eDiFy

Requirements for Evidence-based Templates in Electronic Case Report Forms

Marco Schweitzer, Stefan Oberbichler

eHealth Research and Innovation Unit,
UMIT - University for Health Sciences, Medical Informatics and Technology

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Electronic Data Capture

Total Number of Registered Studies

1 according to http://clinicaltrials.gov
Electronic Data Capture

- Systematically use clinical and epidemiological research
- Collect patient-related data
- Support data integration
- Reduce costs and time for clinical trials
- Medical Data Registries

Different ways to capture data
- Primary data (Prospective) collection: e.g. eCRFs
- Secondary data (Retrospective) collection: e.g. EHR records
Electronic Case Report Forms (eCRF)

- Electronic form aiming to collect patient-related information for clinical trials, etc.
- Structured forms
- Originally evolved from paper based CRFs
- Main items: Data Elements (Metadata)
<table>
<thead>
<tr>
<th>Patient information</th>
<th>John</th>
</tr>
</thead>
<tbody>
<tr>
<td>Given Name:</td>
<td>Doe</td>
</tr>
<tr>
<td>Family Name:</td>
<td></td>
</tr>
<tr>
<td>Birthdate (DD-MM-YYYY):</td>
<td>06-04-1983</td>
</tr>
<tr>
<td>Vital Signs</td>
<td></td>
</tr>
<tr>
<td>Body Weight (kg):</td>
<td>95</td>
</tr>
<tr>
<td>Body Height (cm):</td>
<td>190</td>
</tr>
<tr>
<td>Blood pressure systolic (mm Hg):</td>
<td>95</td>
</tr>
<tr>
<td>Blood pressure diastolic (mm Hg):</td>
<td>70</td>
</tr>
<tr>
<td>Medication</td>
<td></td>
</tr>
<tr>
<td>Currently Prescribed:</td>
<td>Metformin</td>
</tr>
</tbody>
</table>
Metadata

- Metadata: “data that defines and describes other data” (ISO/IEC11179)
- Data about the containers of data
- Data Elements need to have maximum interoperability
- Defined Semantics
  - Identification / data element name [1..1]
  - Definition [1..1]
  - Representation term [1..*]
  - Value properties [0..*]
  - Relation (hierarchy, synonyms,...) [0..*]
eCRF Design

→ creating eCRFs: tedious task

• Selection of data elements → research question
• Data collection
  o unambiguously and in sufficient detail
  o avoid redundancy and unwanted details
• Re-use of existing eCRFs or data elements → Metadata Repository
• Problem: Metadata repositories usually don’t link the evidence based information about data elements
eDiFy: evidence-based Design of Electronic Case Report Forms

- Link eCRFs and data elements to existing sources
- Derive templates for evidence-based eCRFs
- Benefits
  - Decrease needed effort for eCRF creation
  - Enable/increase comparability between clinical studies
- Funded by TWF (Tyrolean Science Foundation)
Objectives

- Analyze existing eCRF design approaches: eCRF/data element standards
- Identify requirements to build templates for evidence-based eCRFs
- Correlate and map defined standards and requirements
Methods - Requirements Engineering

- Literature review
  - Get an overview of existing standards for eCRFs & Data elements
- Use case definition
  - Define and identify necessary functions for the users
- Derive eDiFy requirements
Results - eDiFy Use cases

- Manage annotations
- Compare medical studies
- Conductor of medical study or Medical Data Registry
- Create eCRF templates
- Annotate with evidence-based information
- Manage annotations
- <<includes>>
- eDiFy
- <<includes>>
- eCRF / data element repository
- Annotating actor
Results - Available Standards

- ISO/IEC 11179
  - Describing Metadata within Metadata repositories
  - Examples: Cancer Data Standards Registry and Repository (caDSR), Australian Metadata Online Registry (METeOR),…

![Data Element Concept Diagram]

- Data Element Concept
  - Object Class: body
  - Property: weight
  - Data Element: body weight
  - Value Domain: data unit: kg
  - Data type: number

- Conceptual Domain
  - Weight Measurement
  - Data type: number

- Value Domain
  - data unit: kg
  - Data type: number

- Representational Level

- Conceptual Level
Results - Derived Requirements

- Define a proper structure for eCRFs and its items
- Utilize a semantic enabled structure
- Link eCRF content with evidence based information
- Link existing information repositories
- Standards conformity
Discussion

• Literature review: informal overview on existing standards
• No universal standard for eCRF and data element available
• ISO/IEC 11179: offers high flexibility in modification by using a combination of conceptual and representation models
• DEFINE-XML\(^1\): recommendation by FDA
• Existing metadata repositories don’t provide related evidence-based information on data element level

\(^1\) CDISC DEFINE-XML: www.cdisc.org/define-xml
Outlook & Conclusion

• Use requirements for:
  o Ontology
  o Prototype

• Sharing eCRFs with scientific community and annotate the elements within existing literature
Thank you for your attention!

Contact:

Marco Schweitzer
marco.schweitzer@umit.at
http://ehealth.umit.at

more Information:

eDiFy Project
https://ehealth.umit.at/edify