Common FDA Audit Findings: How do you find them before the FDA does?

By

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Master of Science

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Abstract

The Institutional Review Board of every hospital/research institute oversees that clinical investigators and staff participating on a research study are following institutional and Food and Drug Administration regulations, in order to protect the welfare and safety of human subjects. The very basis of a research project, the protocol and consent form are approved by the IRB and only then is research conducted. Following that, forms such as financial disclosures and curriculum vitae are collected in order to make sure there isn’t any bias in the research activity and that the clinicians are qualified. It’s important to note that even with so many checks and balances, while conducting an audit, FDA has observed numerous violations by institutions, come an audit. In order for institutions and clinicians to keep their credibility, it’s crucial to identify where the mistakes are being made and how to correct them before the FDA finds them.

The results in this paper indicate that, the FDA Bioresearch Monitoring Program has found: failure to follow the investigational plan, inadequate case history records, and consent form not approved/signed/dated as the most frequent inspection observations between fiscal years 2015 to 2018. Therefore, these are the areas of focus before an FDA audit.
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Introduction

The Federal Drug Administration is required to ensure clinical studies are conducted in accordance with laws, regulations and the best protection of human subjects. This paper explores the different findings of FDA audits in medical research programs to obtain an understanding of how common certain findings are, and develop an approach to find them before an FDA audit does.
Review of Literature

“Biomedical research is conducted for the purpose of systematically collecting and analyzing data from which generalizable conclusions may be drawn that may aid in improving the care of currently unknown beneficiaries in the future. The chief role of human participants in research is to serve as sources of needed data. This is a different situation than ordinarily occurs in clinical medicine, in which diagnostic or therapeutic interventions are suggested or carried out solely to benefit the current patient. Consequently, although many ethical issues overlap between the realms of research and clinical medicine, the ethics concerns in human subjects research are not identical to those arising in the diagnostic and therapeutic context” (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1860367/).

The significance of human subjects research training is such that “Beginning on October 1, 2000, the NIH required education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects. To bolster the Federal commitment to the protection of human research participants, several new initiatives to strengthen government oversight of medical research were announced by HHS Secretary Shalala on May 30, 2000. Before funds are awarded for competing applications or contract proposals involving human subjects, investigators must provide a description of education completed in the protection of human subjects for each individual identified as “key personnel” in the proposed research. Key personnel include all individuals responsible for the design and conduct of the study” (https://grants.nih.gov/grants/guide/notice-files/not-od-00-039.html).
“The Food and Drug Administration is charged by statute with ensuring the protection of the rights, safety, and welfare of human subjects who participate in clinical investigations involving articles subject to section 505(i), 507(d), or 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i), 357(d), or 360j(g)), as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA, including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products” (https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm118893.htm).

“FDA regulations that govern clinical trials establish specific responsibilities for clinical investigators (CI, also the principal investigator or PI), sponsors, and Institutional Review Boards. These regulations ensure the proper conduct of clinical trials whose data are intended for submission to FDA and for the protection of the rights and welfare of subjects enrolled in those trials” (https://www.centerwatch.com/news-online/2016/01/01/fda-irb-inspections/).

The National Institute of Mental Health website states issues to consider when conducting human research. It specifically outlines what the grant application must include involving human subjects. Some of the information it specifies is a section that needs to be labeled “Protection of Human Subjects” which should state the risk and what steps will be taken in order to protect the subject. Another important factor is that of mentioning the inclusion of minorities, women and children, and if necessary why a certain group of people might be excluded in said research.

**What does the FDA do and why?**

“The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and
medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation…FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health” (https://www.fda.gov/aboutfda/whatwedo/).

For the purposes of this proposal, this paper will focus on human subjects’ research, the more common areas of noncompliance and how to avoid noncompliance before it occurs.

**What is an audit?**

An audit is “A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed and accurately reported according to the protocol, sponsor’s standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s)” (Hochman and Choi, http://www.feinsteininstitute.org/wp-content/uploads/2014/09/PREP-27_2014-2015.pdf).

**Types of Audit Findings**

There are basically two types audits, routine and for-cause:

“Routine audits can be performed by the sponsor, IRB, FDA or internal quality assurance department. The goal of an audit is to review, inspect and verify the ethical conduct of human
subject research, integrity of previously reported data, adherence to the study protocol, and applicable institutional, state and federal regulations and guidance’s. Most audits involve the review and inspection of informed consent forms, documentation of the consent process, reported data, regulatory records source documents to ensure protocol compliance and drug accountability records…For-cause audits may be conducted if during the monitoring process a sponsor has continual documented accounts of possible noncompliance, data discrepancies or concerns over the ethical conduct of the study by the investigator. The sponsor may contact the FDA and report these concerns which could result in a for cause FDA audit Study participants could also contact the FDA and report these concerns which could result in a for cause FDA audit. The IRB and sponsor can also perform a for cause audit”

(https://ccts.osu.edu/content/audits).

**Examples of Audit Findings**

There are multiple examples of audit findings. Some of which include:

1. Use of an incorrect version of the consent form, inadequate documentation of a consent or performing study procedures prior to obtaining consent
2. Missing essential documents, such as, Clinical Trial Agreement, approval by FDA, Delegation of Authority log (where it lists study staff and their responsibilities), etc. This can lead to lack of documentation of an adverse event assessment
3. Lack of training documentation and delegation of tasks assigned to personnel not licensed or qualified to perform those tasks.
4. Protocol non-compliance, where there are missed visits, procedures, and failure to report deviations.
5. Subject records have missing source documentation, incomplete assessments and incomplete questionnaires

While there are others, in this paper, the focus will be on the more common issues amongst others.

**Previous Attempts**

Previous attempts in order to avoid a finding or 483 (a form used by the FDA to document concerns during audits), have been corrective and preventative actions (CAPA) placed in order to properly execute and document research. Whenever investigators and other research staff have deviated from the protocol, CAPAs have been used to identify the root cause of that issue and what preventative action to take to avoid the same error from occurring again. “CAPAs are improvements to an organizations processes taken to eliminate the causes of non-conformities or other undesirable situations…it focuses on the systemic investigation of the root causes of identified problems or risks in an attempt to prevent their recurrence (for corrective action) or to prevent occurrence (for preventative action)”


Although CAPA is not a part of FDA regulations guidelines, it’s what keeps institutions in check of all processes being documented. The idea is to collect information and on an issue and prevent its recurrence.

It’s not to say that CAPA doesn’t come with its faults. “Poor CAPA investigations continue to be among the top deficiencies issued to companies within the clinical research industry, resulting in

There have been instances where researchers have failed “to adequately document corrective and preventive action (CAPA) programs…CAPA capabilities are often the first thing a U.S. Food and Drug Administration (FDA) expert will examine when onsite. Deficiency in this area is usually the most cited issue in Warning Letters across all aspects of industry, including medical devices, pharmaceuticals, and clinical trials. In a recent Warning Letter to a clinical researcher, FDA acknowledged the firm said it had addressed shortcomings and taken corrective action” (https://acrpnet.org/2016/01/07/fda-inspectors-demand-capa-documentation/).

i. When are clinical investigator audits conducted?

Clinical Investigator inspections are regularly and often randomly conducted to ensure that investigators are conducting clinical studies in accordance to regulatory requirements. The investigators must allow the FDA access to records with regards to the investigational product as well as the subject’s medical history to verify any reports made on behalf of the investigator. The FDA inspector documents how the study was/is being conducted at the site with the records retained at the site even two years after completion of the study.

“FDA conducts both announced and unannounced inspections of clinical investigator sites, typically under the following circumstances:
• to verify the accuracy and reliability of data that has been submitted to the agency;

• as a result of a complaint to the agency about the conduct of the study at a particular investigational site; in response to sponsor concerns;

• upon termination of the clinical site;

• during ongoing clinical trials to provide real-time assessment of the investigator’s conduct of the trial and protection of human subjects;

• at the request of an FDA review division; and

• related to certain classes of investigational products that FDA has identified as products of special interest in its current work plan (i.e., targeted inspections based on current public health concerns)  

ii. How are Clinical Investigator Audits Conducted?

When an FDA inspector arrives at an institution, he/she will provide identification and a Notice of Inspection to the investigator and study staff. Under the Federal Food, Drug, and Cosmetic Act section 704, the FDA can inspect and copy and records related to the clinical investigation. During the inspection the FDA inspector can verify if a site is compliant with use of the investigational product as well as human subject protection by looking at these records and speaking with members of the study team. Some of the aspects of the study that the inspector confirms is who performed activities on the study? Were these individuals qualified to perform these tasks? Next the inspector checks whether the Institutional Review Board has approved the protocol, consent form and other related documents to the study. They have to make sure that the protocol was followed appropriately and any deviations were documented to the IRB.
Furthermore, does the clinical investigator have any financial gain when it comes to the investigational product. A sponsor may be a company that has a contract with the research institute and a sponsor may send a monitor to make sure all the regulations are being followed in the beginning, interim and end of a trial. The FDA also checks the communication between the site and the monitor to get insight on the progress of the study. Finally, if there is room for improvement, what corrective actions were taken to rectify the errors made.

Thus far, the literature review has established the FDA’s responsibilities and why audits are conducted, what an audit is, the different types of audits and what methods institutions have implemented to avoid audit findings. Furthermore, this section covers under what circumstances audits are conducted and how they are conducted.
Problem Statement

Even though the IRB provides oversight of clinical studies, FDA audits find problems in how the studies are being performed. To help ensure the best possible research and avoid the FDA from discovering issues, an approach to finding potential issues prior to FDA audits needs to be developed.
Methodology

An analysis of documents and personal experience were used to develop an internal checklist to proactively identify potential FDA audit findings.
The FDA’s BioResearch Monitoring Program (BIMO) has found the most common audit findings in the past four years, as indicated above.

Based on documentary analysis, the following common audit findings were discovered: collecting/recording informed consent correctly, compliance with the protocol/investigational plan, which mostly includes regulatory compliance, and missing case history documentation that can be linked to an adverse event discovery.

Each of the findings indicated above are very common and often overlooked before an FDA audit. “The FDA has numerous regulations that govern clinical research – but they tend to be the
same rules that trip up research sites and result in compliance violations. From inadequate
informed consents to protocol deviations to problems with drug or medical device accountability,
the FDA is repeatedly citing facilities for the same issues – which can result in warning letters,
debarments, or even having a trial shutdown” (http://www.hcpro.com/HOM-35000-
1303/Sidestepping-the-five-most-common-FDA-compliance-pitfalls.html).

Other institutions that have discovered the same common audit findings as indicated in the
chart above include:

One case study suggests, The Feinstein Institute for Medical Research had an FDA Inspection. It
was found that the PI didn’t supervise the protocol delegated tasks adequately and the following
was determined: “FDA inspection occurred in June 2013 and protocols were reviewed for
compliance. It was found that the site failed to personally conduct or supervise the clinical
investigations 21 CFR312.60 and failed to obtain informed consent in accordance with the
provisions of 21 CFR part 50 [21 CFR312.60 and 21 CFR 50.20].”

A warning letter was issued on February 21, 2014 that stated “When the PI signed the Statement
of Investigator (Form FDA 1572) for the above-referenced clinical trials, they agreed to take on
the responsibilities of a clinical investigator at your site. The general responsibilities as a clinical
investigator include ensuring that the clinical trials are conducted according to the signed
investigator statement, the investigational plan, and applicable regulations; protecting the rights
safety and welfare of subjects under your care; and ensuring control of drugs under
investigation.”
The same institute also commonly failed to obtain consent form in accordance with FDA regulations. “Informed consent wasn’t obtained from 28 of 50 subjects enrolled in the protocol. 10 subjects were enrolled and given investigational drug prior to each signing the informed consent” (http://www.feinsteininstitute.org/wp-content/uploads/2014/09/PREP-27_2014-2015.pdf). Due to serious non-compliance and inappropriate informed consent process, the protocol was suspended and all 50 subjects in the trial were notified. Failing to obtain informed consent before having the subjects perform study tasks can be a risk to the safety and welfare of subjects. In this case study the two most common audit findings are what the FDA discovers.

The main common audit findings and their reasons as found in this paper are listed below:

1. Informed consent process and documentation
   a. Incorrect consent version was used to consent subject
   b. No source documentation of the consent process and the subject did not receive a copy of the consent
   c. Consent was not dated or initialed by the subject
   d. There is missing information in the consent, no HIPAA authorization
   e. Subject was not reconsented when amendment made in protocol or long time between subject signing consent and start of participation

2. Protocol Non-compliance
   a. Changes are made to the protocol without obtaining IRB approval
   b. There’s no documentation of reason for missing tests, appointment changes.
   c. Incorrect delegation of duties/missing delegation of authority log
d. Missing records/poor record storage

3. Adverse Event Reporting
   a. Conflicting data between Study Case Report Forms and subject’s medical record.
      An example: AE is noted in medical record but not on study case report form or vice versa.
   b. AE wasn’t signed and graded a severity by PI. AE wasn’t sent to IRB or sponsor in a timely manner
   c. Failure to follow the reporting requirements

Checklist on How to Survive an FDA Inspection:

Below is a checklist created for internal audits to prevent audit findings. This checklist was developed based on multiple institutions having to answer the same questions when an FDA Officer visited. This checklist has been reviewed by multiple researchers in the process of preparing for an FDA audit.

   o Was the Principal Investigator, study team, IRB and Sponsor informed of the FDA arriving?
   o Was a private conference room reserved for the FDA investigator to work? The room must have internet access, a photocopier and a rest room nearby. One of the research personnel should be in a close by office as well.
   o Is this room available for 2-10 business days? Make sure those working near the room know that there’s an FDA investigator is on site and that they be quiet and respectful.
   o In order to prepare for the inspection:
- Are all the regulatory binders organized?
- Are all IRB and Sponsor correspondence printed and accessible to the inspector?
- Have all the subject files been reviewed for completeness?
- Has any of the data been changed? DO NOT change any data! Make sure there’s a note to file if there was any change made. The original document should stay the same as the FDA loves paper trails!! That’s how they catch mistakes!
- Is there a list of adverse events prepared? Ensure, that there’s a list of adverse events (a harmful effect that may occur from medicine or surgery during the time of a research trial) and protocol deviations (any time the protocol was not followed due to certain circumstances e.g. patient not will, patient cannot come in for a visit). Make certain these are explained and submitted to the IRB in a timely manner.
- Have all the records been reviewed? This includes patient charts, files shared with the Sponsor and reviewing the investigational product. He can request additional documents and information. He/she may even interview certain study personnel and ask to clarify questions. The institution needs to be prepared for this!
- Documents that are reviewed:
  - 1572/Investigator Agreement
  - Appropriate delegation of study tasks to team members by the PI
  - IRB submission
  - Protocol versions approved by IRB
  - Sponsor correspondence
  - Consent form versions approved by IRB
- Enrollment logs (subject recruitment)
- Monitoring activities and reports
  - Some subject records that are reviewed include:
    - Hospital records, lab reports
    - If the subject was eligible and justly added to the study
    - The protocol was followed and any deviations from it were reported
    - If the appropriate consent form was signed and the subject willingly participated
Conclusions

Common findings have been determined and now in order to avoid mistakes, research has shown it’s important to understand the protocol design and focus on following it accurately, and making sure to only include those subjects that qualify according to the inclusion/exclusion criteria. Further conclusions indicate that records need to be maintained, original documents should be preserved and the investigator needs to verify these, which are known as source documents. An institute should complete protocol required procedures, keep a regulatory binder and constantly be audit ready. Changes and corrections made to any documents must be signed and dated, if possible explained and should not obscure the original entry. There needs to be appropriate delegation of staff. Only qualified members need to be performing designated tasks. For example, staff obtaining the consent form must know the consent process and how to document this. Another important task is to record adverse events and look if there’s a trend. Be familiar with the protocol, what the adverse events reporting criteria is and crucial timelines.

Furthermore, in the common audit findings, as indicated in the results above, where collecting/recording informed consent is incorrect, there’s non-compliance with following the protocol and there’s missing source documentation has led to adverse event discovery, the following policies should be in place, so institutions can avoid audit findings.

In the consent documentation instance, “a note regarding the consent process, how it was conducted, whether questions were answered, and the fact that a signed copy was provided” to the subject can be a part of the resolution. Before starting the consent process, the staff member can make sure that the latest approved version from the IRB is being used. The consent forms should not be filled out in advance and HIPAA Authorizations must be included as a part of the consent.
Solutions for protocol adherence include reading the protocol “before starting the trial to make sure it is realistic and to identify differences between what protocol requires and what would typically be done in a treatment situation. If a protocol deviation occurs more than once, determine if protocol modification is appropriate. Document deviations and be aware of reporting requirements” (http://compliance.emory.edu/documents/AuditFindingsinClinicalTrials.pdf). When it comes to the delegation of duties log, make sure to review it with all study team members. Each staff should know what their respective responsibility is towards the trial. For record retention, always look at the Clinical Trial Agreement for document maintenance requirements.

Finally, when it comes to reviewing adverse events, it’s better to review them in real time. The Investigator should always be aware of the reporting obligations to the IRB and sponsor.

An online source reveals that electronic systems can also help with these common risks associated with source data. “An eSource system (such as CRIO) can include built-in procedure logic, which ensures accurate calculations and complete forms. The beauty of software is that it can do calculations and timestamps automatically, as well as alert the coordinator if he/she misses a question or enters a disqualifying patient attribute. In fact, a 3rd-party (non-FDA) review has shown our system to reduce protocol deviations by 50%, thus relieving much of the audit risk for principal investigators.
An FDA audit is a roller coaster of emotions that can happen at any time, but you can take precautions to reduce your chance of being audited and increase your chance of receiving no findings in the case you are audited. Most importantly, eSource enables all-around higher quality clinical trials” (Bedett, https://www.clinicalresearch.io/sites/blog/5-stages-fda-audit).
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http://compliance.emory.edu/documents/AuditFindingsinClinicalTrials.pdf
Employee Information

Saadia Rizvi is an experienced Research Program Coordinator with a demonstrated history of working in the higher education industry. Skilled in Epidemiology, Medical Drugs and Devices, and Healthcare Management. She has a little over a year of CRA experience which include therapeutic areas such as gastroenterology, women's studies, rheumatoid arthritis and neurology. She will be graduating with a Masters’ Degree of Science in Research Administration from Johns Hopkins University in May 2019.

Formal Educational History

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<td>Johns Hopkins University, United States</td>
<td>MS Research Administration</td>
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<td>In Progress Expected graduation: 05/2019</td>
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Employment History

Date of Employment: 11/2018 - Present  
Name of Employer: IQVIA on Assignment with ROCHE  
Job Title: Clinical Research Associate II  
Business Title: Clinical Research Associate II  
Key Responsibilities:

• Perform site selection (if applicable), initiation, monitoring and close-out visits in accordance with contracted scope of work and good clinical practice.
• If applicable, may be accountable for supporting development of project subject recruitment plan on a per site basis. Work with sites to adapt, drive and track subject recruitment plan in line with project needs to enhance predictability.
• Provide monitoring visits and site management for a variety of protocols, sites and therapeutic areas.
• Administer protocol and related study training to assigned sites and establish regular lines of communication with sites to manage ongoing project expectations and issues.
• Evaluate the quality and integrity of study site practices related to the proper conduct of the protocol and adherence to applicable regulations. Escalate quality issues as appropriate.
• Manage the progress of assigned studies by tracking regulatory submissions and approvals, recruitment and enrollment, case report form (CRF) completion and submission, and data query generation and resolution. May support start-up phase.
• Create and maintain appropriate documentation regarding site management, monitoring visit findings and action plans by submitting regular visit reports, generating follow-up letters and other required study documentation.
• Build awareness of features and opportunities of study to site.
• Collaborate and liaise with study team members for project execution support as appropriate

Date of Employment: 08/2017 - 08/2018  
Name of Employer: Syneos Health on Assignment with AbbVie Inc  
Job Title: CRA  
Key Responsibilities:

• Contacted and approved multiple new sites to participate in AbbVie studies
• Support in the in-house organization, management and execution of projects to ensure the clinical trials are conducted, recorded, and reported in accordance with the protocol, federal regulations and applicable local regulations
• Participate in the study startup activities and site opening activities as well as study conduct and site closure tasks.
• Manage the activities of clinical investigative sites across multiple protocols and multiple therapeutic areas.
• Ensure quality of data submitted from study sites and assures timely submission of data, including appropriate reporting and follow-up for all safety events by site personnel.
• Train study site personnel on the protocol and applicable regulatory requirements in collaboration with pertinent project team members. Appropriately escalate serious outstanding issues.

Date of Employment: 03/2014 - 07/2017  
Name of Employer: Johns Hopkins University/Medstar  
Job Title: Sr Research Program Coordinator  
Key Responsibilities: • Published abstracts that were accepted for poster presentation at the American College of Cardiology  
• Made our site third top enroller on a major study  
• Monitored internal PIs within different departments and prepared their teams for FDA audit  
• Responsible for the Institutional Review Board (IRB) submissions including new protocols, continuing reviews, reporting of adverse events, amendments, study completion/closeout  
• Facilitated the organization, entry, maintenance and accuracy of all clinical research data for detailed clinical trials and assists with orientation of less senior research staff in protocol and clinical research information  
• Develops and maintains a protocol database for tracking patient activity, financial management and data analysis.

Date of Employment: 02/2012 - 02/2014  
Name of Employer: Columbia University  
Job Title: Clinical Research Coordinator  
Key Responsibilities: • Facilitated the organization, entry, maintenance and accuracy of all clinical research data for detailed clinical trials and assists with orientation of less senior research staff in protocol and clinical research information  
• Develops and maintains a protocol database for tracking patient activity, financial management and data analysis.  
• Participated in sales of Heartmate II, Heartware and Jarvik heart pump devices in order for patients to receive best possible heart failure care.  
• Conducted prospect research to identify public sources of funding and
worked with staff to match funding sources with programs and submitted proposals to public funding agencies.

Publications, Doctoral Thesis

- Rizvi, Saadia Common FDA Audit Findings: How do you find them before the FDA does?

Other Relevant Information

Licenses and Certifications

- Expert GCP Accreditation Exam, on 07-Jan-2019, 2019