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

Emerging Federated EHR Research platform technology vendors with growing hospital networks in Europe, US and beyond

**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

3. Beasley, "Recruiting" 2008
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

European Association of Health Law, University of Edinburgh
King’s College London
University College London
University of Dundee
University of Edinburgh
University of Glasgow
University of Manchester
Assero Limited

European Platform for Patients’ Organisations, Science and Industry
CustodieX NV

eClinical Forum Association
European Institute for Health Records
National Institute for Health & Medical Research
Public Service – Hospitals of Paris
University of Rennes 1

Medical University of Warsaw
European Molecular Biology Laboratory
Friedrich-Alexander University, Erlangen-Nürnberg
Heinrich-Heine University, Düsseldorf
Telematics Platform Medical Research Networks
Westfälische Wilhelms University, Münster
XClinical GmbH

University Hospital of Geneva
National and Kapodistrian University of Athens

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

Coordinator: Mats Sundgren, AstraZeneca
Electronic Health Records for Clinical Research

Clinical Trial impact

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 turnaround 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 Efuria companies demonstrate significant enhanced recruitment

Societal impact

- 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
- Efuria Champion partners continue collaborate on influence the growth of the network
- EIT Health EHR2EDC project (https://www.eithealut.eu/ehr2edc)
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

**VARIOUS AND DISPARATE DATA**

- Demographics
- Lab Results
- Diagnoses
- Oncology
- Procedures
- Genomics
- Medications
- NLP

**MAPPED TO INDUSTRY STANDARD TERMINOLOGIES**

- HL7
- ICD-10, ICD-9
- CPT
- RxNorm, NDF-RT
- LOINC
- NAACCR, ICD-O
- HGNC, HGVS, ClinVar, dbSNP

**MASTER TERMINOLOGY / INTELLIGENT SYNONYM SEARCH**

**INCLUSION**

- HbA1c

**EXCLUSION**

- Search Term...

**Code**

- TNX:LAB:903

**Term Description**

- Hemoglobin A1c/hemoglobin total in blood

**Patients**

- 3,294,500

**ADD TO QUERY**

- Demographics
- Diagnoses
- Procedures
- Medications
- Labs
- Genomics
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
What can Federated EHR technology?

S1: Enabling protocol testing with real world data in potential trial sites rather than with guestimates.

S2: Speeding up recruitment by making EHR data searchable for investigators and establishing a unified communication path between sponsors and sites.

S3: Facilitating EHR data extraction for applications used during trial execution (e.g. prefilling of CRFs and of SAE reporting).

S4: Emerging services: allowing remote data analytics on large hospital sites. Facilitate bi-lateral cooperation between pharma & hospitals to enable direct data access.
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
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** (streamlining 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

Feasibility turnaround in
<2 days
Reduction of amendment per study
150 KUSD

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/Efpiia, 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)