CDER Data Standards Program Board (DSPB)

CHARTER

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PURPOSE

This charter establishes the Food and Drug Administration, Center for Drug Evaluation and Research (CDER) Data Standards Program Board (DSPB) and sets forth the mission, goals, scope, membership and organization, procedures, and roles and responsibilities.

MISSION

CDER's DSPB is committed to the oversight of a comprehensive Data Standards Program and portfolio of projects focused on improving the overall effectiveness and efficiency of the regulatory review process.

DSPB GOALS

1. Promote the development of data standards for the effective and efficient use of information in regulatory submissions.
2. Provide leadership and strategic oversight to guide CDER's data standards program and portfolio of projects.
3. Drive implementation of standards to maximize usability, predictability, and traceability of data.
4. Ensure the development and publication of policies, guidance, and technical specifications relevant to implementing data standards.
5. Promote collaboration with Standards Development Organizations, and other national and international stakeholders in the life-cycle management of standards that impact CDER.

SCOPE

The DSPB serves as CDER's executive review board for data standards implementation in the Center. The scope covers the full range of data standards currently in use or under consideration to support regulatory activities.

MEMBERSHIP AND ORGANIZATION

The membership is composed of the following representatives:

1. Chair, appointed by the Center Director. The Chair, responsible for directing the activities of the DSPB, is a non-voting member except in the case of a tie. Board membership includes senior leadership or their designee from the Offices listed below[1]:
    - Office of Biostatistics (OB)

[1] The current DSPB membership list is available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm249979.htm

- Office of Business Informatics (OBI)
- Office of Clinical Pharmacology (OCP)
- Office of Compliance (OC)
- Office of Computational Science/Computational Science Center (OCS/CSC)
- 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)

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.

2. A non-voting member from Center for Biologics Evaluation and Research (CBER) and Center for Devices and Radiological Health (CDRH) participate in order to support collaboration, communication and alignment across FDA Centers. Representation from additional Centers may be added as deemed appropriate and necessary.

The organization of the DSPB allows for direct input from the CDER Offices listed above. The DSPB is granted authority by the Center Director and reports to the CDER Executive Committee.

PROCEDURES

Seven (7) members will constitute a quorum. The Board will not meet in a decision-making capacity in the absence of a quorum.

Meetings

- The DSPB will meet quarterly and as needed.
- Special meetings may be scheduled at the discretion of the Chair.

Meeting Materials

- Proposed agenda items may be submitted by a Board member or developed by the Chair. The agenda will indicate if the meeting is decisional.
- Relevant meeting documents requiring review will be provided to the Board members at least four (4) business days before a meeting.
- Meeting minutes with action items and an updated decision log are maintained for each meeting.

Voting

Prior to voting on an item, issues of significance to any CDER discipline or business area are fairly considered.

1. Each Office 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. DSPB members who cannot be present for the vote may convey their vote and proxy (or decision to abstain) to a designated delegate.
5. DSPB members may abstain from voting on issues that are not of significant importance to their Office.
6. The Chair may close voting in the absence of a DSPB member's vote when the Chair judges that the issue is not of significant importance to that member's discipline or business area.
7. Issues of significant disagreement will be referred to the CDER EC.
8. Voting results are recorded by the DSPB Coordinator.

Subcommittees

Subcommittees are chartered to address a need (e.g., data standards development or implementation work or other standards program administrative/operational functions) in a specific area and for a defined duration. The subcommittee charter, approved by the DSPB, will outline the purpose, responsibilities, scope, and membership of such subcommittees.

ROLES AND RESPONSIBILITIES

DSPB Responsibilities

1. Develop CDER's Data Standards Strategy.
2. Monitor the development, execution and periodic update to the Data Standards Strategy – Action Plan.
3. Review a portfolio summary periodically to understand the objectives, goals, and results achieved through these projects and address challenges raised by the projects.
4. Update the EC on the state of the CDER data standards program and recommend data standard program priorities to the EC; issues that cannot be resolved by the DSPB will be presented to the EC for resolution.
5. Review and agree on rules, regulations and guidances, and other position statements for alignment with CDER's Mission and Strategic Plan prior to formal clearance. Understand Data Standards Portfolio and its alignment with the Data Standards Strategy.
6. Review and ratify recommendations to support (implement) new standards or make significant changes to implemented standards. Significant changes do not include version updates.

7. Ensure effective communication within and across CDER Offices and other Agency stakeholders to support attention to data standards development and implementation needs.
8. Establish subcommittees, as required.
9. Ensure the implementation of business processes that will define, adopt and facilitate compliance to the supported standards.

DSPB Member Responsibilities

1. DSPB members will prepare for, attend, and proactively participate in DSPB meetings and activities.
2. DSPB members will serve as liaisons between their home Office, other CDER cross-Center working groups, external partners, and the DSPB. DSPB members will communicate board decisions to impacted stakeholders.
3. DSPB members are responsible for communicating their home Office ongoing initiatives that may have an impact on FDA or CDER policy, guidance, and standards.
4. Depending on the subject matter to be discussed, DSPB members may identify subject matter experts (SMEs) whose role will be to participate, as needed, on particular topics.

DSPB Coordinator

A member of the Data Standards Team provides support for the Board's activities. The DSPB Coordinator has primary responsibility for:

1. Coordinating and supporting CDER Data Standards Program projects;
2. Providing summary of data standards project information to the DPSB;
3. Scheduling DSPB meetings and communicating the agenda prior to each meeting;
4. Following up on DSPB assignments and action items assigned to Project Teams;
5. Preparing DSPB documents;
6. Maintaining the roster of the DSPB and its Project Teams;
7. Maintaining a repository that includes meeting notes, a log and status of issues discussed and actions assigned, and other such documents.
8. Distributing meeting minutes that will summarize key topics of discussion, including substantive proposals, as well as any significant controversies or differences of opinion and action items.

Data Standards Project Teams

The assigned Project Manager for projects in the data standards portfolio works to ensure projects have sufficient resources that could include data standard end users, data analysts, process analysts, or other SMEs. Resource issues that cannot be resolved by the team are escalated to the DSPB for action. Project Teams are generally constituted for the performance period of the specified data standards project. Project Managers provide updates to the DSPB (through Action Plan updates, input from the Operations Subcommittee (OpSC), or direct updates from projects).

CHARTER APPROVAL

This charter is approved by the Center Director. The Data Standards Team is responsible for maintaining and updating the charter as necessary and will submit changes to the DSPB 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 DSPB Chair.

Appendix A: DSPB Charter Revision History:

Date	Version	Summary of Changes
March 31, 2010	1.0	Original Draft Version
December 15, 2010	1.1	Removed draft watermark. Revised as discussed and approved by the Data Standards Program Board.
January 26, 2012	1.2	Grammar corrections and editorial changes. Added additional responsibility to review rules, regulations and guidances for alignment with the CDER Data Standards Program.
December 17, 2013	1.3	General updates: • Removed Charter Definition section • Removed Background section, moved relevant content to Scope section • Clarified membership and organization • Clarified meeting quorum and voting procedures
November 21, 2014	1.4	General updates: • Refined DSPB Goals • Revised Scope • Updated the Procedures section • Clarified the Voting section • Updated DSPB Responsibilities • Refined DSPB Member Responsibilities • Updated Data Standards Team responsibilities to DSPB Coordinator