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A Case Study – Preparing for a Successful FDA Audit

A research site that was conducting clinical trials for a medical device had been very successful in recruiting participants. When the device company submitted their application to the FDA for approval, this institution received a call announcing an audit.

The research coordinator and investigator had a week to prepare. As part of BRANY's service to clients, a member from the quality team went to the research site to work with them to organize the documents for an efficient and orderly FDA review.

The research office and investigator had done a good job in documenting the trial and the institution used an electronic medical record. So the trial was thoroughly documented. However, some of the procedures had occurred over a year prior to the audit and the team needed to refresh their memory.

Also, the FDA auditor had requested all the documentation be printed rather than in electronic form. So materials had to be printed from the electronic medical record and organized appropriately.

BRANY's team organized and labeled all the information to facilitate the review. This can be a very labor-intensive process, . In this case, there were 14 subjects whose documents needed to be organized cohesively.

The FDA audit visit lasted several days and while there were several questions that came up, the investigator and research coordinator were fully briefed and prepared to answer the questions appropriately because they had reviewed the materials with our BRANY consultant.

The FDA audit went well and they successfully addressed any questions that came up.

Here are a few tips for a successful FDA audit:

Start with solid documentation. This research office started on a strong foundation of detailed documentation. While there had been some issues that came up during the trial, the documentation outlined how those issues occurred and managed.

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The Biomedical Research Alliance of New York (BRANY) provides support services to sponsors and investigators in a wide variety of therapeutic areas, medical devices, biologic and diagnostic trials. Staffed by multi-disciplinary experts, BRANY is an AAHRPP-accredited "end-to-end solution" for clinical trials.

BRANY is able to offer turnkey solutions for:

- Site identification
- Expedited study startup
- Payor coverage analysis
- Central IRB
- Monitoring & auditing

Organize each study subject. One of the most time-consuming efforts is organizing and properly labeling the materials. Do not rely on your electronic medical record to stand on its own. Because there are so many applications used by different institutions, regulators and auditors are not likely to want to navigate the software to find the information. The impetus is on the research office to extract and organize the information.

Provide a quiet office that can be used exclusively by the FDA auditor. Remove any distracting materials, files, and documents that are not related to the specific audit. Ensure that the auditor has free and exclusive access to this room throughout the period of the audit.

Have a copy machine nearby. Keeping a copy machine within easy distance will make it easier for the auditor to make any necessary copies without having to walk around your office.

Make a copy for yourself. Sometimes there are follow-up questions or comments after the auditor leaves the site. Keep a copy of all the materials you provided so you can easily reference them.

Refresh your memory. Review all the cases and review any issues that may have come up during the life of the trial. This will reduce your anxiety and risk of fumbling for answers should you be questioned.