U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

FDA EXTERNAL FACT SHEET

About the Office of Bioresearch Monitoring Operations

A specialized office to ensure the protection of subjects involved in clinical research for FDA-regulated products

The Office of Bioresearch Monitoring Operations (OBIMO), a program within the Office of Regulatory Affairs (ORA), is responsible for cross-center activities ensuring the protection of subjects involved in clinical research for FDA-regulated products and that non-clinical research is conducted according to Good Laboratory Practices (GLP) requirements. In addition, OBIMO ensures the quality and integrity of data in clinical and non-clinical studies that support the research and marketing applications submitted for review.

OBIMO oversees all domestic and foreign agency 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.

Chrissy Cochran, PhD, directs OBIMO's day-to-day operations and coordination with FDA centers and ORA's Office of Strategic Planning and Operational Policy (OSPOP). OBIMO provides advice and counsel to the Assistant Commissioner for Medical Products and Tobacco Operations (ACMPTO) and other agency leaders relative to BIMO field operations including emergency response activities. The office includes two divisions — the Division of Bioresearch Monitoring Operations I and II — but does not have compliance branches. OBIMO also includes the Bioresearch Monitoring Operations Staff. The BIMO Program includes Postmarketing Adverse Drug Experience (PADE) and Risk Evaluation and Mitigation Strategies (REMS) inspections.

ORA's program division directors, formerly district directors, are the most senior FDA officials in their geographic area and continue to be the point of contact for local staff, the public, and industry. FDA's local coordination with federal, state, local, tribal, and territorial regulatory and public health agency officials continues to be managed by district state liaisons. Contact OBIMO at **engageORA@fda.hhs.gov.**

For more information, visit:

- Office of Regulatory Affairs
- Office of Good Clinical Practice

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.

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