Audit Pharmacy Review

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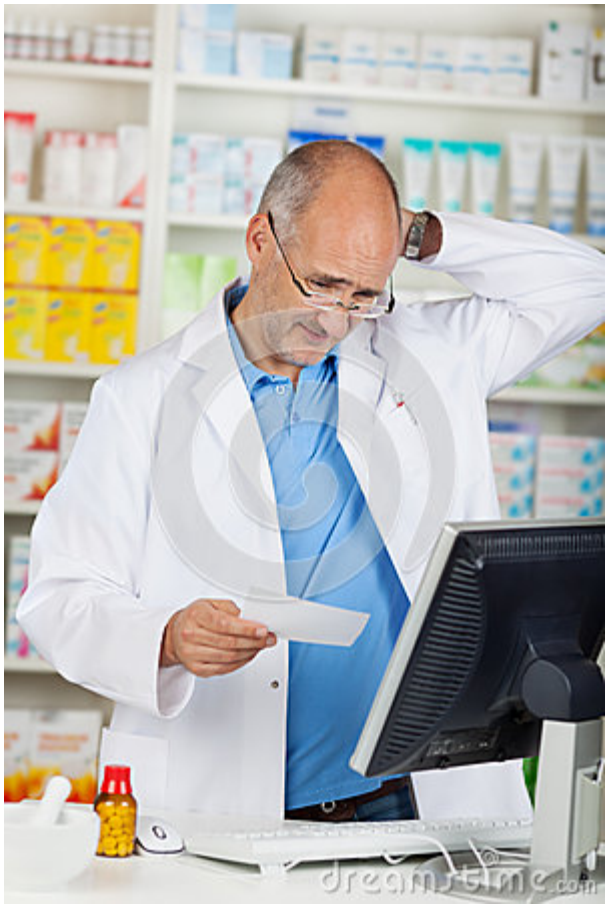
Alliance for Clinical Trials in Oncology, Chicago Office

Audit Workshop, November 5, 2015



So let’s try to help sort this out…

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Presentation Objectives

- Security
- Stability
- DARFs ~ Drug Accountability Record Form
  - DARF
  - Oral DARF
  - eDARF
- Audit

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Security

- Access to Pharmacy
  - Who has access?
    - Security
    - Research Staff
    - Housekeeping personal
  - Locked Unit?
    - Badge Access
    - Key

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Security

- Authorized Prescribers
  - CTEP Registered
  - How often is list updated?

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Storage

- Temperature monitoring
- Alarm
- Shelf storage
  - Research separate
  - Returns separate
    - How are returns handled

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DARFs

- Drug Accountability Record Form
- Used to track the disposition of investigational agents used for NCI clinical trials
- Forms found on CTEP website: http://ctep.cancer.gov/forms

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DARFs

- Original DARF
- Oral DARF
- eDARF

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Print Form | Save As | Reset Form

Collection of this information is authorized under 21 CFR 312.57. The information is collected to ensure compliance with Food and Drug Administration (FDA) requirements for NCI as an IND sponsor and that investigational agents are under the control and accounted for by competent authority. The information may be disclosed to researchers for investigational purposes, sponsors of clinical trials and their company collaborators, the applicable Institutional Review Board, NCI, FDA, and the Department of Health and Human Services. Submission of this information is voluntary however, in order for you to conduct a study in accordance with relevant, current protocols, you must complete all fields.

OMB No. 0925-0613
Expires: 03/31/2016
NIH-2564

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National Cancer Institute

Division of Cancer Treatment and Diagnosis
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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.								

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DARF - Headers

- Common mistakes – Missing information
  - Protocol title
  - Dispensing Area
  - Control/Satellite check box
  - Page number(s)
  - Dose form and strength

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DARF - Headers

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PAGE NO. 1

CONTROL RECORD ☑

SATELLITE RECORD ☐

Investigational Agent Accountability Record

Name of Institution: Southeast Cancer Control Consortium	NCI Protocol No.: CALGB 40503
Agent Name: Bevacizumab/Placebo NSC 704865 Refrigerate	Dose Form and Strength: 100 mg vial (2.5mg/ml - 4 ml vial)
Protocol Title: Endocrine Therapy in Combination with anti-VEGF Therapy: A Randomized, Double-Blind, Placebo-Controlled Phase III Trial of Endocrine Therapy Alone or Endocrine Therapy Plus Bevacizumab For Women with Hormone Receptor- Positive Advanced Breast Cancer	Dispensing Area: Main Pharmacy supplied by Genentech and provided by NCI
Investigator Name: James N. Atkins	NCI Investigator No.: 01234

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Original DARF

- Individual line section of form errors
  - Patient ID number not listed
  - Patient initials not listed
  - Balance totals not completed
  - Correct dosage (daily dose)

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DARF Balances

- Returns
  - Follow protocol for return or destruction
  - Should be done within 90 days per protocol guidelines (this is not pharma)
  - All documentation should be maintained

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Study specific vs. Patient specific

- How is drug supplied
  - For study (open labeled)
  - For specific patient (double blinded study)

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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.								

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Oral DARFs

- Must be used for all NCI studies using an oral agent
- All headers must be completed
- Use correct dispensing row for returns
- Complete date and quantity

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Investigational Agent Accountability Record
Oral agents ONLY

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PAGE NO.
CONTROL RECORD ☐
SATELLITE RECORD ☐

Name of Institution:	Investigator Name:		CTEP Investigator ID:
Protocol Title:	NCI Protocol No:	Local Protocol No:	Dispensing Area:
Agent Name:	Dose Form and Strength:		Bottle size (e.g., # 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.												
2.												
3.												
4.												
5.												
6.												
7.												
8.												
9.												
10.												
11.												
12.												
13.												
14.												
15.												
16.												
17.												

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eDARFs

- If an accountability software is used, a paper copy must be able to be printed that is identical to a NCI DARF

- The PMB does not endorse any pharmacy software package

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Audit

- Pharmacy component of audit is either compliant or non-compliant
- If found non-compliant, re-audit within 12 months
- Re-audit can be solely for pharmacy or entire site

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- PMB information
  - http://ctep.cancer.gov/branches/pmb/
    - Newsletters
    - Training Videos
- CTMB guidelines
  - Section 5.3

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Conclusion

- Questions from Audience
- Answers from Presenter

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