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Welcome to this video tutorial on Agent Dispensing in the PMB Investigational Drug Accountability series.

This video will review recording procedures for agent dispensing on both the Oral DARF and the original NCI DARF.

Agent Dispensing Checklist	
Ordering investigator has an active CTEP registration.	<input checked="" type="checkbox"/>
Ordering investigator is study-eligible.	<input type="checkbox"/>
If study prescription is written by study staff, it is co-signed by a registered, study-eligible investigator.	<input type="checkbox"/>
Study prescription is written for a registered study participant.	<input type="checkbox"/>
Study prescription is written appropriately and patient meets protocol-defined criteria for treatment.	<input type="checkbox"/>

Upon receiving a prescription for study agent for use in an NCI approved protocol, first verify that the ordering investigator has an active CTEP registration.

<http://ctep.cancer.gov/branches/pmb/default.htm>

PHARMACEUTICAL MANAGEMENT BRANCH (PMB)

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CTEP Branches and Offices

- Office of the Associate Director
- Clinical Grants and Contracts Branch

Pharmaceutical Management Branch (PMB)

The Pharmaceutical Management Branch (PMB) is charged with providing pharmaceutical support for clinical trials sponsored by the National Cancer Institute's (NCI) Cancer Therapy Evaluation Program (CTEP). This support includes:

- provision of pharmaceutical information about CTEP IND agents
 - Agent Management
 - Investigators Brochure (IB) List
 - Material Safety Data Sheet (MSDS) List
 - Cytochrome P450 Drug Interaction Tables
 - Patient/Caregiver Ad Hoc Education Template
- registration of all investigators and associates participating in CTEP clinical trials and the maintenance of all registration records
 - Investigator Registration
 - Investigator Registration Expiration Date
 - Associate Registration (CTEP-IAM)



You can check investigator registration status and expiration date here on the CTEP website.

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

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Investigator Registration Expiration Date

Use this form to look up information on CTEP investigator registration status and expiration date.

CTEP Investigator ID:

Investigator Last Name:

CTEP Branches and Offices
Office of the Associate Director

Upon entering both the CTEP Investigator ID and Investigator Last Name, the results will display the investigator registration status and expiration date.

If the CTEP Investigator ID is unknown, you can look it up in OAOP or check with your research coordinator. The CTSU website can also be used if you have access to it. The Regulatory tab provides a list of all investigators at a site with their registration status and CTEP Investigator ID.

Agent Dispensing Checklist	
Ordering investigator has an active CTEP registration.	<input checked="" type="checkbox"/>
Ordering investigator is study-eligible.	<input checked="" type="checkbox"/>
If study prescription is written by study staff, it is co-signed by a registered, study-eligible investigator.	<input type="checkbox"/>
Study prescription is written for a registered study participant.	<input type="checkbox"/>
Study prescription is written appropriately and patient meets protocol-defined criteria for treatment.	<input type="checkbox"/>

The next step requires a copy of the current version of the protocol, in addition to the investigator registration status search results, in order to verify that the ordering investigator is study-eligible to participate on the trial. Let's review a couple examples.

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NCI Protocol#: 1234
Version Date: November 10, 2014
NCIPROTOCOL #: 1234
Local Protocol #: ABC-1234

TITLE: A Phase I Study of Trametinib in Combination with Radiation Therapy
KRAS-, BRAF-, NRAS- or HRAS- Mutant Solid Tumors

Coordinating Center: ABC University & Research Institute (PA123)

Principal Investigator: John Doe, M.D.
Department of Radiation Medicine
PA123 / ABC University & Research Institute
101 Main Street
Hometown, PA 12345
Phone: (123) 456-7898
Fax: (123) 456-7899

Co-Investigators: Jane Doe, M.D.
Department of Radiation Medicine
AZ123 / XYZ University & Research
101 Main Street
Hometown, AZ 45678
Phone: (456) 123-7898
Fax: (456) 123-7899

Romeo Doe, M.D.
Department of Radiation Medicine
FL456 / RST University & Research Institute
101 Main Street
Hometown, FL 91234
Phone: (789) 123-4565
Fax: (789) 123-4566

Non-Rostered Example

CTEP Investigator ID	12345
Investigator Name	Jane Doe
Office CTEP Site Code	AZ123
Office Institution Name	XYZ University & Research Center
Shipping CTEP Site Code	AZ123
Shipping Institution Name	XYZ University & Research Center
Investigator registration status	Active
Investigator registration expiration date	MMDDYYYY
Investigator Affiliations	

For non-rostered single or multicenter studies, each study eligible institution and ordering investigator must be listed on the protocol title page. In this example of a multi-center study we've verified the investigator name, institution, and CTEP site code on the title page with the investigator registration status search results. This investigator has an active CTEP registration and is eligible to participate.

http://ctep.cancer.gov/branches/pmb/expiration_date.htm
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Clinical Investigations Branch
Clinical Trial Monitoring Branch
Investigational Drug Branch
Pharmaceutical

Investigator Registration Expiration Date Last Updated: 07/11/2011

Use this form to look up information on CTEP investigator registration status and expiration date.

CTEP Investigator ID:
Investigator Last Name:

CTEP Investigator ID	56789
Investigator Name	Juliet Doe
Office CTEP Site Code	OH007
Office Institution Name	Ohio State University Comprehensive Cancer Center
Shipping CTEP Site Code	OH007
Shipping Institution Name	Ohio State University Comprehensive Cancer Center
Investigator registration status	Active
Investigator registration expiration date	MMDDYYYY
Investigator Affiliations	ALLIANCE / Alliance for Clinical Trials in Oncology LAO-OH007 / Ohio State University Comprehensive Cancer Center LAO P2C-OH007 / Ohio State University Comprehensive Cancer Center P2C

To check study eligibility of an ordering investigator for a rostered participant protocol, utilize the investigator affiliations in the investigator registration status search results when referring to the protocol title page. In this example, the investigator has affiliations with ALLIANCE, a Lead Academic Organization or LAO, and a Phase 2 Consortium or P2C.

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NCI Protocol: 1234
Version Date: November 10, 2014

NCIPROTOCOL #: 1234

Local Protocol #: ABC-1234

TITLE: A Phase 2 Study of Trametinib in Combination with Radiation Therapy KRAS-, BRAF-, NRAS- or HRAS- Mutant Solid Tumors

Corresponding Organization: P2C-MN026 / Mayo Clinic Cancer Center P2C

Principal Investigator: John Doe, M.D.
 Department of Radiation Medicine
 MN026 / Mayo Clinic Cancer Center (P2C-MN026)
 101 Main Street
 Hometown, MN 12345
 Phone: (123) 456-7898
 Fax: (123) 456-7899

Participating Organizations:

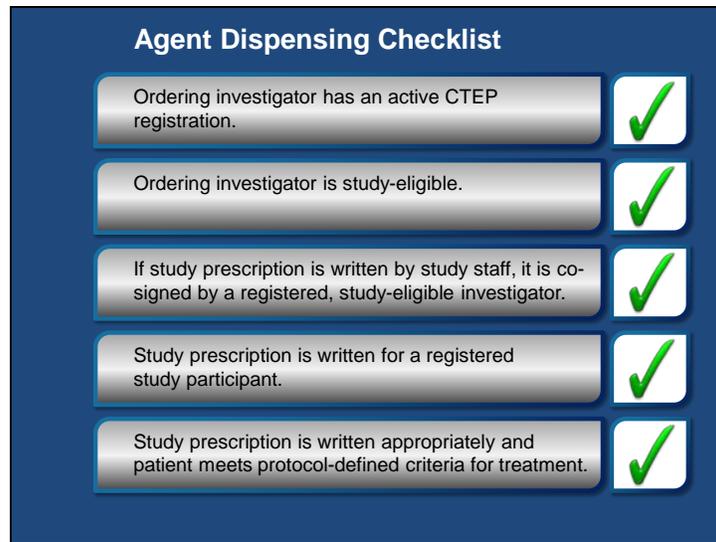
P2C-11030 / University HealthNetwork Princess Margaret Cancer Center P2C
P2C-CA189 / University of California Davis Comprehensive Cancer Center P2C
P2C-FL065 / H Lee Moffitt Cancer Center P2C
P2C-IL057 / University of Chicago Comprehensive Cancer Center P2C
P2C-MN026 / Mayo Clinic Cancer Center P2C
P2C-OH007 / Ohio State University Comprehensive Cancer Center P2C
P2C-TX035 / University of Texas M D Anderson Cancer Center P2C
ECOG-ACRIN / ECOG-ACRIN Cancer Research Group
BMTCN / Blood and Marrow Transplant Clinical Trials Network

Non-Member Collaborators: Jane Doe, M.D.
 Department of Radiation Medicine
 AZ123 / XYZ University & Research Institute
 101 Main Street
 Hometown, AZ 45678
 Phone: (456) 123-7898
 Fax: (456) 123-7899

Rostered Example

CTEP Investigator ID	5029
Investigator Name	John Doe
Office CTEP Site Code	OH007
Office Institution Name	Ohio State University Comprehensive Cancer Center
Shipping CTEP Site Code	OH007
Shipping Institution Name	Ohio State University Comprehensive Cancer Center
Investigator registration status	Active
Investigator registration expiration date	MMDDYYYY
Investigator Affiliations	ALLIANCE - Alliance for Clinical Trials in Oncology LAO-OH007 / Ohio State University Comprehensive Cancer Center LAO P2C-OH007 / Ohio State University Comprehensive Cancer Center P2C

Now refer to the participating organizations on the title page. For rostered studies each study-eligible investigator is NOT listed on the title page. The P2C that this investigator is affiliated with appears on the title page so the investigator is study-eligible for this rostered participant protocol. Investigators without affiliations to the rostered participants need to be listed on the title page as non-member collaborators in order to participate.



The agent dispensing checklist must be complete prior to dispensing study agent. We've verified that the ordering investigator has an active CTEP registration, is study-eligible, and checked that the study prescription is signed or co-signed by the registered study eligible investigator. Ensure the prescription is written for a registered study participant at either a control or satellite dispensing area, that it is written appropriately per protocol, and that the patient meets all protocol-defined criteria for treatment.

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Print Form		Save As		Reset Form									
<small>Caution: This information is submitted under 21 CFR 312.61. This document is controlled under conditions with Food and Drug Administration (FDA) requirements for NCI as an NCI sponsor and that investigational agents are under the control and available for complete audit. This information may be disclosed to members for investigational purposes, sponsor of clinical trials and their company subsidiaries, the appropriate Institutional Review Board, NCI, FDA and Department of Health and Human Services. Submission of this information is voluntary, however, in order to participate in a study or treatment with investigational agents, you must complete it fully.</small>													
<small>Public reporting burden for this collection of information is estimated to average 15 minutes per response, including reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and reviewing and reviewing the collection of information. An agency may not conduct or sponsor 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 the burden, to the Washington Headquarters Office, Paperwork Project, (0304-0001), Washington, DC 20503.</small>													
Investigational Agent Accountability Record Oral agents ONLY				National Institutes of Health National Cancer Institute Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program									
Name of Institution: State University Hospital				Investigator Name: John Smith, M.D.									
Protocol Title: Phase 2 trial of pazopanib for the treatment of patients with advanced renal cell carcinoma.				CTEP Investigator ID: 999999									
NCI Protocol No: 1234		Local Protocol No: SUH-001		Dispersing Area: IDS Pharmacy - 5th Floor Room A100									
Agent Name: Pazopanib hydrochloride (NSC 737754)		Dose Form and Strength: 200 mg Tablets		Bottle size (e.g. # tablets/bottle): 34 Tablets/bottle									
PAGE NO. 1 <input checked="" type="checkbox"/> CONTROL RECORD <input type="checkbox"/> SATELLITE RECORD													
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
4	4/29/2014				Received from the NCI	+ 24	24	GLX 87654321	ZA				
5	5/16/2014	BT	1234-002	800 mg daily	- 4	20	GLX 87654321	AB			6/16/2014	24 tabs	ZA
6	5/24/2014	AZ	1234-001	400 mg daily	- 2	18	GLX 87654321	ZA					
7	6/16/2014	BT	1234-002	400 mg daily	- 2	16	GLX 87654321	ZA					
8	6/24/2014	AZ	1234-001	400 mg daily	- 2	14	GLX 87654321	JT			7/31/2014	8 tabs	JT
9	6/24/2014	AZ	1234-001		Patient return from dispensing on 4/24/2014, page 1, line 3				JT		6/24/2014	1 bottle	JT
10	6/30/2014				Sent to Medical Office Building A Satellite	- 12	2	GLX 87654321	ZA				
11	7/11/2014				Received from the NCI	+ 20	22	GLX 09735555	JT				
12	7/23/2014	BT	1234-002	800 mg daily	- 2	20	GLX 87654321	AB			8/24/2014	4 tabs	ZA
13	7/23/2014	BT	1234-002	800 mg daily	- 2	18	GLX 09735555	AB			8/24/2014	1 BE + 4 tabs	ZA
14	8/1/2014				Returned from Med. Off. Building A Satellite	+ 4	22	GLX 87654321	JT				
15	8/2/2014				Return to the NCI Clinical Repository	- 4	18	GLX 87654321	AB		8/31/2014		
16	9/30/2014				Transfer to NCI Protocol 2441 (T14273-0001)	- 10	8	GLX 09735555	ZA				
17	11/4/2014				Local Destruction per PMB Authorization	- 8	0	GLX 09735555	ZA				

Now let's review agent dispensing accountability examples. On the Oral DARF or the original NCI DARF, each dispensing entry must be complete, with the Date, Patient's Initials and ID Number, Dose, Quantity, Balance, Lot Number, and Recorder's Initials. The Oral DARF is formatted for the dispensing and return information to appear in the same row. Please see PMB's Oral DARF video tutorial for additional information on recording patient returns.

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Print Form		Save As		Reset Form								
<small>Caution: This information is classified under 21 CFR 312.61. This information is classified in accordance with Food and Drug Administration (FDA) regulations for NCI as an ND sponsor and that investigational agents are under the control and protection of the sponsor. This information may be disclosed to researchers for investigational purposes, sponsor of clinical trials and their designees, the appropriate Institutional Review Board, NCI, FDA and Department of Health and Human Services. Submission of this information is voluntary, however, it is required to participate in a study or procedure with research, control patients, and their families or friends.</small>												
<small>Public reporting burden for this collection of information is estimated to average 15 minutes per response, including reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and reviewing and reviewing the collection of information. An agency may not conduct or sponsor 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 the Washington Headquarters Office of Management and Budget, Paperwork Project Collection (0750-0047), Washington, DC 20503.</small>												
Investigational Agent Accountability Record Oral agents ONLY				National Institutes of Health National Cancer Institute Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program								
Name of Institution: State University Hospital				Investigator Name: John Smith, M.D.								
Protocol Title: Phase 2 trial of pazopanib for the treatment of patients with advanced renal cell carcinoma.				CTEP Investigator ID: 999999								
NCI Protocol No: 1234		Local Protocol No: SUH-001		PAGE NO: 1 CONTROL RECORD <input checked="" type="checkbox"/> SATELLITE RECORD <input type="checkbox"/>								
Agent Name: Pazopanib hydrochloride (NSC 737754)				Dispensing Area: IDS Pharmacy - 5th Floor Room A100								
Dose Form and Strength: 200 mg Tablets				Bottle size (e.g. # tablets/bottle): 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					+ 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
4	4/28/2014					+ 24	24 GLX 87654321	ZA				
5	5/16/2014	BT	1234-002	800 mg daily	- 4	20	GLX 87654321	AB		8/16/2014	24 tabs	ZA
6	5/24/2014	AZ	1234-001	400 mg daily	- 2	18	GLX 87654321	ZA				
7	6/16/2014	BT	1234-002	400 mg daily	- 2	16	GLX 87654321	ZA				
8	6/24/2014	AZ	1234-001	400 mg daily	- 2	14	GLX 87654321	JT		7/31/2014	8 tabs	JT
9	6/24/2014	AZ	1234-001	Patient return from dispensing on 4/24/2014, page 1, line 3				JT		8/24/2014	1 bottle	JT
10	6/30/2014			Sent to Medical Office Building A Satellite	- 12	2	GLX 87654321	ZA				
11	7/11/2014			Received from the NCI	+ 20	22	GLX 09735555	JT				
12	7/23/2014	BT	1234-002	800 mg daily	- 2	20	GLX 87654321	AB		8/24/2014	4 tabs	ZA
13	7/23/2014	BT	1234-002	800 mg daily	- 2	18	GLX 09735555	AB		8/24/2014	1 BE + 4 tabs	ZA
14	8/1/2014			Returned from Med. Office Building A Satellite	+ 4	22	GLX 87654321	JT				
15	8/2/2014			Return to the NCI Clinical Repository	- 4	18	GLX 87654321	AB		8/31/2014		
16	9/30/2014			Transfer to NCI Protocol Repository (114273-001)	- 10	8	GLX 09735555	ZA				
17	11/4/2014			Local Destruction per PM Authorization	- 8	0	GLX 09735555	ZA				

Record the date that the agent is prepared for dispensing. It may differ from the date it is provided to the patient or the date the patient begins treatment. Record the patient's initials and patient's ID number. In the dose field, record the prescribed dose. There can be different approaches to recording in the dose field given the space limitations. Keep in mind that this field is intended to support the quantity dispensed. Do not record the total dose dispensed per cycle for oral agents. For example, 2800 mg for an agent that is dosed at 100 mg daily for 28 days.

Quantity Dispensed

Agent Name: Pazopanib hydrochloride (NSC 737754)				Dose Form and Strength: 200 mg Tablets			Bottle size (e.g., # tablets/bottle): 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				
3	4/24/2014	AZ	1234-001	800 mg daily	- 4	0	GLX 12345678	AB				
4	4/29/2014	Received from the NCI			+ 24	24	GLX 87854321	ZA				
5	5/15/2014	BT	1234-002	800 mg daily	- 4	20	GLX 87854321	AB				
6	5/24/2014	AZ	1234-001	400 mg daily	- 2	18	GLX 87854321	ZA				

Dispensing by bottle

Agent Name: Vorinostat (NSC 701852)				Dose Form and Strength: 100 mg Tablets			Bottle size (e.g., # tablets/bottle): 120 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			+ 240	240	NK 12345678	AB				
2	3/24/2014	AZ	1234-001	400 mg daily	- 84	156	NK 12345678	AB				
3	4/24/2014	AZ	1234-001	400 mg daily	- 84	72	NK 12345678	AB				
4	4/29/2014	Received from the NCI			+ 120	192	NK 87654321	ZA				
5	5/16/2014	BT	1234-002	400 mg daily	- 84	108	NK 87654321	AB				
6	5/24/2014	AZ	1234-001	300 mg daily	- 63	45	NK 87654321	ZA				

Dispensing by tablet

The quantity dispensed should be recorded in units supported by information in the protocol. The protocol may state that the agent must be dispensed in its original bottle or the protocol may permit repackaging for dispensing. When recording the balance, verify the quantity of the agent inventory after dispensing. Complete the dispensing line item by recording the lot identifier and recorder's initials. If unsure which lot identifier to record on the DARF, refer to PMB's Agent Receipt video tutorial.

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Investigational Agent Accountability Record Oral agents ONLY										National Cancer Institute Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program		PAGE NO 1 CONTROL RECORD <input checked="" type="checkbox"/> SATELLITE RECORD <input type="checkbox"/>	
Name of Institution: State University Hospital				Investigator Name: John Smith, M.D.				CTEP Investigator ID: 999999					
Protocol Title: Phase 2 trial of pazopanib for the treatment of patients with advanced renal cell carcinoma.				NCI Protocol No: 1234		Local Protocol No: SUH-001		Dispensing Area: IDS Pharmacy - 9th Floor Room A100					
Agent Name: Pazopanib hydrochloride (NSC 737754)				Dose Form and Strength: 200 mg Tablets		Bottle size (e.g., # tablets/bottle): 34 Tablets/bottle							
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward	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		+ 6	6	SLX 12345678	AB					
2	3/24/2014	AZ	1234-001	800 mg daily	- 4	2	SLX 12345678	AB		4/24/2014	18 tablets	AB	
3	4/24/2014	AZ	1234-001	800 mg daily	- 4	0	SLX 12345678	AB		5/24/2014	1 bottle	ZA	
4	4/29/2014		Received from the NCI		+ 24	24	SLX 87654321	ZA					
5	5/15/2014	BT	1234-002	800 mg daily	- 4	20	SLX 87654321	AB		6/15/2014	24 tablets	ZA	
6	5/24/2014	AZ	1234-001	400 mg daily	- 2	18	SLX 87654321	ZA					
7	6/16/2014	BT	1234-002	400 mg daily	- 2	16	SLX 87654321	ZA					
8	6/24/2014	AZ	1234-001	400 mg daily	- 2	14	SLX 87654321	JT		7/21/2014	9 tablets	JT	
9	6/24/2014	AB	1234-003	Dispersed into the	- 1	13	SLX 87654321	JT		8/24/2014	1 bottle	JT	
10	6/24/2014		Save to Medical Office Building A Satellite		- 1	12	SLX 87654321	ZA					
Investigational Agent Accountability Record Oral agents ONLY										National Cancer Institute Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program		PAGE NO 1 CONTROL RECORD <input type="checkbox"/> SATELLITE RECORD <input checked="" type="checkbox"/>	
Name of Institution: State University Hospital				Investigator Name: John Smith, M.D.				CTEP Investigator ID: 999999					
Protocol Title: Phase 2 trial of pazopanib for the treatment of patients with advanced renal cell carcinoma.				NCI Protocol No: 1234		Local Protocol No: SUH-001		Dispensing Area: Medical Office Building A					
Agent Name: Pazopanib hydrochloride (NSC 737754)				Dose Form and Strength: 200 mg Tablets		Bottle size (e.g., # tablets/bottle): 34 Tablets/bottle							
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials	
1	6/23/2014		Received from State Univ. Hospital Control		+ 408	408	SLX 12345678	BC					
2	7/2/2014	RP	1234-003	800 mg daily	- 84	324	SLX 12345678	SF					

Let's review an example of agent dispensing at a satellite location. The satellite received 12 bottles from the control and recorded the quantity as 408 tablets because this agent can be dispensed in the original container or in a pharmacy bottle for dispensing an exact quantity. The Control Dispensing Area is managing inventory by bottle and the Satellite is managing inventory by tablet. It is not necessary for the Control and Satellite Dispensing areas to use the same accountability method. The inventory should be received and maintained consistent with the unit most appropriate for dispensing at the control or satellite location.

Multiple Lots or Multiple Strengths

Agent Name: Sunitinib malate (NSC 736511)					Dose Form and Strength: 12.5 mg Capsules	
4/24/2014	AZ	1234-001	37.5 mg daily	- 1	7	PZ 12345678
4/24/2014	AZ	1234-001	37.5 mg daily	- 1	6	PZ 87654321

Agent Name: Sunitinib malate (NSC 736511)					Dose Form and Strength: 25 mg Capsules	
4/24/2014	AZ	1234-001	37.5 mg daily	- 2	4	PZ 56789123

If multiple lots were used in the same dispensing, record the quantity of each lot used on separate lines of the DARF. If multiple strengths were used in the same dispensing, record on each appropriate DARF. In this example, note that the dose field is consistent between the two DARFs of different strengths. We've finished reviewing examples on the Oral DARF. Next we'll review examples specific to injectable agent accountability on the original NCI DARF. Keep in mind all applicable agent dispensing procedures from the Oral DARF examples.

Single-use Vials

National Institutes of Health National Cancer Institute		Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program		PAGE NO. 1					
Investigational Agent Accountability Record				CONTROL RECORD <input checked="" type="checkbox"/>					
				SATELLITE RECORD <input type="checkbox"/>					
Name of Institution: State University Hospital			NCI Protocol No.: 2458						
Agent Name: Ziv-Aflibercept (VEGF-Trap, AVE 0005), NSC 724770			Dose Form and Strength: 200 mg / 8 mL vial; 25 mg/mL						
Protocol Title: Phase II Study of Ziv-Aflibercept in Metastatic Colon Cancer			Dispensing Area: IDS Pharmacy - 5th Floor Room A100						
Investigator Name: John Smith, M.D.			CTEP Investigator ID: 999999						
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward		Manufacturer and Lot No.	Recorder's Initials
						U	Balance		
1	12/11/2014	Received from NCI			+12		12	SV 12345678	KB
2	12/12/2014	AZ	1234-001	254 mg	- 2		10	SV 12345678	ZA
3	12/15/2014	BT	1234-002	328 mg	- 2		8	SV 12345678	KB
4	12/26/2014	AZ	1234-001	127 mg	- 1		7	SV 12345678	JC
5	12/29/2014	BT	1234-002	320 mg	- 2		5	SV 12345678	KB

When dispensing injectable agents on the original NCI DARE, often the dose dispensed is intended for a single administration. If the dose requires calculations, for example mg/m^2 , record it as the total dose dispensed. Verify the calculations and any dose rounding procedures by referring to the protocol. Dispense the quantity required for dose preparation in vials. If the product is manufactured as a liquid formulation, overfill can be used and documented as such on the DARE. Do not document destruction of agent remaining in single-use vials following dose preparation.

Multi-dose Vials

Tracking by milligram

Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward
				0
Balance				
Received from the NCI			10 vials	10 X 440 mg
AS	12345	288 mg	288 mg	9 vials + 152 mg
BT	12345	320 mg	320 mg	8 vials + 272 mg

Tracking by vial

Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward
				0
Balance				
Received from the NCI			10 vials	10
AS	12345	288 mg	1 vial	9 + partial
BT	12345	320 mg	1	8 + partial

If dispensing from a multi-dose vial, PMB recommends tracking inventory either by milligram or by vial. Tracking by milligram involves more calculations whereas the term partial can be used when tracking by vial. Record either the number of vials plus the word partial when using the vial method, or the number of vials plus the milligram amount remaining in the partial vial. You must document destruction of partial multi-dose vials on the DARF when they are no longer suitable for use.

http://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring.htm

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CLINICAL TRIALS MONITORING BRANCH (CTMB)

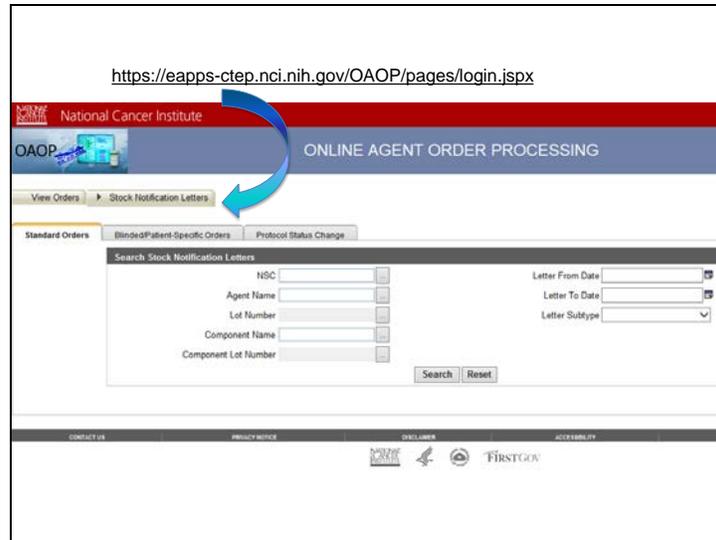
CTMB Documents / Guidances Last Updated: 04/04/14

- NCI Guidelines for Auditing Clinical Trials for the National Clinical Trials Network (NCTN) Program, Community Clinical Oncology Program (CCOP)/NCI Community Oncology Research Program (NCORP) and Research Bases
- NCI Guidelines for Auditing Clinical Trials for the Experimental Therapeutics Clinical Trials Network (ETCTN)
- **CTMB Audit Worksheets**
 - IRB/EC Audit Worksheet
 - Pharmacy Audit Worksheet
 - Patient Case Audit Worksheet
- NCTN Program Guidelines (Revised 12/2012)
- Good Clinical Practices (GCP) Guidance Document

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Clinical Investigations Branch
Clinical Trials Monitoring Branch
Investigational

We've reviewed the agent dispensing checklist and examples of accountability procedures. Another helpful resource is Section 5.3 Agent Accountability and Pharmacy Operations of the NCI Guidelines for Auditing Clinical Trials for the NCTN found on the Clinical Trials Monitoring Branch website. Institution specific policies and procedures should also be in place for dispensing investigational medications.

Slide 19



Dispensing areas should have procedures in place for ensuring the agent is suitable for clinical use. Once an expiration date is known, PMB will issue notification to each ordering investigator and all shipping and ordering designees at each institution. Access PMB stock notification letters through OAOP or contact PMB with any questions prior to dispensing.

Slide 20



Dispensing areas should not mail investigational medications to study subjects.

<http://ctep.cancer.gov/branches/pmb/faq.htm>

PHARMACEUTICAL MANAGEMENT BRANCH (PMB)

Last Updated: 02/14/14

FAQ

- Returning agent to NCI Clinical Repository (06/14)
- Patient returns of oral clinical supplies (12/13)
- How do I access OACP (Online Agent Order Processing)? (11/13)
- We just became aware of an error that involved CTEP-supplied investigational agent. How do we report it, and is there any specific information you need?
- What is a satellite? Or, is it OK for us to send drug that we have ordered from the PMB to one of our other offices/sites?
- How should I record investigational agents that come in oral dosage forms?
- How do I get an Investigator Brochure?
- My actual drug inventory doesn't match the quantities reflected on the Drug Accountability Record Form. What should I do?
- Injectable agents in vials (sharing and overfill)
- Why is my IRB asking all these questions?
- Where can I get a list of clinical trials for specific cancer diagnoses?
- Lost shipment or missing drug

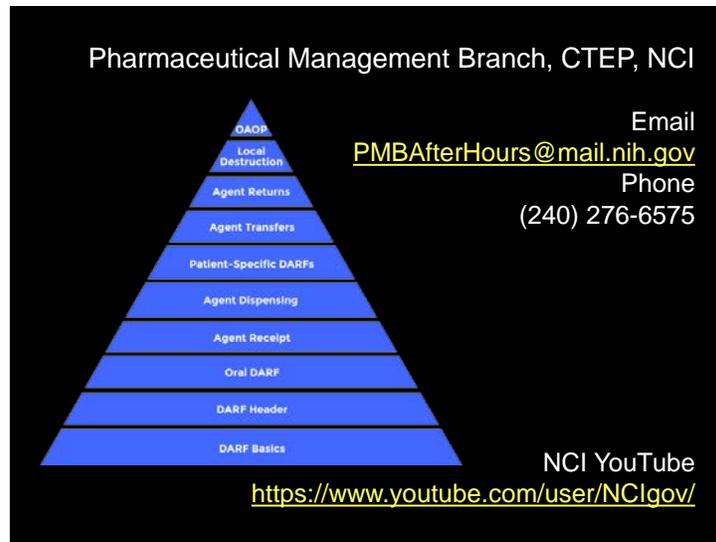
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Lastly if any dispensing errors within a DCTD approved protocol are identified, contact PMB and provide details of the event. Institutional policies and procedures should be in line with institution specific systems to minimize errors. Refer to the FAQ available here on the PMB website for additional information.



Thank you for watching this video tutorial. Additional PMB Investigational Drug Accountability videos are available through our YouTube Playlist.

Please note that the video and any items displayed within the videos are subject to change. Check back periodically for updates.

Questions can be directed to the Pharmaceutical Management Branch, CTEP, NCI by phone Monday through Friday from 8:30am to 4:30pm Eastern Time or by email any time.

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