Setting the
Global Standard
for Clinical Data

FDA Public Meeting:

Information Technology Strategic Planning

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

CDISC Operations and the CDISC Board of Directors

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Question 1.
What would help improve the quality of electronic submissions to the agency?

- standard data collection
  - including from the Healthcare EMR/EHR systems
- standards for content and terminology
- a common standard for data transport of electronic submissions to the agency.
- the adherence to submission standards (SDTM and ADaM) and the associated terminology

It is worth noting that *the quality of the electronic data submitted relies on the quality of the electronic data collected.*

Question 2.
What would help increase the quantity of electronic submissions to the agency?

- A ruling or regulation from FDA that specifies the standards to be used for the electronic submissions to the agency
- Standardized submission formats
- A standardized “e-portal” for eSubmissions
- Clearly defined and easy to use processes for making electronic submissions

Question 3.
How would you prioritize these quality and quantity improvements?

It seems to make best sense to work on the quality of submissions as the priority to enable improvements and streamlining of the processes before going after increased quantity of submissions.

- To Improve Quality
  - Continue to encourage the development of data acquisition standards (Critical Path Initiative)

- To Improve Quantity
  - Mandate eSubmission standards

Question 4.
What data standards are needed to implement these improvements?

- The entire set of CDISC data standards for clinical research
- the HL7 standards for healthcare
- the interface between CDISC standards and HL7 standards including common concepts and terminology

In effect standards for the data “content” and data “format” are needed.

Question 5.
How should FDA engage stakeholders while developing, testing, and implementing these solutions?

- The FDA should continue to engage in its positive manner with standards development organizations and work with those organizations for the build and transport of eSubmissions.

- FDA can continue to engage stakeholders by running collaborative pilots to explore the mechanism (i.e. content and architecture), and quality of the submissions using those models.

Question 6.
What topics are most useful to include in IT plans?

- interoperability of software
- harmonization of intended standards
- bioinformatics architecture
- technology systems
- guidance and timelines for:
  - the implementation of the IT plans, and
  - the overall process of implementation, training, and ongoing support for eSubmissions

Question 7.
What lead time is needed for stakeholders to respond to and be in alignment with FDA initiatives?

- Many stakeholders are already adopting CDISC standards in anticipation of a rule. Hence, the lead time for standards adoption has already begun.

- There should be a 2-3 year transition period for adherence to the standards.

- Perhaps a 3-5 year lead time will be needed to transition to a new ePlatform.

Question 8.
How should FDA coordinate with stakeholders on the adoption and implementation of data standards?

- The FDA can engage stakeholders by running collaborative pilots to explore the mechanism (i.e. content and architecture), and quality of the submission.

- The FDA can also make use of public hearings and discussions to coordinate and take part in standards development activities with stakeholders on the adoption and implementation of data standards.

- It is vitally important for FDA to have clear, open communications with stakeholders in addition to well trained personnel on staff who can operate against well defined processes with the appropriate tools.

Question 9.
What data standards areas provide the greatest challenge?

- The accurate extraction and transmission of healthcare data (both public and private) for examining and supporting therapeutic product safety and assessment

- If pursued, the transition to an HL7 XML transport format for CDISC content will provide a major challenge for stakeholders.
  - The content standards to support Clinical Research safety assessments are available and can be implemented now using SDTM via SAS XPT or CDISC transport formats.

- Global terminology harmonization with healthcare terminology

Clear direction from the FDA will provide stakeholders with the confidence to proactively take steps in the adoption of data standards and formats for electronic submissions.

Question 10.
What approaches will facilitate the most effective and efficient adoption and implementation of data standards?

- An approach that emphasizes *accessibility to and usage of standard technology* that is easy to use

- the willingness of both the industry and the regulatory bodies to collaboratively put that technology into place

- *standard workflow and processes* for analysis of disease population data that is routinely and easily applied to standard data, and that results in a decision support process

CDISC can provide a unique supporting role for these efforts by providing an open, neutral and non-profit environment where this collaboration can take place, and where the resulting work products of this collaboration; i.e. implementation best practices, etc. can be publicly shared.

Question 11.
What key areas require new or expanded electronic submissions guidance?

The following areas are those that CDISC believes require new, or expanded and explicit submissions guidance:

1. Format and content of transport architecture
2. Clear and concise content of the observed, derived and analyzed data as required for the regulatory review process
3. Very concise requirements regarding the data content and standard domains of required safety and efficacy data
4. An e-Platform interface that would allow for the continuous review of electronic data between the sponsor and the agency
5. The clear regulatory requirement for electronic data and CDISC standards

Question 12.
What lessons learned and best practices should FDA consider as we transition from program-specific to enterprise IT solutions using a reusable and modular model?

- A primary lesson learned is that development of an IT modular model must have backward compatibility to currently used systems.

- A secondary lesson learned is that the enterprise technology is usable and accessible by all parties concerned.
  - Foremost, both the information architecture and the technical architecture must be required by the regulation and clearly demonstrated to ultimately enhance the efficient compilation of electronic submissions as well as the regulatory review of the same.
  - Further, the enterprise architecture should work effectively on the Internet and should support public and private institutions and interface both open source technology with proprietary technology.

Question 13.
What specific concerns (i.e., security, confidentiality, etc.) exist for a third party entity or entities providing services related to electronic submissions and review and how can they be addressed?

- A key concern is that third party must provide compliant and validated software and technology that can meet the requirements of Part 11, and would readily adapt to evolving requirements for the use of electronic data in the real-time assessment of safety and efficacy data.

- This would have to be addressed by vendor neutral organizations which can objectively assess Part 11 compliance of the best application and interface of both open source and privately held technology.

- Additionally – the technology and processes any 3rd party would implement should take into consideration the global nature of clinical development and any particular regional/country requirements where appropriate.

Thank You

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