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**POLICY AND PROCEDURES**

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**OFFICE OF STRATEGIC PROGRAMS**

**CDER Data Standards Program**

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**PURPOSE**

This MAPP establishes the operating model to support the development and implementation of data standards in CDER. This MAPP also defines decision making authorities, roles and responsibilities, and assigns accountability for the ongoing governance, daily operations, and project processes of CDER’s data standards. Projects that define requirements for standards, evaluate alternatives, modify or create a new standard, and test or implement a standard are subject to this MAPP. Final determination of the MAPP applicability to a project is made by the CDER Data Standards Operations Subcommittee (OpSC).

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**BACKGROUND**

The U.S. Food and Drug Administration (FDA) receives a vast and growing amount of data in a variety of regulatory submissions from a multitude of sources and in a variety of formats. These data hold great potential to advance CDER’s regulatory and scientific work, however, the present lack of standardized data creates significant challenges to conducting thorough and well-organized reviews.

CDER has an on-going commitment to the development, implementation, and maintenance of a comprehensive data standards program. The CDER Data Standards Program promotes the development of data standards for the effective and efficient

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review of regulatory submissions through stakeholder collaboration, policy development, and project implementation. The key process steps for data standards projects are shown in Attachment 1. Supporting Program documentation referenced in this document is available on [fda.gov](http://fda.gov).

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## **POLICY**

1. CDER will implement open consensus-based data standards in support of CDER's regulatory review process.
  2. CDER data standards projects are selected based on their impacts on improving CDER's regulatory review process.
  3. Data standards-related activities must be performed in support of the goals of and in compliance with the principles identified in the CDER Data Standards Strategy.
  4. The CDER Data Standards Program will be reviewed annually to highlight progress made that year against the CDER Data Standards Strategy, and to forecast future plans.
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## **RESPONSIBILITIES**

### **CDER Center Director**

- Authorizes the CDER Data Standard Program Board (DSPB).
- Appoints the chair of the DSPB.

### **CDER Executive Committee (EC)**

- Provides Center-level support and leadership to the DSPB, as needed.
- Makes decisions on the organizational commitment of resources for potential projects.
- Receives periodic updates on the state of the CDER Data Standards Program from the DSPB.
- Resolves issues escalated by the DSPB.

### **Data Standard Program Board (DSPB)**

- Develops and monitors execution and periodic updates to the Data Standards Strategy and Action Plan.
  - Reviews, approves, and monitors the portfolio of projects being implemented by the OpSC.
  - Presents recommendations, updates, and unresolved issues to the EC.
  - Reviews and ensures relevant rules, regulations and guidances, and other position statements are aligned with CDER's mission and Strategic Plan.
  - Collaborates with committees as needed, such as the Agency's standards and information technology boards.
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- Promotes communication on data standards development and implementation needs within and across CDER Offices and other Agency stakeholders.
- Supports the implementation of business processes that will define, adopt and facilitate compliance to the supported standards.
- Influences the development of national and international standards in areas impacting CDER.
- Establishes subcommittees as required.

**Operations Subcommittee (OpSC)**

- Executes and monitors data standards development and implementation projects in alignment with the Data Standards Strategy.
- Updates the DSPB on the data standards portfolio on a periodic basis.
- Identifies, tracks, coordinates, and resolves data standards-related issues.
- Establishes internal working groups to focus on specific data standards areas.
- Manages changes to external FDA data standards web resources.
- Reviews and makes recommendations on new data standards or updates to currently supported data standards.
- Ensures projects with policy or broader FDA impacts are reviewed by the DSPB.

**Office of Strategic Programs (OSP) Data Standards Team**

- Supports the OpSC, DSPB and Data Standards Program activities.
- Coordinates and develops guidance and policy related to data standards.
- Provides project management support for Data Standards Program projects.
- Tracks and presents data standards project information to the OpSC and DSPB.
- Maintains a portfolio of data standards projects.
- Ensures compliance with data standards guidance and policies.
- Supports the OpSC in the identification, tracking, coordination, and resolution of data standards-related questions and issues.
- Delivers timely internal and external program communications regarding data standards activities and plans, as outlined in the CDER Data Standards Communications Plan.

**Project Manager for Specific Projects**

- Ensures projects have sufficient resources to include data standards end users, data analysts, process analysts, and other subject matter experts (SMEs).
- Establishes reasonable project timelines.
- Reports on project progress and important project changes to the OpSC.

**Project Team for Specific Projects**

- Functions for a specified data standards project.
- Provides regularly scheduled updates to the OpSC.
- Fulfills project objectives within the agreed timeframe.

**Requestor**

- Identifies a data standards need and initiates a request.
  - Participates in all stages of the project from problem identification through solution implementation, if approved.
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**PROCEDURES****I. Define scope and requirements**

1. **Identify the problem.** The need for a change to a currently supported data standard, or the need for a new data standard, may be submitted by CDER staff (the Requestor) to the OSP Data Standards Team. The OSP Data Standards Team reviews the change request for relevance, clarity, and completeness. The OSP Data Standards Team then confirms the problem, and the scope of the problem. If more information is needed, the OSP Data Standards Team works with the Requestor to capture the description of the recommended change, a justification for the change, and other relevant information. If the change request does not apply to data standards, the OSP Data Standards Team transfers the request to the appropriate Office. The OSP Data Standards Team assesses the request for review and action by the OpSC and DSPB, as necessary.
2. **Review request: Define the scope and requirements of the project.** For requests requiring further definition, the OSP Data Standards Team works with the Requestor to further define the problem and provide high-level requirements for the identified data standard change or need.
3. **Submit request for review, prioritization, and approval.** The OpSC and the DSPB review and assess project documentation to determine if and how the proposed project should move forward.

**II. Analyze alternatives**

1. **Assess alternatives.** Based on the scope and requirements, the Requestor and the OSP Data Standards Team identify and assess alternatives against assessment criteria they defined.
2. **Evaluate chosen alternatives.** If there are several potential solutions, more than one alternative may be evaluated.
3. **Make a recommendation.** Based on the assessment or evaluation of chosen alternatives, the Requestor makes a solution recommendation to the OpSC. Solutions may include a data standard and technology or guidance. The OpSC will review and ratify next steps for the data standards project.

**III. Use an existing standard, change a standard, or develop a standard**

1. When an existing standard is selected for use, the project will begin its testing activities.
2. When a change to an existing standard or a new standard is the solution, the OpSC coordinates communication with the appropriate Standards Development Organization (SDO). SDOs follow their processes to develop the data standards with participation from FDA SMEs.

**IV. Test the standard**

1. The Working Group established by the OpSC evaluates the scope of testing required. The scope will determine stakeholders needed, including industry participation, to conduct the testing. The testing recommendation will be reviewed by the OpSC.
2. The Project Team develops a testing plan, and ensures business requirements are captured.
3. If required by the testing method, the Project Team performs the actual test, generation, receipt, and processing of an electronic submission utilizing the data standard.
4. The OpSC decides whether the data standard is ready for the Adoption Process.

**V. Determine data standard adoption**

1. The Project Team delivers input criteria to the OpSC for review. Input examples include, but are not limited to:
  - Project Plan
  - Requirements
  - Alternative analysis results
  - Estimated cost, if applicable
  - Impact on people, process, or systems
  - Any testing reports.
2. The OpSC assesses the results to decide to recommend adoption of the standard. If the standard has broad Center impact, it is referred to the DSPB for final approval.

**VI. Implement the standard**

1. A Project Team develops and executes a plan to implement the standard.
2. Implementation includes:
  - Communication to all stakeholders.
  - Development and delivery of training.
  - Initiation of any IT tools or software changes.
  - Initiation of the necessary process changes.
  - Identification of the needed guidance and policy changes.
3. Implementation is considered complete when the data can be successfully processed, reviewed, and archived utilizing the new standard.

**VII. Develop a Federal Register (FR) Notice**

1. The OSP Data Standards Team coordinates development and publication of a Federal Register (FR) Notice for an update to a standard or a new standard. An FR Notice can be released at any time throughout the project when there is an identified need.
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**REFERENCES**

1. FDA, 2015, Center for Drug Evaluation and Research, *Communications Plan*.
  2. FDA, 2015, Center for Drug Evaluation and Research, *Data Standards Strategy*.
  3. FDA, 2015, Center for Drug Evaluation and Research, *Data Standards Program Board Charter*.
  4. FDA, 2015, Center for Drug Evaluation and Research, *Data Standards Strategy – Action Plan*.
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**DEFINITIONS**

**Action Plan-** A program document providing a quarterly update to internal and external stakeholders, with an overview and progress update of current CDER data standards initiatives.

**Adoption-** For purposes of this MAPP, the decision to implement and support a new or changed data standard.

**CDER Data Standards Communications Plan-** A program document, updated annually, providing a framework that addresses the information needs of internal and external stakeholders regarding the CDER Data Standards Program.

**CDER Data Standards Program-** The comprehensive program within the Center established by CDER to identify and prioritize data standards needs and to implement good practices for standards development.

**CDER Data Standards Strategy-** A multi-year program document reinforcing CDER's ongoing commitment to the development, implementation, and maintenance of a comprehensive data standards program to facilitate an efficient and effective regulatory review process.

**Data standards-** The rules by which data are described and recorded. In order to share, exchange, and understand data, the format as well as the meaning of the data must be standardized.

**Data standards project-** A project aimed at developing documented agreements on the definition, representation, format, transmission, and management of data, in support of the receipt, utilization, and archival of the data in the regulatory review process.

**Implementation-** The incorporation of a data standard change 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.

**OSP Data Standards Team-** The team comprised of members from the Office of Strategic Programs supporting the OpSC, DSPB and Data Standards Program activities.

**Project Team for Specific Projects-** A team comprised of a Project Manager and relevant members from CDER Offices to facilitate the progression of a data standards project from scope definition through implementation.

**Receipt, review, and processing-** The assurance that submitted data can be received, validated for format and content, and viewed and analyzed in a manner that supports CDER's review needs.

**Requestor-** A group or individual internal to the FDA who identifies a data standards need and initiates the request.

**Standards Development Organization-** An organization external to FDA that focuses on the development of data standards for health care, product development, and regulatory submission information (e.g., Health Level 7 (HL7), Clinical Data Interchange Standards Consortium (CDISC)). This group develops and maintains data standards using a documented, open, consensus-based format.

**Testing-** An activity performed to ensure data standards meet FDA's needs and requirements and can be implemented.

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## **SUMMARY OF CHANGES**

This is the first version of this MAPP with no document changes.

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## **EFFECTIVE DATE**

This MAPP is effective upon date of publication.

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ATTACHMENT 1 Operational Elements

