CDER DATA STANDARDS AND DATA GOVERNANCE (DSDG) BOARD

CHARTER

Version : 9.0

Version Date : 2/17/2020

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1.0 PURPOSE OF PROJECT CHARTER

This charter establishes the Food and Drug Administration, Center for Drug Evaluation and Research (CDER) Data Standards and Data Governance (DSDG) Board and sets forth its scope, goals, objectives, membership, organization, communications, deliverables, and member's roles and responsibilities.

2.0 Background

Data Standards Program Board (DSPB) has been CDER's executive decision-making body on data standards initiatives since 2010. Over the years, the number of projects in CDER's data standards portfolio has substantially increased and the need to have a more structured approach to manage the center's data initiatives has become imperative. To address this, CDER expanded the scope of the Data Standards Program Board and was re-charted to include oversight of data governance functions. The DSPB was renamed as the Data Standards and Data Governance (DSDG) Board.

DSDG Board is committed to the oversight of CDER's portfolio of Data Standards and Data Governance initiatives and is focused on improving the overall effectiveness and efficiency of the regulatory review process. The DSDG Board directly reports to the Business Informatics Governance Board and maintains oversight of data standard initiatives through the Operations Sub-Committee (OpSC) and data governance activities through the Data Control Boards.

3.0 SCOPE

The CDER Data Standards and Data Governance (DSDG) Board establishes the organization's overarching strategic data planning and direction, creation of data policies, oversight of all CDER's operational data, and data management practices that are focus on improving the overall effectiveness and efficiency of the CDER regulatory review process.

The CDER Data Standards and Data Governance (DSDG) Board has 2 major focus areas and serves as CDER's executive review and policy setting board for:

1. Data Standards development and implementation in the Center. The scope covers the full range of data standards currently in use or under consideration to support regulatory activities.
2. Data Governance definition and implementation in the Center. This covers all regulatory data in CDER's IT portfolio.

The board will ensure that CDER aligns with the goals of the overall FDA data standards and data governance policies and implement policies of the FDA Data Standards Advisory Board (DSAB). Issues that cannot be resolved by the DSDG Board will be escalated to the BIG Board.

4.0 GOALS

The DSDG Board will undertake a leadership role to outline approaches and propose specific recommendations for data standards to improve data consistency, transparency, collaboration, integration and unity of effort within CDER.

Key goals and objectives of the CDER Data Standards and Data Governance Board will be:

G1 – Provide **leadership and strategic oversight** to CDER data standard and data governance programs.

i. Develop an Action Plan to monitor the development, execution and periodic updates to the Data Standards Strategy.
ii. Understand Data Standards Portfolio and its alignment with the Data Governance and Data Standards Strategy.
iii. Review portfolio summary to understand the goals, objectives, and results achieved through these projects and address challenges raised by the projects.

G2 – Ensure **development and implementation of data standards and associated policies** to maximize usability, predictability, traceability of data, and to promote effective and efficient use of information in regulatory submissions.

i. Review and agree on proposed regulations, and guidance for alignment with CDER's Mission and Strategic Plan.
ii. Review and ratify recommendations to implement new standards or make significant changes to implemented standards.
iii. Ensure the implementation of business processes that will define, adopt, and facilitate compliance to the supported standards.
iv. Provide guidance, oversight and decision-making support for data.
v. Facilitate coordination with other data initiatives.

G3 – **Ensure collaboration and alignment within CDER and externally with Standards Development Organizations**, and other national and international stakeholders in the management of standards that impact CDER.

i. Address regulatory needs and other external requirements pertaining to Data Standards and Data Governance.

G4 – **Ensure clear lines of accountability and responsibility** for board members, and data stakeholders.

i. Establish subcommittees as required.
ii. Review and analyze data change requests as needed.

G5 – Support **communications and process improvement**.

i. Update the BIG Board on the state of the CDER data standards program and recommend data standard program priorities.
ii. Ensure effective communication within and across CDER Offices and other Agency stakeholders.

iii. Promote data governance key components (compliance, structured accountability, transparency, collaboration, etc.,) with BIG Board, PMO and Office stakeholders.

iv. Encourage continuous improvement via feedback and instill a positive environment that embraces the value of data in achieving data governance business and IT goals.

v. Ensure development and implementation of a data governance methodology.

5.0 MEMBERSHIP, ROLES and RESPONSIBILITIES

The membership is composed of the following representatives:

a) Chair will be appointed by the Center Director. The Chair will be responsible for directing all activities of the DSDG Board and will be a non-voting member except in the case of a tie.

b) Board membership includes senior leadership or their designee from the Offices listed below:

- Office of Biostatistics (OB)
- Office of Business Informatics (OBI)
- Office of Clinical Pharmacology (OCP)
- Office of Compliance (OC)
- Office of Computational Science (OCS)
- Office of Generic Drugs (OGD)
- Office of Medical Policy (OMP)
- Office of New Drugs (OND)
- Office of Pharmaceutical Quality (OPQ)
- Office of Strategic Programs (OSP)
- Office of Surveillance and Epidemiology (OSE)
- Office of Translational Sciences (OTS)
- CDER Data Architect (DA)
- Office of Regulatory Policy (ORP)
- Office of Chief Scientist

Board members will serve at the discretion of their supervisor or the CDER Office Director. Nominees for Board members will be submitted to the Chair for approval. Additional non-voting members include:

1. A non-voting member from Center for Biologics Evaluation and Research (CBER) and Center for Devices and Radiological Health (CDRH) participate to support collaboration, communication and alignment across FDA Centers.
2. Representation from additional Centers may be added as deemed appropriate and necessary.
3. Other members (e.g., PMO, OIMT, EA) may be added in the advisory role for consultation on as needed basis.
4. A facilitator to support the board chair and to maintain communications with the DCBs, OpSC, and Working Groups.

The organization of the DSDG Board allows for direct input from the CDER Offices listed above. The DSDG Board is granted authority by the Center Director and reports to the CDER Business Informatics Governance (BIG) Board.

This section describes the key roles supporting the DSDG Board.

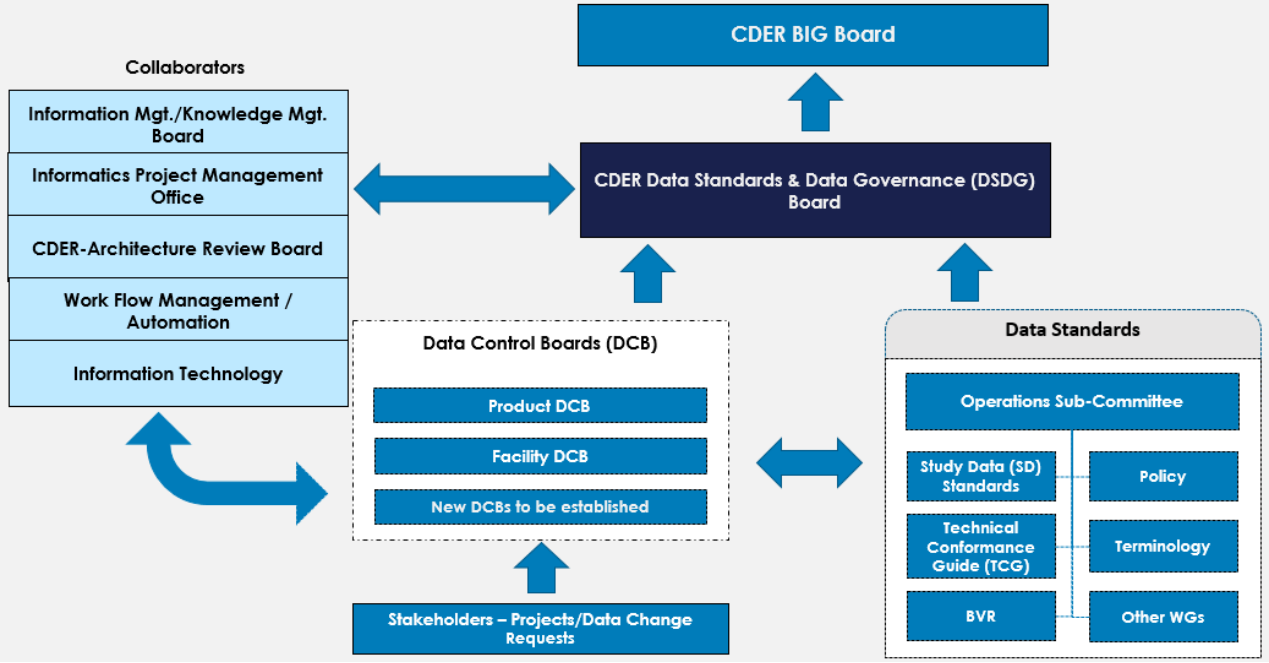
Role	**Responsibilities**
Chair	Provide strategic direction and alignment of the board activities to the goals/objectives. Sets board priorities, meeting agenda, facilitate board meetings, and report to the BIG Board.
CDER Data Architect	Serves as CDER's data architecture SME supporting board's decision making and policy setting responsibilities. Ensures that CDER data projects align with CDER's data architecture.
CDER Board Member	Responsible for reviewing requests submitted from the different data domains, participate in discussions and come to a decision on the requests. Communicate the action items, decisions and other data related information to their office.
OpSC Representative (Non-voting member, participates as needed)	Provide regular updates from OPSC and share the DSDG information to their stakeholders.
CDER Data Control Board Representative	Provide regular updates from the control board and shares the DSDG information to their stakeholders.

Role	Responsibilities
(Non-voting member, participates as needed)	
FDA Center Representative (Non-voting member, participates as needed)	Provide data standards updates from their respective center (e.g., CBER, CDRH) and shares DSDG information with their Center stakeholders.
PMO Representative (Non-voting member, participates as needed)	Reaches out to the Board based on PMO projects being reviewed, participates in the decision process to ensure decisions align with overall portfolio.
OIMT – Technical Representative (Non-voting member, participates as needed)	Provide technical direction to the project with consideration to OIMT process.
FDA Enterprise Architecture (EA) Critical Partner Representative (Non-voting member, participates as needed)	Ensures CDER data initiatives align with FDA's overall EA initiatives and requirements.

6.0 STRUCTURE

The following figure outlines the proposed structure highlighting the data standards and data governance components along with connections to the Informatics PMO and the Knowledge Management Steering Committee.

Figure 1. CDER Data Standards and Data Governance Model



7.0 Procedures

Meetings

- The DSDG will meet bi-monthly.
- Special meetings may be scheduled at the discretion of the DSDG Board Chair.

Meeting Materials

- Proposed agenda items will be submitted by Members or other governance groups. The agenda will indicate what topics are decisional.
- Relevant meeting documents requiring review will be provided at least 3 days before the meeting.
- Meeting minutes with action items and an updated decision log will be maintained for each meeting.

Voting

Seven (7) members will constitute a quorum. Prior to voting on an item, issues of significance to any CDER discipline or business area will be fairly considered.

1. Each CDER office representative has one vote.
2. A simple majority vote is required to pass an item.
3. Items intended for voting will be identified as such on the agenda.
4. DSDG members who cannot be present for the vote may convey their vote and proxy to a designated delegate.
5. DSDG members may abstain from voting on issues that are not of significant importance to their office, subject to the quorum.
6. Issues of significant disagreement will be referred to the BIG Board.
7. Voting results will be recorded by the DSDG Board Coordinator.

Workgroups

Cross-office (based on the business impacts) workgroups will be chartered to address tasks in a specific area and for a defined duration. The Workgroup charter, approved by the DSDG Board, will briefly outline the purpose, responsibilities, scope, and membership.

The assigned workgroup leads will ensure required resources that include data experts, data analysts, process analysts, or other business SMEs. Resource issues that cannot be resolved by the workgroups leads will be escalated to the DSDG for action. Leads will provide updates to the DSDG (through project updates, input from the Data Governance Committee, or direct updates from projects).

8.0 DATA STANDARDS AND DATA GOVERNANCE CHARTER APPROVAL

This charter will be approved by a majority vote by the DSDG Board members. The approved charter will be submitted to the CDER BIG Board for final approval. The DSDG Board is responsible for maintaining and updating the charter as necessary and will submit changes to the

Board for approval. Any member can make recommendations to supplement this charter by attaching an addendum. Recommendations must be brought before the full Board for consensus and approval by the Chair.

VERSION HISTORY

Version Number	Implemented By	Revision Date	Description of Change
1.0	DRT Strategies	06/15/2019	Initial draft
2.0	DRT Strategies	07/30/2019	Revised draft
3.0	DRT Strategies	08/25/2019	Updated and combined with DSPB Charter to create initial draft of a DSDG Board Charter
4.0	DRT Strategies	09/10/2019	Updated draft after internal review
5.0	DRT Strategies	09/11/2019	Updated after review with DSPB
6.0	DRT Strategies	11/13/2019	Updated Board Membership in Appendix-A
7.0	DRT Strategies	12/30/2019	Moved Board membership list to a separate document
8.0	DRT Strategies	1/27/2020	Updated the organization chart
9.0	DRT Strategies	2/17/2020	Updated the organization chart to include CDER-ARB, and Appendix-B

APPENDIX A: Membership

DSDG Membership List (Link)

APPENDIX B: KEY ACRONYMS

The following table provides definitions for acronyms used in this document.

Term	Definition
DSDG Board	CDER Data Standards and Data Governance Board
DSAB	FDA Data Standards Advisory Board
FDCB	CDER Facilities Data Control Board
PCDB	CDER Products Data Control Board
RSDCB	CDER Regulatory Science Data Control Board
OpSC	CDER Operations Sub Committee
DA	CDER Data Architect
EA	FDA Enterprise Architect
OB	Office of Biostatistics
OBI	Office of Business Informatics
OCS	Office of Computational Science
CSC	Computational Science Center
OC	Office of Compliance
OGD	Office of Generic Drugs
OSP	Office of Strategic Programs
OMP	Office of Medical Policy
OND	Office of New Drugs
OPQ	Office of Pharmaceutical Quality
OSE	Office of Surveillance and Epidemiology
OTS	Office of Translational Sciences
DSPB	Data Standards Program Board
OIMT	Office of Information Management and Technology
PMO	Program Management Office
CDER-ARB	CDER – Architecture Review Board
IM/KM	Information Management/Knowledge Management
WFM	Work Flow Management