CDISC to FHIR Joint Mapping IG

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Committee Approval Date:

2020/11/10

Publishing Lead:

Lloyd McKenzie

Contributing or Reviewing Work Groups:

BR&R

FHIR Development Project Insight ID:

1636

Scope of coverage:

The implementation guide provides mappings between the current official release of the core FHIR specification and the current official releases of the CDISC SDTM and CDASH specifications

Content location:

https://github.com/HL7/fhir-cdisc-mapping

Proposed IG realm and code:

uv/cdisc-mapping

FHIR Core version(s):

R4

Maintenance Plan:

CDISC expects to work with the BR&R work group to continue to maintain and potentially expand the mappings as FHIR and the CDISC specifications continue to evolve

Short Description:

This implementation guide defines authoritative mappings between the CDISC LAB, SDTM and CDASH standards and the corresponding HL7 FHIR resources to ease interoperability and data conversion between systems implementing these standards.

Long Description:

CDISC's LAB, SDTM and CDASH specifications are widely used in the clinical research community, while HL7 FHIR is becoming increasingly dominant in clinical systems. This implementation guides defines 'best practice' mappings based on the expertise of both organizations. Because of variations in implementation and study design, the mappings will need to be adapted to specific implementations. However, having a jointly published (and publicly reviewed) set of mappings between the two organization's specifications will increase interoperability and reduce costs for converting between the standards.

Involved parties:

CDISC, TransCelerate Biopharma

Expected implementations:

These mappings aren't expected to be implemented directly, but rather to guide mapping and conversion efforts by different organizations.

Content sources:

CDISC and HL7 specifications

Example Scenarios:

- Real-world evidence studies will be able to extract data from clinical systems for use in regulatory submissions
- Clinical research management systems can support data capture directly in clinical systems while still making it available for regulatory submission
- Researchers designing retrospective studies can identify where particular data elements are typically exposed in clinical systems

IG Relationships:

Overlaps in part with the Clinical Research Sponsor Laboratory Semantics in FHIR implementation guide. The Clinical Research Sponsor Laboratory Semantics in FHIR IG covers content not covered by this mapping IG - it defines profiles and implementation requirements. On the other hand, this IG covers most CDISC domains, including vital signs, medications, adverse events, while Laboratory Semantics in FHIR only covers the lab domain (CDISC LAB and LB standards). BR&R expects to resolve the overlap such that authoritative mappings are maintained in only one IG, while domain-specific implementation guidance will exist in other IGs.

Timelines:

January 2021 cycle

FMG Notes