

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: February 9, 2022

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 advice and counsel to the Assistant Commissioner for Operations, Medical Products and Tobacco Operations (ACOMPTO) and other Agency leaders relative to BIMO field operations including emergency response activities.
- C. Coordinates, directs and assists with BIMO investigative activities.
- D. Directs and coordinates Office of Regulatory Affairs (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 and conduct of 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. 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-Agency committees, workgroups and task forces.

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

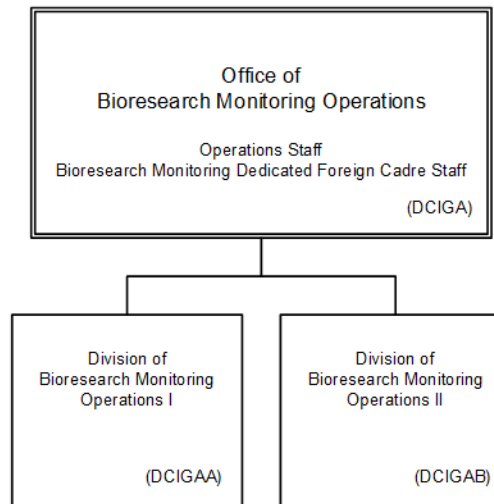
3. Bioresearch Monitoring Dedicated Foreign Cadre Staff (DCIGA2).

- A. Plans and coordinates all international BIMO inspection assignments received from all six commodity centers.
- B. Reviews all international BIMO inspection assignments and determines whether to assign to the dedicated cadre, to an Office of Global Policy and Strategy (OGPS) Global Office or announce for volunteers.
- C. Contacts international establishments to notify of inspection and obtain logistical information. Identifies firms to be inspected during specified timeframes putting trips together for assignment or announcement.
- D. Reviews and endorses all BIMO inspection reports conducted by staff detailed to the Office of Global Policy and Strategy (OGPS).
- E. Implements the BIMO program international work plan within OBIMO. Assists other offices and divisions in interpretation of work plan implementation.
- F. Reviews and evaluates implementation of existing procedures and guidance related to international BIMO inspections.
- G. Serves as subject matter expert on field operations relative to BIMO on external and internal cross-Agency committees, workgroups and task forces.
- H. Provides technical and programmatic expertise to the field and centers through cadre investigators.
- I. Coordinates and participates in international harmonization with other national regulatory authorities and standards setting organizations as appropriate.

4. Authority and Effective Date.

The functional statements for the Office of Bioresearch Monitoring Operations were approved by the Deputy Secretary for Health and Human Services and effective on February 9, 2022.

**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**



Staff Manual Guide 1121.21a
Organizations and Functions
Effective Date: February 9, 2022

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 Operations organization structure depicting all the organizational structures reporting to the Director:

Operations Staff

Bioresearch Monitoring Dedicated Foreign Cadre Staff

Division of Bioresearch Monitoring Operations I (DCIGAA)

Division of Bioresearch Monitoring Operations II (DCIGAB)