

CDISC Roadmap Discussion Document

Purpose

This document has been written to provide a basis for discussion amongst the CDISC TCC, the Board and the IAB regarding what should be contained within the CDISC road map document.

The road map document is intended as the vehicle for the specification of the technical products that CDISC will develop over the coming years.

End Point

'The primary end-point of the road map is that, by 2010 or earlier, there will be a single CDISC standard for the full life-cycle of a clinical trial or study from protocol representation through the capture of source data to analysis, submission and archive. This single standard will comprise a set of fully integrated, interoperable and consistent models which will form logically and organically from our current set.'

It is suggested that success should be measured against three criteria:

- a) all submissions to the FDA are being made using the CDISC standard;
- b) the set of CDISC models in use across the full life-cycle of clinical trials;
and
- c) the CDISC standard being globally adopted.

In outline, CDISC, in 2005, achieved the goals outlined in its original mission statement and will focus on the work needed to achieve that defined within the new mission statement between now and 2010 or earlier.

Principles

During the discussion on the road map, the following were noted as a series of guiding principles for the continued development of the CDISC standard.

- a) Stay aligned with BRIDG.
- b) Strive towards a single CDISC standard
 - a. ODM is format
 - i. ODM will map to HL7
 - ii. Maintain platform-independence and platform-neutrality
 - iii. Maintain clinical research scope
 - b. SDTM, LAB, ADaM, and Protocol Representation define content
 - i. Standard ItemGroups
 - ii. Standard Items
 - iii. Standard business rules and code lists
 - iv. Other metadata and information necessary to support analysis
 - c. Define.xml provides common metadata
- c) Complete original mission, but need to expand the mission to include harmonization among the CDISC models
- d) BRIDG is the portal to HL7 and Healthcare.
- e) Cross-functional teams

- f) Fund projects not just teams
- g) We will strive to achieve stability and maturity for all current standards – and align projects with teams (as stewards)
- h) Focus more on processes instead of separate, individual models: conduct of trial, submission of data. Teams become maintenance organizations and stewards of the standard
- i) Models should support sites as stakeholders, as well as sponsors and FDA.
- j) Goals should include: Improving patient safety, process optimization, facilitating scientific and regulatory review

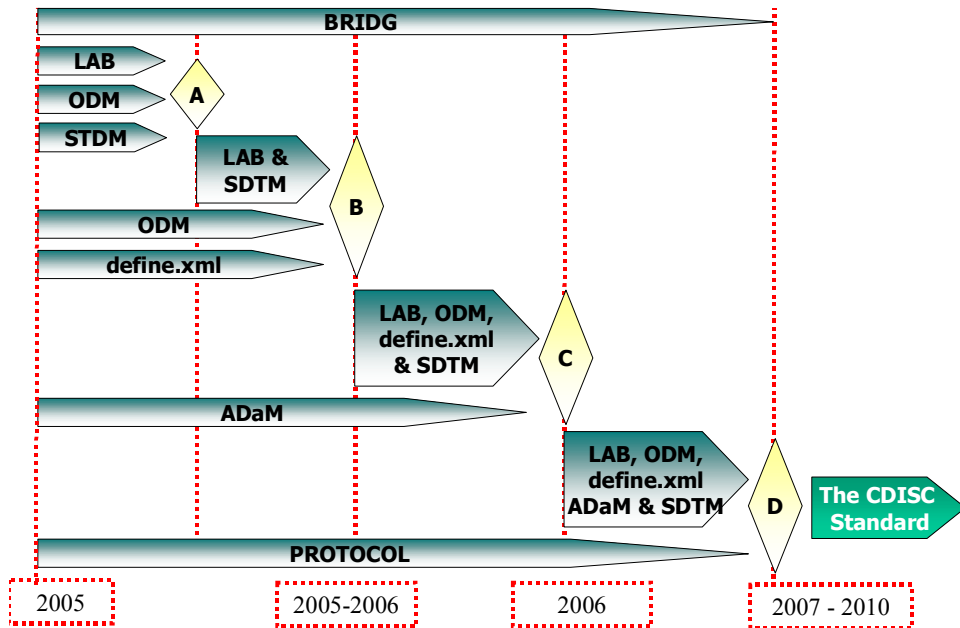
Road Map

At the current point, Sponsors have been comfortably implementing individual models such as LAB, ODM, SDTM and ADaM, but have been unclear on how to effectively use all of the collective models in combination. The road map is structured around four milestones, which are pictured in the Roadmap Timetable below:

- A. the final alignment of the LAB model with SDTM and ODM. At this point, Sponsors should be comfortable implementing all 3 of these models and understand how they work together.
- B. the ability to transport all CDISC submission data using the ODM transport mechanism and ensure consistency with the protocol representation standard. At this point, Sponsors should be comfortable submitting SDTM data in ODM format using Define.xml.
- C. the addition of the appropriate analysis datasets and analysis programs into the CDISC submission model and the alignment with the protocol representation standard and the statistical analysis plan. At this point, Sponsors will be able to submit both tabulation and analysis data as well as analysis programs in a standardized format using SDTM, ADaM, ODM and define.xml
- D. the final harmonisation of the models and the full protocol representation standard. At this point Sponsors will be able to define protocols that can be used to plan conduct and submit trials using the CDISC standard.

PICTURES

Roadmap Timetable



Milestone A
The final alignment of the LAB model with SDTM and ODM



Milestone B
The ability to transport all CDISC SDTM submission data using the ODM transport mechanism and ensure consistency with the protocol representation standard



Milestone C
The addition of the appropriate analysis datasets and analysis programs into the CDISC submission model and the alignment with the protocol representation standard and the statistical analysis plan



Milestone D
The final harmonization of the models and the full protocol representation standard

Overall Vision

Data Flow Using CDISC Standard

