The Clinical Investigator Role

An FDA Operational Perspective on Inspections and Responsibilities

Frontiers Clinical & Translational Science Institute

University of Kansas Medical Center

Grand Rounds – July 27, 2023

Anne E. Johnson, Director

Office of Bioresearch Monitoring

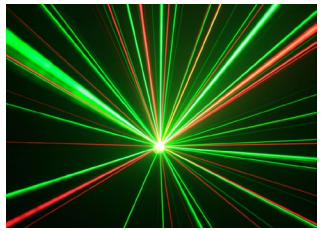
Division I (East)

U.S. Food and Drug Administration

What Does FDA Regulate?

- Human and Animal Foods
- Pharmaceutical Drugs
- Biological Products
- Medical Devices
- Radiation Emitters
- Supplements
- Cosmetics
- Veterinary Products
- Tobacco Products

…and more…



Products Without Borders

FDA is Global – International Offices and Inspection Programs

International production of FDA-regulated goods and materials

Integrated Supply Chains

FDA U.S. FOOD & DRUG ADMINISTRATION

OFFICE OF REGULATORY AFFAIRS

Dr. Robert Califf, M.D.

Commissioner of FDA

- Center for Biologics Evaluation and Research
- Center for Drug Evaluation and Research
- Center for Devices and Radiological Health
- Center for Food Safety and Applied Nutrition
- Center for Tobacco Products
- Center for Veterinary Medicine

Office of Regulatory Affairs

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

Acting, Associate Commissioner for Regulatory Affairs (ACRA)

Assistant Commissioner for Import Operations

Assistant Commissioner for Medical Products & Tobacco Operations

Assistant Commissioner for Human & Animal Food Operations

Assistant Commissioner for Criminal Investigations

OBIMO

OBPO

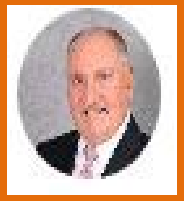
OMDRHO

OPQO

TOS

HAF-E

HAF-W PD



Inspectional and Investigational Offices

How We Gather Information…

- **Inspections**
- **Applications and Updates**
- Sample Analyses
- Investigations
- Consumer Complaints
- Field Exams

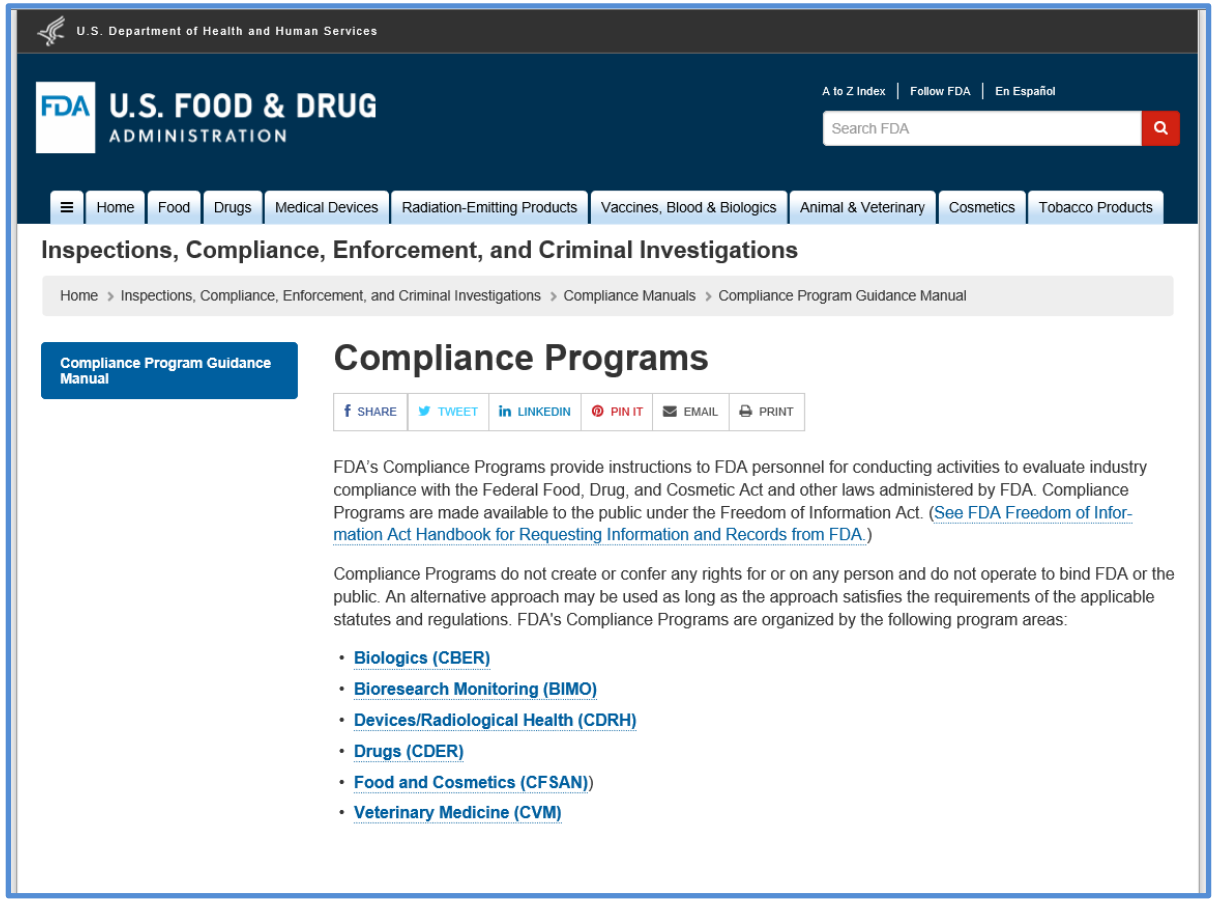
- Adverse Event Reports/Medwatch
- 806 Reports (devices)
- Field Reports
- Disasters/Accidents
- Reportable Registries

Bioresearch Monitoring Operations Objectives - Access

- To protect the rights, safety, and welfare of human research subjects
- To ensure the quality, reliability, and integrity of data collected
- To maintain the integrity of the FDA review process by ensuring that FDA-regulated research is conducted in compliance with applicable regulations

PREPARING FOR INSPECTION

Know what we know…



Compliance Program Guidance Manual

- Regulatory References
- Specific procedures
- Internal guidance to our field and center staff.

- https://www.fda.gov/ICECI/ComplianceManuals/ComplianceProgramManual/default.htm

Know what we know…

7348.811 Clinical Investigators and Sponsor Investigators

7348.810 Sponsors and Contract Research Organizations

I-Background (Law, regs, etc)

II-Implementation

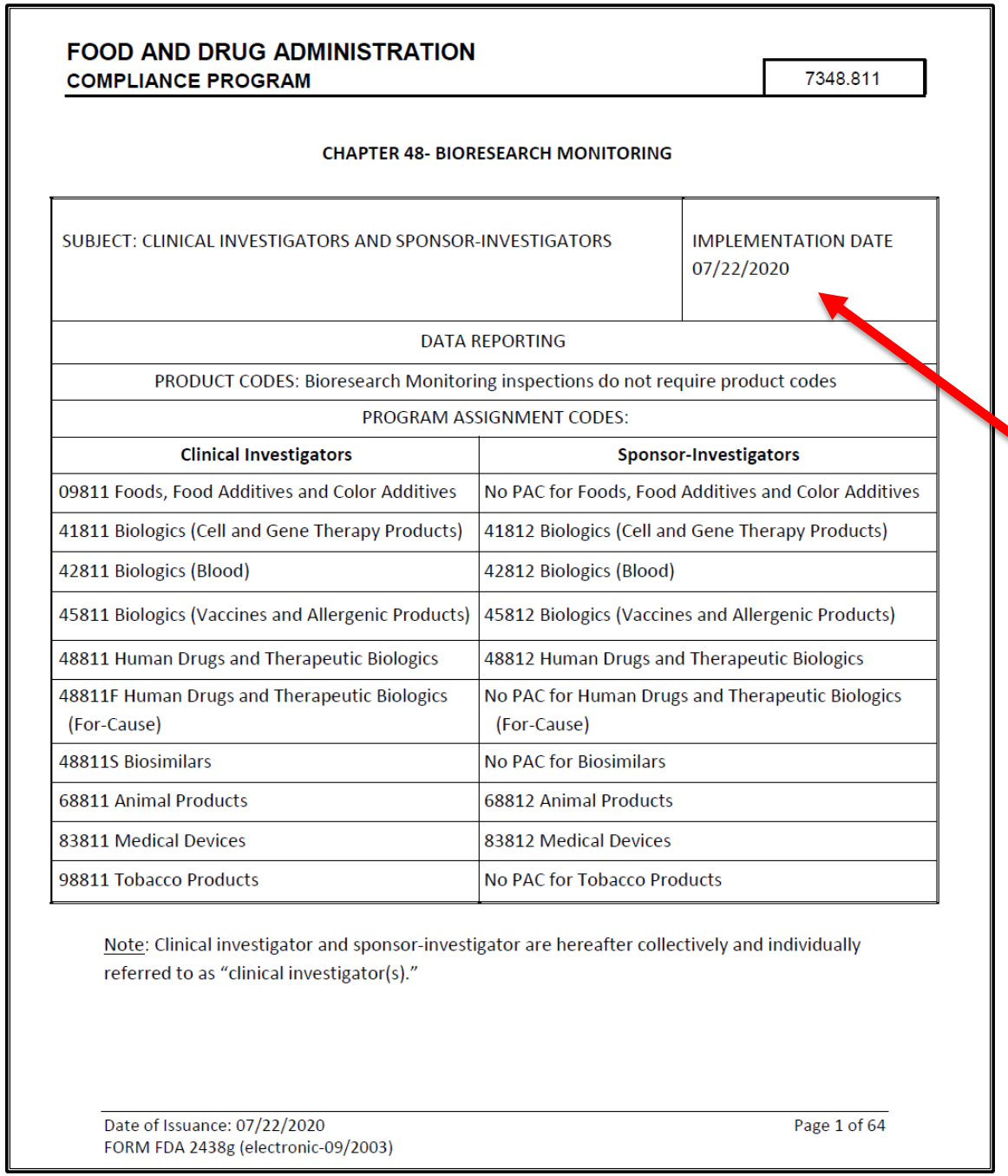
III-Inspectional

IV-Analytical

V-Regulatory/Administrative

VI-References/Program Contacts

VII- HQ Responsibility



FOOD AND DRUG ADMINISTRATION
COMPLIANCE PROGRAM 7348.811

CHAPTER 48- BIORESEARCH MONITORING

SUBJECT: CLINICAL INVESTIGATORS AND SPONSOR-INVESTIGATORS	IMPLEMENTATION DATE 07/22/2020
DATA REPORTING	
PRODUCT CODES: Bioresearch Monitoring inspections do not require product codes	
PROGRAM ASSIGNMENT CODES:	
Clinical Investigators	**Sponsor-Investigators**
09811 Foods, Food Additives and Color Additives	No PAC for Foods, Food Additives and Color Additives
41811 Biologics (Cell and Gene Therapy Products)	41812 Biologics (Cell and Gene Therapy Products)
42811 Biologics (Blood)	42812 Biologics (Blood)
45811 Biologics (Vaccines and Allergenic Products)	45812 Biologics (Vaccines and Allergenic Products)
48811 Human Drugs and Therapeutic Biologics	48812 Human Drugs and Therapeutic Biologics
48811F Human Drugs and Therapeutic Biologics (For-Cause)	No PAC for Human Drugs and Therapeutic Biologics (For-Cause)
48811S Biosimilars	No PAC for Biosimilars
68811 Animal Products	68812 Animal Products
83811 Medical Devices	83812 Medical Devices
98811 Tobacco Products	No PAC for Tobacco Products

Note: Clinical investigator and sponsor-investigator are hereafter collectively and individually referred to as "clinical investigator(s)."

Date of Issuance: 07/22/2020 Page 1 of 64
FORM FDA 2438g (electronic-09/2003)

Know what we know…

Investigations Operations Manual

Chapter 5 – Inspections

BIMO Chapter – 5.10

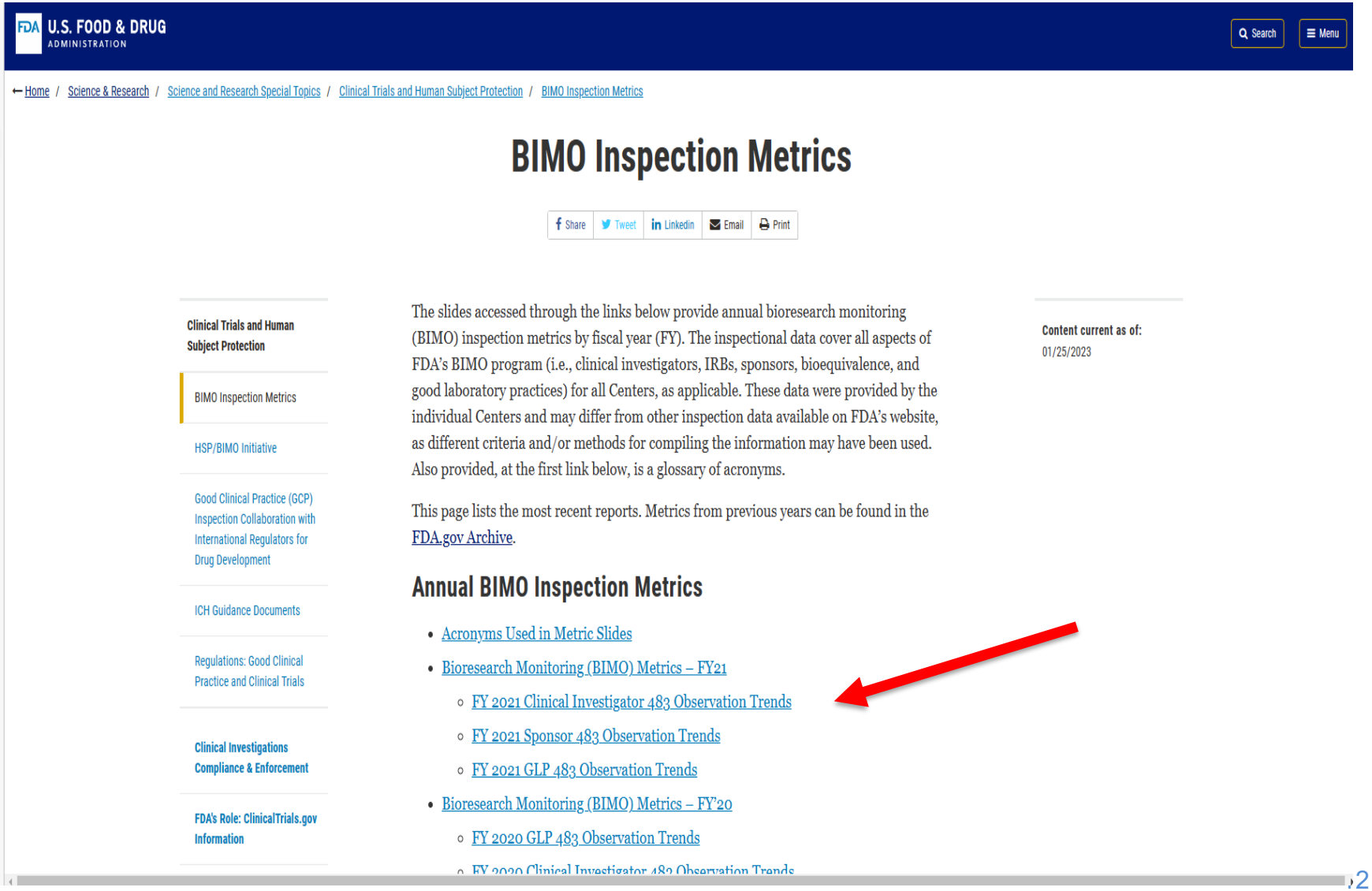
https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual

Before FDA Arrives…

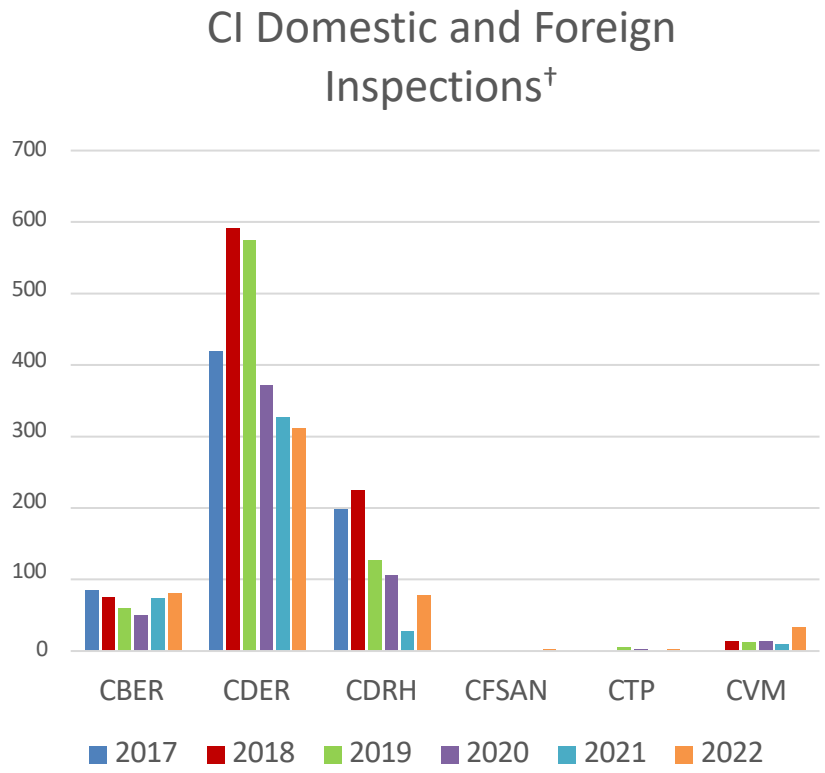
https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm261409.htm

What are we finding?

What are the trends?



Clinical Investigator Inspections Conducted FY 2017- 2022*

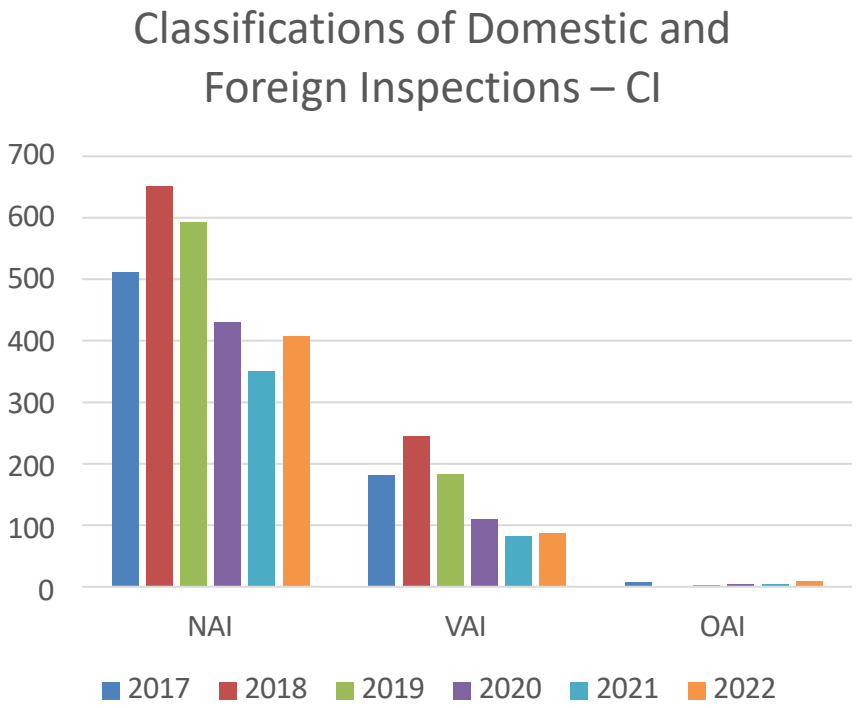


Center	2017	2018	2019	2020*	2021*	2022
CBER	84	75	60	50	74	80
CDER	419	591	574	372	327	311
CDRH	198	225	126	106	27	77
CFSAN	0	0	0	0	0	2
CTP	0	0	5	2	0	2
CVM	0	13	12	14	9	32

* Due to the COVID-19 pandemic, RRAs (not reflected in the above table) were conducted. See slide 31 for more details.

†Based on final classification date

Clinical Investigator Inspections Final Classified FY 2017-2022



	2017	2018	2019	2020	2021	2022
NAI	512	651	592	430	350	408
VAI	182	244	184	110	82	87
OAI	7	1	3	5	5	9

Return to the inspections conducted slide

Common Clinical Investigator Inspectional Observations*

- Failure to follow the investigational plan; protocol deviations
- Inadequate and/or inaccurate case history records; inadequate study records
- Inadequate accountability and/or control of the investigational product
- Failure to comply with Form FDA 1572 requirements
- Inadequate subject protection; informed consent issues
- Safety reporting; failure to report and/or record adverse events
- Failure to comply with 21 CFR part 56 (IRB) requirements.

*Most common observations collected from issued FDA Form 483s

Preparation is the Key

Success is where Preparation and Opportunity Meet

Regulations
Documentation
Procedures

Knowledge
Training
Open Communications

Mock Audits
Quality Reviews

Knock, Knock
“The Opportunity”

THE INSPECTION

What to do when FDA calls…

- Don’t panic! Grab a pen and paper.
- Identify any commitments which cannot be changed (annual conferences, surgery, etc.)
- Mark your calendar
- Gather your records
- Allocate time and workspace
- It’s courtesy call and not subject to delays

Opening Meeting

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.
1431 Harbor Bay Parkway
Alameda, CA 94502
(510)337-6700

TO

2. NAME AND TITLE OF INDIVIDUAL
Helen E. Castro, President

3. DATE
07/28/13

4. FIRM NAME
ABC Bread Company

5. HOUR
7:30 a.m.
p.m.

6. NUMBER AND STREET
579 Main Street

7. CITY AND STATE & ZIP CODE
Richmond, CA 94805

8. PHONE NO. & AREA CODE
(510)123-4567

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or Subtitle III of the Public Health Service Act [42 U.S.C. 262-264][2]

As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman.

FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombuds@oc.fda.gov.

For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) *(Food and Drug Administration Employee(s))*
Sidney H. Rogers

10. TYPE OR PRINT NAME(S) AND TITLE(S) *(FDA Employee(s))*
Sidney H. Rogers, Investigator

Not actual credentials, but the layout is *indicative* of FDA Credentials. Federal law prohibits photographs of our credentials.

While FDA is on-site

- During the inspection
  - Have the right personnel available
  - Be accessible to answer questions, provide copies
  - Don’t delay unnecessarily, if time is needed to retrieve records/answer, explain why
- Daily wrap up
  - Daily progress
  - Concerns and Questions
  - Plan for following day

What records are needed?

- Protocol with amendments
- Investigator's Brochure
- Sponsor, IRB, and Monitor Correspondence
- Informed Consent Forms
- FDA-1572 / Statement of Investigator, or Investigator's Agreement for devices
- Financial Disclosure forms
- Case Report Forms

What records are needed? (cont.)

- Medical Records
- Source Data
- Test Article Accountability, incl. storage temps
- Curriculum Vitae/licensure
- Recruiting Materials
- List of Studies conducted by the CI
- Electronic records (EMRs, eCRFs)

Subject Records are **ALCOA-C**

Attributable to the person creating the data

Legible and permanent

Contemporaneously recorded

Original or a true copy

Accurate

Complete

Part 11-A Quick Review
Predicate Rule Requirement

21 CFR 11- Electronic records, Electronic Signatures final rule

- Certain sections of part 11 are currently enforced under regulatory discretion as defined in FDA's Guidance for Industry Part 11, Electronic Records; Electronic Signatures - Scope and Application (August 2003)
  - "Part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in Agency regulations."
  - "Part 11 also applies to electronic records submitted to the Agency under the Federal Food, Drug, and Cosmetic Act (the Act) and the Public Health Service Act (the PHS Act), even if such records are not specifically identified in Agency regulations

Electronic Records

- Test Article Accountability
- LIMS
- Deviation Databases
- Complaint Handling
- SOPs
- Environmental Control
- Maintenance and Calibration
- Study Protocols, Reports
- Animal Feeding Logs
- CRFs, e-mails, Monitoring Databases

Access to **all** study data including electronic data and copy records.

…and more…

Closing Discussion

- Most responsible/knowledgeable parties present
- Is there an FDA-483?
  - Observations clear?
  - Do you have additional documentation not reviewed during inspection?
  - Verbal response? Will be included in Establishment Inspection Report
  - Do you plan to respond in writing?

15-day recommendation

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Minneapolis District 250 Marquette Ave. South, Suite 600 Minneapolis, MN 55401 Industry information: www.fda.gov/oc/industry	10/5-7/2008 FEI NUMBER 0000112233

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: William S. Gundstrom, Vice President, Production

FIRM NAME	STREET ADDRESS
Topline Pharmaceuticals "T.L.P."	2136 Elbe Place
CITY, STATE AND ZIP CODE Jackson, MN 55326	TYPE OF ESTABLISHMENT INSPECTED Tablet Repacker

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) ~~WE~~ OBSERVED:

List your significant observations ranked in order of significance.

See IOM 5.2.3, 5.2.3.1, 5.2.3.2, and 5.2.3.3

Observations listed here...

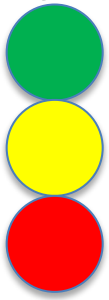
After the Inspection has ended

- Written Responses (recommended, not required)
  - Recap observation
  - Provide explanation if appropriate
  - Describe corrective actions, include documentation and timeframes
  - Consider impact on any other on-going or future studies
  - If received within 15 days, will take into consideration prior to action
- No FDA-483, but discussion items?
  - Consider any impacts and corrective actions you may need to do
  - Consider a written response, the items will be reported in the Establishment Inspection Report and reviewed

When the inspection is over…Exhale!

- Send responses to: ORABIMOE.Correspondence@fda.hhs.gov or ORABIMOW.Correspondence@fda.hhs.gov

- Agency review and final classification decision



NAI no objectionable conditions or practices

VAI objectionable conditions or practices were found and need voluntary correction

OAI objectionable conditions or practices warrant consideration for advisory, administrative, or judicial action

- Copy of the report will be sent to you, in most instances

CLINICAL INVESTIGATOR RESPONSIBILITIES

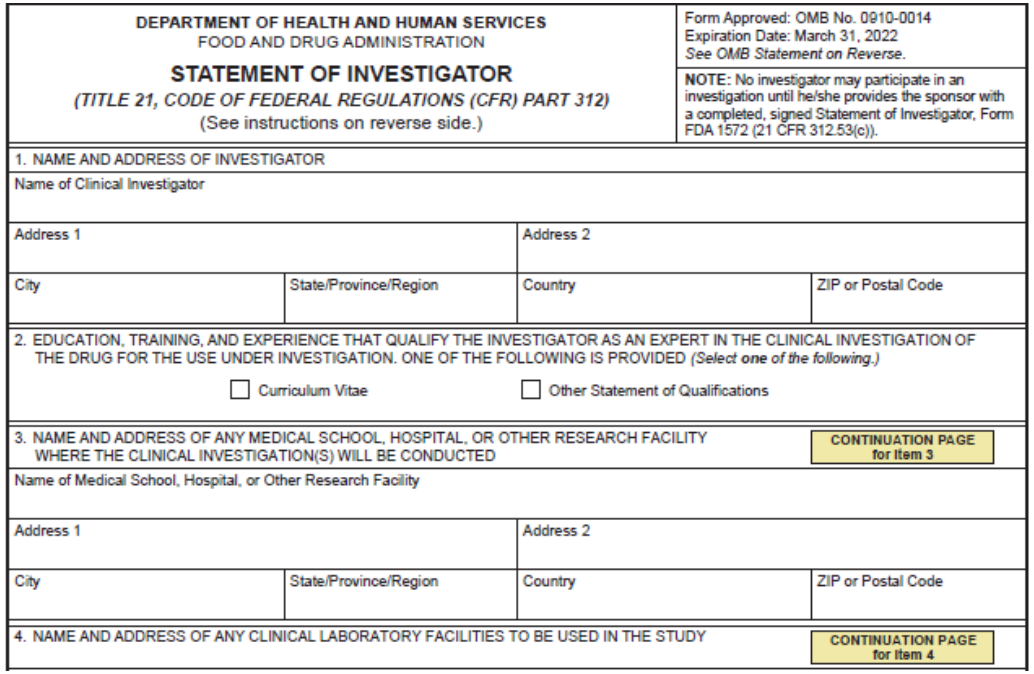
Who is a clinical investigator?

- An individual **who actually conducts a clinical investigation** (i.e., under whose immediate direction the drug is dispensed to a subject.)
- In the event an investigation is conducted by a team of individuals, the investigator is **the responsible leader** of the team.

[21 CFR 312.3] [21 CFR 812.3]

General Clinical Investigator Responsibilities

- Ensuring that an investigation is conducted according to
  - The signed investigator statement (**Form 1572**)
  - The investigational **plan**
  - Applicable **regulations**



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR

(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)

(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014
Expiration Date: March 31, 2022
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED *(Select one of the following.)*

☐ Curriculum Vitae ☐ Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED — CONTINUATION PAGE for Item 3

Name of Medical School, Hospital, or Other Research Facility

Address 1		Address 2	
City	State/Province/Region	Country	ZIP or Postal Code

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY — CONTINUATION PAGE for Item 4

[21 CFR 312.60] [21 CFR 812.100]

[21 CFR 812.43 – Investigator Agreement]

Statement of Investigator - Form FDA 1572

Commitments:

- I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) **and will only make changes** in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.
- I agree to **personally** conduct or supervise the described investigation(s).

Statement of Investigator - Form FDA 1572

Commitments:

- I agree to **inform** any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining **informed consent** in 21 CFR Part 50 **and institutional review board (IRB) review** and **approval** in 21 CFR Part 56 are met.

Statement of Investigator - Form FDA 1572

Commitments:

- I agree to report to the sponsor **adverse experiences** that occur in the course of the investigation(s) in accordance with 21 CFR 312.64.
- I have **read and understand** the information in the **investigator's brochure**, including the potential risks and side effects of the drug.

Statement of Investigator - Form FDA 1572

Commitments:

- I agree to **ensure that all** associates, colleagues, and employees assisting in the conduct of the study(ies) are **informed about their obligations** in meeting the above commitments.
- I agree to **maintain adequate and accurate** records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

Statement of Investigator - Form FDA 1572

Commitments:

- I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the **initial and continuing review and approval** of the clinical investigation. I also agree to **promptly report to the IRB** all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I **will not make any changes** in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

Supervision of a Clinical Trial

- The investigator should have sufficient time to properly conduct and supervise the clinical trial.
- The level of supervision should be appropriate to the staff, the nature of the trial, and the subject population.

Delegation of Study-Related Tasks

- Duties involving clinical / medical judgment must be delegated to individuals **qualified by education, experience**, local licensing requirements and according to the protocol

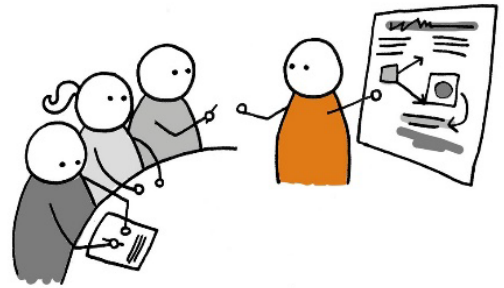
- Examples include:
  - Assessing screening results and medical histories for eligibility
  - Physical Exams
  - Adverse Event Evaluation/Classification
  - Assessments of Study Endpoints
  - Obtaining Informed Consent

Training

The investigator must ensure **all current** and **future** staff participating in the conduct of the clinical trial are adequately trained and competent to perform the tasks they are delegated, prior to participation.

Training Should Cover:

- The purpose of the study, an understanding of the investigational product, and protocol requirements specific to their delegated duties
- Good Clinical Practice (GCP) regulatory requirements and acceptable standards for the conduct of clinical trials
- Updated with any pertinent changes during the conduct of the trial



Contributing Factors of inadequate oversight

- Lack of regulatory knowledge, expectations, training
- Inexperienced or not enough staff
- Protocol complexity (eligibility, assessments, critical timing, length of study, numerous amendments)
- Large number of subjects enrolled at a site
- Seriously ill subject population (large numbers of adverse events and concomitant medications)

A Word about ClinicalTrials.gov
FDAAA Title VIII, 42 CFR 11.4

Sponsor of the clinical trial (as defined at 21 CFR 50.3); or

Principal investigator of the clinical trial; if designated by sponsor, grantee, contractor, or awardee, so long as the PI:

- Has access to and control over the data,
- Has the right to publish the results of the trial, and
- Has the ability to meet all of the requirements for the submission of clinical trial information.

KEY GCP REGULATION REFERENCES AND RESOURCES

Good Clinical Practice (GCP) Review

21 CFR 312.60 (IND) – General responsibilities

"An investigator is responsible for ensuring that an investigation is **conducted according to the signed investigator statement, the investigational plan, and applicable regulations**; for **protecting the rights, safety, and welfare** of subjects under the investigator's care; and for **control of drugs** under investigation."

(Medical Devices - 21 CFR 812.100-812.110)

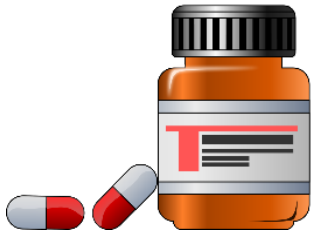
GCP Review (cont.)

21 CFR 312.60 – General responsibilities

"An investigator **shall**, in accordance with the provisions of part 50 of this chapter, **obtain the informed consent** of each human subject to whom the drug is administered, except as provided in §§ 50.23 or 50.24 of this chapter.

Additional specific responsibilities of clinical investigators are set forth in this part and in parts 50 and 56 of this chapter."

(Medical Devices - 21 CFR 812.100-812.110)



GCP Review (cont.)

21 CFR 312.61 – Control of the Investigational Drug.

"An investigator shall **administer the drug** only to subjects under the investigator's **personal supervision** or under the supervision of a sub-investigator responsible to the investigator. The investigator **shall not supply the investigational drug to any person not authorized** under this part to receive it."

(Medical Devices - 21 CFR 812.110(c))

GCP Review (cont.)

21 CFR 312.62 - Investigator recordkeeping and record retention

(a) **Disposition of drug** – dates, quantity, use - return unused supplies to the sponsor

(b) **Case histories** – prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual – to include: consent, MD/RN progress notes, hospital charts – documentation that informed consent was obtained prior to participation

(c) **Record Retention** – 2 years after approval

(Medical Devices - 21 CFR 812.140)

GCP Review (cont.)

21 CFR 312.64 - Investigator Reports

a) Progress Reports- regular submission of study data to the sponsor

b) Safety Reports – https://www.fda.gov/media/152530/download

c) Final Report- submission of all study data to the sponsor at completion

d) Financial Disclosure Reports (21 CFR 54)

(Medical Devices - 21 CFR 812.150 & 812.110(d))

GCP Review (cont.)

21 CFR 312.66 – Assurance of IRB review

"An investigator shall assure that an IRB that complies with the requirements set forth in part 56 will be responsible for the initial and continuing review and approval of the proposed clinical study. The investigator shall also assure that he or she will **promptly** report to the IRB all **changes** in the research activity and all **unanticipated problems** involving risk to human subjects or others, and that he or she will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects."

(Medical Devices - 21 CFR 812.110(a) & (b); 812.150(a)(4))

GCP Review (cont.)

21 CFR 812.150(a)(1) – **Unanticipated adverse device effects** must be reported to the Sponsor and IRB within 10 days

21 CFR 312.68 – Inspection of investigator's **records and reports** *(Medical Devices - 21 CFR 812.145)*

21 CFR 312.69 – Handling of **controlled substances**

21 CFR 312.70 – **Disqualification** of a clinical investigator *(Medical Devices - 21 CFR 812.119)*

Guidances

- Decentralized Clinical Trials for Drugs, Biological Products, and Devices – Draft, May 2023

- Digital Health Technologies for Remote Data Acquisition in Clinical Investigations – Draft, December 2021

- Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects – Final, October 2009

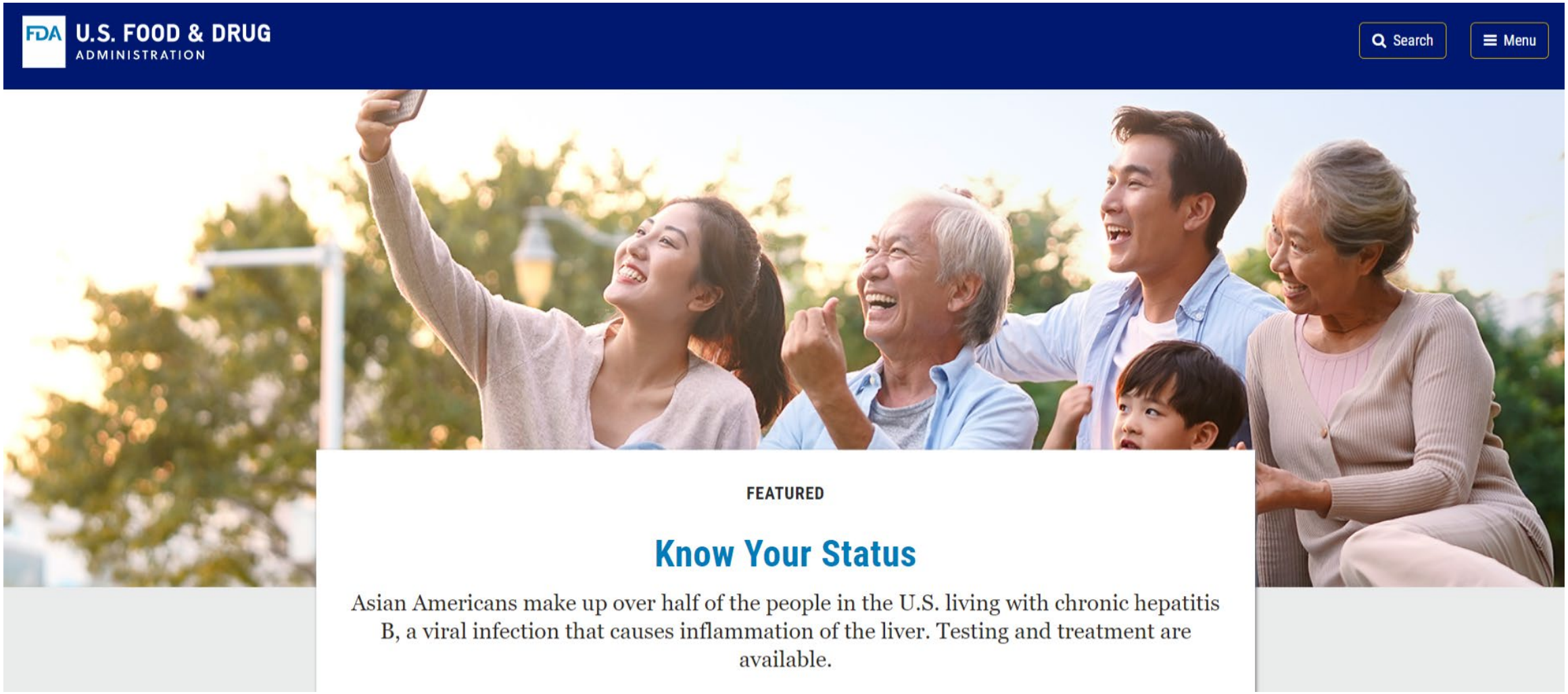
Informational Resources

- Clinical Investigator Inspection Search:

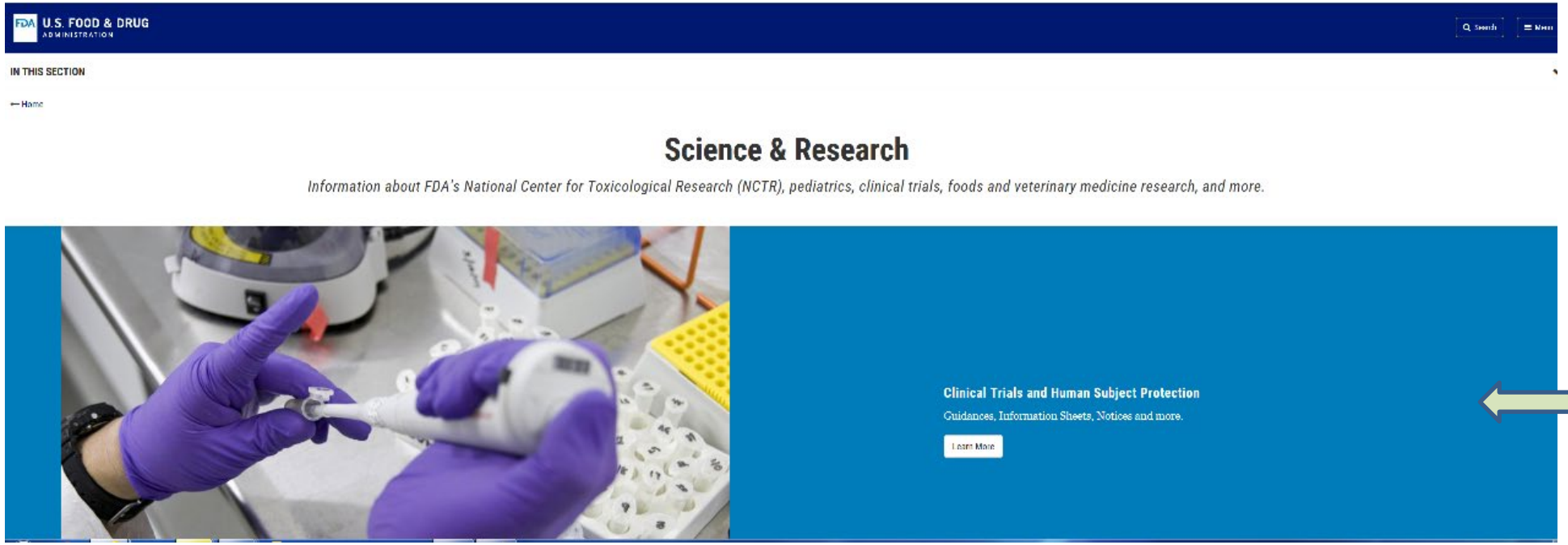
https://www.accessdata.fda.gov/scripts/cder/CLIIL/index.cfm

- Good clinical practice: gcpquestions@fda.hhs.gov

FDA.GOV [Science & Research]



FDA.GOV



SCROLL DOWN TO SEE:
Science, Research and Special Topics
Clinical Trials
Human Subject Protection
Guidance Documents Finalized
Information Sheets

Bioinformatics
Meetings, conferences, and Workshops
Womens Health Research
References

…and so much more…

Clinical Trials and Human Subject Protection

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Protecting the rights, safety and welfare of people who participate in clinical trials is a critical aspect of the FDA's mission. FDA oversees clinical trials to ensure they are designed, conducted, analyzed and reported according to federal law and good clinical practice (GCP) regulations. FDA's regulations and guidances for clinical trials help support efficient medical product development, while assuring trials generate the robust evidence needed to assess product safety and efficacy. The agency works to ensure its GCP policies continue to facilitate new approaches to generating quality clinical evidence.

View Clinical Trials Guidance Documents

Content current as of:
11/30/2021

Latest activity

- Digital Health Technologies for Remote Data Acquisition in Clinical Investigations - Draft Guidance for Industry, Investigators, and Other Stakeholders
- FDA Takes Action For Failure to Submit Required Clinical Trial Results Information to ClinicalTrials.Gov
- FDA Publishes Guidance on Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank (August 2020)
- FDA Publishes Guidance on Institutional Review Board Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During COVID-19 Public Health Emergency
- FDA issues Guidance on Conduct of Clinical Trials of Medical Products During the COVID-19 Pandemic

Reporting Complaints Related to FDA-Regulated Clinical Trials

Good Clinical Practice Inquiries

COVID-19 Pandemic

Bioresearch monitoring

FDA's bioresearch monitoring (BIMO) program is a comprehensive program of on-site inspections and data audits designed to monitor all aspects of the conduct and reporting of FDA-regulated research.

View BIMO Compliance Programs

Workshops, meetings, and conferences

- Conferences
- Workshops and meetings

Contacts

- Good clinical practice: gcpquestions@fda.hhs.gov
- IND/IDE contacts
- Bioresearch monitoring program contacts
- How to report complaints or problems about clinical trials to FDA

Report problems to FDA

- Reporting complaints related to FDA-regulated clinical trials
- Mandatory IRB reporting: FDA contacts

Resources For You

- Clinical trial forms
- ClinicalTrials.gov (NIH)
- Office of Clinical Policy
- Dockets management
- Approvals of FDA-Regulated Products

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OBIMO's highly skilled, collaborative, and agile workforce ensures research subjects are protected and the data used to support FDA decisions is reliable