EHR4CR: RESULTS OF THE PROTOCOL FEASIBILITY PILOTS

November 2014
Welcome to the EHR4CR Webinar

- Duration is 1 hour
- All on Mute
- Use the Q&A button. *We will answer questions at the end*
- Session is being recorded
- Please respond to polls if they are presented

www.ehr4cr.eu
Overview

- Welcome
- EHR4CR project
- Protocol Feasibility scenario
- Platform for Protocol Feasibility
- Protocol Feasibility pilots
- Summary
THE EHR4CR PROJECT

Mats Sundgren, AstraZeneca
Parallel industry-centric growth in ICT

Most clinical trials use Electronic Data Capture

Electronic data capture of Clinical Trial data

Physician/Investigator

Patient Care Data

Patient health records

In some countries nearly 90% of all healthcare records are digital

Over 40% of clinical trial data are entered into health record and EDC1

Source data issues

Inefficient processes

Clinical trial research data

The inefficiencies become obvious at the clinical trial interface
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…
A win for all stakeholders is critical

**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 new 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.
EHR4CR: 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

To be extended by 12 months
Brings together key stakeholders

35 participants including pharmaceutical industry, academia, hospitals, small and medium-sized enterprises, patient associations and public authorities.

10 Pharma Companies

11 hospital sites

Advisory boards and other experts
Project deliverables

**TECHNICAL PLATFORM**
A set of tools and services
1. Protocol Feasibility
2. Patient Identification and Recruitment
3. Clinical Trial Data Exchange

**BUSINESS MODEL**
Towards sustainability
1. A self-sustaining economic model
2. A roadmap for adoption
THE PROTOCOL
FEASIBILITY
SCENARIO

Florence Botteri, Novartis
EHR4CR scenarios

Technical Platform

- EHR4CR Kick-off (March 2011)
- Protocol Feasibility (PF)
- Refinement
- Patient Identification and Recruitment
- Refinement
- CT Data Exchange
- EHR4CR End (March 2015)
EHR4CR Scenarios

Optimise Protocol
Identify regions

Map eCRF to CDW

Identify Recruitment Candidates

Minimise Data Entry

Site approved and initiated

Mapping approved

Informed consent
Protocol feasibility: the challenge

34%: avoidable protocol amendments
43%: amendments before first patient first dose

There is a need for better upfront protocol optimisation and planning...

We need to...

- Understand the impact of clinical trial complexity and optimise the protocol
- Identify regions and sites with suitable patient populations

A third of protocol amendments are avoidable, at a cost of $0.5m per amendment.
Protocol feasibility: the setting today

**Most companies**…

Use feasibility questionnaires issued to candidate sites

But this…

- Relies on “rule of thumb” knowledge by Principal Investigators of the patient pool available in their catchment area

**Some companies**…

Use pooled datasets extracted from the healthcare environment

But this is…

- Expensive and time consuming
- Difficult to query the data
- Of limited reliability

Such techniques are notoriously unreliable!
EHR4CR scenario

We imagine being able to **improve protocol design** by …

- Electronically searching millions of EHRs to evaluate the size of patient populations matching clinical trial criteria
- Optimising protocol design by changing clinical trial criteria to maximise success
- Identifying the location of patient populations in order to identify countries and sites
- From one user interface
EHR4CR Protocol Feasibility Services…

Features:

- One user interface to develop query
- Site controls query running and data access
- Query runs on segregated, de-identified data
- Only aggregated numbers leave site
- Fuzzing protects low counts
- Central platform returns aggregated data to user
EHR4CR workflow for Protocol Feasibility

1. Develop feasibility query on Service Provider workbench

2. Distribute query to central platform

3. Distribute query via EHR4CR network to selected sites

4. Query local EHR4CR de-identified dataset

5. Return number of patients

6. Consolidate numbers to required level

7. View results (and refine)
THE PLATFORM FOR PROTOCOL FEASIBILITY

David Voets, Custodix
Protocol Feasibility demo

EHR4CR - Demonstration of the Protocol Feasibility Platform

http://www.ehr4cr.eu/
PROTOCOL FEASIBILITY
PILOTS

Justin Doods, Westfaelische Wilhelms-Universitaet Muenster
Protocol Feasibility pilot

- Tested viability and performance of EHR4CR platform to support protocol feasibility service
  - 11 major hospitals in five countries
  - EHR4CR-compliant data warehouses were established at all pilot sites
  - Large set of eligibility criteria from EFPIA trials analysed to identify commonly used data elements
  - De-identified data from >five million patients was loaded for these elements into local EHR4CR-compliant data warehouses as far as available at the sites
  - 12 clinical studies evaluated

- Germany (WWU, FAU)
- France (AP-HP, U936)
- UK (UoD, UoG, UoM, UCL, KCL)
- Switzerland (HUG)
- Poland (MuW)
PFS proof-of-concept (POC)

- Initial POCs
  - October 2012: Initial POC with four studies, test scripts with 52 steps
  - January 2013: Extended POC with 10 studies

- User functionality testing
  - October 2013: Three independent testers, validation of patient counts

- Scalability testing
  - September 2014: 200 – 200,000 patients per site: query responses < 5 minutes

- Effectiveness and Efficiency testing (including chart review)
  - September 2013 - October 2014

- User satisfaction evaluation: Q4 / 2014 - ongoing
We identified priority EHR data elements for PFS

- Consented PFS Data Inventory (EFPIA members)
- 75 data elements prioritised
- Data inventory published in *Trials*
- Data elements readily available in hospitals
- Plans to seek standardisation of data elements across variable EHR systems

Standardised EHR data is a valuable asset for hospital data processing and warehousing
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Data elements for PFS: EHR data completeness
End user view of the application: PFS query workbench
End user view of the application: Results

- 0 patients match all criteria
- 115 patients match gender in [SNOMED Clinical Terms:248153007, "Male"]

<table>
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<th>Male</th>
<th>Female</th>
<th>Undefined</th>
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<td>34</td>
<td>0</td>
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<td>34</td>
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</table>

- 200 patients match born at least 17 year before now
- 0 patients match last diagnosis([ICD-10-CM,"Malignant neoplasm of prostate"])
- 6 patients match last diagnosis([ICD-10-C86-C89,9,"Malignant neoplasms of ill-defined, secondary and unspecified sites"] at most 3 month before rule(3)
- 6 patients match last procedure([SNOMED Clinical Terms:386634006,"Bilateral orchiectomy"])
- 6 patients match last medication([ATC:G03HA01, "cyproterone"],[ATC:L02AB02, "medroxyprogesterone"])
- 200 patients match not last procedure([SNOMED Clinical Terms:267820000,"Cryotherapy"],[SNOMED Clinical Terms:90470006,"Prostatectomy"],[SNOMED Clinical Terms:108230001,"Radiation oncology AND/OR radiotherapy"] at most 6 month before now

- UNIVDUN (0)
- UofG (0)
PFS proof-of-concept outcome

- Conclusion of defined POC success criteria:
  - Retrieving information from hospital sites: 🟢
  - Timely response: 🟢 but endpoints without data can delay query execution
  - User functionality testing: patient counts validated for test dataset: 🟢
  - Precision of patient counts depends on quality of eligibility criteria and EHR data: 🟢 🟣
  - Query modification and re-running of queries: 🟢 🟣
  - Transnational platform across systems and hospitals: 🟢
We succeeded in overcoming key hurdles

Interoperability
Real clinical data uploaded transnationally, from very complex and diverse IT systems, across 10 trials, covering >five million patients and >446 million data points
- 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
- Ongoing refinement based on outcomes
- Improved hospital EHR data structures to align with international research standards

Further refinement ongoing based on insights from the pilot
What is needed to become an EHR4CR pilot site

- Approval for EHR data access (de-identified data, no patient level data)

- Review of local EHR system:
  availability and data quality of top data elements

- Mapping of local EHR data elements to EHR4CR terminology:
  Local expertise regarding Your EHR system is required

- Setup of EHR4CR endpoint
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
- To drive innovation both in research and healthcare operations
That is achieving expectations

Succeeded in overcoming key challenges

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
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Confidence in data
- EHR4CR platform generated results
  - Patient counts validated by User Functionality Testing
  - Improved hospital data structures to align with international research standards
Thank You!

Developing a platform and services to re-use EHR data

Overcoming barriers that limit access to EHRs for research

Deployment of a sustainable network

Driving innovation in research and healthcare operations

Contact us: comms@ehr4cr.eu

Supported by

The EHR4CR project is partially funded by the IMI Programme.

The Innovative Medicines Initiative (IMI) is a unique public-private partnership designed by the European Commission and European Federation of Pharmaceutical Industries and Associations (EFPIA). It is a pan-European collaboration that brings together large biopharmaceutical companies, small- and medium-sized enterprises (SMEs), patient organisations, academia, hospitals and public authorities.
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November 2014