På väg mot en Europeisk plattform för användning av EHR data för klinisk forskning

Mats Sundgren, AstraZeneca Coordinator

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Objectives

- Overview of the EHR4CR project
- Explain the platform and services development and the deployment activities
- Awareness for the European Institute for Innovation through Health Data
- Reflections on the importance of collaboration

www.ehr4cr.eu
PROBLEM STATEMENT
There is a need to bridge the gap

We have imagined an environment where de-identified patient data can be re-used within healthcare and research for clinical research purposes…

- Across countries
- Across systems
- Across sites

…to speed up protocol design, patient recruitment, data capture, safety reporting…
THE PROJECT
A unique initiative

- EHR4CR – Electronic Health Records for Clinical Research
  - Re-use of EHR data for optimising Clinical trials
- Mandated by IMI
- One of the largest European public/private partnership projects in this area
- 4-year project (2011-2015)
  - Extended into 2016 for making the transition to a sustainable platform.
- Budget of € >17m

For more information: http://www.ehr4cr.eu/
EHR4CR brings together multiple stakeholder groups to achieve something that individual groups cannot realise alone.
Project deliverables

TECHNICAL PLATFORM

A set of tools and services

1. **Protocol Feasibility**
2. **Patient Identification and Recruitment**
3. Clinical Trial Data Exchange

Validated through pilots

- Different therapeutic areas (e.g. oncology, neuroscience, diabetes, CVS…)
- Several countries (under different legal frameworks)
Provide an open platform that allows expansion of services for re-use of EHR data to support innovation in both research and healthcare operations

- Open platform
- Configured for expansion
- Enabling services beyond EHR4CR
Wins that are being validated through real-life pilots demonstrating that barriers that limit access to EHRs for research are being overcome

Interoperability
- Successful mapping of local terminology to central EHR4CR terminology

Data security, privacy & ethics
- Relevant approvals secured for upload of de-identified data to data warehouses
- No patient-level data left the hospital environment
- Platform generated patient counts only

Confidence in data
- EHR4CR platform generated results
  - Patient counts validated by User Functionality Testing
  - Improved hospital data structures to align with international research standards
EHR4CR Pilots (example protocol feasibility)

- Validation of protocol feasibility
  - Large set of eligibility criteria from EFPIA trials analysed to identify commonly used data elements (>75 EHR data elements from 12 studies)
- Tests done with data from 9 sites done
  - Various UAT’s performed with end-users from pharma, 4 clinical studies
- Summer 2014 – final pilot validation
  - 12 studies, de-identified data from ~500k patients over 11 sites

- Germany (WWU, FAU)
- France (AP-HP, U936)
- UK (UoD, UoG, UoM, UCL, KCL)
- Switzerland (HUG)
- Poland (MuW)
EHR4CR Protocol Feasibility Services…

Protocol Feasibility Services
Central Workbench
DEPLOYMENT PLAN AND EARLY ADOPTION
Where we are now…

Project pilot hospitals
- 11 major hospitals in 5 countries.
  - Germany (2), France (2), UK (5), Switzerland (1), Poland (1)
  - 12 studies, de-identified data from >500k patients over 11 sites

Scaling up the solutions!
- Technology
- Operations
- Governance
- Sustainability

Operational pan-European platform
- Permanent network of clinical sites giving access to millions of patients in close to real time
- Trial design and recruitment supported by real-world evidence on a European scale
- Governance by the European Institute for Innovation through Health Data

EHR4CR - IMI research project
Developing An Open Innovation Ecosystem

The European Institute for Innovation Through Health Data

Data aggregation and access services through standard EHR4CR interfaces

Applications access and deliver EHR4CR services

An governing Institute to consolidate sustainability

Champion projects to kick start adoption

A champion program to drive early adoption

Stakeholder communities that ensure co-creation
Operational pan-European platform

- **Permanent network** of clinical sites giving access to millions of patients in close to real time
  - Connecting major hospitals in Europe
  - Fully *compliant* with governing legislation
  - Reaching out to the rest of the world
- **Primary customers (revenue)**
  - Pharma (PRO), CRO, CRU
- **Services offered (initially)**
  - Protocol feasibility services
  - Patient recruitment support
The services

Protocol feasibility services

- Develop protocol eligibility criteria and immediately test them in multiple sites in various countries
- Conduct “what-if” assessments using different eligibility criteria in order to optimise protocols
- Receive back results in minutes or hours rather than days or weeks.
- 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 allowing for timely identification of problems.
- Be ensured of optimal recruitment due to tools provided to hospitals (time optimisation & reduction of false negatives)

Service model (preliminary)

- Protocol feasibility services
  - Subscription model
  - Site finder fee
- Patient recruitment
  - Per trial fee
  - Patient finder fee

Benefits

- Increased probability of achieving the clinical trial objectives
- Improved planning and reduction in clinical trial timelines
- Reduction or avoidance of protocol amendments (~300 k€ each).
- Significant reduction of actual person-time and costs.
Terminology services

Centrally managed information model (data elements and terminologies)

Mapping to local data elements and terminologies
Pharma champion program

- What we expect from pharma champions
  - Bring hospitals to the network
  - Assist in determining the operational requirements
  - **Commit to become a customer** (when milestones are reached)

- What pharma gets in return …
  - Favourable service fees
  - Opportunity to **prioritise the functionality** and flow of the services as they are further developed
  - **Steer the growth path** with respect to pathology and site selection
Hospital champions

- What we expect from hospitals and other champion data providers
  - Agree with the operational model and **sign up for joining the operational network**
  - Help us to improve our systems by giving feedback
  - Assist us in **connecting to their IT systems** and with importing and mapping data
  - Join in early projects

- What they get…
  - **Early access to technology**, support during internal experiments with clinical data management (IT, mapping of data, etc)
  - Possibility to define **local site application** functionality
  - Increase reputation in scientific community (demonstrable innovation, publications, etc.)
  - **Premium version** of local site applications **for free**
This can create value for hospitals

Better patient care
Improved route to inclusion in clinical trials. Enhances treatment options, giving patients access to trial drugs and care pathways with no cost to the Trust.

Improved clinical research
Improved efficiencies and interconnectivity with other hospitals facilitates, streamlines and enriches clinical research.

Enhanced reputation
Greater visibility of hospital/clinicians in scientific community. Improved ability to participate in/conduct clinical trials.

Income stream
Better placed to generate income from clinical research. At a time of squeezed budgets, income from research can help drive innovation and efficiency with better outcomes for patients.

Better quality EHR data
Improved monitoring, performance benchmarking, reporting and management (e.g. reimbursement coding). Drives optimisation of patient care and improved efficiencies.
GOVERNANCE AND THE ROLE OF

THE EUROPEAN INSTITUTE FOR INNOVATION THROUGH HEALTH DATA
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

… shared by multiple IMI projects
Demonstrating value from the use of health data

Value to hospitals

Public awareness of the benefits to patients

Value to Pharma

Develop comprehensive value assessment program, to demonstrate:

- faster and more efficient clinical trials
- better information for public health
- improved quality of EHR data
- good practice in privacy protection
- successful eHealth/eResearch ICT sector
- budget impact assessments for key stakeholders
- positive patient and societal acceptance

Grow Networks of Excellence

Promote globally
Creating a win:win for key stakeholder groups

- **Pharma, academia, CROs**: Clinical trial development will become more efficient by reducing the time it takes to bring new drugs to market, thus generating substantial value.

- **Health community/governments**: Able to offer improved quality of healthcare with reduced healthcare costs.

- **Hospitals**: Able to participate in more clinical research programmes, benefiting their patients.

- **EU**: More attractive for R&D investment.

- **Health authorities**: Access to new and better evidence to underpin health policy, strategy and resource planning.

- **Patients**: Faster access to safer and effective medicines, improving health outcomes across Europe.
The EHR4CR project is an important initiative

- Bringing together multiple stakeholders
- Overcoming barriers that limit access to EHRs for research
- Developing a platform and services for trustworthy re-use of EHR data
Summary

2015 is an important year for EHR4CR by scaling up the two sustaining deliverables:

- EHR4CR platform were Custodix as the first EHR4CR service provider is actively pursuing means to accelerate platform deployment and service models will take shape

- The European Institute for Innovation through Health Data will support and governing the ecosystem of EHR enabled services

- The opportunity for collaboration and acceleration is here
Thank You!

Contact us: comms@ehr4cr.eu