

eDiFy

Requirements for Evidence-based Templates in Electronic Case Report Forms

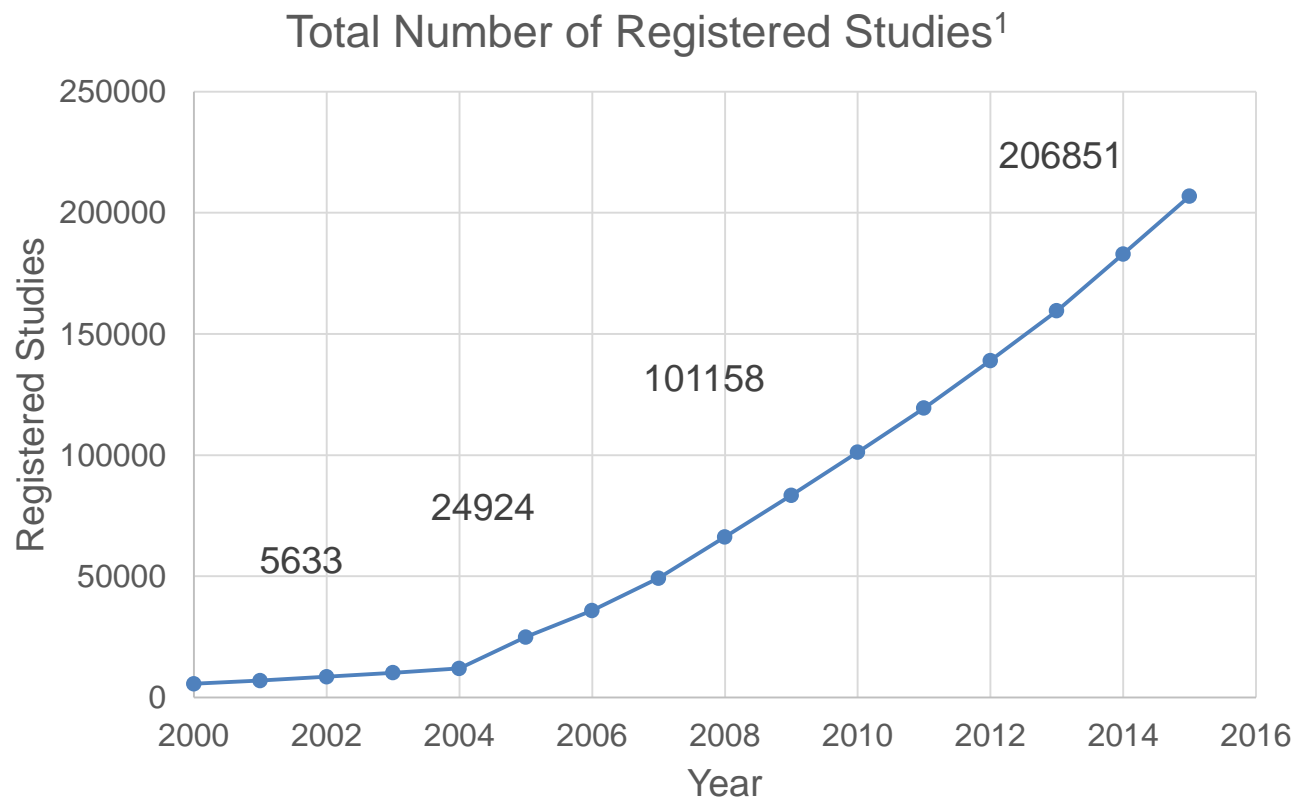


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Electronic Data Capture



¹ according to <http://clinicaltrials.gov>

Electronic Data Capture

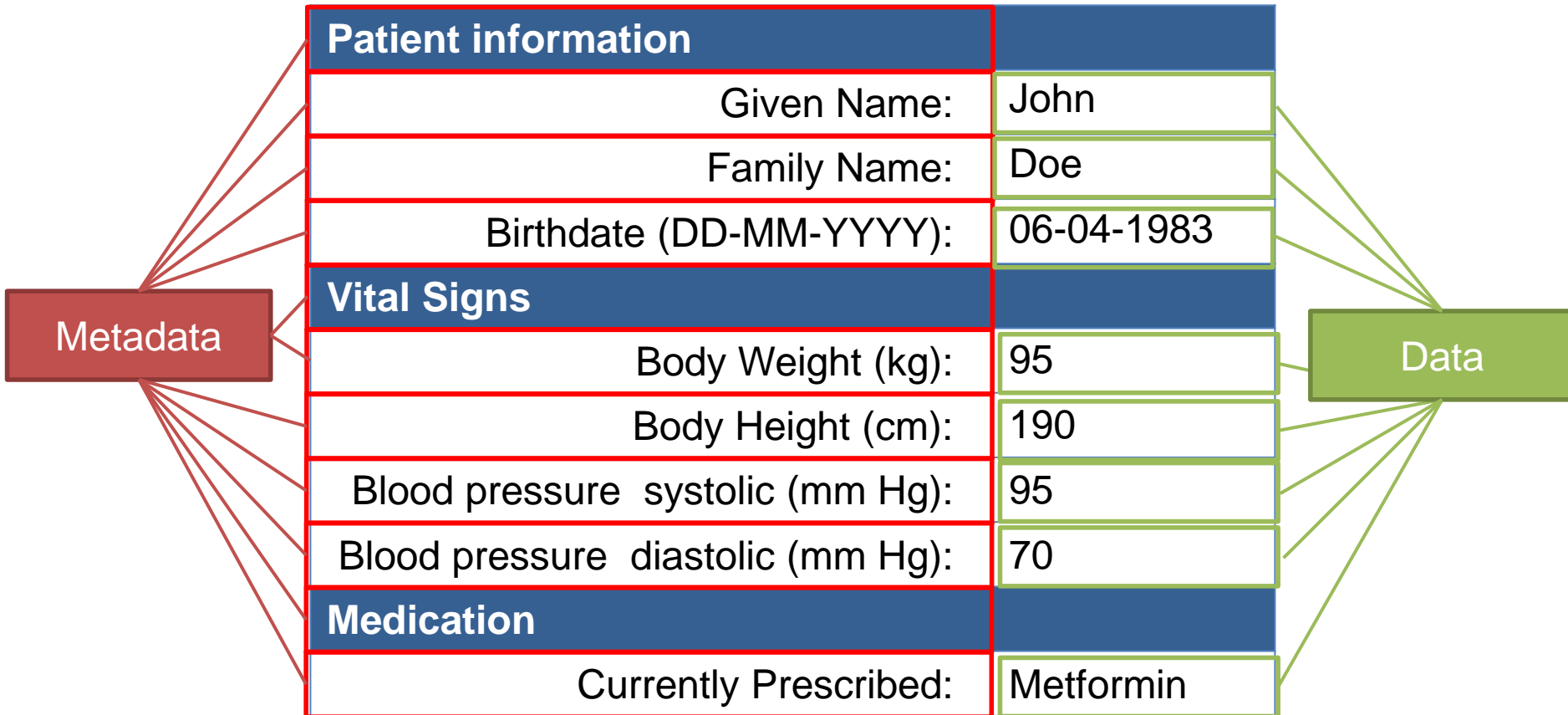


- Systematically use clinical and epidemiological research
- Collect patient-related data
- Support data integration
- Reduce costs and time for clinical trials
- Medical Data Registries
- Different ways to capture data
 - Primary data (Prospective) collection: e.g. eCRFs
 - Secondary data (Retrospective) 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)

Metadata



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..*]

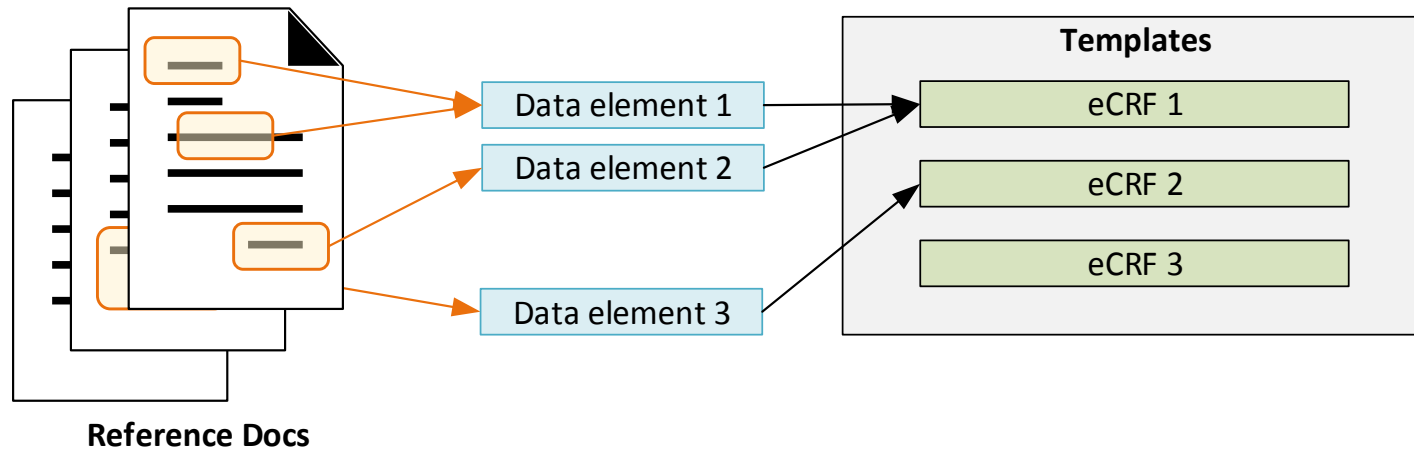


eCRF Design

→ *creating eCRFs: tedious task*

- Selection of data elements → research question
- Data collection
 - unambiguously and in sufficient detail
 - 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



- **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

Existing standards



eDiFy requirements

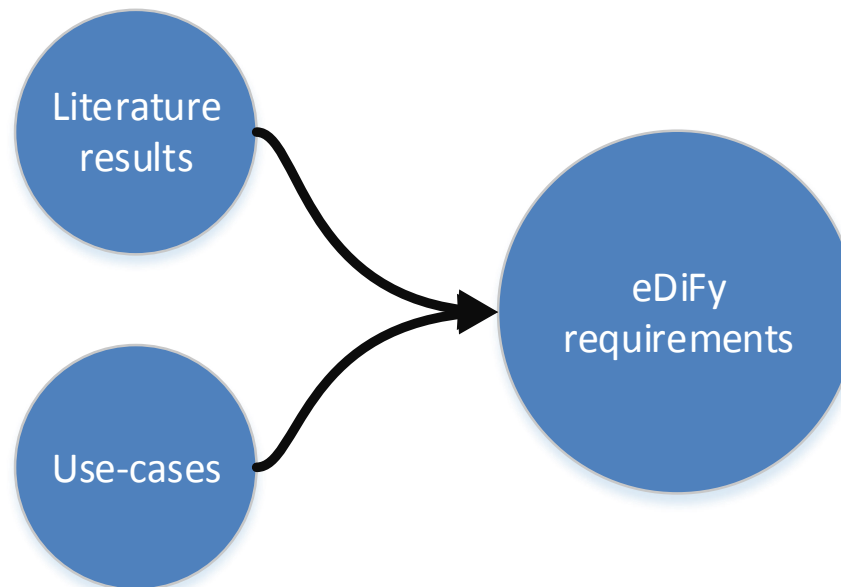


Concept

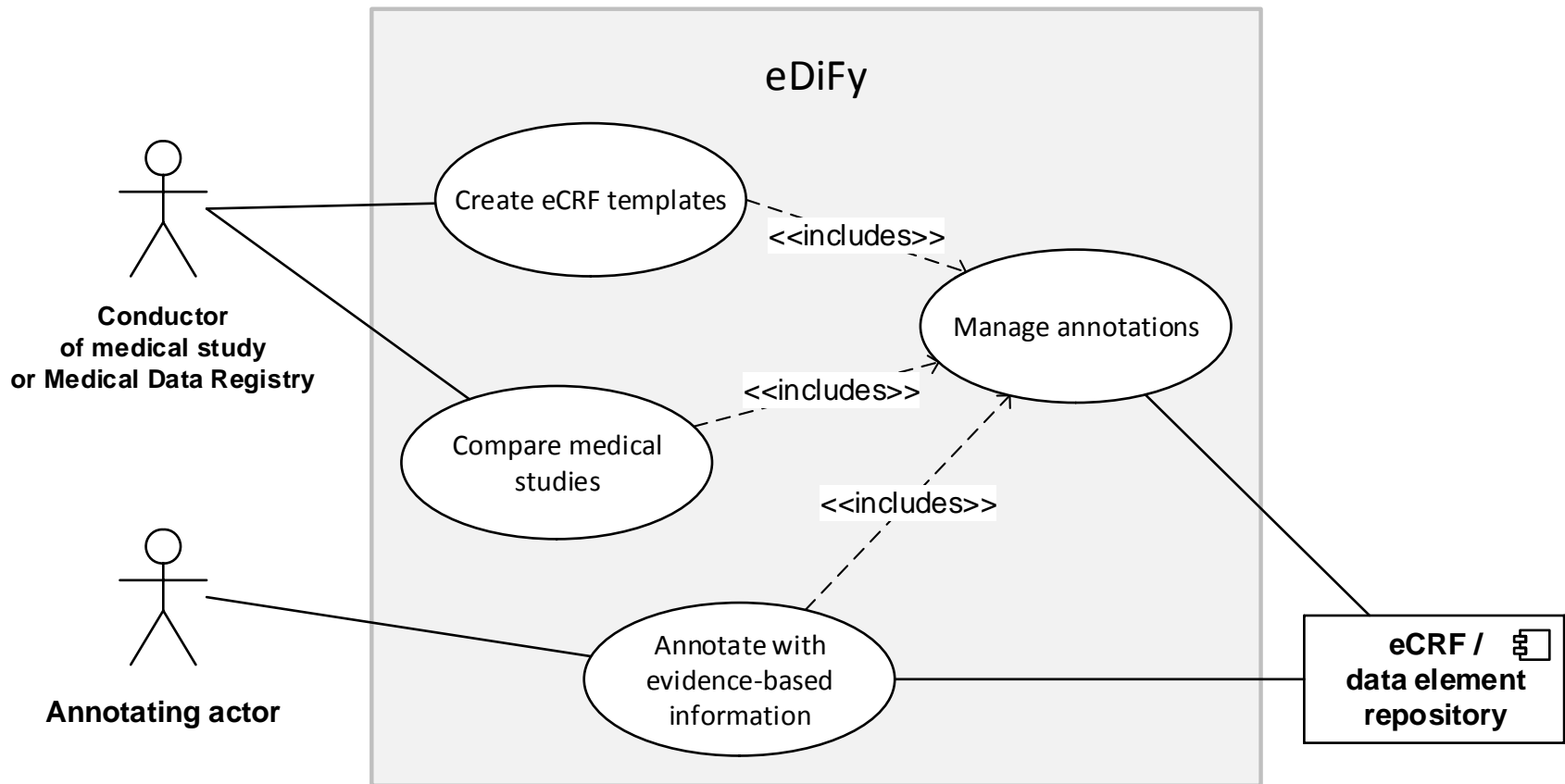
- Analyze existing eCRF design approaches: eCRF/data element standards
- Identify requirements to build templates for evidence-based eCRFs
- Correlate and map defined standards and requirements

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

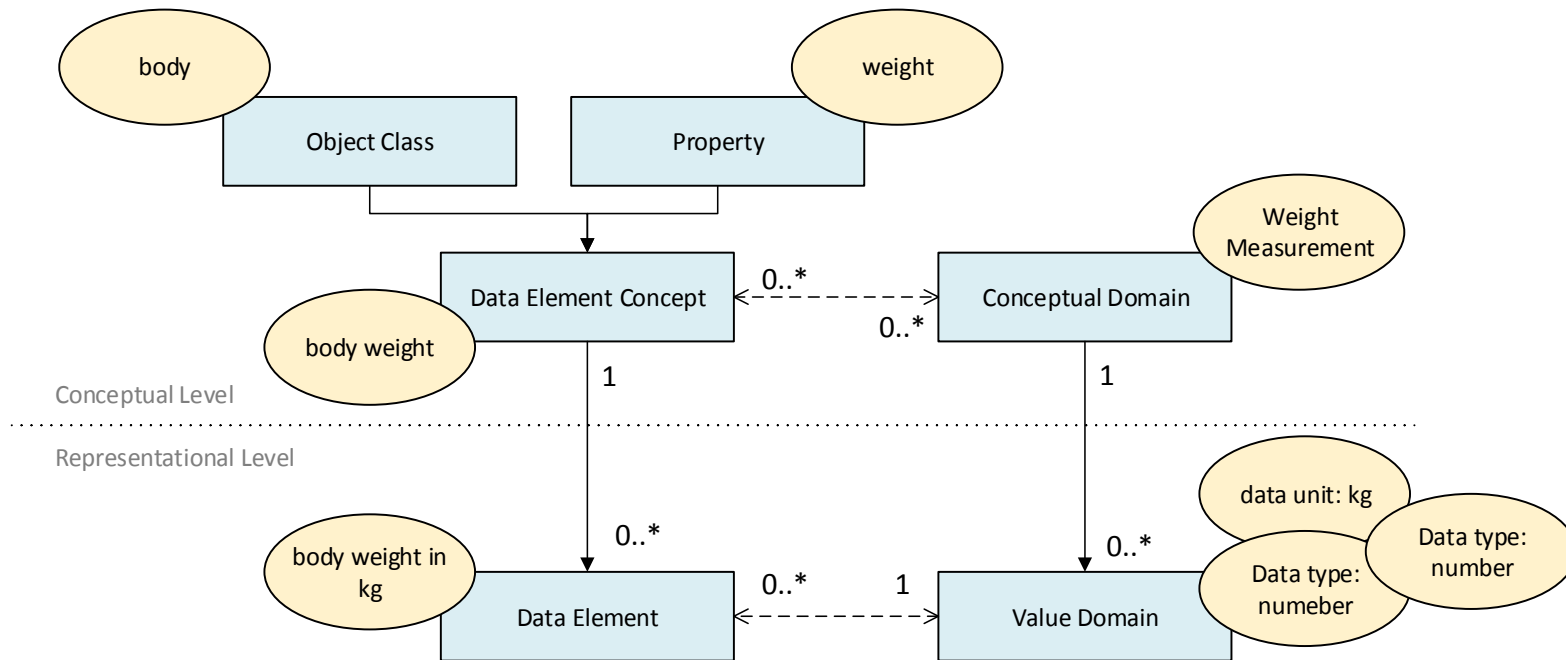


Results - eDiFy Use cases

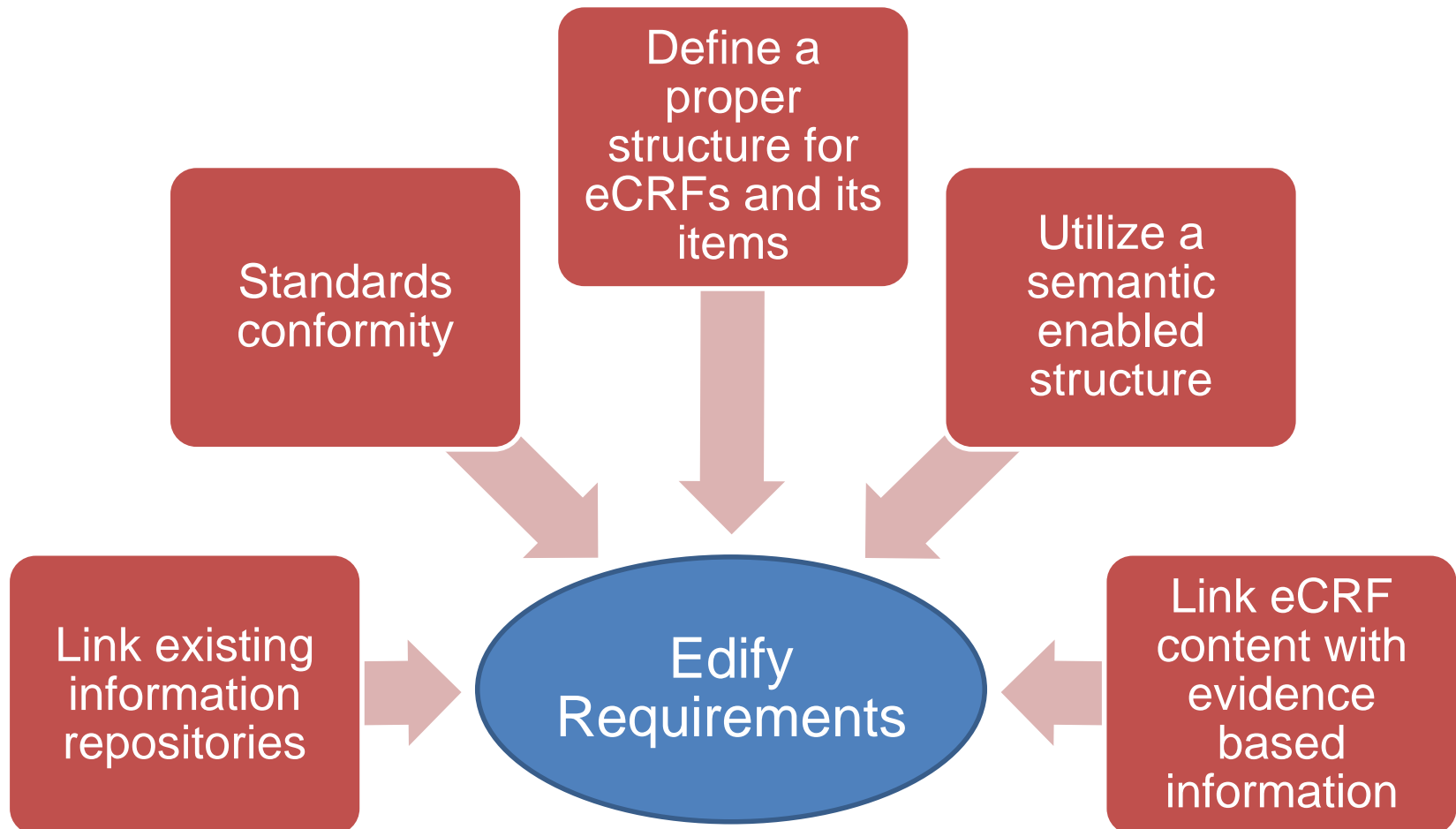


Results - Available Standards

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



Results - Derived Requirements



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-XML¹: 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:
 - Ontology
 - Prototype
- Sharing eCRFs with scientific community and annotate the elements within existing literature

Thank you for your attention!

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