



20 Ways to Improve Your Pharmacy Audit

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For CALGB Participants Only

20: Notification

- Notify pharmacy person (may be pharmacist, pharm tech, nurse, etc) responsible for INDs of scheduled audit
- Verify the responsible pharmacy person will be available and working day of audit

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19: Shipping Invoices

- When shipment of IND arrives, verify contents with shipping invoice
- If shipping invoice not provided, notify PMB or other supplier
- Provide shipping invoices as documentation of shipment – organized per study
- Note date IND received on shipping invoice

18: NCI Transfer Approvals

- Check with supplier on Industry supplied IND agent – transfer may or may not be allowed
- Provide NCI approvals for transfer of IND drug from one protocol to another using same IND agent

17: Return Drug Forms

- Provide NCI or supplier return IND forms for all returned drug
- Note NCI or supplier return on DARF
- Subtract vials/bottles returned from DARF balance

16: Labeling of INDs

- Label all containers (boxes, plastic bags or other containers) with protocol number, drug name, and drug strength (i.e., 100mg or 500 mg)
- Label should be clearly visible
- Maintain separate storage for investigational drug versus commercial drug

15: Storage Area

- Investigational drug should be kept in a secure storage area behind a locked door
- Only select personnel should have access to the investigational drug
- General public should not have access to storage area

14: DARF

- Utilize the most current NCI Investigation Drug Accountability Record Form (DARF)
- Current form can be located and completed with protocol information at:
<http://ctep.info.nih.gov/forms/index.html>
(bookmark this page)

13: DARF Completion

- Complete the top section of the DARF with the institutional identifying information and with protocol specific information – no section should be left blank
- Best if done with word processor on-line so that information is legible

12: DARF for Each Drug

- Verify drugs utilized in the study are either provided/investigational or commercial
- Maintain a separate DARF for each drug utilized in the study

11: DARF for Each Drug Strength

- Maintain a separate DARF for each strength of drug
- Verify the supplied strength of each drug; i.e., may be supplied in 100mg, 200mg, and 500mg
- Note mg/ml provided in protocol on DARF

10: Lot Numbers

- Record lot #(s) for each shipment on DARF
- If multiple lot #s, enter separately on DARF
- Utilize “Julian date” if lot # is not provided on vial/bottle

Julian date = year + day of year;

i.e., 08 024 = Jan 24, 2008

9: Receipt of IND on DARF

- When drug shipment is received, note day on DARF after drug unpacked from shipping box
- Log in as “Received from NCI” or other supplier
- Note number of vials/bottles received
- Sign out drug to patient after entering receipt of drug

8: Transfer on DARF

- Note drug transfer from one protocol to another on DARF after NCI approval
- Make notation of transfer on DARFs for both protocols
- Add the number of vials/bottles to one DARF while subtracting the number of vials/bottles from the other DARF when transferring IND

7: Return Drug on DARF

- When drug is returned to NCI or other supplier, make notation on DARF
- Record date drug returned to NCI or supplier
- Note when drug is returned/destroyed per protocol directions; i.e., expired drug or per supplier request
- Note and subtract number of vials/bottles returned from balance

6: Dispensing Drug for Patient Treatment

- Keep DARF in same area as investigational study drug
- Complete all boxes on DARF
 - dose should be recorded in mg or units
 - quantity received should be (+) vials, etc
 - quantity dispensed should be (-) vials, etc
- Helpful to keep list of all pts in pharmacy

5: Study Closure

- Communicate promptly to responsible pharmacy personnel when study closes or if patient expires or stops treatment
- After study closure, return study drug within 90 days of study closure or when last patient is treated with study drug

4: Double Blind Studies

- Maintain patient specific DARF on double blind studies as directed in protocol
- Note patient initials and patient ID # at top of DARF
- HINT: If shipping invoice notes patient initials or other identifiers, then patient specific DARF should be utilized

3: Internal Audit

- Verify balance on DARF matches shelf inventory
- Perform internal audits on all investigational study drug
- Ideally should be done monthly so that errors or omissions can be caught promptly

2: Satellite Pharmacy/Clinic

- Transfer of investigational study drug from the main institution to a satellite should be noted on the DARF as number of vials/bottles
- Satellite DARF notes receipt of drug transferred from main institution
- Satellite DARF records dosage of drug given to patient at the satellite location

1: Correcting DARF Errors

- No “White Out”
- No “markovers”
- No “black outs”

(Be sure to line through error,
initial and date)

Resources

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