Study Data Standards in eCTD: What You Need to Know About the New Technical Rejection Criteria

Ron Fitzmartin, PhD, MBA  
Senior Advisor  
Office of Business Informatics

Lisa Lin  
Senior Regulatory Analyst  
Office of Business Informatics

Virginia Hussong  
Director of DDMSS  
Office of Business Informatics

Crystal Allard  
Special Assistant to the Director  
Office of Computational Science

Center for Drug Evaluation and Research  
Food and Drug Administration

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The views and opinions presented here represent those of the speakers and should not be considered to represent advice or guidance on behalf of the Food and Drug Administration.
GUIDANCE AND POLICY
Study data standards describe a standard way to exchange clinical and nonclinical research data between computer systems.

SDTM (including Therapeutic Areas)  SEND  ADaM  Define-XML

...and more

For the full list of study data standards, see the Data Standards Catalog at www.fda.gov/ForIndustry/DataStandards/StudyDataStandards
When Will Study Data Standards be Required?

- Published December 17, 2014
- Required for NDAs, BLAs, ANDAs
  - December 17, 2016
- Required for Commercial INDs
  - December 17, 2017
- Compliance:
  - Studies starting AFTER required date
    - MUST use the standards in the Data Standards Catalog
      (NDAs, ANDAs, BLAs)

www.fda.gov
What Study Data Standards Will be Required?

FDA Data Standards Catalog
Study Data...SDTM, ADaM, SEND, Define.XML

December 2016

For the full list of study data standards, see the Data Standards Catalog at www.fda.gov/ForIndustry/DataStandards/StudyDataStandards
www.fda.gov
How Will Data Study Standards be Required?

Version 3.2 to be posted October 2016

Can FDA RTF / RTR Submissions for Non-conformance?

Yes!

eStudy Guidance requires the electronic submission of NDAs, BLAs, ANDAs, INDs in standardized format.
BUT FDA DOES NOT WISH TO RTF / RTR FOR NON-CONFORMANCE… SO
FDA will implement a process for rejection of submissions that do not conform to the required study data standards.
Study Data Standards Validation

Sponsor NDAs, BLAs, INDs, ANDAs

Study Data Conformance Validation

Study Data Quality Validation

Data Repositories

Analytic Tools

Review Decisions

www.fda.gov
Conformance Validation…

How will it work?

Sponsor NDAs, BLAs, INDs, ANDAs

Do study data conform to required standards?

YES

Acknowledgement sent via ESG on successful validation and processing

EDR

Data Quality Validation

Data Repositories

Analytic Tools

NO

Acknowledgement sent via ESG on unsuccessful validation and processing

Technical Rejection of the Submission

Acknowledgement sent via ESG on unsuccessful validation and processing

Data

Technical Rejection of the Submission
Demographic dataset (DM) and the define.xml must be submitted in Module 4 for nonclinical data; DM dataset, the Subject level analysis dataset (ADSL) and define.xml must be submitted in Module 5 for clinical data.

Trial Summary (TS) dataset must be presented for each study in Module 4 or 5.

Correct STF file-tags must be used for all standardized datasets:
- Data-tabulations-dataset-sdtm
- Data-tabulations-dataset-send
- Analysis-dataset-adam

For each study, no more than one dataset of the same type should be submitted as new.
SO WHICH IS BETTER?

Oh No RTF!

Technical Rejection Yay!
Standardized Study Data

76% of study data submitted within all NDA submissions are in standardized SDTM format**

85% of study data submitted in support of NEW NDAs are in standardized SDTM format**

*FY2016

**Source: Office of Business Informatics, CDER - One or more explicitly stated SDTM studies (or study data structure that resembled SDTM).
In Study Data Technical Conformance Guide (TCG)

4.1.1.3 SDTM Domain Specifications

- Trial Design Model (TDM) - All TDM datasets should be included in the submissions and Trial Summary (TS) dataset will be used to determine the time of study start. TS should include TSPARMCD = SSTDTC and TSVAL="yyyy-mm-dd" (ISO8601)
4.1.3.3 SEND Domain Specification

- Trial Design (TDM) – All TD datasets should be included in the submissions and TS dataset will be used to determine the time of study start. TS should include TSPARMCD = STSTDTC and TSVAL="yyyy-mm-dd" (ISO8601)
Legacy data submissions

- TS should be submitted and should include TSPARMCD = SSTDTC or STSTDTC (non-clinical data) and TSVAL="yyyy-mm-dd" (ISO8601)
### TRIAL DESIGN DOMAIN

- **Example**
  - TS for clinical data

```
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<thead>
<tr>
<th>STUDYID</th>
<th>DOMAIN</th>
<th>TSSEQ</th>
<th>TSGRPID</th>
<th>TSPARMCD</th>
<th>TSPARM</th>
<th>TSVAL</th>
<th>TSVALNF</th>
<th>TSVALCD</th>
<th>TSVCDREF</th>
<th>TSVCDVER</th>
</tr>
</thead>
<tbody>
<tr>
<td>UX003-CL201</td>
<td>TS</td>
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<td>STDTC</td>
<td>Study Start Date</td>
<td>2013-11-18</td>
<td>ISO 8601</td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
```

- TS for non-clinical data

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SUMMARY & KEY POINTS

• Starting 12/18/2016: **All** clinical and nonclinical trials, regardless of study type, must use the standards in the FDA Data Catalog

• FDA will validate submissions upon receipt and will assess conformance to required study data standards

• A technical rejection notice will be sent if the submission fails validation

• Technical Conformance Guide…. is key document to help you get it right

• FDA will provide 30 days’ notice prior to the validation criteria being effective
INFORMATION FOR INDUSTRY

Click for:

• **Data Standards Catalog**
• **Study Data Technical Conformance Guide**
• **PDF of today’s slides**
• Contact the CDER eData Team for assistance related to study data and standards:
  
  edata@fda.hhs.gov

Questions about material presented during this webinar?

  CDERSBIA@fda.hhs.gov

Open Q&A begins shortly – type in your questions now.

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