Regulatory New Drug Review: Solutions for Study Data Exchange Standards

Summary and Further Discussion with DC CDISC

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• The current study data exchange format supported by FDA is the ASCII-based SAS Transport (XPORT) version 5 file format

• The purpose of the meeting was to solicit input from industry, technology vendors, and other members of the public regarding the advantages and disadvantages of current and emerging open, consensus-based standards for the exchange of regulated study data

• FDA also sought input on a set of pre-meeting questions about standards and implementation
Raise of Hands…

1. How many provided comments directly or as part of your company’s response?

2. How many attended last Monday’s session at White Oak?

3. How many commented during the session?

4. How many were satisfied with the presentations, comments, and discussions?
Purpose of Data Exchange Session

• The goal seemed to be confusing
• 2 parts of the problem
  – Transport Vehicle
  – Vehicle Content
• Both need help!

• Let’s recap last week’s session then…
Vehicle Issues

- Outdated
- Technical Limitations
- Newer versions of same SAS transport file format available currently being used in newer versions of SAS
- Not extensible enough for new domains or variables…
Vehicle Solutions

• SAS mentioned a V5 “extended”
  – Improved technical abilities
  – Presumably addresses character lengths and wasted space issue
** Is this a permanent or temporary solution? **

• Other options?
  – ODM
  – XML (HL7)
  – SAS V7
  – Ontology-based data management
Content Issues

• Often times, the content issues are independent of vehicle
  – Issue will arise in any vehicle transport
• Poor programming techniques and best practices
• Standards Implementation
• Traceability
• EDC systems
• CRF design and execution
• Coding Dictionaries
Big Questions
(we want your feedback!)

1. HL7 or CDISC?
2. What are the data management processes you all perform currently to address some of these issues internally?
3. Do you actually understand CDISC?
   – ODM, BRIDG, CDASH, SDTM, ADaM, SEND
4. How many of you utilize CDISC?
5. Based on your experiences at your companies, how much time do you need to implement a new standard version?
Big Questions
(we want your feedback!)

6. If you have not yet discussed with management, what is the estimated financial burden for changing the vehicle type?

7. What assistance would you like from FDA in your data management or submission processes?

8. What mistakes or myths do you believe your peers are making or believe in regarding your company’s standard of choice?

9. Do you believe CDER reviewers understand the data?
10. Are separate data-centric meetings beneficial?
11. Thoughts on providing audit data?
12. How do you handle ad-hoc requests for data?
13. ODM Pilot? SAS extended Pilot?
14. Would you prefer to submit your Oracle database?
Big Questions
(we want your feedback!)

• Send questions/comments to: eData@fda.hhs.gov
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Thank You!

Please save your questions until Q&A session.