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TRANSITION PLAN
CDISC SDTM to HL7 STUDY DATA STANDARD
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General Strategy

1. The Food and Drug Administration (FDA) Vision is to have a set of HL7v3 standards (the *Study Data Standards*) that are capable of representing any data that may be needed to evaluate the safety and efficacy of a regulated product, and can be used to exchange data between FDA and regulated industry. This capability should not be confused with an FDA requirement that sponsors submit all data that can be represented by the Study Data Standards. The actual data that is submitted by sponsors will be a function of law, FDA policy, and the needs of the individual FDA reviewing division conducting the review.

2. The FDA vision for the future does not imply a change in direction regarding the use of existing standards. Until the FDA vision of a complete set of Study Data Standards is fully realized FDA wishes to continue to encourage the use of existing standards such as SDTM, ADaM, define.xml files, along with any other data standards used by FDA reviewing divisions. Details on standards currently in use at FDA are available in the current version of the eCTD Study Data Specifications which is available at: http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm

3. To ensure its ability to work effectively with these current standards, FDA will continue to work with CDISC (Clinical Data Interchange Consortium) and sponsors to improve and enhance the SDTM, ADAM, and define.xml standards.

4. However, in parallel with the use of existing standards, the new Study Data Standards are being developed as part of HL7's RCRIM (Regulated Clinical Research Information Management) work group in close association with CDISC and regulated industry.

5. The HL7v3 Study Data Standards are currently comprised of four individual HL7v3 standards: Study Design, Study Participation, Subject Data, and Individual Case Safety Report (ICSR). These standards will also be designed to interoperate with other HL7 standards and standards adopted by the Joint Initiative Council.

6. The HL7v3 Study Data Standards will be tested and implemented incrementally over a period of years.

7. FDA wishes to involve sponsors in the testing process through pilot data submission projects and meetings.

8. FDA will test the Study Data Standards, and develop the infrastructure needed to implement the Study Data Standards at the FDA centers. FDA encourages sponsors to perform further testing within their own environments.

9. Even after the new study data standards begin to replace the existing standards, it is the intention of the FDA that reviewers will have access to a variety of data views, including SDTM views, created from the HL7 study data via a Janus data mart.

10. FDA will not implement any part of the HL7 Study Data standards until it has been demonstrated that it can be successfully implemented, i.e. it has been shown that it can be successfully implemented by sponsors and submitted to FDA through pilot data submissions, and it can be used to provide reviewers with data sets that are as good as or better than the data sets provided in sponsor's current submissions.

11. Once the Study Data Standards have been tested and the needed infrastructure is in place, FDA reviewing divisions will be able to request sponsors to submit study data using the HL7 Study Data Standards.

12. There will be an adequate transition period during which FDA will accept data submitted in SDTM, ADAM, define.xml as well as HL7 Study Data standards. Sponsors will be given sufficient time to ensure that the necessary infrastructure changes can be made within their organizations to ensure a smooth transition.

High Level Uses for HL7 Study Data Standards

FDA has currently identified 9 high level uses for the Study Data Standards. FDA intends to develop templates for creating files that support these uses, and will test and implement the templates independently.

1. Study Design
    a. *Study Characteristics:* High level description of the study.
    b. *Experimental Design*: Detailed data describing the experimental design in machine readable form. Includes information about the treatment plan and definition and timing of Epochs, Arms, and Study Cells, blinding, and allocation strategy.
    c. *Schedule of Activities:* Detailed data describing the planned activities performed as part of the conduct of the study in machine readable form.

2. Study Participation (accrued and final)
    a. *Investigators*: Information on study investigators. At a minimum this includes the information provided by FDA form 1572.
    b. *Subjects and Other Participants*: Information (including unique identifiers) on subjects participating in the study, and information on other individuals and organizations participating in the study. Includes DSMBs, CROs, laboratories, etc.

3. Subject Data
    a. *Narratives and Demographics*: Free-text clinical documentation of some aspect of the patient and stable attributes of the subject and subject attributes needed to determine if subject meets the inclusion criteria. (some overlap with Study Design; used in combination with Study Participation Standard)
    b. *Case Report Form Data*: Data that is collected via the study's case report form. (Some overlap with Demographics).
    c. *Other Subject Data:* Data documenting patient care that is not specified in the schedule of activities.

4. Individual Case Study Report (ICSR)
    a. *Expedited AE reports:* Adverse event data that occur during the conduct of a study and need to be reported to FDA.

Prioritization of Use Cases

The following list corresponds to FDA's relative priorities and estimated timing for testing the use cases.

1. Patient Narratives (Day 0)
2. Investigators, Form 1572 (Day 90)
3. Expedited AE Reports (Day 90)
4. Study Characteristics (Day 180)
5. Experimental Design (Day 270)
6. Study Participation and Subject Demographics (Day 270)
7. Schedule of Activities (Day 630)
8. CRF Subject Data (Day 700)
9. Non-CRF Subject Data (Day 700)

If these priorities are inconsistent are with the priority of other stakeholders, FDA is willing to consider reprioritizing or accelerating the testing provided resources are available.