EHR4CR – AN INNOVATIVE PLATFORM AND BUSINESS MODEL
ACDM Annual Conference, 9 March 2014
Richard Perkins, eClinical Forum

Industry-centric growth in ICT

The inefficiencies become obvious at the clinical trial interface

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

A win-win for all stakeholders is key

- 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
- Hospitals: Able to participate in more clinical research programmes, benefiting their patients
- Health authorities: Access to more and better evidence to underpin health policy, strategy and resource planning
- Health community/governments: Able to offer improved quality of healthcare with reduced healthcare costs
- EU: More attractive for R&D investment
- Patients: Faster access to safe and effective medicines, improving health outcomes across Europe
The EHR4CR Project brings together stakeholders

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)

**Business Model**

Validated Through Pilots

- Different therapeutic areas (e.g. oncology, neuroscience, diabetes, CVS...)
- Several countries (under different legal frameworks)
Scenario 1: 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…
Scenario 2: 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**

---

3. Beasley, "Recruiting" 2004
EHR4CR Patient Recruitment Services…

Site tools to…

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

Scenario 3: Data capture/exchange

Divided patient care & clinical research information leads to inefficiencies

The result…

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

---

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

Business Model

Towards Sustainability
1. A self-sustaining economic model
2. A roadmap for pan-European adoption

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
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 \textit{revenues minus expenses}
- Profitability ratio \textit{revenues divided by expenses}

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
Road Map: Engagement with stakeholders

Stakeholder Engagement Conference in Brussels

- April 8th… Satellite event for Pharma
- April 9th… Key event with European hospitals
- April 10th… Satellite event for potential service providers

Summary: 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
- Offering a new paradigm for clinical research in Europe
Any Questions…