Research, Innovation & Impact

FDA AUDITS

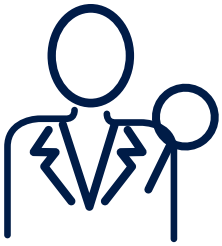
How to Prepare and What to Expect

An FDA inspection can feel daunting, but with the right knowledge and preparation you can feel confident in your team's ability to successfully navigate the process. You're encouraged to reach out to the Quality Assurance Office with any questions or to schedule some time to chat. **(520) 621-5196 | bpernic@arizona.edu**

BEFORE THE INSPECTION

- Notify all appropriate parties of impending audit (IRB, Sponsor, Banner Research)
- Reserve audit location with access to phone and workspace table
- Review study and organize files (all versions)

DURING THE INSPECTION



- PI should set aside time each day with inspector and be available to answer questions honestly
- Designate a study liaison to coordinate all FDA requests and answer questions
- Request an end of day discussion during each day to review any preliminary findings

EXIT INTERVIEW

- Notify PI and appropriate compliance representatives
- Liaison should note any observations, comments and commitments
- PI should seek to correct any errors in the findings

Advance Preparation

Be prepared and have the following regulatory documents in order before the inspection.

Study Documentation

- ☐ Delegation of Authority log
- ☐ Inclusion / Exclusion Criteria met
- ☐ Document reason for exclusion
- ☐ Adverse events
- ☐ Deaths
- ☐ Monitoring Log
- ☐ Notes to file
- ☐ Investigator brochures
- ☐ Communication from Sponsor/CRO

IRB Documents

- ☐ Protocol
- ☐ Protocol exceptions
- ☐ Amendments
- ☐ IRB Amendment/Renewal approvals
- ☐ IRB approval letter
- ☐ Consents (screened and enrolled)
- ☐ Consent versions
- ☐ Partial waiver of consents

Investigator Information

- ☐ CV's for PI and Sub PI
- ☐ FDA 1572

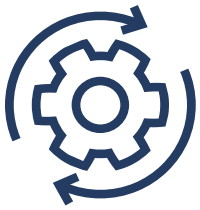
Test Article / Labs

- ☐ Drug Receipts, Dispensing, Return
- ☐ Dose modifications
- ☐ Concomitant medications
- ☐ Lab certifications
- ☐ Lab reports
- ☐ Diagnostic test reports

Subject Documentation

- ☐ Subject CRFs / Source Docs
- ☐ Subject Condition at entry of study
- ☐ Documentation of attempts to contact patient and certified letter
- ☐ Early withdrawals
- ☐ Subject diary

Guidance & Best Practices



Pre-Audit Preparation

- ☐ Be positive, confident, and never guess, speculate or argue with the inspector
- ☐ Be concise, clear, and honest – only answer what is asked and do not volunteer information
- ☐ Do not sign affidavit – consult with Senior Leadership and General Counsel
- ☐ Prepare legal name and address for Sponsor, CRO, UA/ Banner, IRB of Record
- ☐ Prepare PI and Sub-I contact name, mailing address, phone and email
- ☐ Have a list of all regulated studies PI is involved with including IRB of record
- ☐ Prepare copies of all protocol versions, IRB approval letters, and all ICF versions

FDA document requests

- ☐ Make 2 copies
- ☐ Stamp FDA copy “Confidential”
- ☐ Retain 1 copy for your records
- ☐ Maintain an inspection record log
- ☐ Photographs – if FDA takes them, take duplicate photo

Common Questions

PI Interview

- How long has PI has been practicing medicine?
- How long has PI been doing research?
- Who does PI report to and what are their titles?
- Is PI a full-time employee?
- Does PI have a private practice outside?
- Does PI have hospital privileges with Banner?
- Did you receive protocol training from sponsor?
- Do you have a vested interest in the sponsor or study drug?
- Do you have a relationship with sponsor outside of the study?
- Have you done any other studies with this sponsor?
- How many studies is PI responsible for?
- Who was involved as a sub investigator?
- Have you been inspected by the FDA or any other agency?

General Questions

- Dates of employment for all study staff, including Regulatory, Manager, Directors
- How many research employees are employed?
- Explain role and dates they were involved in study
- What version is your electronic source software? (ex. Redcap, Rave)
- Who is the manufacturer of the program?
- When was it last validated?

Data Collection, Retention & Transmission

- What is the process for data entry?
- What do you do if the data needs correction?
- Who can make data corrections?
- How is the PI kept abreast of changes or needs with data?
- How did the monitors review the data?
- Who is authorized to access system?
- How do you maintain the security of the paper records? (ex. Stored in secure locked area, only accessible to study personnel)
- How do you maintain security of electronic records? (Ex. Audit trail tracks all changes, kept secure through unique password).
- How do you know if the record has been changed?

Test Article

- How was the investigational drug sent to the site?
- How was the investigational drug received by the site?
- What records are kept for this investigational drug?
- What was your role in preparation and dispensing the investigational agent?
- How was the test article stored?
- Where was the investigational drug prepared and dispensed?
- Can you show me the records of the storage and shipment of the investigational drug?
- How is the investigational drug labeled?
- Who labels the investigational drug?

Closing Meeting & Compliance Evaluation

After an inspection, the FDA determines if the areas evaluated are following applicable laws and regulations. During the closing meeting, the PI and appropriate compliance representatives should be in attendance. The PI can address observations, provide corrective action steps to be implemented and actions to prevent future occurrences.

There are 3 classifications that may follow:

- **No Action indicated** - No objectionable conditions or practices were found during the inspection (or the objectionable conditions found do not justify further regulatory action.
- **Voluntary Action Indicated** - Objectionable conditions or practices were found but the agency is not prepared to take or recommend any administrative or regulatory action. This may lead to discussion at the close out.
- **Official Action Indicated** - Regulatory and/or administrative actions will be recommended. This is where form 483 will be issued for a violation of the FDA's regulations/requirements. A response to the FDA is due within 15 days.

A **Warning Letter** is issued if the auditing FDA Center believes that a serious violation of FDA regulations/requirements may exist based on the information collected during and after the audit (including the response to the Form 483). A response to a warning letter is required in the timeframe specified within the letter. The PI should review each violation and discuss them in detail with inspector(s), make corrections if possible, and describe the next steps, such as corrective actions with timeframes for resolutions.

Resources & Helpful Links

- FDA BIMO Compliance Program for Clinical Investigators and Sponsor-Investigators: **https://www.fda.gov/media/75927/download**
- FDA Information Sheet on FDA Inspections of Clinical Investigators: **https://www.fda.gov/media/75185/download**

Research, Innovation & Impact

Quality Assurance – A unit of Research, Innovation & Impact | (520) 621-5196 | **bpernic@email.arizona.edu**