CDER Data Standards Communications Plan

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1.0 Introduction

The Center for Drug Evaluation and Research (CDER) Data Standards Program Board (DSPB) is responsible for achieving the program objectives and goals defined in the Data Standards Strategy document. The Strategy reflects the goals and objectives for both the Center for Biologics Evaluation and Research (CBER) and CDER and reflects the growth of the program as CDER and CBER encourage the development of data standards for the effective and efficient review of regulatory submissions through stakeholder collaboration, policy development, and project implementation. The document outlines the data standards projects and objectives to meet the Center's defined goals and summarizes the ongoing efforts in each of the key program areas.

A successful program requires clear communication for both internal and external stakeholders. The DSPB is chaired by a member of the CDER Office of Strategic Programs (OSP) and is responsible for ensuring collaboration and communication across CDER and the FDA Centers. To ensure stakeholder communication remains open, representatives from the CBER and the Center for Devices and Radiological Health (CDRH) attend DSPB meetings. In addition, cross-center coordination meetings are scheduled on an as-needed basis. This plan outlines CDER's approach to the Data Standards Program's communications.

1.1 Purpose and Scope of the Communications Plan

The purpose of this Communications Plan is to provide a framework that addresses the information needs of internal and external stakeholders regarding the CDER Data Standards Program (DSP). The Plan outlines the requirements of the communications efforts to reach and inform each group, as well as to receive feedback. The Plan is a key tool for promoting support, cooperation, participation, coordination and transparency among all stakeholders. Internal and external feedback loops will provide knowledge of the plan's effectiveness, whether the right communication tools were deployed, and their influence on the stakeholders.

The Plan is the responsibility of the CDER DSPB. Its implementation and maintenance will be the responsibility of the CDER Data Standards Operations Subcommittee (OpSC). The effectiveness of CDER DSP communications should be measured against feedback received from the stakeholders, and the plan adjusted accordingly.

2.0 Communications Stakeholders and Requirements

The CDER DSP has internal and external stakeholders. The following sections outline details regarding these stakeholders.

2.1 Internal Stakeholders

Table 1 outlines internal FDA stakeholders, the organization's relationship or function as it relates to CDER's DSP. The CDER Data Standards Program **intranet** webpage provides program overview, project highlights, process information, and FAQs.

Section 2.2, External Stakeholders, provides links to key web resources that are available to both internal and external to FDA stakeholders.

See Appendix A for a description of each of the internal FDA stakeholders.

Table 1. Internal FDA Stakeholders

Internal FDA Stakeholders	Relationship / Function to CDER Data Standards Program
FDA Data Standards Advisory Board (DSAB)	• Serves as review and advisory body for data, terminology, and exchange standards initiatives relevant to the Agency and to identify • Captures CDER's data standards business needs and feedback
CDER Executive Committee (EC)	• Reviews, evaluates, and approves long-range strategic plans, budget formulations, resource allocation, and process improvements for data standards activities and projects
Other FDA Centers	• Provides end-user expertise and feedback to DSPB on drug evaluation and review process and data needs
CDER Offices	• Participate in data standards activities
CDER DSPB	• Provides oversight of CDER data standards activities • Recommends investments in data standards development • Ensures development of key data standards • Recommends and monitors implementation of CDER processes which define, adopt, and enforce deployed standards • Ensures that reviewers have the tools and support to use standardized data
CDER Data Standards Operations Subcommittee (OpSC)	• Formed under the auspices of the DSPB • Monitors and coordinates the Center's implementation and use of data standards and resources • Fulfills the day-to-day oversight responsibilities for data standards governance throughout the full lifecycle
Office of Computational Science (OCS)	• Focuses on building technical expertise to enhance CDER's capabilities to use modern scientific computing tools • Participates in the development and implementation of needed data standards, encourages electronic submissions and access to electronic data, provides and expands the use of electronic review tools to the reviewer community and measures impact and value • Develops a resource for the CDER community to support review tool management, best practice development, review tool development, and consultation needs
Office of Business Informatics (OBI)	• Provides leadership and coordination of informatics activities across CDER and makes recommendations that support long-term strategic goals • Provides guidance for new systems design and project selection, leads architecture decisions in support of long-term strategic goals and establishes the CDER Informatics innovation process and portfolio • Provides Data Management Services and Solutions to streamline electronic and traditional submissions and delivers solutions to enable rapid adoption of emerging electronic data standards. Provides accurate and timely guidance on electronic submission issues and supports

Internal FDA Stakeholders	Relationship / Function to CDER Data Standards Program
	development of guidance, specifications, and regulations associated with data management issues
Office of Information Management and Technology (OIMT) and the Agency CIO Council	• Coordinates and oversees all activities related to business automation planning, acquisition, and implementation decisions throughout FDA

2.2 External Stakeholders

Table 2 outlines the external FDA stakeholders and the organization's relationship or functions as it relates to CDER's DSP.

- CDER Data Standards Program webpage. The CBER-CDER Data Standards Strategy, Action Plan, Annual Assessment of the Data Standards Program, Therapeutic Area Project Plan, DSPB Charter are available here.
- FDA Study Data Standards Resources webpage. The Data Standards Catalog, links to applicable guidance documents, Study Data Technical Conformance Guide, and validation rule documents are available here.
- CDER-CBER Study Data webpage. Information on what study data is, types of submissions subject to study data requirements, CBER study data submission specifications, current versions and updates of study data standards, and FDA guidance documents are available here.

Table 2. External FDA Stakeholders

Organization Stakeholder	Description
Organization Trade Groups	Associations or groups that represent the interest of regulated industry including pharmaceutical research and biotechnology companies (e.g., Pharmaceutical Research and Manufacturers of America (PhRMA), Biotechnology Industry Organization (BIO), Generic Pharmaceutical Association (GPhA))
Sponsor Companies (General)	A general term for an individual, company, institution, or organization that takes responsibility for the initiation and management of a clinical trial
Contract Research Organizations (CROs)	A general term for any company that supports pre-clinical and/or clinical stages of product development on behalf of a Sponsor company. The efficient capture, analysis and submission of standardized study data to FDA will further facilitate the efficient and effective review of regulatory submissions
Standards Development Organizations (SDOs)	• Focuses on the development of data standards for health care, product development, and regulatory review • Partnership with FDA, National Institutes of Health (NIH), Industry (e.g., sponsor companies, CROs), and SDOs (e.g., Health Level 7 (HL7), Clinical Data Interchange Standards Consortium (CDISC) to develop standards for the capture, transport, analysis and submission of data to the FDA by sponsor companies

Organization Stakeholder	Description
Technology Vendors	System integration / consulting companies (e.g., IBM, TCS, Syntel) and software development companies (e.g., SAS, Oracle, TIBCO) develop tools that both sponsors and FDA use during the product development process and regulatory review, respectively
Other U.S. Government Agencies	FDA may have interest in collaboration with other Agencies, such as the Office of the National Coordinator (ONC) or NIH, that are involved in data standards and electronic data exchange of health care data
Professional Organizations	Nonprofit organizations seeking to further a particular profession, the interests of individuals engaged in that profession and the public interest. Examples are: Drug Information Association (DIA), American Statistical Association (ASA)
The General Public	FDA advances the public health by helping to speed product innovations and to get the public science-based information they need

3.0 Communications Framework

This section outlines the overall communications framework being used by the CDER DSP. It is expected that the methods utilized will change over time as feedback from stakeholders is assessed.

3.1 Methods Matrix

The communications methods matrix, shown in Table 3, is used to define details regarding the communications methods including documents and web resources that are in use for the CDER DSP. The matrix is developed and maintained by the Data Standards Team and approved by the OpSC.

Table 3. Data Standards Program Communications Methods Matrix

Communication Method	Stakeholder Audience	Overview	Feedback Method
Public Presentations/Meetings			
Data Standards Webinars and Industry Meetings	**External:** Sponsor Companies, CROs, SDOs, Technology Vendors, Professional Organizations	• Support outreach and communications of CDER's data standards initiatives to external stakeholders. • Updated as needed or semi-annually by Data Standards Team. • Presented via in-person meetings and/or via webinars.	**External:** CDER Data Standards Mailbox: CDERDataStandards@fda.hhs.gov
Documents			
CBER-CDER Data Standards Strategy	**Internal:** All (as referenced in Table 1) **External:** All (as referenced in Table 2)	• Provides comprehensive strategy to prioritize the development of data standards that are needed to facilitate regulatory decisions, and ensure successful use • CBER-CDER Data Standards Strategy Document is maintained by the DSPB. • Posted to the CDER Data Standards website and referenced as needed at external meetings.	**Internal**: Review and approval by DSPB **Internal and External**: CDER Data Standards Mailbox: CDERDataStandards@fda.hhs.gov
Data Standards Action Plan	**Internal:** All **External:** Sponsor Companies, CROs, SDOs, Technology Vendors	• Complements CBER-CDER Data Standards Strategy outlining projects and other ongoing efforts being conducted in support of the Center's data standards goals. • Updated quarterly by the OpSC. • Posted to the CDER Data Standards website.	**Internal and External:** CDER Data Standards Mailbox: CDERDataStandards@fda.hhs.gov

Communication Method	Stakeholder Audience	Overview	Feedback Method
Annual Assessment of Data Standards	**Internal:** All **External:** Sponsor Companies, CROs, SDOs, Technology Vendors	• Provides annual assessment of the CDER data standards program. • Updated annually by the Data Standards Team. • Posted to the CDER Data Standards website.	**Internal:** Review and approval by the DSPB **Internal and External:** CDER Data Standards Mailbox: CDERDataStandards@fda.hhs.gov
Study Data Technical Conformance Guide	**Internal:** CDER Offices **External:** Sponsor Companies, CROs, SDOs, Technology Vendors	• Facilitates interactions between sponsors and CDER review divisions; communicates general CDER preferences for submissions. • Update bi-annually in March and October and, as needed by the OpSC. • Posted to the Study Data Standards Resources website and referenced at relevant external meetings.	**Internal and External:** CDER Data Standards Mailbox: CDERDataStandards@fda.hhs.gov
Therapeutic Area (TA) Project Plan & Priority TAs	**Internal:** CDER Offices **External:** Sponsor Companies, CROs, SDOs	• Provides FDA's thinking on timing and prioritization of standardization efforts in therapeutic areas and list of TAs. • Updated annually by the Data Standards Team. • Posted to the Priority Therapeutic Areas for Development website.	**Internal and External:** CDER Data Standards Mailbox: CDERDataStandards@fda.hhs.gov
Standing Meetings			
DSPB Meetings	**Internal:** DSPB	• Include discussions, program updates, and decisions. • Facilitated by the Data Standards Team and available internally to DSPB members.	**Internal:** Feedback at DSPB meetings
Data Standards OpSC Meetings	**Internal:** DSPB, OBI, OCS, CDER and Other FDA Centers	• Include discussions, project and working group updates, document reviews, and decisions. • Updated by the Data Standards Team and available to internal stakeholders.	**Internal:** Meeting discussions and email to Data Standards Team
DSAB meetings	**Internal:** DSPB	• Discuss reviews from advisory body on data, terminology, and exchange standards initiatives related to the Agency.	**Internal:** Feedback at DSAB meetings
eData Questions meetings	**Internal:** CDER Offices **External:** Sponsor Companies, CROs, SDOs	• Review questions and defines responses to questions received to the edata@fda.hhs.gov email address.	**Internal and External:** CDER eData mailbox: edata@fda.hhs.gov

Communication Method	Stakeholder Audience	Overview	Feedback Method
EC Meetings	**Internal:** DSPB	• Review, evaluate, and approve long-range strategic plans, budget formulations, resource allocation, and process improvements for data standards activities and projects.	**Internal:** DSPB chair coordinates communications.
Websites and Resources			
FDA.gov Study Data Standards Resources Website	**Internal**: All **External**: All	• Communicates updates and changes to the DSP and standards development process. • Includes the Data Standards Catalog and Study Data Technical Conformance Guide. • Updated by the OpSC as needed.	**Internal and External:** CDER Data Standards Mailbox: CDERDataStandards@fda.hhs.gov
CDER Data Standards Program Website	**Internal**: All **External**: All	• Communicates updates and changes to the DSP and standards development process. • Updated by Data Standards Team as needed.	**Internal and External:** CDER Data Standards Mailbox: CDERDataStandards@fda.hhs.gov
CDER Connections Newsletters	**Internal**: CDER Offices	• Provide general updates on standards development activities. • Updated and submitted as needed by Data Standards Team and distribute as inclusion in monthly CDER-wide email newsletter.	Not required

3.2 Key Trigger Events

Below are some key events that may trigger a communication to all or selected stakeholders:

- Project / Program milestone dates (e.g., initiation, progress, completion) as outlined in the Data Standards Action Plan
- Updates to a version of a standard or formation of new project teams within, and reporting to the DSPB as outlined in the Data Standards Action Plan.

3.3 Assumptions

It is assumed that:

- The CBER-CDER Data Standards Strategy is supported by CDER senior leadership (as represented on the CDER EC) and that efforts outlined in the strategy are resourced for successful implementation.
- The communication methods and distribution methods outlined in this Communications Plan will be available when needed.
- Sufficient resources will be available to implement and maintain the Communications Plan.
- The communication resources have the required level of support and expertise.
- The Communications Plan will require ongoing review and update to reflect the needs of and changes to the CDER DSPB.

4.0 Archive and Amendments

4.1 DSPB Communications Document Location

The Communications Plan will be made available on the external CDER Data Standards website and stored internally in the CDER DSPB internal collaboration space (SharePoint) in a folder named Communications Management Strategy.

4.2 Amendments to the Communications Plan

Recommendation for amendments to the Communications Plan will be presented to the DSPB by the Data Standards Team. The OpSC will review the change request and determine any impact prior to initiating action. The Communications Plan will be reviewed by the OpSC annually to ensure that the plan is accurate and reflects the communication needs of the stakeholders. The DSPB Chair is the final approval authority.

Appendix A: Internal Stakeholders Description

Stakeholder Name	Description
FDA Data Standards Advisory Board (DSAB)	The FDA DSAB is comprised of members from all the FDA Centers, the Office of Regulatory Affairs (ORA), Office of International Programs, and Office of Health Informatics. This board serves as a review and advisory body for data, terminology, and exchange standards initiatives relevant to the Agency and to identify and sponsor the cross-organizational data standardization needs of the Agency.
CDER Executive Committee (EC)	The CDER Executive Committee is comprised of the CDER Center Director and the Office Directors of all of the main CDER Offices. For a CDER organizational chart see: http://www.fda.gov/AboutFDA/CentersOffices/OrganizationCharts/ucm347877.htm
Other FDA Centers	When referenced in this document, other FDA Centers include: CBER, CDRH, Center for Veterinary Medicines (CVM), Center for Food Safety and Applied Nutrition (CFSAN), Center for Tobacco Products (CTP), ORA, and the National Center for Toxicological Research (NCTR).
CDER Offices	When referenced in this document, CDER Offices includes all the main CDER Offices as outlined in the CDER organizational chart.
CDER DSPB	The CDER DSPB is responsible for the overall governance of the Center's data standards activities. The board is comprised of senior level data standards representatives from the CDER Offices that are involved with conducting regulatory review. The DSPB Charter is available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm508192.htm
CDER OCS	The OCS supports CDER in continually improving the drug evaluation and review processes across the drug lifecycle through innovation, supporting the submission and use of high quality data, and providing access to high-end analytical tools and training.
OBI	The CDER OBI provides leadership and coordination of informatics activities across CDER and makes recommendations that support long-term strategic goals.
CIO Council	OIMT manages information technology (IT) and other related services including technical oversight of system development processes, policies, and methodologies and management of IT infrastructure. The CIO Council provides overall governance for the FDA's IT investment portfolio and is comprised of senior leadership (e.g., Center Directors) from all FDA Centers, Office of the Commissioner (OC), and ORA.

REVISION HISTORY

Version Number	Approved By	Revision Date	Description of Change
1.0	DSPB	05/01/2012	Initial document
1.1	DSPB	09/28/2012	Scheduled update
1.2	OpSC	12/13/2013	Added communication methods to Table 1, added OBI as a stakeholder to Table 1 and Appendix A, modified SDOs as stakeholders in Table 2
1.3	OpSC	02/04/2015	Scheduled update
1.4	OpSC	01/08/2016	Scheduled update
1.5	OpSC	7/18/2018	Updated the following areas: Section 1.0 • Deleted the communication methods column so that the internal and external table are consistent. • Moved external information from the internal section to external section. Section 2.2 • Added introduction paragraph. • Moved the two bullet points from section 2.1 to this section. • Inserted a new bullet point to reflect CDER-CBER Study Data Web Page info. Section 3.1 • Updated Table 3 to make sure the Communication Method and Stakeholder Audience columns have the same information as Tables 1 and Table 2. • Updated the overview column to read as actionable.