SMG 1121.21a

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of Regulatory Affairs

Office of Medical Products and Tobacco Operations

Office of Bioresearch Monitoring Operations

Effective Date: December 14, 2018

1. Office of Bioresearch Monitoring Operations (DCIGA).

A. Oversees all domestic and foreign Food and Drug Administration (FDA) field inspectional operations related to the Bioresearch Monitoring (BIMO) Program, including all clinical and nonclinical research conducted in support of preapproval, licensing, premarket and marketing clearance applications submitted to the agency for products regulated by all FDA product centers.

B. Provides direction and counsel to the Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) and other FDA leaders relative to BIMO field operations including emergency response activities.

C. Coordinates, directs and assists with BIMO investigative activities.

D. Directs and coordinates ORA's response to reports of adverse events relative to clinical and nonclinical research in collaboration with the Centers.

E. Supports the development of policy and guidance for investigations for BIMO.

F. Serves as an operational liaison for BIMO inspection programs to FDA's foreign offices.

G. Coordinates international BIMO regulatory activities, including the planning of all BIMO foreign inspections and investigations.

H. As needed, participates in system recognition efforts with other FDA components and national and international governments.

I. Participates as subject matter experts in the design, implementation and presentation of BIMO training programs.

J. Monitors emerging issues and advancements in technology and recommends program improvements as necessary.

K. Develops and maintains cooperative relationships with other Federal agencies; serves on interagency councils, encourages improved consumer protection programs pertinent to FDA-enforced laws and regulations.

L. Plans and evaluates program activities and manages a Quality Assurance Program.

M. Coordinates emergency activities with and provides assistance to Department components and other external stakeholders in the event of a natural disaster or other emergency.

N. Conducts investigations and inspections related to the BIMO program.

O. Provides technical assistance regarding BIMO investigational operations.

2. Bioresearch Monitoring Operations Staff (DCIGA1)

A. Coordinates and supports BIMO program investigative activities, including all clinical and nonclinical research conducted in support of preapproval, licensing, premarket and marketing clearance applications submitted to the agency for products regulated by all FDA product centers.

B. Provides inspectional and technical support to other offices on BIMO inspectional and regulatory matters.

C. Provides technical and programmatic expertise to the field and Centers through national technical and program experts.

D. Performs BIMO inspections, as necessary.

E. Creates, reviews, and/or facilitates issuance of field assignments with Centers for BIMO programs. Monitors and serves as technical point of contact for these assignments.

F. Implements the BIMO program work plan within OBIMO. Assists other offices and divisions in interpretation of work plan implementation.

G. Reviews and evaluates implementation of existing procedures and guidance related to BIMO programs.

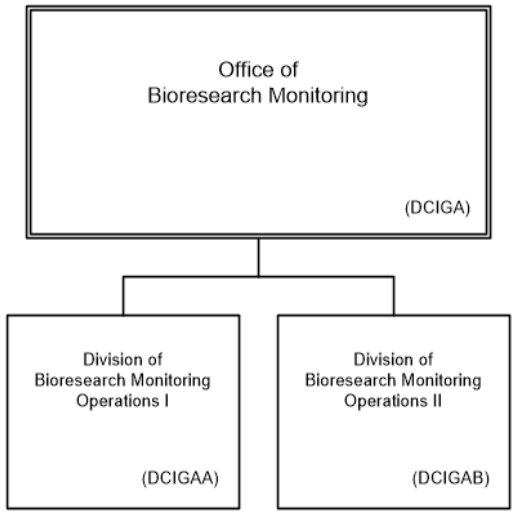
H. Serves as subject matter expert on field operations relative to BIMO on external and internal cross-FDA committees, workgroups and task forces.

I. Coordinates and participates in international harmonization with other national regulatory authorities and standards setting organizations as appropriate.

3. Authority and Effective Date.

The functional statements for the Office of Bioresearch Monitoring Operations were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Medical Products and Tobacco Operations
Office of Bioresearch Monitoring



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The following is the Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs, Office of Medical Products and Tobacco Operations, Office of Bioresearch Monitoring organization structure depicting all the organizational structures reporting to the Director:

These organizations report to the Office of Bioresearch Monitoring (DCIGA):

Division of Bioresearch Monitoring Operations I (DCIGAA)

Division of Bioresearch Monitoring Operations II (DCIGAB)