SMG 1220.2

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Biologics Evaluation and Research

Office of Regulatory Operations

Division of Informatics

Effective Date: September 30, 2022

1. Division of Informatics (DCBIA)

A. Responsible for the collection, classification, storage, retrieval, and dissemination of recorded knowledge used by CBER in the review and regulatory process.

B. Oversees receiving, tracking, storing, and managing CBER's regulatory submissions and records.

C. Promotes and coordinates the development and management of regulatory standards for review of regulatory submissions, provides support for CBER review staff and administers compliance of submission with electronic standards.

2. Records Management Branch (DCBIA3)

A. Responsible for receiving, tracking, storing and managing CBER's regulatory submissions and assigned documents.

B. Serves as CBER’s Assistant Records Liaison Officer (ARLO) and provides life-cycle, media neutral, records management support services for the Center’s digital and physical records, both onsite and at various commercial and government storage facilities.

C. Manages the Scientific Data Abstraction Task Order and is responsible for the regulatory data abstraction process associated database.

D. Manages the CBER Document Control Center, the CBER Onsite Records, Document Management Task Order, and the FDA offsite records storage contract.

E. Manages databases and tools for CBER's regulatory submissions and assigned documents and the CBER Electronic Records Repository.

3. Regulatory Information Branch (DCBIA4)

A. Serves as data stewards and managers for regulatory and review data and manages data governance.

B. Provides reports and analytical assessments to support internal and external requests and CBER operations.

C. Support capacity planning assessments within CBER and FDA.

D. Manages overall data quality in CBER.

E. Performs initial submission assessment and data entry into CBER regulatory databases for select regulatory submissions.

4. Data Standards Branch (DCBIA1)

A. Promotes the development of data standards for the effective and efficient review of regulatory submissions through stakeholder collaboration, policy development, and project implementation.

B. Develops, implements, and maintains regulatory data standards internal processes and guidance documents.

C. Analyzes and evaluates current regulatory data standards requirements and makes authoritative recommendations to CBER management to revise or modify existing policies and procedures. Identifies areas for improvement and promotes data standard innovation.

D. Strengthens CBER's advocacy for regulatory data standards that facilitate efficient and effective data review, integration, and training.

E. Represents CBER on working groups and committees with stakeholders within and outside of the federal government.

F. Manages electronic validation criteria to ensure sponsor submissions conform to published data standards.

5. Authority and Effective Date.

The functional statements for the Office of Regulatory Operations, Division of Informatics, were approved by the Commissioner of Food and Drugs and effective on September 30, 2022.

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluations and Research
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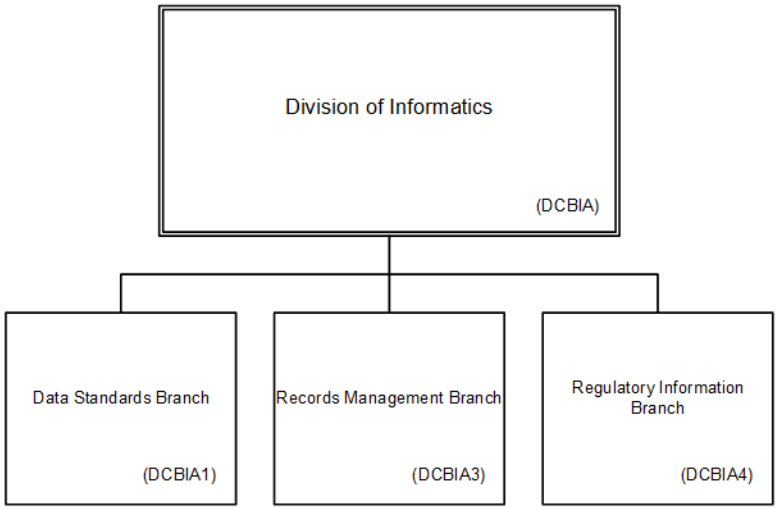

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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Regulatory Operations, Division of Informatics organization structure depicting all the organizational structures reporting to the Director:

Division of Informatics (DCBIA)

These organizations report to the Division of Informatics:

Data Standards Branch (DCBIA1)

Records Management Branch (DCBIA3)

Regulatory Information Branch (DCBIA4)