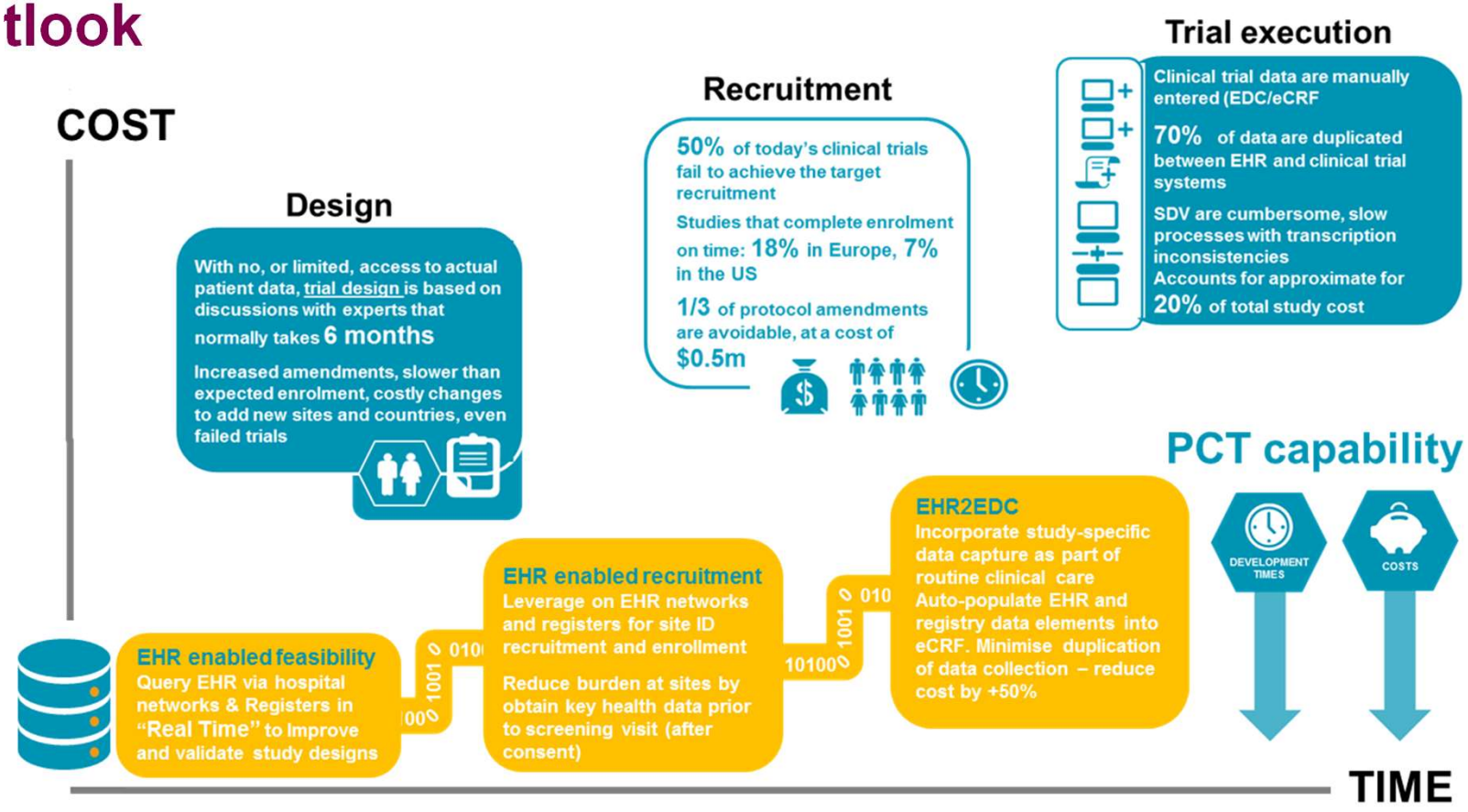


Treatment Pathways
Analyze how patients are treated and when they switch treatments. Compare lines of treatment for any disease.

- Understand typical care pathways
- Analyze characteristics of patients who switch treatments
- Compare outcomes across different lines of treatment

Outlook

Outlook



Federated EHR platform technology connecting RWD into the clinical trial process and provide gateway to Pragmatic Clinical Trials

Key impact areas of FED EHR

- **Real time access at source** (digitized centric & continuous data flow capabilities)
- **Stronger collaboration and trust with health care/hospitals** (stream lining operations)
- **Gateway for cost effective data exchange services at sites** (e.g. direct data capture into EDC (clinical trial, submission, genomics and RWE capabilities)
- **The emerging capability is to conduct multi-centre and multi-country PCTs rapidly**

Additional value propositions: federated EHR platforms

Protocol optimization/feasibility service

show that under optimal conditions this technology can significantly reduce current **+61 days feasibility** (industry standard turn around time per protocol) to less than 2-3 days (including multiple iterations of I/E criteria) using less resources

Reducing amendments & time!

By assuming industry standard of 2.3 amendments per study, in which **1/3 relate to protocol description** or patient eligibility criteria, show cost saving 150 KUSD, BUT also to save time (median time is 65 days/amendment) multiplied by 2.3 amendments equals **four to five months of lost time)**

Enhanced trial execution at site

Automatic transfer of EHR data to eCRF at site. Downstream, this technology provide a new vehicle for conducting pragmatic clinical trials e.g. EHR2EDC capability

Gains for hospitals

Faster clinical setup and initiation, speed up recruitment, reduced site burden, enhance quality, consolidated access to own EHR sources, and new research opportunities

Save feasibility time by

2 months

Feasibility turnaround in

<2 days

Reduction of amendment per study

150 KUSD

Reduction of Source Data Verification (SDV)

Reduce **feasibility saturation @site**. Data driven & real time feasibility replace questionnaires……

Thank You

Thank You

Scaling up the technology provide new opportunities to collaborate!

This shown in deploying the output from the IMI EHR4CR project (European hospitals, Industry/Efpia, Custodix and i-HD), and with new vendors and industry partners

This is a good example of a Nash equilibrium……

"Best results will come when everyone in the group do what is best for themselves, and the group"

(Governing dynamics - John Nash, Nobel Laureate in Economics, 1962)