CDISC Customer Requirements Analyses

About CDISC

The Clinical Data Interchange Standards Consortium (CDISC) is an open, multidisciplinary, non-profit organization committed to the development of industry standards to support the electronic acquisition, exchange, submission, and archiving of clinical trials data and metadata for medical and biopharmaceutical product development. The mission of CDISC is to lead the development of global, vendor-neutral, platform-independent standards to improve data quality and accelerate product development in our industry.

CDISC originated as a "grass roots" effort in late 1997 with a vision to streamline clinical trials through data interchange standards for the biopharmaceutical industry. Two working groups were formed: the Data Modeling Group and the Glossary (Nomenclature) Group. In 1999 the data modeling group was split into two active working groups: one focusing on data and metadata standards to support electronic submissions (Submissions Data Modeling and Submission Data Standards –SDS Team) and one to focus on data and metadata standards to for collecting clinical data (Data Acquisition Standards-DAS Group). The latter subsequently became the Operational Data Modeling (ODM) Team. The current CDISC scope is, therefore, to focus on clinical data standards in the primary areas of Submission Data Modeling (SDM) and Operational Data Modeling (ODM) through the activities of modeling teams.

Background of the CDISC Data Model for Clinical Data Acquisition

At the Annual DIA Meeting in June 1999, CDISC presented a metadata model to support electronic submissions. In conjunction with this event, the first meeting to address standards to support the acquisition of clinical data was held. Two models to support data acquisition for clinical research were proposed, one by Phase Forward and one by PHT Corporation/Lincoln Technologies. The CDISC attendees were interested in further determining the implications and opportunities for achieving a common industry-wide data model to support data acquisition, and agreed to take action. At a face-to-face meeting in Chicago in September 1999, the two models were presented in more detail to the data acquisition group.
The broader goals of this working group were stated as follows:

- ?? Support interchange and archiving of data.
- ?? Enable interchange between applications used in collecting, managing, analyzing and archiving.
- ?? Enable full description of all data and meta-data required to produce regulatory submissions.
- ?? Reduce costs of accumulation and conversion

The meeting outcome was the formation of a Customer Requirements sub-team and a Technical Analysis sub-team. The Customer Requirements sub-team was charged with surveying the potential 'customers' of the CDISC models and prioritizing the relevant requirements. The Technical Analysis sub-team was charged with further analyzing the two models and recommending next steps for CDISC towards developing an open, vendor-neutral data and metadata model to support data acquisition and all relevant regulatory requirements. The outcome of the Technical Analysis sub-team was a consolidation of the two initial models, with a newly defined set of terms. This Version 0.8 model eventually became the CDISC ODM Version 1.1 through the efforts of the CDISC ODM team. The results of the Customer Requirements sub-team efforts are further elucidated below.

Results of the CDISC Customer Requirements Survey

The Customer Requirements sub-team developed an initial survey to obtain feedback in prioritizing their efforts to achieve the vision of developing standards to improve the process of acquiring and exchanging clinical trials information. Active members were R. Kush, R. Feller; J. Tunicliffe, L. Hauser, and S. Cassells. An initial survey was distributed at the DIA Electronic Data Capture Workshop in Durham, NC on 9 November 1999. Results were analyzed primarily as an exercise to determine whether the questionnaire was adequate and appropriate and, if not, and how to design a superior questionnaire to prioritize the requirements. The survey was revised to correct areas that were confusing (formatting, evaluation scales, wording) and was distributed as a final version at the DIA Standards Workshop on 30 November 1999 in Washington, D.C. There were 48 respondents. The results were analyzed by R. Feller and R. Kush are summarized below.

Types of Organizations of Respondents: Respondents represented 30 pharmaceutical companies, 4 biotechnology companies, 4 contract research organizations, 2 academic institutions, 5 technology providers, 2 consulting companies, and 1 central laboratory.

Importance of Industry Standards: On a scale of 0 -7, regarding the overall importance of standards for our industry, there were twenty-one respondents who expressed the highest level of importance (value of 7), twelve expressed a value of 6, eight expressed a value of 5 and seven did not respond to the question.

Timeframe of Availability: Two respondents stated that standards should be available in 6 months, fourteen responded 1 year, two responded 1.5 years, fourteen responded 2 years, four responded with 3 years, two with 5 years, one ASAP, one 'last year' and eight did not respond.

Priorities for Requirements for Industry Data Standards: Possible scores for prioritization ranged from 0 (should not be considered) to 7 (should be given a very high

priority). With 48 respondents, the highest potential total value for a given requirement would be 336.

Prioritized requirements were divided into four categories:

I. Data Standards to Facilitate Regulatory Submissions
II. Attributes of Data Standards
III. Standards to Facilitate Data Interchange
IV. Standards to Facilitate Metadata Interchange.

Of these, Category II had the highest-ranking requirements overall, followed by Categories III, I and IV in that order.

Subcategories were then prioritized within each category as follows (actual scores in parentheses – potential of 336 if every respondent marked 7):

Standards to Facilitate Regulatory Submissions (Category I):

1) CDM data to electronic regulatory submissions (257)
2) AE systems to and/or from regulatory submissions (253)
3) EDC data to electronic regulatory submissions (212)

Attributes (Category II):

1) Uphold patient confidentiality and integrity (306)
2) Adhere to global regulatory guidance documentation (290)
3) Vendor neutral; application independent (284)
4) Support the cooperation multiple systems and technologies (273)
5) Consistent with world wide web standards (254)
6) Support 'real-time' (vs. delayed) transfer (206)

Standards to Facilitate Data Interchange (Categories III):

1) Laboratory data into CDM systems (272)
2) Data from CRO to sponsoring company (271)
3) Data from AE reporting systems to and/or from CDM systems (243)
4) Data from EDC applications to CDM systems (237)
5) Data between CDM systems of different vendors (233)
6) AE information from EDC applications to CDM systems (222)
7) Laboratory data into EDC systems (220)
8) Laboratory data into data warehouses (219)
9) ePatient Diaries/self-collection tools to CDM systems (214)
10) Transfer/archiving of audit trail information (211)

Standards to Facilitate Metadata Interchange (Category IV):

1) Ensure consistency between systems (236)
2) Support data warehousing applications (227)
3) Archiving trial data long-term for audit requirements (222)

[Note that there were additional requirement that received lower ratings, but none had a total number less than 180, indicating that there were no listed requirements that should not be considered in the standards effort.]
Below is a table listing the top three or four requirements in each category from the survey. The percentage of total possible points is shown with each item.

Table 1.

	#1	#2	#3	#4
Facilitate Data Interchange	Laboratory data into CTMS (81.0%)	Data from CRO to Sponsor company (80.6%)	Data from AE reporting sys. to CDMS (72.3%)	Data from EDC applications to CDMS (70.5%)
Facilitate Metadata Interchange	Ensure consistency between systems (70.2%)	Support data warehousing applications (67.6%)	Archiving trial data long-term for audit requirements (66.1%)	--------
Facilitate Regulatory Submissions	CDM Data to electronic regulatory submissions (76.4%)	AE systems to and/or from regulatory submissions (75.2%)	EDC data to electronic regulatory submissions (63.1%)	--------
Attributes of Data Standards	Uphold patient confidentiality and integrity (91.1%)	Adhere to global regulatory guidance documentation (86.3%)	Vendor neutral; application independent (84.5%)	Support the cooperation of multiple systems and technologies (81.3%)

CDISC Actions Resulting from the Customer Requirements Survey

Based upon the customer requirements survey, CDISC has taken certain steps to respond to the items that ranked highest in priority. Specific steps have included the following:

- ?? Development of a set of principles that were designed to address certain of the attribute requirements and expressed concerns;
- ?? Definition of the fundamental requirements for the Operational Data Model for data interchange and archive;
- ?? Initiation of a CDISC LAB team to address the specific needs of interchanging clinical laboratory data;
- ?? Commitment to continue to perform additional industry surveys to collect information that will help CDISC prioritize its efforts in meeting the needs of its constituencies.


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