THE EHR4CR PROJECT

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AstraZeneca
The EHR4CR project

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

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

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

- Mandated by IMI
- One of the largest European public/private partnership projects in this area
- 4-year project (2011-2015)
- Budget of € >16m

For further information see www.ehr4cr.eu or contact Geert Thienpont (EuroRec) geert.thienpont@ramit.be
Brings together key stakeholders

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<tr>
<th>Electronic Health Records for Clinical Research</th>
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<td>35 participants including pharmaceutical industry, academia, hospitals, small and medium-sized enterprises, patient associations and public authorities</td>
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<td>11 hospital sites</td>
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<td>Advisory boards and other experts</td>
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<tr>
<th>KMIT</th>
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<th>A NETWORK POWERED BY PEERS</th>
<th>EuroRec</th>
<th>Université de DUNDEE</th>
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<tr>
<td>SANOFI</td>
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<td>ASSISTANCE PUBLIQUE HOPITAUX DE PARIS</td>
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<td>clinical</td>
<td>Inserm</td>
<td>Janssen</td>
<td>UKchip</td>
<td>King’s College London</td>
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<td>Data Mining International</td>
<td>Bayer</td>
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Electronic Health Records for Clinical Research
To address key challenges to enable the re-use of EHR for clinical research

Interoperability
EHRs generated by single institutions (the doctor has a set of information for each patient; if the patient goes to another doctor there is another set of information)
- Separate and disparate systems
- Incompatible EHR systems
- Different models
- Variable quality, uniformity and organisation of the data
- Different coding and content standards
- Structured (e.g. prescriptions) versus unstructured (e.g. clinical narrative)
- Different languages across Europe

Data security, privacy & ethics
Complying with ethical, legal and privacy requirements that differ from country to country is critical to gain acceptance with the general public, patients and medical professionals

Confidence in data
All data has to be complete and accurate at the point of capture. A single error presents risk that can be magnified as data transmits downstream

Scalability and sustainability
Solutions need to be adaptable and reusable and governed within a sustainable ecosystem
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)
Protocol Feasibility

Protocol design based on estimates and not optimised

- With no, or limited, access to actual patient data, trial design is based on discussions with expert clinicians
- Increased amendments, slower than expected enrolment, costly changes to add new sites and countries, even failed trials

A third of protocol amendments are avoidable\(^1\), at a cost of $0.5m per amendment.\(^2\)

2. Industry Standard Research, 2010
EHR4CR Protocol Feasibility Services…

Protocol Feasibility Services Central Workbench
...Deployed across 11 pilot sites
Patient Recruitment

A major cause of trial delay

- With no searchable patient database, identifying and recruiting suitable patients and trial sites are principal causes of trial delays
- Delayed trials increase the burden for sites, waste costly resources and slow access to new drugs

The percentage of studies that complete enrolment on time:

18% in Europe, 7% in the US

Almost half of all trial delays caused by patient recruitment problems

Each day a drug is delayed from market, sponsors lose up to $8m

EHR4CR Patient Recruitment Services...

Site tools to...

- Re-use/adapt feasibility query
- Identify potential candidates
- Contact treating physicians
- Evaluate and recruit patients
Data capture

Divided patient care & clinical research information leads to inefficiencies

The result…

- Cumbersome and slow processes
- Redundant data entry
- Transcription errors
- Source issues

Over 40% of clinical trial data are entered into the patient’s health record, the clinical trial EDC system, and, possibly, a third paper copy.

Over 70% of data are perceived by sites as duplicated between EHR and clinical trial systems.

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1. Integrating Electronic Health Records and Clinical Trials: An Examination of Pragmatic Issues, Michael Kahn, University of Colorado.
Project deliverables

**TECHNICAL PLATFORM**

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**BUSINESS MODEL**

Towards sustainability
1. A self-sustaining economic model
2. A roadmap for pan-European adoption
Model: value propositions

Cost-Benefit Assessment (CBA)

To establish the value
- Compare EHR4CR conditions to current practice

Business Model Simulation

To forecast business results
- Balance sheets \(\text{revenues minus expenses}\)
- Profitability ratio \(\text{revenues divided by expenses}\)
Model: a free market ecosystem

An organisation that contributes data for EHR4CR e.g. hospital

An organisation that provides EHR4CR services to Service Users

An organisation that uses EHR4CR services such as a pharmaceutical company or an academic institution
Road map: seeding the system

At project end there will be

- A growing network of data providers
- First service provider(s)
- Committed service users
- Institute based in Belgium
  - Oversight and governance
  - Specifications
  - Shared IP
  - Standards
  - Certification of systems
  - Promotion