CDER Data Standards Communications Plan

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REVISION HISTORY

Version Number	Implemented By	Revision Date	Description of Change
1.0	CDER DSPB	05/01/2012	Initial document
1.1	CDER DSPB	09/28/2012	Scheduled update
1.2	CDER 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	CDER OpSC	02/04/2015	Scheduled update
1.4	CDER OpSC	01/08/2016	Scheduled update

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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 CDER Data Standards Strategy document. The Strategy document reflects the growth of the program as CDER encourages 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 Center for Biologics Evaluation and Research (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, and a description of how the CDER DSP communicates with these groups. There are resources available to all internal stakeholders, including:

- Internal CDER Data Standards Program web page. Program description, highlights, process information, and FAQs are available here.
- External CDER Data Standards Program web page. The 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 web page. The Data Standards Catalog, links to applicable guidance documents, Study Data Technical Conformance Guide, and validation rule documents are available here.

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	Communication Methods
FDA Data Standards Advisory Board (FDA DSAB)	• Reports to the FDA Chief Health Informatics Officer (CHIO) and collaborates and makes recommendations to the Chief Information Officer Council (CIOC) • Captures CDER's data standards business needs and feedback	• Attend DSAB meetings
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	• DSP Road Show • Provide data standards program updates to the EC
Other FDA Centers	• Provides end-user expertise and feedback to DSPB on drug evaluation and review process and data needs	• CBER and CDRH representatives attend the CDER DSPB and OpSC meetings • Direct communication with their Data Standards POCs
CDER Offices	• Consistent oversight and implementation of data standards activities	• DSP Road Show • CDER Offices involved with data standards are members of the DSPB and OpSC
CDER Data Standards Program Board (DSPB)	• Provides consistent 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	DSPB Meeting
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	• OpSC Meeting
Office of Computational Science	• Focuses on building technical expertise to enhance CDER's capabilities to use modern scientific computing tools	• Direct communication through participation in recurring OpSC and DSPB meetings

Internal FDA Stakeholders	Relationship / Function to CDER Data Standards Program	Communication Methods
	• 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 development of guidance, specifications, and regulations associated with data management issues	• Direct communication through participation in recurring OpSC and DSPB meetings
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	• Coordination and communication on a project-by-project basis

2.2 External Stakeholders

Table 2 outlines the external FDA stakeholders and a high level description of each stakeholder group.

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

Organization Stakeholder	Description
	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
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
Presentations/Meetings			
Data Standards Program Road Show or updates	**Internal:** CDER Offices	• Branded overview of the Data Standards Program and its activities as they relate to each identified audience. • PowerPoint presentation by the Data Standards Team at pre-determined meeting (e.g., all-hands meetings, pre-defined Office or Division meetings) and updated according to audience.	**Internal**: Feedback in-person during question and answer portion of scheduled meeting.
Data Standards Webinars and Industry Meetings	**External:** Sponsor Companies, CROs, SDOs, Technology Vendors, Professional Organizations	• Vehicle for outreach and communicating reviewer needs to industry. • Updated as needed or semi-annually by Data Standards PM. • PowerPoint presented in-person and via webinar hosting platform.	**External:** CDER Data Standards Mailbox: CDERDataStandards@fda.hhs.gov
Documents			
Data Standards Strategy	**Internal:** All (as referenced in Table 1) **External:** All (as referenced in Table 2)	• Comprehensive strategy to ensure prioritized development of data standards needed to facilitate regulatory decisions, and ensure successful use. • Updated by the DSPB. • Posted externally to 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,	• Complements Data Standards Strategy outlining projects and other ongoing efforts being conducted in support of the Center's data standards goals.	**Internal and External:** CDER Data Standards Mailbox: CDERDataStandards@fda.hhs.g

Communication Method	Stakeholder Audience	Overview	Feedback Method
	SDOs, Technology Vendors	• Updated quarterly by the Data Standards Team. • Distributed on the CDER Data Standards website.	ov
Annual Assessment of Data Standards	**Internal:** All **External:** Sponsor Companies, CROs, SDOs, Technology Vendors	• Annual assessment of data standards performance against stated goals. • Updated annually by the Standards Project Manager. • Distributed internally via email and posted externally on 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 interaction between sponsors and CDER review divisions; communicates general CDER preferences for submissions. • Updated bi-annually in March and October of each year and, as needed by the CDER OpSC. • Distributed externally on the CDER Study Data Standards Resources website and referenced at relevant external meetings.	**Internal and External:** CDER Data Standards Mailbox: CDERDataStandards@fda.hhs.gov
Therapeutic Area Project Plan	**Internal:** CDER Offices **External:** Sponsor Companies, CROs, SDOs	• Displays FDA's thinking on timing and prioritization of standardization efforts in therapeutic areas. • Updated annually by Data Standards PM and posted to external CDER Data Standards website.	**Internal and External:** CDER Data Standards Mailbox: CDERDataStandards@fda.hhs.gov
Standing Meetings			
DSPB Meeting Materials	**Internal:** DSPB	• Records discussions, decisions and short-term action items captured from oversight meetings. • Updated for each meeting by CDER Data Standards Team and posted internally to the DSP SharePoint site.	**Internal:** Feedback at DSPB meetings
Data Standards OpSC and Terminology Subcommittee Meeting materials	**Internal:** DSPB and OpSC	• Records discussions and decisions, as well as short-term (less than 90 days) action items. • Updated bi-weekly by the CDER Data Standards Team and posted internally to the DSP SharePoint site.	**Internal:** Meeting discussions and email to Data Standards Team
eData Questions meeting	**Internal:** CDER Offices **External:** Sponsor	• 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
	Companies, CROs, SDOs		
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 Newsletter	**Internal**: CDER Offices	• General updates on standards development activities. • Updates submitted as needed by Data Standards Team and distributed 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
- External (e.g., PhRMA, CDISC, HL7) request for FDA information or a meeting requiring coordinated and consolidated input from several CDER Offices or FDA Centers
- Internal CDER meetings or FDA-wide meetings
- Industry (e.g., Drug Information Association (DIA) Annual, DIA specialty meetings, CDISC, HL7) meeting milestones to present updates
- Formation of new project teams within, and reporting to, the DSPB as outlined in the Data Standards Action Plan
- Updates to a version of a standard (updated standards available, standards being retired) or accepting a new standard
- Changes to board charters which include the DSPB, OpSC.

3.3 Assumptions

It is assumed that:

- The 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.

3.4 Risks and Mitigations

To ensure successful implementation of this Communications Plan, Table 4 outlines key risks and defined mitigations put in place by the Data Standards Team.

Table 4. Communications Plan Risks and Mitigation Strategies

Risk	Mitigation
If resources are not available to support the Communications Plan, then there will be delays in getting up-to-date information to stakeholders.	Notifications and updates are planned as part of all data standards tasks and will be streamlined to support critical communications only, if necessary.
If the overall requirements for communication change during the progression of the DSP, then stakeholders needs will not be met.	The plan is scheduled to be reviewed and updated regularly to reflect new requirements. In addition, the listed feedback loop mechanisms will ensure the plan remains current and addresses stakeholder needs.

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 at the request of the DSPB. 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 of the FDA Centers and the Office of Regulatory Affairs (ORA), including liaison representatives from the Office of Information Managements and Office of International Programs. This council is responsible to coordinate the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency and the standards are consistent with those used outside the FDA.
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: Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), Center for Veterinary Medicines (CVM), Center for Food Safety and Applied Nutrition (CFSAN), Center for Tobacco Products (CTP), ORA, National Center for Toxicological Research (NCTR).
CDER Offices	When referenced in this document, CDER Offices includes all of the main CDER Offices as outlined in the CDER organizational chart.
CDER Data Standards Program Board (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: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm249979.htm
CDER Office of Computational Sciences (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.
Office of Business Informatics (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.