Data Standards Program
Action Plan

Version: 2.6

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REVISION HISTORY

Version Number	Implemented By	Revision Date	Description of Change
1.0	CDER DSPB	February 21, 2013	Initial Document
1.1	CDER OpSC	July 29, 2013	Quarterly Update
1.2	CDER OpSC	October 23, 2013	Quarterly Update
1.3	CDER OpSC	February 5, 2014	Quarterly Update
1.4	CDER OpSC	May 30, 2014	Quarterly Update
1.5	CDER OpSC	October 2, 2014	Quarterly Update
1.6	CDER OpSC	January 21, 2015	Quarterly Update
1.7	CDER OpSC	April, 8 2015	Quarterly Update
1.8	CDER OpSC	July 8, 2015	Quarterly Update
2.0	CDER OpSC	October 14, 2015	Update to reflect Data Standards Strategy v2.0 and quarterly project update
2.1	CDER OpSC	February 3, 2016	Quarterly Update
2.2	CDER OpSC	May 25, 2016	Quarterly Update
2.3	CDER OpSC	August 31, 2016	Quarterly Update
2.4	CDER OpSC	November 18, 2016	Quarterly Update
2.5	CDER OpSC	March 15, 2017	Quarterly Update
2.6	CDER OpSC	June 29, 2017	Quarterly Update

Table of Contents

Tables

Figures

1. Introduction

The Center for Drug Evaluation and Research (CDER) Data Standards Program Board (DSPB) serves as the governing body for data standards initiatives. To facilitate this effort, the DSPB established subcommittees to monitor projects, provide updates and recommendations to the DSPB, and manage data standards-related issues. With the governance structure and supporting process framework in place, the DSPB oversees a portfolio of projects to deliver to its internal and external stakeholders. These initiatives directly align with the CDER Data Standards Strategy published in 2015 and, where applicable, published Information Technology (IT) plans.

2. Purpose

This Action Plan provides a quarterly update to internal and external stakeholders, with an overview and progress update of current CDER data standards initiatives. The plan will continue to be updated quarterly to reflect progress of current projects, as well as, initiation of new projects.

3. Program Initiatives

The program initiatives are derived from the major areas of regulatory business activities. A detailed description of these major areas can be found in the CDER's Data Standards Strategy. These areas are shown in **Figure 1.**

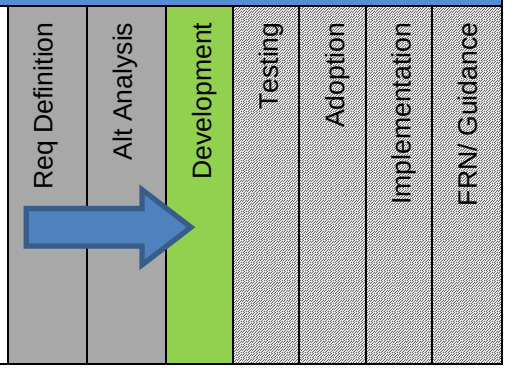
Figure 1. Data Standards Program Initiatives

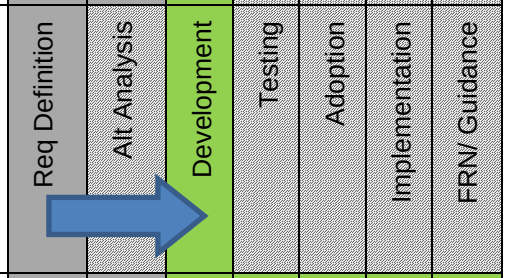
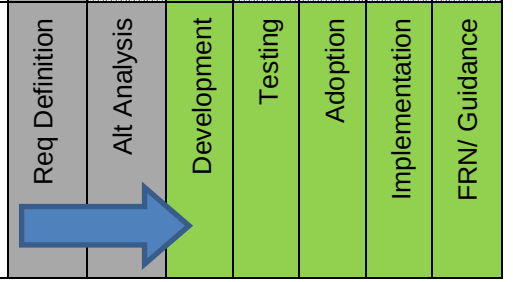
For each project, this plan includes the project title, brief description and a status of the project. The project stage* illustrates the current phase of development for the project. Completed stages are shown in gray, stages in progress or to be completed are shown in green, and stage(s) that do not apply to a project are marked with black stripes. The definitions of the project stage are defined in **Table 5**.

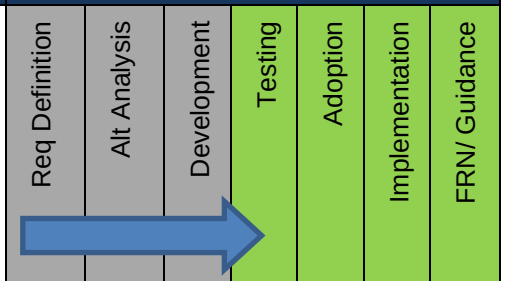
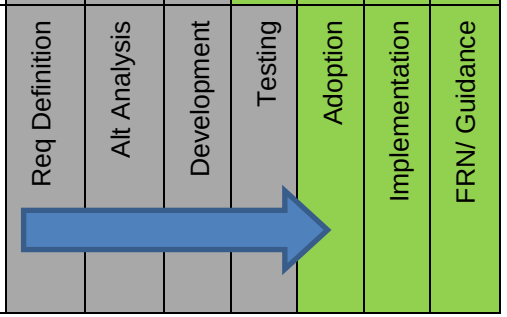
A. Drug Development and Pre-Market Review

Projects in this regulatory business area focus on development of Clinical and Non-clinical Study Data submitted in Investigational New Drugs (INDs), New Drug Applications (NDAs), Biologics License Application (BLAs) and Abbreviated New Drug Application (ANDAs) to support the Center's need to conduct rigorous science-based pre-market review to help ensure that drugs marketed to the public are safe and effective.

Table 1. Drug Development and Pre-Market Review Standards Projects

Project Title and Description	Project Update	Project Stage*
Projects that will impact the data received/reviewed during the pre-market review of submissions		
BRIDG Architecture Review Conduct an architectural review of the Biomedical Research Integrated Domain Group (BRIDG) model. The project started in FY2016 Q1. This effort proposes three aims: Mapping BRIDG to Fast Healthcare Interoperability Resources (FHIR), formalizing a model-by-reference approach, and developing a plan to reorganize BRIDG classes.	Phase 1 of the project almost completed, including: • Developed BRIDG-based profiles and extensions for select classes • Developed a complete BRIDG Unified Modeling Language (UML) to FHIR elements meta mapping, and identified major gaps eveloping semantic mapping of existing FHIR resources to BRIDG model (in progress).	

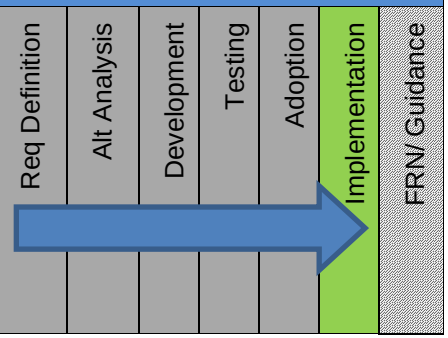
Project Title and Description	Project Update	Project Stage*
Grant Projects for Therapeutic Areas & Animal Efficacy and Natural History Studies Provide program and subject matter expertise to awarded grant projects.	The following Clinical Therapeutic Area (TA) grants are in progress: • Development of a Clinical Data Interchange Standards Consortium (CDISC) Therapeutic Area Data Standard for: o Lung Cancer is in the initial scoping stage o Clostridium Difficile associated Diarrhea is in the initial scoping stage o Treatment of HIV is in the initiation stage. The following Animal Efficacy and Natural History Studies are in progress: • Development of a CDSIC Data Standard for: o Animal Efficacy Studies is in the development stage o Natural History Studies for Animal Rule Applications is in the development stage. To see the list of the grant projects underway, see CDER's Grant Program for Data Standards Development webpage.	
FDA Therapeutic Areas Data Standards Analysis Recommendations Develop the approach for standardizing analysis data sets.	The project is working to accomplish the following: • Finalizing analysis recommendations for four therapeutic areas (Rheumatoid Arthritis, Prostate Cancer, Lung Cancer, and Colorectal Cancer) • Developing recommendations for the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE).	
Bioanalytical Methods Validation Terminology Transform the Office of Generic Drugs (OGD) technical specifications into a terminology that can be used by sponsors for the submission of these data.	A request for a project is working with CDISC to form a working group for bioanalytical methods data standardization project is in review.	

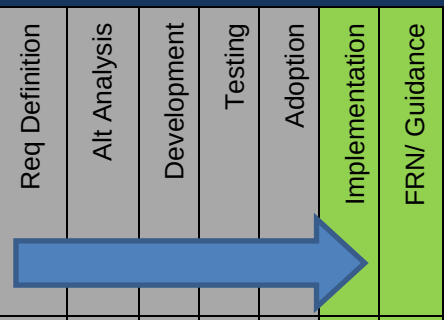
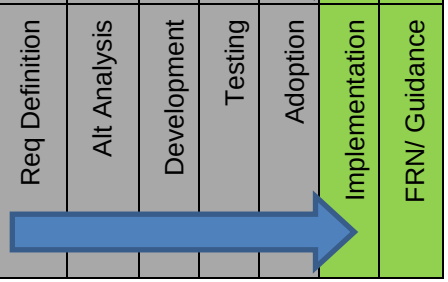
Project Title and Description	Project Update	Project Stage*
Study Data Standards Testing Using the established testing methodology, available data standards will be prioritized and tested.	The following highlights progress of the Study Data Standards Testing project: • To-date 14 TAs have been tested during the CDISC Public Review stage and after final publication. 10 TAs are supported; 3 are scheduled for retesting after final publication • Last quarter 5 TAs were retested after final publication and are reflected in the Technical Conformance Guide • Next quarter 3 TAs are planned for testing during the public review period.	
eCTD v4.0 Project Support the development, testing, adoption, and implementation of the next major version of the electronic Common Technical Document (eCTD) version 4 which includes two-way communication. FDA currently uses eCTD version 3.2.	The International Council for Harmonisation (ICH) updated the ICH Implementation Package for eCTD v4.0 and the updated implementation package is posted on the ICH eCTD v4.0 Step 4 webpage. The FDA updated the USFDA regional Module 1 eCTD v4.0 Implementation Package and the updated implementation package is posted on the FDA Electronic Common Technical Document (eCTD) v4.0 webpage.	

B. Drug Safety Performance and Promotion

Projects listed in this regulatory business area are efforts related to support the oversight of post-market risk management strategies as well as drug marketing and promotion which includes pharmacovigilance and surveillance.

Table 2. Drug Safety Performance and Promotion Standards Projects

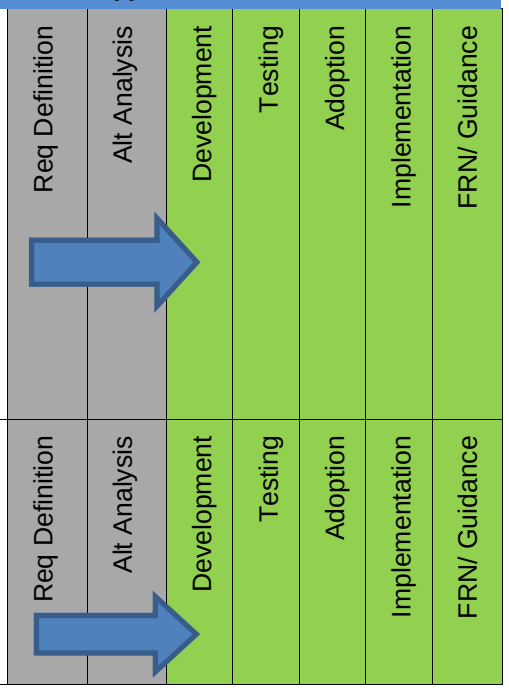
Project Title and Description	Project Update	Project Stage*
Projects that impact post-market risk management strategies		
ISO IDMP 11238 Implementation Implement International Organization for Standardization (ISO) 11238 - "Identification of medicinal product – Data elements and structures for the unique identification and exchange of regulated information on substances" standards with reliable and robust repositories and processes to support efficient, consistent, and timely decision making in the regulation of medicinal products throughout the product development lifecycle.	The project is moving to establish the Global Substance Registration System (GSRS) in the FDA environment. Production release 1 which includes specified substance group 1 and all modules of substance is in place as of April 30, 2017.	

Project Title and Description	Project Update	Project Stage*
Integrity Product Domain Enhancements Implement the Product Master Data and the IDMP compliant integrated product dictionary convergence strategy to ensure the continuity of current business operations supported by the existing product master data. This Product Master Data domain is designated as the authoritative repository for CDER regulated products and will be referenced by other CDER applications, as appropriate.	The project is in the process of validating existing requirements and performing a gap analysis. By the FY2018 Q1 timeframe, existing product data and the integrated product dictionary will be combined as the single product domain to support CDER's day to day regulatory review operations, as appropriate.	
Integrating REMS Information into SPL Capture and submit structured information about Risk Evaluation and Mitigation Strategies (REMS) and official FDA-approved REMS Documents in SPL.	FDA completed the pilot and is now able to receive REMS in SPL format. A guidance that will require submission of the REMS in SPL format is currently in internal review.	

C. Pharmaceutical Quality

Projects listed in this regulatory business area focus on the regulatory review of INDs, NDAs, BLAs, ANDAs; pre-approval manufacturing facility inspections and product availability.

Table 3. Pharmaceutical Quality Standards Projects

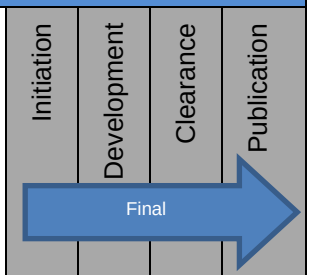
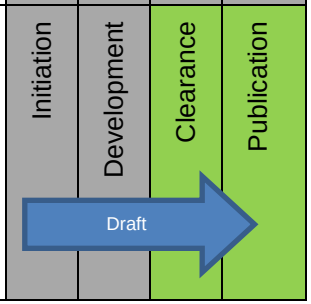
Project Title and Description	Project Update	Project Stage*
Projects that impact review of chemistry, manufacturing and controls (CMC) submissions and supplements		
Pharmaceutical Quality (PQ)/, Chemistry, Manufacturing, and Controls (CMC) Data Standardization Establishing common drug quality data standards continues to provide new opportunities to transform the submission data into useful information to potentially enhance FDA's drug review process. This project will identify and standardize data elements, terminologies, and data structures to enable automation of important analyses of PQ/CMC data to support more efficient and effective regulatory decision-making.	Data elements as well as data elements that require terminology value sets have been identified. The project is currently evaluating data exchange standards for PQ/CMC data. Federal Register Notice to request comment on data elements and terminologies is expected to be published in 2017.	
[1]Annual Report Project Improve submission requirements to ensure that essential facility location and production information is captured completely and in a form conducive to electronic receipt, storage and usage.	The project continues to assess and refine the proposed changes to ensure essential annually reportable information is captured completely. These possible changes are undergoing internal agency review.	

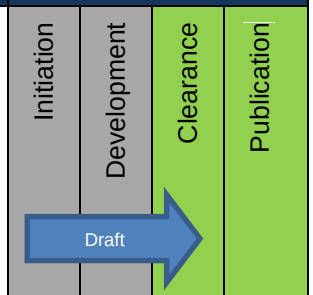
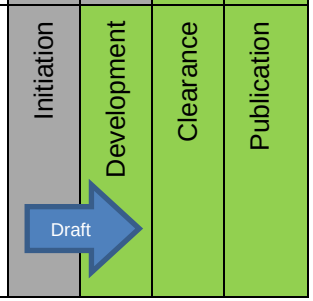
[1] Formally titled Facilities Production/Distribution Standardization Project.

D. Policy

Projects listed in this regulatory business area focus on the development of CDER regulations and guidance related to data standards. The definitions of the project stage are defined in **Table 6**.

Table 4. Policy Standards Projects

Project Title and Description	Project Update	Project Stage*
Projects to develop or update guidance & other documents that provide assistance to regulated industry and the FDA by clarifying requirements imposed by legislation and regulation		
Study Data Standards Technical Conformance Guide The Study Data Technical Conformance Guide, supplements the revised draft guidance for industry Providing Regulatory Submissions in Electronic Format--Standardized Study Data (eStudy Data guidance) by providing technical specifications, recommendations, and general considerations on how to submit standardized electronic study data using FDA-supported data standards identified in the Data Standards Catalog.	Version 3.3 of the Technical Conformance Guide was published March 2017. The next scheduled update of the Technical Conformance Guide is planned for October 2017.	
Providing Regulatory Submissions in Electronic Format Content of the Risk Evaluation and Mitigation Strategies Document	Draft guidance is in clearance with publication estimated in 2017.	

Project Title and Description	Project Update	Project Stage*
[2]**Providing Submissions in Electronic Format - Draft Guidance for Industry NDA and BLA Content for Planning and Conduct of Bioresearch Monitoring Inspections (BIMO) for CDER Submissions** Provide guidance to industry on information needed for conduct of BIMO inspections and site-level standardized data elements used in the selection clinical sites and/or facilities for inspection as part of a regulatory application or supplement containing clinical data.	Draft guidance is in clearance with publication estimated in 2017.	
Guidance for Industry: Providing Electronic Submissions - Bioanalytical Methods Validation Data Binding guidance being developed by the Office of Generic Drugs.	Draft guidance document currently under review.	

[2] This is the new draft guidance title which was previously "Providing Submissions in Electronic Format- Summary Level Clinical Site Data for CDER's Inspection Planning".

Appendix A. Project Stage and Description

Table 5. Standard Development Project Stages

The Stage Name column lists the stage name as outlined in **Figure 2** and a shortened name listed in the tables above. The rows highlighted in yellow***** are processes owned by Standards Development Organizations (SDOs), other rows are CDER owned processes. As discussed in the next section, there is variation in all data standards projects so not all processes are needed for every project.

Stage Name	Stage Description
Define Scope and Requirement (Req Definition)	A plan 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.
Analyze Alternatives (Alt 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).
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.

Stage Name	Stage Description
Public Release*	An initial release of the study data standard is released for public use.
Test Standards (Testing)	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. 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.
Determine Data Standard Adoption (Adoption)	If needed, policy, regulatory, guidance, and technical specification needs identified for a given data standards change are addressed to support implementation.
Implement Standard (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. Implementation is considered complete when data can be successfully processed, reviewed, and archived utilizing the new standard.
Federal Register Notice (FRN)/Guidance	FDA will issue a Federal Register Notice (and guidance as needed) if the use of a new standard is required.

Table 6. Policy Project Stages

Policy Project Stage	Stage Description
Initiation	The business need is articulated and a work plan for the project is developed.
Development	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	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	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.

Appendix B. Process Framework

This section provides more detail on the processes utilized by the projects described in Section 3. **Figure 2** illustrates the process framework CDER has implemented for its data standards identification, development, and implementation projects. Depending on the scope, projects will proceed through the appropriate phases (i.e., not every project will proceed through all of the listed processes). For example, projects only capturing CDER's TA recommendations will not proceed through Testing, Adoption, and Implementation stages. Those would be addressed in a subsequent project. Most processes in this framework require collaboration with external stakeholders; areas where this occurs most frequently are the SDO development process (process 4) and during testing (process 5).

Figure 2. Data Standards Development Framework