Data Standards in Clinical Trials, A Regulatory Perspective

NIH Data Standards Forum: Maximizing Innovation by Standardizing

Mary Ann Slack
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

October 19, 2012
Realities of the Drug Development Process

- **Drug Discovery**: 5,000–10,000 compounds, 3–6 years
- **Preclinical**: 250, 5
- **Clinical Trials**: Phases 1–3, 6–7 years
- **FDA Review**: 0.5–2 years
- **Scale-up to MFG.**: 1,000–5,000 volunteers
- **Post-Marketing Surveillance**: Indefinite

Source: PhRMA
# New Drug Review: Workload

<table>
<thead>
<tr>
<th>Unit</th>
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<td>Drugs/Biologic Commercial INDs with Activity</td>
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*In fiscal 2012, CDER received an average 1280 study datasets per week*
Current New Drug Review Timelines

1. Pre-Submission Activities
2. Process Submission
3. Plan Review
4. Conduct Review
5. Take Official Action
6. Post Action Feedback

New Drug Application and Biologic License Application Reviews (NDA/BLA Review Process)
Drug Dispensing

19.9% of facilities inspected annually

Postmarket Surveillance

Foreign Manufacturing
The Challenge

• The extreme variability and unpredictability of the format and content of submitted application data present a major obstacle to timely, consistent, and efficient review

• Lack of standardized clinical data:
  – Limits ability to address in-depth questions and late-emerging issues in a timely manner
  – Impedes timely safety analysis to inform REMS decisions
  – Limits ability to transition to more standardized and quantitative approaches to benefit-risk assessment
FDA Safety and Innovation Act (FDASIA)

- Reauthorizes the fifth instance of Prescription Drug User Fee Act (PDUFA V)
- Authorizes the new Generic Drug User Fee Act and Biosimilars User Fee Act
- FDASIA Section 1136:
  - Allows FDA to require standardized fully electronic submissions related to marketing applications
- Phased-in through guidance to industry according to an agreed timetable
D. Clinical Terminology Standards: Using a public process that allows for stakeholder input, FDA shall develop standardized clinical data terminology through open standards development organizations with the goal of completing clinical data terminology and detailed implementation guides by FY 2017.

- FDA shall develop a project plan for distinct therapeutic indications, prioritizing clinical terminology standards development within and across review divisions. FDA shall publish a proposed project plan for stakeholder review and comment by June 30, 2013. FDA shall update and publish its project plan annually.
ELECTRONIC SUBMISSIONS AND STANDARDIZATION OF DRUG APPLICATION DATA

E. FDA shall periodically publish final guidance specifying the completed data standards, formats, and terminologies that sponsors must use to submit data in applications. In the case of standards for study data, new data standards and terminology shall be applicable prospectively and only required for studies that begin 12 months after issuance of FDA's final guidance on the applicable data standards and terminology.
FDA Safety and Innovation Act (FDASIA)

These enhancements will help to:
- Improve efficiency of drug review
- Establish “common language” through well-understood concepts and controlled terminologies
- Enable data sharing and data pooling
- Build a foundation for broader benefits in clinical research, premarket analysis and safety signal detection
Enhanced Review Capabilities

- Submission Content
  - Clinical Study Data Repository
  - Integrated Electronic Document Room
  - Data Validation

- Review Tools, e.g.
  - eDISH
  - jReview
  - NIMS
  - MAED
Enhanced Review Capabilities

- Improved Decision Support Tools
  - Data Mining

- Supportive Documentation
  - Electronic Archive of FDA Documentation
  - Enhanced Search Tools

- Review Management Tools
  - Tracking and Analysis
  - Automated Workflow
CDER Data Standards - Operating Principles

Process
- Open and inclusive of stakeholders
- Transparent
- Predictable
- Focused on near-term improvements and long-term goals

Policies, Standards, Requirements
- Practical
- End-user oriented
- Cost-sensitive
- Sustainable
CDER Data Standards Activities – What’s Happening Now

• “e” Guidance - draft guidance in process:
  – eSubmissions Guidance –
    • In clearance, anticipated draft in 2012
  – eSource Guidance –
    • In clearance, anticipated revised draft in 2012
  – eStudy Data Guidance –
    • pre-PDUFA draft published; comments received, revised PDUFA draft anticipated
CDER Data Standards Activities – What’s Happening Now

• Study Data Content Standards in Progress:
  – 9 projects underway in CDISC; several released for public comment or provisional use
  – **CFAST Initiative** – CDISC and Critical Path Institute partnership to tackle clinical study data content standards identified in PDUFA V
  – Industry and FDA are active participants

• Grants program:
  – 6 grants awarded in 5 Therapeutic Areas
  – (Schizophrenia, Cardiovascular Imaging, Cardiovascular Endpoints, Major Depressive Disorder, Virology)
CDER Data Standards Activities - What’s Happening Now

Study Data Exchange

- Public Meeting, November 5\textsuperscript{th} - Solutions for Study Data Exchange Standards
  - Migration from SAS transport files
  - Input from Industry, tech vendors, SDOs, academia and others sought on current and emerging alternatives
  - Meeting feedback will provide input to value assessment of a transition - for FDA and regulated Industry
Conclusion

Unless sponsor-submitted application data becomes fully electronic and consistent with FDA-specified standards, the review process will remain “captive” to the unpredictable and highly-variable nature of current submissions.
Links & Contacts

FDA Data Standards website:

Data Standards Catalog:
http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm

Questions:  CDER-edata@fda.hhs.gov

Contact:  MaryAnn.Slack@fda.hhs.gov
CDER Computational Science Center

Better Data, Better Tools, Better Decisions
Computational Science Center:
Leveraging High Quality Standard Data to Benefit the Public Health

Friday, October 19, 2012

Chuck Cooper, M.D.
Computational Science Center
Office of Translational Sciences
CDER, FDA
Outline

- Overview of Computational Science Center
- Current Ongoing Data Standards Activities
- CSC Modern Review Environment
Computational Science Center Overview

**Vision:** The CSC will aid CDER decisions through supporting high-quality quantitative analysis to assess efficacy, safety, and product quality over the product life-cycle

**Mission:** To support CDER in continually improving the optimal drug evaluation and review process for the entire drug lifecycle
Creation of an integrated review environment

- Bio-informatics/business intelligence platform
- Easy access to multiple useful review tools
- Data management support
- Review tool development support
- Training
Principles for Delivery Approach

- **Efficiency**
  - Reviewers can launch analyses without having to learn new software

- **Transparency**
  - All code and specifications can be shared with the public (incl. sponsors)
  - Less surprises for industry, better communication, better quality NDA/BLA submissions
  - Sponsors don’t need to go through a software vendor
  - Sponsors will have better idea of how to submit data

- **Consistency**
  - Via Standardization of review methods
  - Less reviewer-to-reviewer variability

- **Analytic control**
  - Methods placed in hands of reviewers
  - Less reliance on sponsor’s analysis (or vendor software)

- **Flexibility**
  - Ability to modify, adapt, extend, create new analyses without having to go to a software vendor
Result of Inconsistent Data

- No Ability to build modern review tools
  - Decreased efficiency, effectiveness
- Inconsistency between reviewers, divisions
- Inability to complete review work defined by the review guidances, 21st century review
- Introduces Risk to the review process
Examples of Ongoing Data Standards Activities in CDER

Training for Reviewers:

New On-Demand Resource

This eResource was developed by the CSC to provide reviewers with an on-demand resource to utilize when they receive a submission with standardized data.

It includes:
- An overview of CDISC study data standards
- What does standardized data look like?
- How to identify standardized data
- Approaches for using standardized data
- Conversations with sponsors
- What is SEND?

This is a supplement to the Data Standards Training offered by the CSC.

:: STUDY DATA STANDARDS ERESOURCE ::

ENTER
Examples of Ongoing Data Standards Activities in CDER

Training for Reviewers:

CSC Data Standards Training

CDER Data Standards Training for Reviewers

Please contact Trish Koussis for questions about the class.

Module 1
Intro to Standard Data and Your Review

Module 2
Working with Standard Clinical Data in a Clinical Review

Module 3
Working with Standard Analysis Data in a Statistical Review

Course Title: Module 1: Introduction to Standard Data and Your Review

Primary Audience: Clinical Reviewers, Statistical Reviewers, OBI Staff

Prerequisite: None

Course Description: Two-hour course designed for anyone in CDER who is working with clinical data in a submission. The course will approach standardized data from the reviewer’s perspective. It will provide:

- A basic introduction of the lifecycle of standardized clinical data and how it can be of benefit to reviewers
- Presentation by a CDER reviewer of experiences using standardized data
- An introduction to Study Data Tabulation Model (STDM)
- An introduction to the Analysis Data Model (ADaM)

Learning Objectives:

- Gain an understanding of the lifecycle of data in a submission
- Gain an understanding of the common challenges that non-standardized submissions present during a review
- Introduction to standardized submission formats currently being submitted to CDER
- Gain an understanding of the benefits of using standardized data
CDER Data Standards Infrastructure

- CDER Data Standards Program Board
- OPI
- Division Data Standards Leads
- CDER Data Standards Questions Team
- CDER Common Data Standards Questions Database
- CDER Data Standards Plan
- Therapeutic Area Standards Development
Study Data Standards for Submission to CDER

CDER strongly encourages IND sponsors and NDA applicants to consider the implementation and use of data standards for the submission of applications. Such implementation should occur as early as possible in the product development lifecycle, so that data standards are accounted for in the design, conduct, and analysis of studies. These resources are intended to assist submitters in the preparation and submission of standardized study data to CDER. This webpage will be updated regularly to reflect CDER’s growing experience in order to meet the needs of its reviewers.

- **CDER Data Standards Common Issues Document Updated Version 1.1, December 2011 (PDF - 104KB)** - The goal of this document is to communicate general CDER preferences and experiences regarding the submission of standardized data to aid sponsors in the creation of standardized datasets. The document is not intended to replace the need for sponsors to communicate with review divisions regarding data standards implementation approaches or issues, but instead, it is designed to complement and facilitate the interaction between sponsors and divisions.

- **Study Data Specifications (v2.0) (PDF - 96KB)** - Study specifications for submitting animal and human study datasets in electronic format.

- **CDISC Study Data Tabulation Model (SDTM)**
  - SDTM Implementation Guide for Human Clinical Trials (SDTM IG) - Developed by the Clinical Data Interchange Standards Consortium (CDISC), the SDTM IG is an implementation of the SDTM for clinical study data. The conceptual model and SDTM IG can be obtained from the CDISC web site at: [http://www.cdisc.org/sdtm](http://www.cdisc.org/sdtm)
  - Standard for Exchange of Nonclinical Data Implementation Guide (SEND IG) - Developed by the Clinical Data Interchange Standards Consortium (CDISC), the SEND IG is an implementation of the SDTM for data collected from animal toxicology studies. The production version of the SEND Implementation Guide (IG) Version 3.0 (SEND IG v3.0) is NOW available at [http://www.cdisc.org/SEND](http://www.cdisc.org/SEND)

- **CDISC Analysis Data Model (ADaM)** - Developed by the Clinical Data Interchange Standards Consortium (CDISC), ADaM is an analysis dataset standard accepted by CDER. The Model and Implementation Guide can be obtained from the CDISC web site at: [http://www.cdisc.org/adam](http://www.cdisc.org/adam)

Technical Assistance
The Center for Drug Evaluation and Research (CDER) is strongly encouraging sponsors to submit data in standard form as a key part of its efforts to continue with advancement of review efficiency and quality. CDER has been collaborating with CDISC, a standards development organization (SDO), in the development of standards to represent study data submitted in support of regulatory applications. Study data standards are vendor-neutral, platform-independent, and freely available via the CDISC website (www.CDISC.org). CDISC study data standards include SDTM (Study Data Tabulation Model) for representation of clinical trial tabulations, ADaM (Analysis Data Model) for clinical trial analysis files, and SEND (Standard for Exchange of Non-clinical Data) for representation of nonclinical animal toxicology studies tabulations.

CDER has accepted SDTM datasets since 2004; however, due to differences in sponsor implementation of the standard, CDER has observed significant variability in submissions containing “standardized” electronic clinical trial data. CDER has received numerous “SDTM-like” applications over the past several years in which sponsors have not followed the SDTM Implementation Guide. Furthermore, aspects of particular sponsor implementations have actually resulted in increased review difficulty for CDER reviewers. In addition, some sponsors have wrongly believed that the submission of SDTM datasets obviates the need for the submission of analysis datasets,
Leveraging Quality Standard Data

Examples of Important Tools:
- DataFit
- Data Transformation Tools
- Data analysis tools for reviewers
DataFit – CDER’s Data Validation Platform
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<th>Score</th>
<th>Pass/Fail</th>
<th>Domains</th>
<th>Issues</th>
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### PROFILE EVALUATION REPORT: LIVER FUNCTION

**Evaluation Date:** 17-Sep-2012 10:29 PM

**Domains** | **Issues** | **Rules** | **History**
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#### TOTAL ISSUES
- **11**

#### TOTAL CHECKS
- **28**

#### TOTAL FAILURES
- **29,727**

#### TOTAL DATAPoints
- **138,501**

#### ISSUE RATE
- **21.4%**

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Showing 1 to 11 of 11 entries (filtered from 12 total entries)
Standard Analyses

- Common Key Standard Analyses (SAS)
  - 50–60 programmed automated analyses
  - Demo, disposition, adverse events, exposure

- JReview Standard

- Analyses Catalog

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- Contact Information
- 7.1.2 Serious Adverse Events
  - FDA.712.0001 SAE Incident Rates
  - FDA.712.0002 SAE Incident Rates
  - FDA.712.0003 Serious Adverse Event SOC Rates by Arm
- 7.1.3 Dropouts
  - FDA.713.0001 Dropouts Disposition Event Standard Terms
  - FDA.713.0002 Dropouts DS Events 2D Bar Chart
- 7.1.5 Common Adverse Events
  - FDA.715.0001 AE Incident Rates by Arm
  - FDA.715.0002 AE SOC Rates by Arm
  - FDA.715.0003 AE Coding Table
  - FDA.715.0004 AE Coding Table by SOC
- 7.1.7.3 Standard Analyses of Explorations of Lab Data
  - FDA.7173.0001 Liver Function Baseline Box Whisker Analysis
  - FDA.7173.0001 Baseline vs Max Scatter Plots
  - FDA.7173.0101 Baseline vs Min Scatter Plots
  - FDA.7173.0101 Shift Tables
- 7.1.7.5 Special Assessments
  - FDA.7175.0001 Hy’s Law Plots: ALT/BILI/ALP
  - FDA.7175.0002 Hy’s Law Plots: AST/BILI/ALP
  - FDA.7175.0005 Hy’s Law Patient Listing
- 7.1.8 Vital Signs
  - FDA.7183.0001 Vital Signs Baseline Values Box Whiskers Plot
  - FDA.7183.0101 DBP vs SBP Plot with Normal Range Grid
  - FDA.7813.0151 Systolic/Diastolic Shift Tables
Example: Liver Enzyme Analysis
Data Transformation

- To allow for data transformation per reviewer and review tool requirements
- CDER has no enterprise data management function
- Examples:
  - SAS Clinical Data Integration
  - Clinical Trials Repository
eDISH Tool for Detecting Drug-Induced Liver Injury

eDISH
A New Graphic Tool for Evaluation of Drug-Induced Serious Hepatotoxicity
in Clinical Studies Using SAS/IntrNet v.9

2006 Release 1.0

John R. Senior, Ted Guo, Kate Gelperin,
Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Data library: exanta RSR05 - Exanta

A member of the data library represents an NDA or clinical study

powered by sas

This request took 8.80 seconds of real time (v8.2 build 1391).
Evaluation of Drug-Induced Serious Hepatotoxicity

1980 on Ximelagatran  1982 on Warfarin

Peak TBL, xULRR vs. Peak ALT, xULRR

Ximelagatran N = 19  Warfarin N = 19
Ximelagatran N = 14  Warfarin N = 1
Ximelagatran N = 127  Warfarin N = 15
Time Course of Liver Tests

Patient #5402

Liver Test Values, x ULIR

Study Days

ALTxULN
ASTxULN
ALPxULN
BILxULN

Close Window | Go to Narrative of Patient No. 5402
21st Century Review

“The goal of the 21st Century Review is to make the new drug review process more organized, with a more integrated level of management that allows sufficient time at the end of the process to be sure all concerns have been heard and addressed by the decision makers.” Dr. Woodcock

Clearly defining the business process of the CDER NDA/BLA review
Conclusion

- Rapidly moving towards a modernized, integrated bioinformatics standards-based review environment
- High quality, standardized data pre-requisite
- Easy data analysis using best practices
- Access to powerful, standard data-based review tools
- Additional efficiency through introduction of business process management