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The New Investigative Site: Take Nothing for Granted

By Elizabeth Weeks-Rowe

Several years ago, I monitored sites for a simple, low-risk eczema study. One of my sites was new to clinical research, so I was often reminded how much training and experience new investigators and study coordinators need to become proficient. The following incidents illustrate the importance of keeping a close eye on new sites. They also show how to build an inventory of corrective and preventive action (CAPA) plans.

Incident 1. Study drug receipt and verification

Within a few minutes of arriving at the site, I was walking through the patient waiting area looking at investigational product stored in unlocked cabinets along with the over-the-counter aesthetic beauty products displayed for purchase by patients. Some of the cabinets were open and within close reach of patients.

As it happened, the receptionist was not expecting the study drug — why would she? — so she simply stocked the shelves as she would with any other product.

Problems:

- Study drug was stored with marketed product in a non-secure area with access by patients and non-research staff.
- An unqualified individual received and stored the study drug.
- This individual was not properly listed on the delegation of authority log.

Corrective actions:

- I instructed the study nurse to immediately store the study drug in a locked, secure area with limited access.
- I instructed the study coordinator to count the study drug to confirm that it was all present and accounted for.
- I assisted the study coordinator in faxing receipt notification to the sponsor.
- I instructed the study coordinator to add the receptionist to the site delegation of authority log for drug receipt and verification.
- I advised the study coordinator to train the receptionist on the correct procedure for study drug receipt and documentation, and to document the training on a training log and file it in the investigator site file.

Incident 2. Investigator signature on informed consent form

I observed that the investigator's signature was absent from the last page of all 12 executed informed consent forms (ICFs), contrary to IRB requirements.

Problem:

- Investigator was not signing the ICFs.

Corrective actions:

- I instructed the study coordinator to have the investigator sign and date all ICFs with the current date, with a note-to-file explaining the date discrepancy.
- I advised the study coordinator to report the ICF violation to the IRB.

Incident 3. Study drug assignment

In this study, the first subject randomized was assigned the first study drug tube, the second subject randomized was assigned the second tube, etc. Each tube was labeled with its corresponding randomization number. There was a 24-hour window between randomization and study drug assignment. The protocol specified that if a subject was randomized but then withdrew consent prior to study drug assignment, his or her tube would not be used, so subject randomization numbers would always correspond with the numbers on the tubes.

I noticed that five subjects had been randomized but only four tubes had been used. As it happened, Subject 001 withdrew from the study, so Subject 002 was assigned tube 001. The screening and enrollment log identified the subject as number 002, but the source documents and drug accountability log identified this subject as number 001. The investigator had considerately instructed the study coordinator to reassign tube 001 so it would not be wasted, not realizing the havoc such reassignments could cause.

Problem:

- Randomization and study drug assignment processes did not comply with the protocol.

Corrective actions:

- I instructed the study coordinator to explain what happened in a note-to-file.
- I instructed the study coordinator to attach a copy of the note-to-file to the screening and enrollment log to clarify the numbering discrepancy and also file it in the investigator site file.
- I instructed the study coordinator to add a late-entry notation to the drug accountability log explaining what happened.
- I retraining the investigator and study coordinator on the screening and randomization procedures, and ensured the retraining was documented on the site training log, which was filed in the investigator site file.

Conclusion

These are only three examples of the many problems I observed and remedied at this site. Even the simplest things may not be obvious to a new investigator or study coordinator — we were all there once. Experienced sites had fewer problems, but none had zero problems. Many of the CAPA plans proved useful at multiple sites. (Not all of the plans were as simple as those in the examples above.) All of my sites completed the study, and I hope they have continued in clinical research.

Author

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