Data Standards Program
Action Plan

Version: 2.5

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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

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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.**

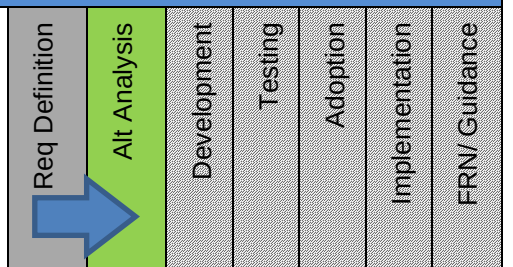
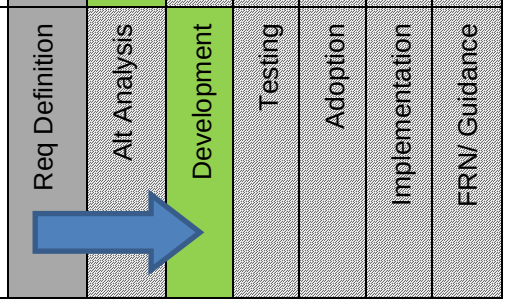
Figure 1. Data Standards Program Initiatives

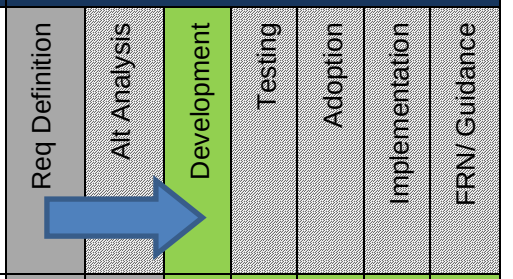
For each project, this plan includes the project title, brief description and a status of the project. The project stage* illustrates the current phase of development for the project. Completed stages are shown in gray, stages in progress or to be completed are shown in green, and stage(s) that do not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

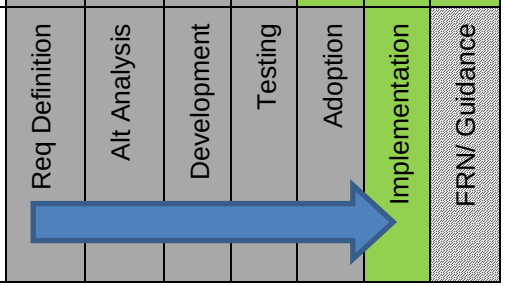
Projects in this regulatory business area focus on development of Clinical and Non-clinical Study Data submitted in Investigational New Drugs (INDs), New Drug Applications (NDAs), Biologics License Application (BLAs) and Abbreviated New Drug Application (ANDAs) to support the Center's need to conduct 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 stated 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.	To-date, the project investigated and assessed available FHIR resource-building tools and is currently working to accomplish the following: • Investing the capabilities of the HL7 publishing tool • Researching the utilization of HL7 FHIR tools for BRIDG re-architecture.	
Grant Projects for Therapeutic Areas & Animal Efficacy and Natural History Studies Provide program and subject matter expertise to awarded grant projects.	To see the list of the grant projects underway, see CDER's Grant Program for Data Standards Development webpage.	

Project Title and Description	Project Update	Project Stage*
FDA Therapeutic Areas[1] 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 • 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 Clinical Data Interchange Standards Consortium (CDISC) to form a working group for bioanalytical methods data standardization project is in review.	
Standards Testing and SOP Enhancement Using the established testing methodology, available data standards will be prioritized and tested. Testing process documentation will be updated as needed based on lessons learned.	CDISC foundational standards and Therapeutic Area (TA) extension standards are prioritized for testing iteratively based on the availability. To date, 15 foundational and TAs have been assessed with five now supported. Testing continues in 2017 with five planed in the first quarter.	

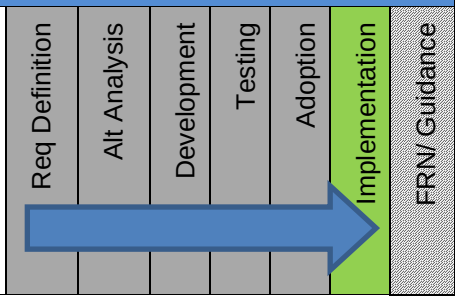
[1] Hepatitis C Virus (HCV) resistance data Pilot has been completed.

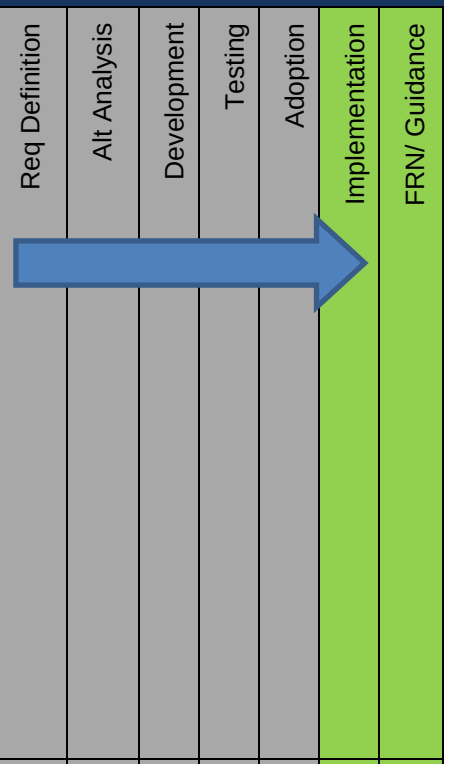
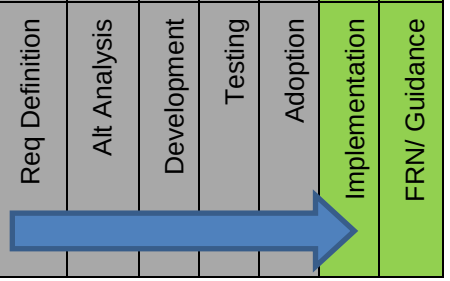
Project Title and Description	Project Update	Project Stage*
eCTD v4.0 Project Support the development, testing, adoption, and implementation of the next major version of the electronic Common Technical Document (eCTD) version 4 which includes two-way communication. FDA currently uses eCTD version 3.2.	The International Council for Harmonisation (ICH) is updating the ICH Implementation Package for eCTD v4.0 and plan to post the updated implementation package in early 2017. The FDA is updating the USFDA regional Module 1 eCTD v4.0 Implementation Package and plan to post the updated implementation package in early 2017.	
DataFit Project Develop an advanced data quality and conformance checking program (i.e., DataFit service) for use by CDER to evaluate and report on clinical trial data that is submitted in standard format in support of regulatory applications.	The scheduled production release was deployed for into production in January 2017.	

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

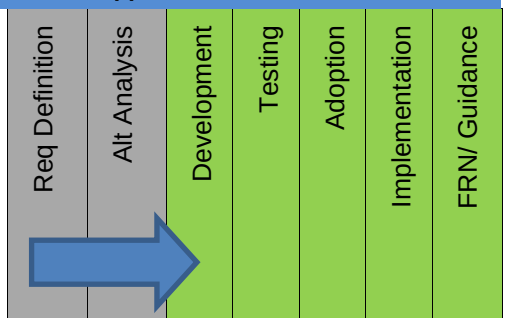
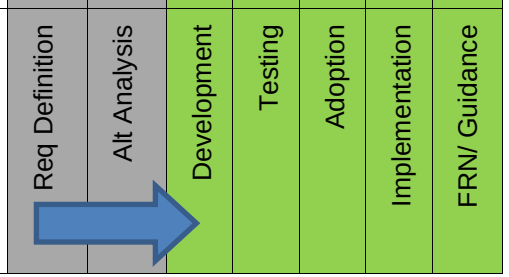
Project Title and Description	Project Update	Project Stage*
Projects that impact post-market risk management strategies		
ISO IDMP Implementation Implement International Organization for Standardization (ISO) Identification of Medicinal Product (IDMP) standards with reliable and robust repositories and processes to support efficient, consistent, and timely decision making in the regulation of medicinal products throughout the product development lifecycle.	Project is moving to establish Global Substance Registration System (GSRS) in production environment and Phase 1 to be completed FY2017 Q2.	

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. Implementation will provide product data compliant with the ISO 11615 Medicinal Product Identifier (MPID) standard which will be further refined once the ISO Technical Specifications for MPID and Pharmaceutical Product Identifier (PhPID) reach International Standards status. The product domain is designated as the authoritative repository for CDER regulated products and will be referenced by other CDER applications. The FDA Adverse Event Reporting System (FAERS) implemented a FAERS Product Dictionary (FPD) based on Structured Product Labeling (SPL) and Substance Registration System (SRS) data, plus other validated sources. Any future use of IPD in FAERS would necessitate (1) integration /mapping between FPD and IPD (2) development of dictionary-related functions for FAERS, such as an autocoding module, maintenance module, browser, etc.	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 operations.	
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

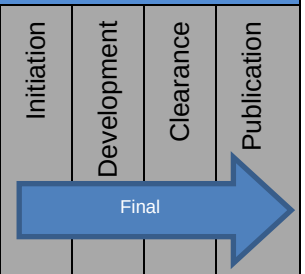
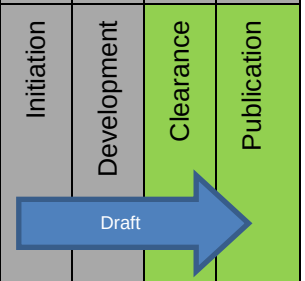
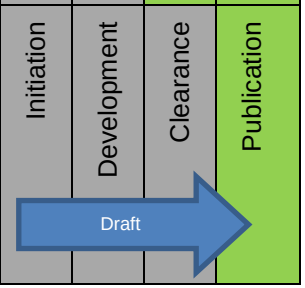
Project Title and Description	Project Update	Project Stage*
Projects that impact review of chemistry, manufacturing and controls (CMC) submissions and supplements		
Pharmaceutical Quality (PQ)/, Chemistry, Manufacturing, and Controls (CMC) Data Standardization Establishing common drug quality data standards 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.	
[2]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 is currently in the internal review steps for the proposed regulation changes. Deliverables are being finalized to initiate internal clearance process.	

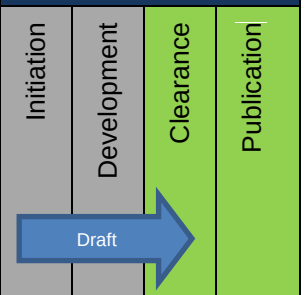
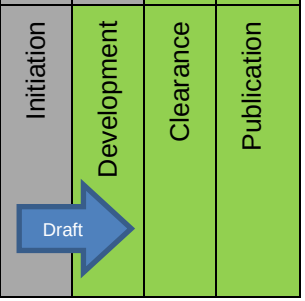
[2] Formally titled Facilities Production/Distribution Standardization Project.

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 3.2 of the Technical Conformance Guide was published October 2016. The next scheduled update of the Technical Conformance Guide is planned for March 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	
Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Submission of Manufacturing Establishment Information Issue Guidance for the submission of electronic information about manufacturing establishments.	Draft guidance published December 29, 2016.	

Project Title and Description	Project Update	Project Stage*
[3]**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.	Comments were received to the December 2012 draft release. The information in this draft guidance and revisions based on comments are being incorporated into an expanded draft guidance describing CDER's Office of Scientific Investigations (OSI) data needs for planning and conducting of BIMO inspections Draft guidance is in clearance.	
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.	

[3] 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