

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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Office of the Associate Director

Clinical Grants and Contracts Branch

Pharmaceutical Management Branch (PMB)

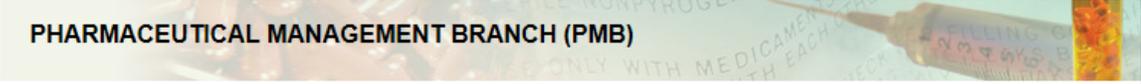
The Pharmaceutical Management Branch (PMB) is charged with providing pharmaceutical support for clinical trials sponsored by the National Cancer Institute's (NCI) Cancer Therapy Evaluation Program (CTEP). This support includes:

- 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.

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:

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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.

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

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Investigator Registration Expiration Date Last Updated:

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

CTEP Investigator ID:

Investigator Last Name:

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	<input type="text" value="Active"/>
Investigator registration expiration date	MM/DD/YYYY

Investigator Affiliations

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- Clinical Grants and Contracts Branch
- Clinical Investigations Branch
- Clinical Trials Monitoring Branch
- Investigational

This is an example of an investigator with an active CTEP registration status. Note that this investigator does not have any current affiliations. Investigator affiliations indicate eligibility to participate on rostered participant protocols.

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.

NCI Protocol#: 1234
Version Date: November 10, 2014

NCIPROTOCOL #: 1234

Local Protocol #: ABC-1234

TITLE: A Phase 1 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 Center
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	MM/DD/YYYY
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 Trials Monitoring Branch

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Pharmaceutical Management Branch

Last Updated: 07/

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 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	MM/DD/YYYY
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.

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
BMTCTN / 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	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	MM/DD/YYYY
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.

Agent Dispensing Checklist

Ordering investigator has an active CTEP registration.	
Ordering investigator is study-eligible.	
If study prescription is written by study staff, it is co-signed by a registered, study-eligible investigator.	
Study prescription is written for a registered study participant.	
Study prescription is written appropriately and patient meets protocol-defined criteria for treatment.	

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.

Print Form		Save As		Reset Form								
<small>Collection of this information is authorized under 21 CFR 312.57. This 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 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.</small>										<small>Form Approved OMB No. 0925-0013 Expires: 03/31/2016</small>		
<small>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 7924, Bethesda, MD 20895-7774, ATTN: PRA (3025-0013). Do not return the completed form to this address.</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		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 - 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				
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 Btl + 4 tabs	ZA
14.	8/1/2014	Returned from Med. Off. Build. 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 2841 (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.

Print Form		Save As		Reset Form								
<small>Collection of this information is authorized under 21 CFR 312.57. This 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 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.</small>										<small>Form Approved OMB No. 0925-0013 Expires: 03/31/2016</small>		
<small>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 7924, Bethesda, MD 20895-7774, ATTN: PRA (3025-0013). Do not return the completed form to this address.</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		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 - 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				
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 Btl + 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 841 (T14273-001)			- 10	8	GLX 09735555	ZA				
17	11/4/2014	Local Destruction per PMR 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	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
						Balance						
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 87654321	ZA				
5.	5/16/2014	BT	1234-002	800 mg daily	- 4	20	GLX 87654321	AB				
6.	5/24/2014	AZ	1234-001	400 mg daily	- 2	18	GLX 87654321	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	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
						Balance						
1.	3/21/2014	Received from the NCI			+ 240	240	MK 12345678	AB				
2.	3/24/2014	AZ	1234-001	400 mg daily	- 84	156	MK 12345678	AB				
3.	4/24/2014	AZ	1234-001	400 mg daily	- 84	72	MK 12345678	AB				
4.	4/29/2014	Received from the NCI			+ 120	192	MK 87654321	ZA				
5.	5/16/2014	BT	1234-002	400 mg daily	- 84	108	MK 87654321	AB				
6.	5/24/2014	AZ	1234-001	300 mg daily	- 63	45	MK 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.

Investigational Agent Accountability Record Oral agents <u>ONLY</u>				National Institutes of Health 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 - 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				
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				
Investigational Agent Accountability Record Oral agents <u>ONLY</u>				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 Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned		
1.	6/30/2014	Received from State Univ Hospital Control			+ 408	408	GLX 12345678	BC				
2.	7/2/2014	RP	1234-003	800 mg daily	- 84	324	GLX 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
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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
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4/24/2014	AZ	1234-001	37.5 mg daily	- 2	4	PZ 56789123
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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. <i>1</i>	
Investigational Agent Accountability Record				CONTROL RECORD <input checked="" type="checkbox"/>	
				SATELLITE RECORD <input type="checkbox"/>	
Name of Institution: State University Hospital			NCI Protocol No.: 2468		
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
						<i>0</i>		
						Balance		
<i>1.</i>	<i>12/11/2014</i>	<i>Received</i>	<i>from NCI</i>		<i>+12</i>	<i>12</i>	<i>SV 12345678</i>	<i>KB</i>
<i>2.</i>	<i>12/12/2014</i>	<i>AZ</i>	<i>1234-001</i>	<i>254 mg</i>	<i>- 2</i>	<i>10</i>	<i>SV 12345678</i>	<i>ZA</i>
<i>3.</i>	<i>12/15/2014</i>	<i>BT</i>	<i>1234-002</i>	<i>328 mg</i>	<i>- 2</i>	<i>8</i>	<i>SV 12345678</i>	<i>KB</i>
<i>4.</i>	<i>12/26/2014</i>	<i>AZ</i>	<i>1234-001</i>	<i>127 mg</i>	<i>- 1</i>	<i>7</i>	<i>SV 12345678</i>	<i>JC</i>
<i>5.</i>	<i>12/29/2014</i>	<i>BT</i>	<i>1234-002</i>	<i>320 mg</i>	<i>- 2</i>	<i>5</i>	<i>SV 12345678</i>	<i>KB</i>

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/m², 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	12346	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	12346	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/CC Audit Worksheet
 - Pharmacy Audit Worksheet
 - Patient Case Audit Worksheet
- NCTN Program Guidelines [Revised 12/2012]
- Good Clinical Practices (GCP) Guidance Document



CTMB Main

- ▢ CTMB Documents / Guidances
- ▢ Joan K. Mauer Memorial Award
- ▢ Links to CTMB Resources
- ▢ Staff, Picture and Bios
- ▢ Organization Chart

CTEP Branches and Offices

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

<https://eapps-ctep.nci.nih.gov/OAOP/pages/login.jspx>

National Cancer Institute

OAOP ONLINE AGENT ORDER PROCESSING

View Orders Stock Notification Letters

Standard Orders Blinded/Patient-Specific Orders Protocol Status Change

Search Stock Notification Letters

NSC ... Letter From Date

Agent Name ... Letter To Date

Lot Number ... Letter Subtype

Component Name ...

Component Lot Number ...

Search Reset

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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.



Dispensing areas should not mail investigational medications to study subjects.

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

PHARMACEUTICAL MANAGEMENT BRANCH (PMB)

- PMB Main
- PMB Newsletter
- PMB After Hours
- **FAQ**
- Staff Biographies
- Organization Chart
- Online Agent Order Processing (OAOP)
- Investigational Drug
- Accountability Training Videos

FAQ

Last Updated: 08/14/14

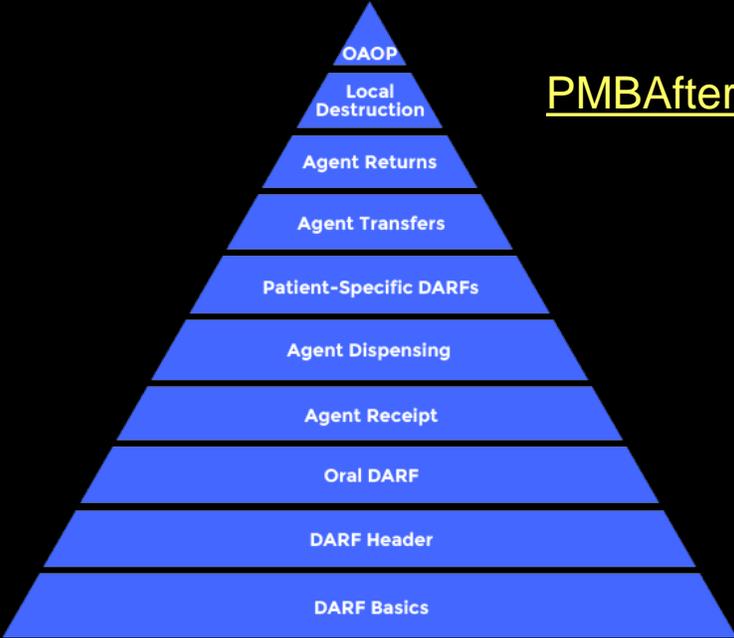


- Returning agent to NCI Clinical Repository (06/14)
- Patient returns of oral clinical supplies (12/13)
- How do I access OAOP (Online Agent Order Processing)? (11/13)
- We just became aware of an error that involved CTEP-supplied investigational agent. How do we report it, and is there any specific 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

- CTEP Branches and Offices
- Office of the Associate Director
- Clinical Grants and Contracts Branch
- Clinical Investigations Branch

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.

Pharmaceutical Management Branch, CTEP, NCI



Email
PMBAfterHours@mail.nih.gov
Phone
(240) 276-6575

NCI YouTube
<https://www.youtube.com/user/NCIgov/>

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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<http://ctep.cancer.gov/>

1-800-4-CANCER

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