Safeguarding the Science: Best Practices for Investigational Drug Documentation and Management

QA Webinar Q&A

06/30/2026

Question: Are all these common findings hard stops in Aurora so we can't omit? Can the system automatically check the lot # with what was sent?

> ***Answer:*** Aurora provides end-to-end accountability tracking. When using eDARFs from Aurora, it starts accountability from drug ordering through dispensation and destruction. All of this information is already in Aurora for each specific treatment, which helps reduce the need for manual transcription and minimizes the risk of transcription errors.
>
> However, this is not a perfect system and there is still room for human error when managing inventory. For example, if the user selects the incorrect quantity received or the wrong transaction type, an inventory discrepancy may occur. Overall, the system can significantly reduce the likelihood of errors, but the user must ensure that the correct information is entered and the appropriate transactions are selected.

Question: If we are reconciling our monthly inventory on a spreadsheet for quantities and expiration dates, should we be documenting this activity in Aurora, too?

> ***Answer:*** Ideally, yes if you are using an Aurora electronic drug accountability form. I think it would be best practice if everything is in the same system. Aurora does have a transaction function that does inventory review, so I think that is a feature that you can use to reconcile or do your monthly inventory check. Many sites use a commercial electronic inventory system, so the Aurora eDARF is often only used for ordering drug. In terms of drug accountability recording, the site can still use either a commercial system or paper.

Question: With the studies that were given as examples, the adherence percentage for males and the overall adherence rate for each study were reported. Were statistics also analyzed comparing adherence or compliance between males and females, and was there a higher percentage for either group? Additionally, was the involvement of a significant other evaluated to determine whether having someone assist patients in taking their medication improved adherence? Did any of the studies include surveys asking whether interventions such as medication instructions, pill diaries, or follow-up appointments, as recommended by the guidelines, made a difference in patients' compliance?

> ***Answer:*** For the purposes of this session, only the overall adherence data and their outcomes were reviewed. However, there was breakdown depending on patient characteristics such as male vs female. The references provided in the slides should be able to provide you with the information you are requesting.

Polling:

1. *Which of the following is the MOST common root cause of investigational drug accountability findings during inspections?*
    a. Temperature excursion
    b. Drug theft
    c. Documentation deficiencies
    d. Incorrect storge location

    Answer: C. Documentation deficiencies

2. *What should the current inventory be?*
    a. 10
    b. 11
    c. 12
    d. 13

    Answer: C. 12

3. *What is the most appropriate way to manage this situation?*
    a. Accept the pill diary as accurate and continue treatment without changes?
    b. Document non-adherence, reconcile discrepancies, and address nausea with supportive care and patient re-education
    c. Ignore drug accountability since patient-reported adherence is more reliable
    d. Discontinue the patient from the study due to non-adherence
    e. Only update the pill count and do not modify clinical management

    Answer: B. Document non-adherence, reconcile discrepancies, and address nausea with supportive care and patient re-education