Introduction into the Bioresearch Monitoring Program

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Objectives

- Explain the objectives of the FDA's Bioresearch Monitoring Program
- Recognize the specific roles involved in device clinical trials
- Describe the different compliance programs
- Identify the FDA regulations that apply to BIMO
- Understand where to obtain additional information

Presentation Topics

- Background
- Program Objectives
- Program Functions
- Inspection Programs
- Applicable Regulations
- Guidance and Information

BIMO Program Background

Known as “BIMO”

- 1975-1976 Congressional Hearings
- Directed FDA to establish an agency-wide program
- Encompass all operational bureaus & regulated products
- Authorized $16M & 606 FTEs

BIMO Program Background

A comprehensive, agency-wide program of on-site inspections and data audits designed to monitor all aspects of the conduct and reporting of FDA-regulated research

BIMO Program Background

The BIMO program monitors:

- Sponsors/Contract Research Organizations (CROs)/Monitors
- Institutional Review Boards (IRBs)
- Clinical Investigators (CIs)
- Nonclinical Laboratories

BIMO Program Objectives

- Protect the rights, safety, and welfare of human research subjects
- Assure the quality, reliability, and integrity of data collected

BIMO Program Functions

- Audit clinical data
- Inspect ongoing clinical research
- Inspect nonclinical laboratories
- Inspect IRBs
- Educate and train
- Implement FDA's Application Integrity Policy

What may Prompt an Inspection of Device Research?

- New Product or Indication
- New Technology
- Complaints
- History of non-compliance
- Routine Surveillance

BIMO Inspection Programs

- Routine
  - Surveillance
  - Compliance follow-up
- Directed
  - Data audits of device submissions
- For Cause
  - Investigate problems
  - Investigate complaints

BIMO Inspection Programs

Inspection Classifications

- NAI – No Action Indicated
- VAI – Voluntary Action Indicated
- OAI – Official Action Indicated

BIMO Compliance Programs

- Clinical Investigators
- Sponsors, Contract Research Organizations, and Monitors
- Institutional Review Boards
- Good Laboratory Practices

www.fda.gov/ora/cpgm/default.htm#bimo

Clinical Investigator (CI)

An individual who actually conducts a clinical investigation, under whose immediate direction the test article is administered, dispensed, or used.

Sponsor

- Takes responsibility for and initiates a clinical investigation, but does not actually conduct the investigation
- May be an individual, company, government agency, academic institution, private organization

Monitor

- Individual designated by a sponsor or contract research organization to oversee the progress of an investigation
- Must be qualified by training and experience to monitor the device investigation

Contract Research Organization (CRO)

A person who assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor

Institutional Review Board (IRB)

Any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and conduct periodic review of, biomedical research involving human subjects

Sponsor-Investigator (SI)

An individual who both initiates and actually conducts, alone or with others, an investigation, and under whose immediate direction the investigational product is administered, dispensed, or used. The obligations include both those of a sponsor and an investigator

Non-Clinical Laboratories

- Animal laboratories where pre-clinical studies are conducted

FDA Regulations that apply to BIMO

- 21 CFR 50: Protection of Human Subjects
- 21 CFR 54: Financial Disclosure
- 21 CFR 56: Institutional Review Boards (IRB)
- 21 CFR 58: Good Laboratory Practice for Non-Clinical Laboratory Studies (GLP)

FDA Regulations that apply to BIMO

- 21 CFR 809: In Vitro Diagnostic Products (IVD)
- 21 CFR 812: Investigational Device Exemption (IDE)

Guidance and Information

- Computerized Systems Used in Clinical Investigations, May 2007
- Protecting the Rights, Safety, and Welfare of Study Subjects – Supervisory Responsibilities of Investigators, May 2007

Guidance and Information

- The Review and Inspection of Premarket Approval Applications under the Bioresearch Monitoring Program, January 2008
- Guidance for Sponsors, Clinical Investigators, and IRBs – Data Retention When Subjects Withdraw from FDA-regulated clinical trials, October 2008

Guidance and Information

- Draft Guidance
  - Protecting the Rights, Safety, and Welfare of Study Subjects – Supervisory Responsibilities of Investigators
- Information Sheets
  - Frequently Asked Questions About IRB Review of Medical Devices
  - Significant and Non-significant Risk Medical Device Studies

For More Information

- FDA Home Page **www.fda.gov**
- Center for Devices and Radiological Health **www.fda.gov/cdrh/**
- Device Advice **www.fda.gov/cdrh/devadvice**
- CDRH BIMO site **www.fda.gov/cdrh/bimo/html**

For More Information

- FDA Good Clinical Practices
  www.fda.gov/oc/gcp/default.htm
- Code of Federal Regulations (CFR) Main Page
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfmw
- FDA Consumer Magazine
  www.fda.gov/fdac/

Summary

- Objectives of the BIMO program
- Specific roles in clinical trials
- Four compliance programs
- FDA regulations applicable to BIMO
- Additional information