Cdisc Lab Model FHIR IG Proposal
Contents

- 1 CDISC LAB Model
  - 1.1 Owning work group name
  - 1.2 Committee Approval Date:
  - 1.3 Contributing or Reviewing Work Groups
  - 1.4 FHIR Development Project Insight ID
  - 1.5 Scope of coverage
  - 1.6 IG Purpose
  - 1.7 Content location
  - 1.8 Proposed IG realm and code
  - 1.9 Maintenance Plan
  - 1.10 Short Description
  - 1.11 Long Description
  - 1.12 Involved parties
  - 1.13 Expected implementations
  - 1.14 Content sources
  - 1.15 Example Scenarios
  - 1.16 IG Relationships
  - 1.17 Timelines
  - 1.18 When IG Proposal Is Complete
  - 1.19 FMG Notes
CDISC LAB Model

Owning work group name
BR&R

Committee Approval Date:
Please enter the date that the committee approved this IG proposal

Contributing or Reviewing Work Groups
None

FHIR Development Project Insight ID
1425

Scope of coverage
Clinical trials routinely exchange lab data between labs, contract research organizations, and trial sponsor companies. On the clinical research side the required format is the CDISC LAB or LB format. The IG will show how data from Labs in FHIR format can be converted into the required CDISC format.

IG Purpose
Without an IG the mapping from FHIR to the CDISC format is likely to be inconsistent.

Content location
https://github.com/HL7/cdisc_lab

Proposed IG realm and code
uv/cdisc-lab

Maintenance Plan
Current resources are committed to completion of the initial publication. Thereafter the WG expects to maintain this IG from an administrative perspective and for minor revisions. Any major revision will depend on appropriate provision of resource, but this is very likely to be forthcoming.

Short Description
The IG shows how laboratory data in FHIR format can be converted into the CDISC LAB or LB format.

Long Description
Clinical trials routinely exchange lab data between labs, contract research organizations, and trial sponsor companies. On the clinical research side the required format is the CDISC LAB or LB format. The IG shows how laboratory data in FHIR format can be converted into the CDISC LAB or LB format.

Involved parties
Created by a collaboration between HL7 BR&R and Transcellerate Biopharma
Expected implementations
Transcellerate Biopharma has prioritised this as a requirement for their member bodies. Lilly already have working code following this guide.

Content sources
CDISC LAB and LB

Example Scenarios
1. Laboratory provides results in FHIR format - Clinical Trial software converts results to CDISC LAB format and add to data submission for analysis by sponsor

This is probably the only scenario since the CDISC standards are only of use in Clinical Trials

IG Relationships
None

Timelines
May 2019

When IG Proposal Is Complete
When you have completed your proposal, please send an email to FMGcontact@HL7.org

FMG Notes