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FDA Staff Manual Guides, Volume III – General Administration

FDA Official Councils and Committees

FDA Data Standards Advisory Board

Effective Date: 01/17/2024

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1. Purpose

The purpose of the FDA Data Standards Advisory Board (DSAB) is to provide oversight of data standards relevant to the mission of the FDA, in alignment with current policies, laws, and regulations, to ensure that common data standards are used throughout the agency. Data standards are rules, formats, and terminologies that provide structure and consistency for the electronic exchange and use of data. They facilitate the predictable and consistent exchange of data and are in the form that analytical tools can use. Data standards support the FDA's strategic public health goals focused on science, technology, and data integrity and traceability to improve the FDA's own efficiency and effectiveness.

The DSAB provides:

1. a forum to discuss and resolve issues related to health and regulatory data standards.

2. objective, effective, and accurate information to all Centers' and Offices' data standards program boards.

3. a focal point for coordinating activities within the Department of Health and Human Services, other agencies, and interested parties in the standardization of health and regulatory data.

4. a forum to learn about other ongoing data standardization initiatives at other agencies, share lessons learned, and address challenges.

5. oversight of the FDA Data Standards Catalog.

2. Policy

The DSAB is an Agency-wide forum to ensure that supported data standards provide for predictable and consistent exchange, evaluation, and reporting of data that contribute to the FDA's public health mission. The DSAB ensures alignment of FDA's centers and offices and facilitates internal consensus and development of unified FDA positions on cross-cutting data standards issues. The DSAB is a resource to the FDA on matters relevant to data standards.

Generally, the DSAB does not meet with external stakeholders, however, it may communicate, as needed, with external stakeholders (e.g., Standards Development Organizations, technology providers), as well as other Federal Government agencies to provide responses to requests for information or to gather information to understand related issues or to move forward recommendations.

3. Responsibilities

The DSAB is responsible for coordinating the identification, evaluation, adoption of health and regulatory data standards and terminologies supporting the Agency's mission. Specific roles and responsibilities include:

A. Co-Chairs

1. Provide leadership and direction to the membership consistent with the vision and direction of the FDA's Chief Data Officer.

2. Preside at regular meetings and guide the development of agendas.

3. Promote consistency and alignment of DSAB governance of data standards with Center and Office data standards governance.

4. Ensure that decisions are made in a transparent manner and discrepant opinions are recorded.

5. Ensure DSAB recommendations are communicated to the Center and Office Directors and to Agency management by prototype demonstration.

6. Establish working groups and sub-committees and ensure they have leadership, resources, and oversight necessary to meet their remits.

B. Members

1. Serve as point of contact and represent and communicate data standards needs and initiatives for their constituency Centers and Offices.

2. Ensure relevant recommendations developed by the DSAB are communicated to their constituency and / or Center or Office Director.

3. Ensure alignment between the DSAB and their organization by presenting Center or Office data standards-related initiatives and addressing constituents' needs for data standardization or other related matters.

4. Ensure that all FDA constituencies have the opportunity for input into the DSAB, as appropriate.

5. Identify and promote cross-organizational collaboration with constituency Centers and Offices.

6. Engage with external experts to understand challenges and potential standard alternatives.

7. Discuss and make recommendations concerning specific data exchange standards policy issues for the application of healthcare information technology.

8. Participate in sub-committees and working groups, as needed.

4. Procedures

A. Meetings

1. The DSAB co-chairs, with input from the membership, shall establish an annual calendar of meetings.

2. DSAB meetings will be chaired by the DSAB co-chairs or a delegated alternate member.

B. Sub-committees and Working Groups

1. The DSAB can establish Sub-committees to address an ongoing area of focus (e.g., Terminologies, Data Standards Catalog).

2. The DSAB can establish temporary Working Groups to address a specific issue of limited scope.

5. Effective Date

The effective date of this guide is 01/17/2024.

6. Document History - SMG 2010.22, "FDA Data Standards Advisory Board"

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	06/30/2023	N/A	ODT/ODAR/HIS	Ram Iyer, Director, ODT/ODAR