Practical and informatics challenges of using data from the electronic health record: From ePCRN to TRANSFoRm

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www.transformproject.eu
History

ePCRN
- Funder NIH (US) 2005-8 Pilot for NIH Roadmap
- University of Minnesota, University of Birmingham, UCSF.
- Additional funds 2008-9 from NIHR NSPCR (Bham)

TRANSFoRm
- Funder EU FP7 ICT, €7m integrated project 2010-15
- 16 partner universities in 9 EU countries led by KCL
- Builds on and links to ePCRN
Aims of ePCRN

Data linkage between eHRs and clinical research

• To identify eligible subjects

A standards-based system for generating web-based data capture for RCTs

• To control data items via a meta-data repository
• For re-use of data elements
• To generate forms and databases from the meta data
ePCRN brings the technologies of the NCI cancer Bioinformatics Grid (CaBIG) into the Primary Care setting

- Extends the BRIDG data model
- Integrates the Enterprise Vocabulary Service
- Enables the creation and reuse of data elements and forms via the Data Standards Repository
Confidentiality and data security

- Confidentiality - for subjects not having consented to use of their data for research
  - Search reports only ‘counts’ - NO DATA is extracted
  - Subjects are flagged locally

- Security
  - OGSA-DAI & GTK4(certificates and authorisation)
ePCRN: Recruitment

1. Capture protocol definition
2. Drill down to capture eligibility criteria via ‘semantic workbench’
3. Browse CaBIG Enterprise Vocabulary Service
4. Construct query in selected vocabulary
5. Authorise and run
Controlled vocabulary

caBIG enterprise vocabulary service

SNOMED-CT

ICD9

ICD10

umlS

Additional local mappings

Read

ICPC2
Define eligibility criteria

Include Male and Female Patients with age $\geq 20$ AND $\leq 50$
Define the problem semantically
Count eligible community subjects
Clinical Trial Data management Systems

Proprietary hell
Numerous partial solutions, open source forms are often quite basic in functionality
Little standardisation in spite of CDISC
Like buying a new CD player for every album
No ‘one system’ for every domain
The solution

Separate domain semantics from the system implementation……
Requirements

A domain object model

A system that can author specific (xml) documents as an instance of the domain model for a specific study

A system to write the xml representation into a set of forms and a database
Primary Care Research Object Model v2.0
PCROM
Define a new data element
Use a data standards repository
Create your own form design
PCROM and ISO11179

ISO 11179 is a six part international standard for meta data registries where each data element is

- Registered
- Uniquely identified
- Named
- Defined – for which a domain model is useful
- May be classified – for which a domain model is essential
Progress planned from 2010

ePCRN is an open source project
€7M of funding from the European Commission via the TRANSFoRm project (www.transformproject.eu)

Plans for widely usable tools for:
• Authoring searches using controlled vocabulary
• Working with metadata and forms
• Writing computable protocols
Where does the future lie?

Open systems
Standards
**Standardized** computable trial protocols
Ability deploy studies in a variety of different software systems
TRANSFoRm

SAFER CLINICAL PRACTICE

TRANSFoRm
- INTEGRATION
- INTEROPERABILITY
- SERVICES

MORE RESEARCH EVIDENCE

KNOWLEDGE TRANSLATION

EPIDEMIOLOGICAL STUDIES AND RCTS

Page 21
Demonstration and dissemination

User requirements
Development and Evaluation

WP1
RESEARCH USE CASES

WP2
PATIENT SAFETY USE CASE

WP3
LEGAL ETHICAL & SECURITY FRAMEWORK

WP4
DECISION RULES AND EVIDENCE

WP5
USER AND SOFTWARE SERVICES

WP6
CONCEPTS OF DATA INTEGRATION

WP7
SYSTEMS AND SERVICES FOR DATA INTEGRATION

WP8
DEMONSTRATION
INDUSTRY CONTRACT RESEARCH ORG ACADEMIA

WP9
DISSEMINATION
WEBSITE PUBLICATION WORKSHOPS PROTOTYPES COLLABORATION INFRASTRUCTURE TECHNOLOGY PLATFORMS

WP10 MANAGEMENT
System Integration

Using the models, based on use cases to inform the development of a system that has shared concepts:

- Provenance model
- Protect the data via provenance and common security model
- Consent model
- Middleware based on open source and standards (and building on ePCRN)
Workflow Integration

For research
- Seamless prompts, reminders and data collection

For clinical practice
- DSS have failed
- Strong emphasis on development from MDM experimental approach
  - Prompting v Alerting
  - Data entry interface and design
Knowledge translation

Understand how systems work with human judgment

Need to enable a much finer granularity of interaction between the eHR and research systems

Use the openEHR standard

- Observations, archetypes, templates
- User interface design
CEN 13606: independence of semantic representation.
Archetypes

A computable expression of a domain content model in the form of structured constraint statement based on a reference information model.

Often encapsulated together in Templates.

Sit between lower level knowledge resources and production systems

Independent of interface and system
Interoperability of research data

Model based

- CDISC ODM
- BRIDG
- PCROM

ISO/IEC 11179 Metadata Registry standard

Integrate Vocabulary service, Metadata registry and core interoperability model as a seamless service.
Current progress

Use case development
Experimental background to DSS
Survey of network capacity and IT resource
Model of data comparability
Legal and ethical survey
Provenance framework
Security Framework
QA Framework
Potential areas for co-operation

Standards

- Clinical data representation/ archetypes
- Standard computable representation of clinical research / trial data

Common Implementation

- eHR interface
- Middleware / system integration

Common Business Models

- Open but exploitable
- epSOS and EHR4CR projects
Overcoming the barriers

Funding for research

- FP7, ARRA, CTSA inhibit ‘ePCRN style’ collaborative research

Funding for networking and collaboration

- Goes beyond individual projects and needs LONG TERM investment

Involvement of standards bodies

- Cannot be a short term aim

Agile and open

- Should encompass all those working in the area