What Can You Do Now to Prepare for Pharmacy Audits?

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Alliance Spring 2016 Group Meeting

Objectives

- Identify common non-compliant issues.
- Identify correct procedures for IND handling.
- Explain how daily activities help prepare for pharmacy audits.
- Correctly complete DARFs and Oral DARFs.

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Most Common Non-compliant Pharmacy Audit Issues

1) DARF not completely & correctly filled out:

- Header boxes left blank (i.e., CTEP #)
- Required entry columns left blank (i.e., doses)
- DARF should not contain write-overs or scratch-outs, white out, or erasures, but rather have single line through errors, initial, and date

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National Institutes of Health
National Cancer Institute

Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

PAGE NO.
CONTROL RECORD ☐
SATELLITE RECORD ☐

Investigational Agent Accountability Record

Name of Institution:	NCI Protocol No.:
Agent Name:	Dose Form and Strength:
Protocol Title:	Dispensing Area:
Investigator Name:	CTEP Investigator ID:

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								

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Most Common Non-compliant Pharmacy Audit Issues

Con't: DARF not completely & correctly filled out:

- DARFs maintained lot specific, rather than DARFs maintained only for each drug & strength
- All entry columns have not been completed
- eDARF does not match NCI DARF, i.e., must be able to print e-DARF to look identical to NCI DARF

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Most Common Non-compliant Pharmacy Audit Issues

2) Oral DARFs are not maintained when drug is supplied as p.o. drug

- Transfer to Oral DARFs must be completed (required as of Sept 1, 2014 for all studies)

NOTE: Oral DARF:

1) Header is different from the original in two ways: Local protocol #-leave blank or write NA if there is no local #; and Bottle size.
2) Contains columns for pt drug returns

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Print Form | Save As | Reset Form

Investigational Agent Accountability Record

Oral agents ONLY

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Division of Cancer Treatment and Diagnosis
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PAGE NO. 1
CONTROL RECORD ☒
SATELLITE RECORD ☐

Name of Institution:	Investigator Name:	CTEP Investigator ID:
State University Hospital	John Smith, M.D.	999999

Protocol Title:	NCI Protocol No:	Local Protocol No:	Dispensing Area:
Phase 2 trial of pazopanib for the treatment of patients with advanced renal cell carcinoma.	1234	SUH-001	IDS Pharmacy - 5th Floor Room A100

Agent Name:	Dose Form and Strength:	Bottle size (e.g., # tablets/bottle):
Pazopanib hydrochloride (NSC 737754)	200 mg Tablets	34 Tablets/bottle

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
1.	3/21/2014	Received from the NCI			+ 8	8	GLX 12345678	AB				
2.	3/24/2014	AZ	1234-001	800 mg daily	- 4	4	GLX 12345678	AB		4/24/2014	16 tabs	AB
3.	4/24/2014	AZ	1234-001	800 mg daily	- 4	0	GLX 12345678	AB		5/24/2014	1 bottle	ZA

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Most Common Non-compliant Pharmacy Audit Issues

3) DARFs not maintained on a timely-basis

- Dispensing of drug is entered before the receipt of drug is entered on DARF
- Shelf stock review determines less drug on shelf than listed on DARF – discovery of drug dispensed without noting entry on DARFs

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Most Common Non-compliant Pharmacy Audit Issues

4) NCI supplied drug is re-packaged and shipped to patient or satellite pharmacy

- May be transported by Research Personnel, the Physician, or a certified courier service; May NOT be repackaged and shipped by Fed Ex, UPS, etc.

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Most Common Non-compliant Pharmacy Audit Issues

5) NCI-supplied agent not stored separately by protocol, strength, dosage form

- Study drug stored in baggies with patient's ID for study that is open-labeled, not supplied patient specific
- Patient returned drug stored with drug that can be dispensed

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Recent Unacceptable Pharmacy Audits

Example #1

1) Five NCI DARFs were not completely and correctly filled out.

2) One drug receipt was missing.

3) Expired drug on shelf from November 2014. Patient had progressed on treatment 10 months ago.

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Recent Unacceptable Pharmacy Audits

Example #2

- The three studies reviewed maintained DARFs as pt specific DARFs, when drug is open-labeled (i.e., not supplied per pt. ID)
- Once pt completed therapy, remaining agent was transferred to a "Generic stock for off-study patients" DARF.

>> This led to an abundance of 228 syringes!

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Recent Unacceptable Pharmacy Audits

Example #2 (con't)

- Late entries on control and satellite DARFs. (Entries were not made in real time.)
- Pt ID left blank on several entries.
- Corrections not lined through, initialed, or dated.
- DARFs do not have page numbers, protocol titles, NCI investigator numbers, or control box checked.

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Recent Unacceptable Pharmacy Audits

Example #3

- DARF header page number and control box not completed.
- Pt specific Oral DARF used when drug is supplied open labeled.
- An entry transfers 1 bottle to stock. There was no stock DARF.
- This bottle was entered onto a different pt specific DARF.

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Recent Unacceptable Pharmacy Audits

Example #3 (con't)

- Storage - No separation between pt returns and current supply and no pt ID on returned drug baggies.
- Bottles stored in individual baggies labeled w/ pt name. Drug is not supplied by pt.
- There is no procedure in place to verify authorized prescribers.

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Recent Unacceptable Pharmacy Audits

Example #4

- Original DARF was transcribed to a cleaned up version, since original DARF contained many write overs and scribbles.
- The transcribed version left off an entry for in-house treatment on 2/12/2015.
- Shelf stock did not match DARF balance.

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Recent Unacceptable Pharmacy Audits

Example #5

- No DARFs or shipping records were available for audited patient. The site believes that these records were inadvertently destroyed. Therefore, there are no source documents for the handling of this IND agent.

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Recent Unacceptable Pharmacy Audits

Example #6

- Dispensing on 02 JAN 2014 was not recorded until after 03 SEP 2014.
- Last dispense date was 15 SEP 2014 and the study closed to accrual 08 DEC 2014. One vial remains in stock 11 months later.

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Recent Unacceptable Pharmacy Audits

Example #7

- Site does not maintain the required NCI Drug Accountability Reporting Form to track the receipt and disposition of study supplied drugs. Only drug orders and receipts were available.

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What are some Tricks of the Trade?

- Tricks for 90 day return rule:
  - ***Communication w/ Pharmacy is Key!*** Staff should inform Investigational Pharmacist when pts go off study *and* of study closures
  - Include Pharmacist in research meetings
  - Pharmacist should periodically review list of site active trials
  - Subscribe to PMB listserv: Use PMB Newsroom to subscribe: http://ctep.cancer.gov/branches/pmb/pmb_newsroom/

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NIH-986 (REV. 2/97) 03/09

National Institutes of Health — Division of Cancer Treatment and Diagnosis
National Cancer Institute — Cancer Therapy Evaluation Program

Return Drug List

Return only agents supplied by:
CTEP, DCTD, National Cancer Institute

The agents listed below were ordered by (one investigator per form only):

Dr.

NCI Investigator No.:

Address: (Including Institution)

☐ **Check here if returned receipt should be mailed to the above address, OR fill in a fax number below**

FOR NCI USE ONLY

Return. No.:

Signature of Authorizing Official:

Date of Authorizati...

	NSC Number	Agent Name	NCI Protocol Number	Strength & Formulation (Specify vials, capsules, or tablets)	Lot Number (or Patient ID for Blinded Trial)	Manufacturer	Quantity (Specify whole or partial containers)	Container Number	Action
1									
Reason for return:	☐ Lot expired	☐ Protocol closed/complete	☐ IND withdrawn/inactivated	☐ Patient cross over	☐ Patient expired/went off treatment	☐ Unsuitable			
2									
Reason for return:	☐ Lot expired	☐ Protocol closed/complete	☐ IND withdrawn/inactivated	☐ Patient cross over	☐ Patient expired/went off treatment	☐ Unsuitable			
3									
Reason for return:	☐ Lot expired	☐ Protocol closed/complete	☐ IND withdrawn/inactivated	☐ Patient cross over	☐ Patient expired/went off treatment	☐ Unsuitable			
4									
Reason for return:	☐ Lot expired	☐ Protocol closed/complete	☐ IND withdrawn/inactivated	☐ Patient cross over	☐ Patient expired/went off treatment	☐ Unsuitable			

REPOSITORY COMMENTS

Date Received:

INSTRUCTIONS:

1. Properly complete all sections to receive credit for the return.
2. Type all information-one item, lot, or protocol per line.
3. DO NOT mark in shaded areas.
4. Investigator signature or signature of individual preparing this form:

Signature / Printed Name *Date*

Title *Phone No.*

5. Pack the agent(s) well to minimize breakage and leakage.
6. All agents may be returned via room temperature
7. Enclose the completed list with the agent(s) and return to:

NCI Clinical Repository
627 Lofstrand Lane
Rockville, MD 20850
Attn: Returns

RETURN RECEIPT: To obtain a return receipt by fax, provide your number in the space below.

FOR NCI USE ONLY

What are some Tricks of the Trade?

Tricks for communication between study staff and pharmacy:

1) Notify pharmacist when pt is given ICF, but f/u if pt enrolls or not

2) Research staff provides a monthly list of active patients to pharmacist

3) Double count returned # of pills by CRP and pharmacist

4) Sharing of more tricks?

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What are some Tricks of the Trade?

Compliance item:

Assure DARFs are patient specific vs study specific.

Trick:

Review protocol to see how drug should be ordered. Review drug receipt to see if drug is supplied w/ pt identifier # and initials.

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What are some Tricks of the Trade?

Compliance item:

Expired drug on hand > 90 days, and to prevent over-stock of drug supply.

Trick:

Order drug under one investigator per protocol for open label drugs to minimize the number of DARFs needed. Also, use transfer form to transfer drug to another study when possible.

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Activities to help prepare for pharmacy audits

- Check out CTMB Guidelines section 5.3
- View PMB training videos – seven 5-6 min segments

http://ctep.cancer.gov/branches/pmb/drug_training_videos.htm

- PMB website FAQs
- In-house audits using audit forms from Alliance website or CTMB website

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New Expiration Date on NCI DARF & Oral DARFs

Note: Old DARFS expired 3/31/2016

NEW DARF and Oral DARF expiration date is: **03/31/2019**

Even though no changes were made, the new DARF and Oral DARF should be used when starting a new page or a new study.

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You too can complete compliant DARFs and Oral DARFs!

- Small group discussions to find common DARF errors

Q&A

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Thank you!

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