Audit Pharmacy Review

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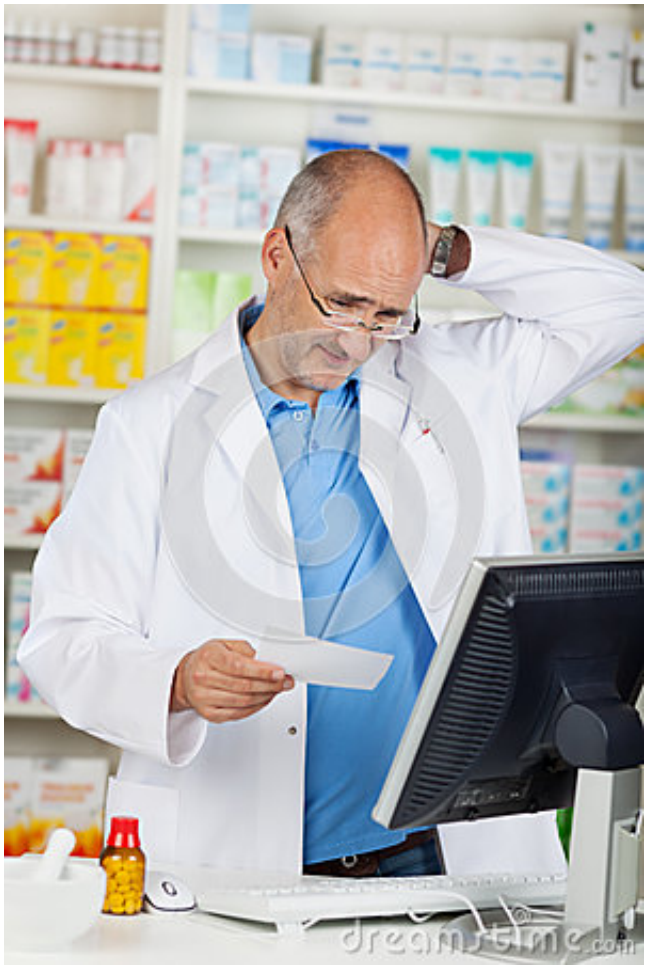
Alliance for Clinical Trials in Oncology, Chicago Office

Audit Workshop, November 3, 2016

- So let's try to help sort this out…



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Presentation Objectives

- Pharmacy security is important. Are supplied drug stored under proper conditions? Are the NCI DARFs being used and correctly maintained? What are the expectation at the time of the audit?
- Is storage of drug appropriate?
- DARFs ~ Drug Accountability Record Form
  - Standard DARF
  - Oral DARF
  - eDARF

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Security

- Access to Pharmacy
  - Who has access?
    - Pharmacy Staff
    - Research Staff
  - Is the unit locked ?
    - Badge Access
    - Key
    - A bell to get into the Pharmacy

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Authorized Prescribers

- Who are the authorized Prescribers?
  - Are all Investigators CTEP registered?
  - Is there a process in place to be sure each investigator remains compliant ?
  - Only Physicians can be CTEP registered to order and dispense investigational drug. Nurse Practitioners, PA and NP cannot order supply drug unless the order is cosigned by a CTEP registered Physician

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Stability

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Storage

- Is there temperature monitoring?
- Is there an Alarm
- Shelf **storage**
  - Is the study drug stored separately from commercial drug?
  - Is the returned drug stored separately?
  - How are patient drugs returned?

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DARF

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DARFs

- Drug Accountability Record Form
- Standard DARF
- Oral DARF
- eDARF
- These DARF's are used to track the disposition of investigational agents used for NCI clinical trials

- DARF forms can be found on CTEP website: http://ctep.cancer.gov/forms

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Standard DARF

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: 03/31/2019
NIH-2564

Public reporting burden for this collection of information is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0613). Do not return the completed form to this address.

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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.								

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Oral DARFs

- Must be used for all NCI studies using an oral agent
- All headers must be completed
- You must use the correct dispensing row to document patient drug return by completing the date returns and the quantity returns

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Oral DARF

Print Form | Save As | Reset Form

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Investigational Agent Accountability Record
Oral agents ONLY

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Cancer Therapy Evaluation Program

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.												
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17.												

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DARF - Headers

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

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DARF

- Common audit entry errors
  - Entry of the drug received from the NCI
  - Patient initials not listed
  - Balance totals not completed
  - Correct patient dose

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Example of an incomplete DARF

Investigational Agent Accountability Record

Oral agents ONLY

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Cancer Therapy Evaluation Program

PAGE NO.
CONTROL RECORD ☐
SATELLITE RECORD ☐

Name of Institution:	Investigator Name:	CTEP Investigator ID:
Hematology and Oncology of America	Janey Smith, MD	987654

Protocol Title:	NCI Protocol No:	Local Protocol No:	Dispensing Area:
Phase II Trial of Enzalutamide vs. Enzalutamide, Aberaterone and Prednisone for Castrate Resistant Metastatic Prostate Cancer	A031201		Control Pharmacy

Agent Name:	Dose Form and Strength:	Bottle size (e.g., # tablets/bottle):
Enzalutamide		120 capsules/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.	6-1-15	RW	1111111	40mg	-1bottle	2	12345-6	PM13	7-31-17	6-29-15	10capsules	PM13
2.	7-1-15	rec'd	from biologics	40mg	+3bottles	5	2345-6	PM13	9-15-17			
3.	6-29-15	RW	1111111	40mg	-1bottle	4	12345-6	PM13	7-31-17	7-27-15	5capsules	PM13
4.	7-5-15	T13	2222222	160mg	-1bottle	3	12345-6	PM13	7-31-17			
5.	7-29-15	RW	1111111	40mg	-1bottle	2	2345-6	PM13				
6.												
7.												

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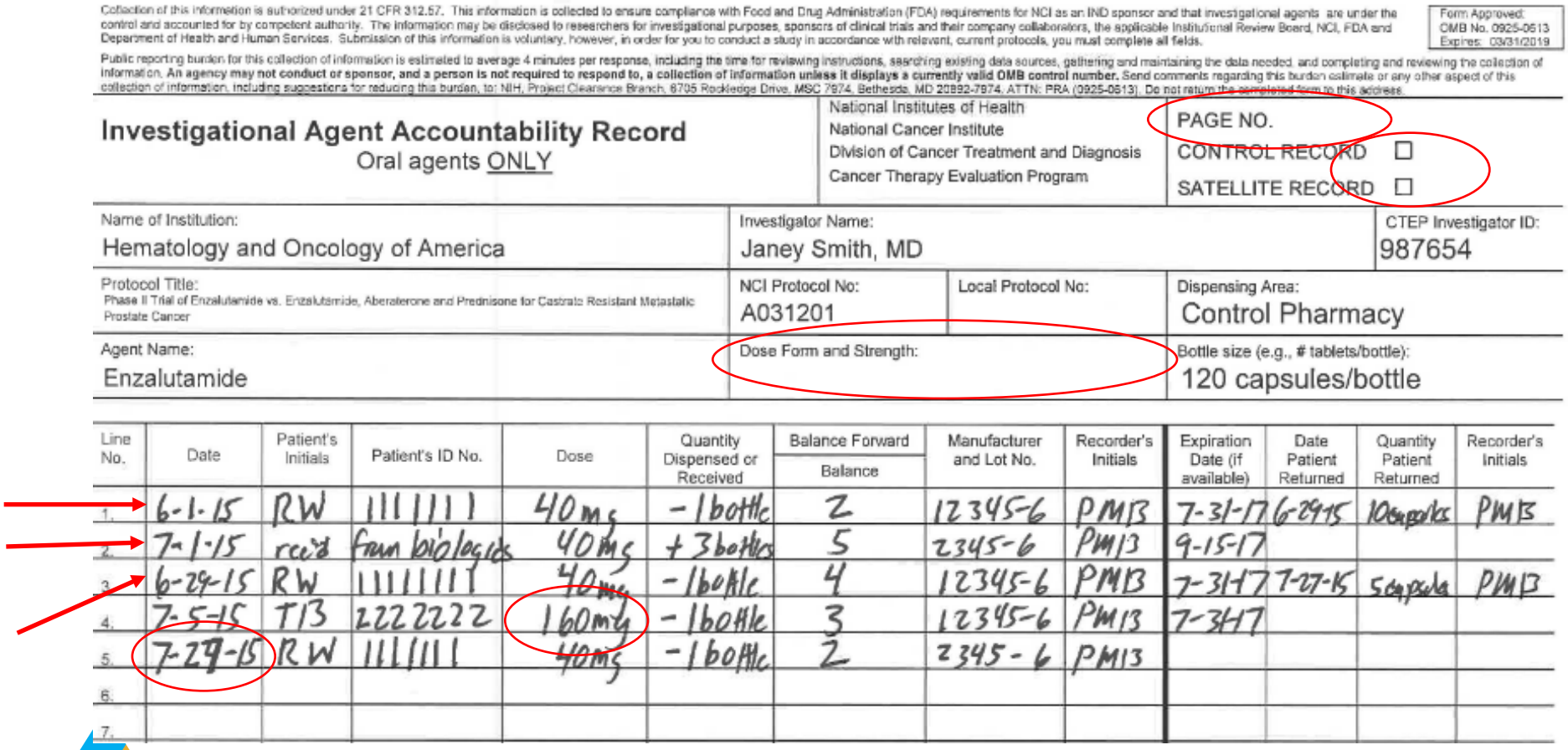
Example of an incomplete DARF



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Form Approved: OMB No. 0925-0513 Expires: 03/31/2019

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Oral agents ONLY

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National Cancer Institute
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Cancer Therapy Evaluation Program

PAGE NO.
CONTROL RECORD ☐
SATELLITE RECORD ☐

Name of Institution: Hematology and Oncology of America

Investigator Name: Janey Smith, MD

CTEP Investigator ID: 987654

Protocol Title: Phase II Trial of Enzalutamide vs. Enzalutamide, Aberaterone and Prednisone for Castrate Resistant Metastatic Prostate Cancer

NCI Protocol No: A031201

Local Protocol No:

Dispensing Area: Control Pharmacy

Agent Name: Enzalutamide

Dose Form and Strength:

Bottle size (e.g., # tablets/bottle): 120 capsules/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.	6-1-15	RW	1111111	40mg	-1bottle	2	12345-6	PM13	7-31-17	6-29-15	10capsules	PM13
2.	7-1-15	recd	from biologics	40mg	+3bottles	5	2345-6	PM13	9-15-17			
3.	6-29-15	RW	1111111	40mg	-1bottle	4	12345-6	PM13	7-31-17	7-27-15	5capsules	PM13
4.	7-5-15	T13	2222222	160mg	-1bottle	3	12345-6	PM13	7-31-17			
5.	7-29-15	RW	1111111	40mg	-1bottle	2	2345-6	PM13				
6.												
7.												

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Completed Oral DARF

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Investigational Agent Accountability Record

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SATELLITE RECORD ☐

Name of Institution:	Investigator Name:	CTEP Investigator ID:
Hematology and Oncology of America	Janey Smith, MD	987654

Protocol Title:	NCI Protocol No:	Local Protocol No:	Dispensing Area:
Phase II Trial of Enzalutamide vs. Enzalutamide, Aberaterone and Prednisone for Castrate Resistant Metastatic Prostate Cancer	A031201		Control Pharmacy

Agent Name:	Dose Form and Strength:	Bottle size (e.g., # tablets/bottle):
Enzalutamide	40 mg capsules	120 capsules/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.	5-20-15	Rec'd	from biologics	40mg	+3 bottle	3	12345-6	PMB	7.31.17			
2.	6-1-15	RW	1111111	40mg	-1 bottle	2	12345-6	PMB	7.31.17	6.29.15	10 capsules	PMB
3.	6-29-15	RW	1111111	40mg	-1 bottle	1	12345-6	PMB	7.31.17	7-27-15	5 capsules	PMB
4.	7-1-15	rec'd	from biologics	40mg	+4 bottles	5	23456-7	PMB	9.15.17			
5.	7-5-15	TB	2222222	40mg	-1 bottle	4	23456-7	PMB	9-15-17			
6.	7-27-15	RW	1111111	40mg	-1 bottle	3	12345-6	PMB	7-31-17			
7.	8-3-15	TB	2222222	40mg	-1 bottle	2	12345-6	PMB	7-31-17			

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eDARF's

- If a Pharmacy accountability software is used, a paper copy must printed for the audit that is identical to an NCI DARF

- The NCI/PMB does not endorse any pharmacy software package

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DARF's shipping receipts
Study specific vs. Patient specific

- How is drug supplied ?
  - Is the DARF study specific (open label) ?
  - Is the DARF patient specific (double-blinded) ?

Standard Order Shipping Record

Pharmaceutical Management Branch
Cancer Therapy Evaluation Program, DCTD, NCI
9609 Medical Center Drive
Room 5W228, MSC 9725
Bethesda, MD 20892-9725
Phone (240) 276-6575 Fax (240) 276-7893
Email: PMBafterhours@mail.nih.gov

SHIPMENT RECORD OF CLINICAL DRUG REQUEST
Date Authorized: 08/12/2014
Date Needed: 08/26/2014

Courier:
Account #
Acct Ref #
Order # 2014224-0043
Order Ref # O-1039409

NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
IDS-1111	724772	Sorafenib (BAY 43-9006; Nexavar)	200 mg Tablets 140 Tablets/Bottle	4	BAY CT1931/32

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Patient-Specific Order Shipping Record

Pharmaceutical Management Branch
Cancer Therapy Evaluation Program, DCTD, NCI
9609 Medical Center Drive
Room 5W228, MSC 9725
Bethesda, MD 20892-9725
Phone (240) 276-6575 Fax (240) 276-7893
Email: PMBafterhours@mail.nih.gov

SHIPMENT RECORD OF CLINICAL DRUG REQUEST
Date Authorized: 08/12/2013
Date Needed: 08/26/2013

Courier:
Account #
Acct Ref #
Order # 2014224-0008-BLI
Order Ref # O-1039409

NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
E1111	724772	Sorafenib 200 mg or Placebo	bottle 140 Tablets	4	

PATIENT ID: 1212121 PATIENT INITIAL: A, XX

?

The key is to check the drug receipt

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DARF Drug Returns

- Returns
  - Follow protocol for return or destruction
  - If possible transfer drug to another study , they will need to follow PMB guidelines.
  - Returns should be done within 90 days per CTMB guidelines (this is not pharma)
  - All documentation of return or destruction of drug should be maintained

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Pharmacy audit results

- Pharmacy review categories are either compliant or non-compliant
- If the Pharmacy section has too many non-compliant issues an unacceptable rating will be assigned.
- An unacceptable will require a re-audit within 12 months
- Re-audit can be for the pharmacy section only or a full re-audit

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

  *ctep.cancer.gov/branches/**ctmb**/clinicalTrials/monitoring*

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Questions

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"It's safe to come out - the auditors have gone."

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2016 Fall Group Meeting
November 3 -5 / Chicago, IL