



Data Standards Strategy – Action Plan

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1.0 Introduction

In 2010, the Data Standards Program Board (DSPB) was chartered to serve as the governing body for the Center for Drug Evaluation and Research (CDER) data standards initiatives. In this capacity, the DSPB oversees a portfolio of projects to deliver to its internal and external stakeholders. This action plan outlines the data standards initiatives under the authority of the DSPB. These initiatives are directly aligned with the Data Standards Strategy (<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm249979.htm>) and, where applicable, to the Prescription Drug User Fee Act (PDUFA) Informatics Plan. CDER's DSPB interfaces closely with standards teams in other centers, collaborating on projects and direction wherever feasible.

2.0 Purpose

The Action Plan provides internal and external stakeholders with an overview and progress of current CDER data standards initiatives. The plan is updated quarterly to indicate progress of current projects as well as initiation of new projects.

3.0 Program Initiatives

The initiatives in the CDER DSPB portfolio align with the Center's data standards strategic goals. For purposes of this plan, the goals are categorized in following manner:

1. **Policy and Process** – Key activities to establish critical data standards-related policy or process (e.g., standards development and adoption, guidance development process and schedule, other specific guidance).
2. **Standards Development and Implementation** – Projects to identify, develop, test, and implement a standard to meet a regulatory need.
3. **Study Data Standards** – Projects that develop, test, or implement advancements in study data terminology and content standards.
4. **Research and Development** – Projects to assess a potential approach to meet a standards-related need without immediate intent to implement; these are to inform future direction.

A. Policy and Process

The Data Standards Strategy outlines policy and process initiatives to support CDER's data standards goals. The projects commenced to address the outlined policy and process initiatives are in **Table 1**. The progress arrows in the table indicate the current stage of progress for each project. **See Table 5** for a description of the stages.

Guidance and other public documents that set policy follow a development, clearance, and publication process at the draft stage and again after the review and disposition of public comments and publication of the final document. This process is aligned with Good Guidance Practices (GGP) for issuing guidances as described in 21 Code of Federal Regulations (CFR) 10.115.

B. Standard Development and/or Implementation

CDER is implementing a consistent approach for its standards requirements, development and implementation projects. An overview of the development framework is provided in the Appendix. The framework is intended to be flexible enough to accommodate any number of

standards needs, from simple vocabulary change requests, to changing existing standards, to implementation of new standards.

Further detail regarding the projects specific to study data are outlined in Section C. **Table 2** highlights current standards projects.

C. Study Data Standards

This section elaborates the Data Standard Project *Development* Stage for a study data standard. These projects are categorized separately from other data standards efforts because it is expected that most will be incremental enhancements to existing standards. For example, as discussed in the Data Standards Strategy document, it is expected that therapeutic area standards development will enhance existing “cross-cutting” Clinical Data Interchange Standards Consortium (CDISC) domains (e.g., demographics, adverse events, vital signs) and potentially add small therapeutic area (TA) -specific sets of elements and relationships. The Appendix describes the process overview and the FDA’s roles/activities in the development of study data standards.

Most current study data standard development projects are led by organizations external to FDA (e.g., CDISC, Critical Path Institute, Duke Clinical Research Institute (DCRI)). This enables CDER to meet one of its strategic goals: to support open, consensus-based data standards development. To ensure that those standards can be implemented for regulatory review purposes, FDA participates at critical junctures throughout the development phase to identify scope and requirements, provide subject matter expertise and feedback, and to perform acceptance and implementation testing. When a standard is available for public release from the relevant Standards Development Organization (SDO) it is available for use but is not necessarily adopted by FDA. FDA will perform testing to determine whether the released standard meets regulatory review needs and is suitable for regulatory adoption. After any issues are addressed, FDA will update study data guidance as necessary and publish draft guidance for public comment.

While this approach relies on the successful performance of these external organizations, FDA is not a passive stakeholder and participates on many levels to influence project scope (e.g., through requirements development and expert reviews), promote timely progress, and prioritize projects through participation in steering groups (e.g., Coalition for the Advancement of Standards and Therapies (CAST¹)) and leadership support in relevant HL7 working groups.

A list and status of development projects addressing therapeutic areas are available online at: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm287408.htm>. **Table 3** highlights study data standards related projects that are not on the therapeutic area standards development list.

D. Research and Development

The process for research and development initiatives is similar to that of other data standards development efforts. To ensure that CDER’s standardization needs are met in the long term, research and development initiatives are undertaken to assess new approaches without immediate intent to implement, but rather to inform future direction.

Over the past few years, CDER has increased its support for standardized study data submissions using CDISC standards, and will continue to do so in the foreseeable future. On November 5, 2012, FDA coordinated the Solutions for Study Data Exchange Standards Meeting

¹ <http://www.cdisc.org/therapeutic>

to solicit input from industry, technology vendors, and other members of the public regarding the advantages and disadvantages of current and emerging solutions for the exchange of regulatory study data. Based on public input, FDA has initiated a project to capture and analyze both submission and study life-cycle exchange requirements. The results will inform further pilot activities in this area.

4.0 Risk Mitigation

Quarterly updates to the portfolio will ensure that stakeholders are kept informed of the status of each project. The risks listed below are monitored and mitigations applied on a continual basis to manage impacts to the portfolio.

4.1 Risks

1. The required FDA staff and support resources are not available as expected, or severely limited;
2. A reduced budget scenario occurs;
3. Required resources from external stakeholders are not available or severely limited;
4. External environmental factors (e.g., regulatory, legislative, economic, technological) arise that directly impact one or more key programs.

4.2 Mitigation

1. Projects will not be initiated unless there is sufficient commitment (e.g., budget and staffing) to meet the project's planned objectives.
2. Projects that are not resourced adequately, by both internal and external parties, will be eliminated or delayed.
3. Projects will include planned decision points in the overall schedule with escalation oversight where necessary to address issues. Decision points will be used to adjust project scope and/or direction to continue to progress within identified constraints.

Table 1. Policy and Process

Project Title	Center	Project Description	Output and Estimated Timeframes	Stage			
				Initiation	Development	Clearance	Publication
Guidance on Electronic Submission of Applications	CDER CBER	Issue draft Guidance in fiscal year (FY)2013 specifying the requirement of electronic submission of applications.	Draft for public comment FY2013 Q1 ²				
Guidance on Electronic Standardized Study Data	CDER CBER	Issue draft Guidance to industry specifying requirements for electronic data standards under the Food and Drug Administration Safety and Innovation Act (FDASIA).	Draft for public comment FY2013 Q3				
Therapeutic Area Standards Plan	CDER CBER	Create and publish a TA Development Plan.	Draft for public comment FY2013 Q2				
Data Fit Project	CDER	Publish data validation rules for industry use prior to submission; Perform content validation at regulatory submission.	Draft for public comment FY2014 Q1				
Technical Resource Conformance Guides	CDER CBER	Conduct a review of existing technical resource conformance guides (e.g., Study Data Specification, Common Issues Document, voluntary legacy data conversion traceability), and define an approach for public release of the guides that includes a formal notification (e.g., Federal Register Notice of Availability) and public comment period.	Draft for public comment FY2013 Q4				

² FY2013 refers to the Federal government fiscal year (i.e., Q1 October-December, Q3 January-March)

Project Title	Center	Project Description	Output and Estimated Timeframes	Stage			
				Initiation	Development	Clearance	Publication
Quality Data and Other Areas of Standardization	CDER	Conduct an assessment and develop a strategy document/plan to outline data needs and uses for non-clinical data areas (e.g., Chemistry, Manufacturing, and Controls (CMC), product, facility). This strategy may lead to other projects (for guidance or standards development) and is linked to other efforts outlined in this plan (e.g., Identification of Medicinal Products (IDMP) Implementation).	Draft needs assessment FY2013 Q43/Q4				
Draft Guidance for Industry; Providing Regulatory Submissions in Electronic Format-- Submission of Manufacturing Establishment Information	CDER	Issue draft Guidance in FY 2013 to request voluntary submission of electronic information about manufacturing establishments. Guidance is collaborative effort with CBER; working group involves CDER/OC, ONDQA (Office of New Drug Quality Assessment), OGD (Office of Generic Drugs), OBP (Office of Biotechnology), ORP (Office of Regulatory Policy), OBI; CBER	Draft ready for clearance by late Q2/early Q3 FY 2013; actual clearance time is unknown (will depend on constituent offices)				

Table 2. Standard Development

Project Title	Center	Project Description	Output and Estimated Timeframes	Stage						
				Req Definition	Alt Analysis	Development	Testing	Adoption	Implementation	FRN ³ / Guidance
eCTD v4.0 Project	CDER CBER	FDA currently uses electronic Common Technical Document (eCTD) version 3.2. This project is to support the development, testing, and adoption of the next major version of the eCTD (version 4) which includes two-way communication.	Message Testing complete FY2013 Q4 (estimated)							
Product Dictionary – FAERS	CDER	Maintain a product dictionary comprised of content from multiple dictionary sources for initial use by the FDA Adverse Event Reporting System (FAERS).	FAERS production release FY2013 Q1							
IDMP Implementation	CDER	Implement International Organization for Standardization (ISO) Identification of Medicinal Products (IDMP) standards to support next generation product dictionary and consistent product identification. Implementation of this effort will be through the Center's overall Master Data Management effort.								
Quality Standards Needs Assessment	CDER	Assess current baseline of standards in place for generic products (as part of GDUFA) and determine gaps in standards needs.								
ICSR R3 (E2B R3) Implementation Assessment and Planning	CDER	Assess ICSR R3 implementation requirements and considerations; develop implementation plan based on assessment findings.	Assessment findings estimated FY13 Q4							

³ Federal Register Notice (FRN)

Table 3. Study Data Standard Development

Project Title	Center	Project Description	Output and Estimated Timeframes	Stage							
				Req Definition	Initiation	Development	Testing	Adoption	Implementation	FRN/Guidance	
SEND Cardiovascular and Respiratory Safety Pharmacology Pilot	CDER	Pilot the Standard for Exchange of Nonclinical Data (SEND) data standard for cardiovascular and respiratory safety pharmacology study types.	Pilot completion estimated FY13 Q4								
Small Clinical Model (TA Requirements Development) Project	CDER	Establish and pilot a process to capture data requirements for review of clinical efficacy for defined therapeutic areas.	Pilot completion estimated FY13 Q4								
Study Data Testing Methodology	CDER	Define considerations for testing approaches, types of test efforts, and appropriate measurement criteria to enable FDA to assess standards in the review environment.	To be determined								
Site-Level Standardized Data Elements	CDER	Provide guidance to industry on site-level standardized data elements used in the selection clinical sites and/or facilities for inspection as part of a regulatory application or supplement.	Draft guidance released December 2012								

Table 4. Research and Development

Project Title	Center	Project Description	Output and Estimated Timeframes
HL7 Study Data Standards Project (Research and Development)	CDER	Conduct a proof of concept (POC) and test the use of HL7 v.3 xml messages and/or documents (e.g., Clinical Document Architecture (CDA)) as a possible exchange method for certain use cases (e.g. patient narrative, clinical investigator information, study design, subject data). The project includes drafting implementation guides and conducting testing.	Phase 1 – Testing Clinical Investigator Information complete FY13 Q1; Testing Patient Narrative complete FY13 Q2 Phase 2 – Testing Structured Protocol Information complete FY13 Q4
Submission and Exchange Standards Analysis	CDER CBER	Document a pathway for the replacement of SAS XPORT files used for transport of CDISC content with a more robust and flexible transport mechanism	Draft plan TBD

Table 5. Policy and Process Project Stages

Policy and Process Project Stage	Center	Stage Description
Initiation	CDER CBER	The business need is articulated and a work plan for the project is developed.
Development	CDER CBER	During this stage the proposed new or changed policy/process is developed and a draft of the new/revised policy or process is created and internally reviewed by subject matter experts. Once complete, the document will begin the clearance process.
Clearance	CDER CBER	This is a formal process whereby a guidance document is reviewed for consistency with CDER policy, Good Guidance Practices, format, style, clarity and content. The review is conducted by leadership at the office and center levels prior to submission and review at the Agency level and subsequent publication.
Publication	CDER CBER	For guidance and other external documents having policy impact, a notice of availability is published in the Federal Register and the document is made accessible to internal and external stakeholders. For internal processes, publication is made as a CDER Manual of Policies and Procedures (MaPPs) if appropriate.

Table 6. Standard Development Project Stage and Description

Rows highlighted in yellow* are processes owned by Standards Development Organizations, other rows are FDA owned process. As discussed in the next section, there is variation in all data standards projects so not all processes are needed for every project.

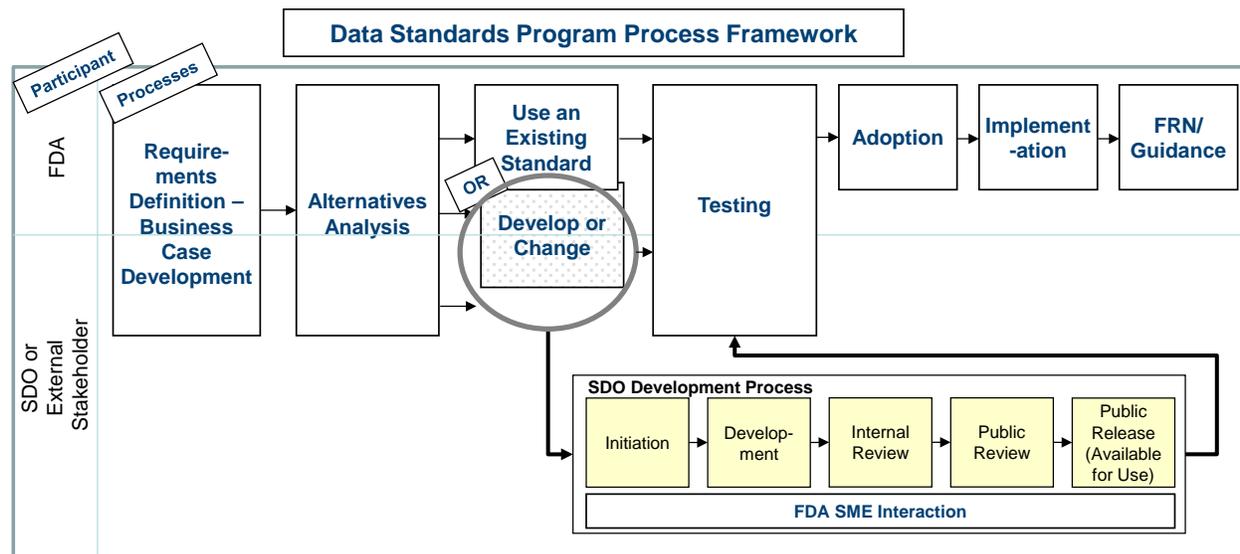
Data Standard Project Stage	Stage Description
Requirements Definition - Business Case Development	A business case is developed that can include a description of the data standard need, impact on tools, processes, and information technology infrastructure, high-level concept of operations, future state benefits, and high level requirements. For study data-related projects, FDA subject matter experts and document resources (e.g., case report forms, guidance documents) are used to develop requirements for study data standards development.
Alternatives Analysis	If needed, FDA can conduct alternative analyses to assess options and recommendations for addressing the data standards need defined in the business case. Stakeholder input is a critical part of this effort and could include a request for public comment or input in addition to planned communications (as outlined in the Communication Plan).

Data Standard Project Stage	Stage Description
Alternatives Analysis - Pilot	If needed, FDA would conduct a single option pilot to further assess the feasibility of a data standards alternative or a competitive pilot to compare more than one identified alternative that meets the business need.
Initiation*	The SDO, grantee, or other lead group working with the FDA and other subject matter experts defines the project scope (e.g., what is needed for regulatory review decision making), develops a charter to define the project and ensure available resources, develops a plan, and conducts a kick off of the project.
Development*	The SDO, grantee, or other lead group conducts an iterative process of data element identification (e.g., elements need to describe the study primary endpoint), definition, validation, and conducts a review with defined expert groups. FDA's subject matter experts participate throughout the development phase. A key output is an implementation guide for the study data standard.
Internal Review*	During this stage, the lead group conducts an internal review to ensure readiness for the public review period.
Public Review*	The lead group facilitates a public review comment period. Comments are addressed per the lead group's process.
Public Release*	An initial release of the study data standard is released for public use.
Testing	<p>A project may be required to test that all identified factors are assessed (e.g., scale, impact, suitability for FDA regulatory review needs, compatibility with FDA infrastructure) and that all policy, regulatory, guidance, and technical specification needs are identified.</p> <p>For study data, FDA may use converted or sample data sets to test the study data standard to simulate regulatory review decision making. Having the business rules and/or conformance checks available for a new or updated standard at time of SDO release will be important to FDA's testing efforts.</p>
Adoption	If needed, policy, regulatory, guidance, and technical specification needs identified for a given data standards change are addressed to support implementation.
Implementation	The data standard change is being implemented into the FDA environment. This phase includes all the steps to make this part of the regulatory review process.
Federal Register Notice (FRN)/Guidance	FDA will issue final guidance if the use of a new standard is required.

Appendix A. Standard Development and/or Implementation Project Stage Description

This section provides more detail on the processes utilized by the projects described in Section 3.0B and 3.0C. **Figure 1** illustrates the process framework CDER is implementing for its data standards identification, development and implementation projects. Most processes in this framework require collaboration with external stakeholders, these are depicted as process boxes that cross between the FDA and SDO or External Stakeholder participant rows.

Figure 1. Data Standards Development Project High Level Process



Use of this approach ensures that identified data standards needs are articulated, reviewed and approved internally, external stakeholders are engaged, adequate testing is conducted, and that roll out is planned. The figure also illustrates the general development process utilized by external SDOs (shown with yellow boxes). As discussed in Section 3.0C, these projects are led by groups external to FDA (e.g., CDISC, Critical Path Institute) and FDA participates throughout the process to provide subject matter expertise. **Table 6** summarizes the definitions for each of the process stages in the framework.