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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 DARP and the original NCI DARP.

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Item	Status
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.

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

**PHARMACEUTICAL MANAGEMENT BRANCH (PMB)**

- PMB Mission
- PMB Services
- PMB After Hours
- FAQ
- Staff Directory
- Organization Chart
- Online Agent Order Processing (DART)
- Investigational Drug Accountability Training Videos

**CTEP Branches and Offices**

- National Cancer Institute
- Clinical Oncology and Cancer Research

**Pharmaceutical Management Branch (PMB)**

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

- provision of pharmaceutical information about CTEP PNC agents
  - Agent Memorandum
  - Investigator Brochure (IB) List
  - Molecular Safety Data Sheet (MSDS) List
  - Cyclophosphamide (PCN) Drug Interaction Tables
  - Patient Caregiver Ad-Hoc Education Toolboxes
- 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 Registrations (CTEP-JAM)

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

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The screenshot shows the 'Investigator Registration Expiration Date' form on the CTEP website. The URL is [http://ctep.cancer.gov/branches/pmb/expiration\\_date.htm](http://ctep.cancer.gov/branches/pmb/expiration_date.htm). The page title is 'PHARMACEUTICAL MANAGEMENT BRANCH (PMB)'. The form includes a navigation menu on the left with options like 'PMB Home', 'PMB Newsletter', 'CTEP After Hours', 'FAQ', 'Staff Biographies', 'Organization Chart', 'Online Agent Trainer', 'Pharmacist (DANCP)', 'Investigational Drug', and 'Accountability Training'. The main content area has a heading 'Investigator Registration Expiration Date' and a sub-heading 'Use this form to look up information on CTEP investigator registration status and expiration date'. There are two input fields: 'CTEP Investigator ID' and 'Investigator Last Name', both with a 'Submit' button below them.

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.

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The screenshot shows the same 'Investigator Registration Expiration Date' form, but with search results displayed. The 'CTEP Investigator ID' field contains '12345' and the 'Investigator Last Name' field contains 'Doe'. The 'Submit' button has been clicked, and the results are shown below. The results include: 'CTEP Investigator ID: 12345', 'Investigator Name: Jane Doe', 'Office CTEP Site Code: A2123', 'Office Institution Name: XYZ University & Research Center', 'Mailing CTEP Site Code: A2123', 'Mailing Institution Name: XYZ University & Research Center', 'Investigator registration status: Active', and 'Investigator registration expiration date: MM/DD/YYYY'. There is also a section for 'Investigator Affiliations' which is currently empty.

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.

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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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Non-Rostered Example	
<b>Coordinating Center:</b> ABC University & Research Institute (PA112)	
<b>Principal Investigator:</b> Julie Doe, MD Department of Radiation Medicine PA112 ABC University & Research Institute 112 Main Street Hometown, PA, 12345 Phone: (123) 456-7890 Fax: (123) 456-7899	
<b>Co-Investigators:</b> Jane Doe, M.D. Department of Radiation Medicine AZ113 - XYZ University & Research Institute 112 Main Street Hometown, AZ, 45678 Phone: (156) 123-7890 Fax: (156) 123-7899	
Bryan Doe, M.D. Department of Radiation Medicine FL406 - RST University & Research Institute 112 Main Street Hometown, FL, 91234 Phone: (789) 123-4567 Fax: (789) 123-4566	
<b>CTEP Investigator ID</b>	0570
<b>Investigator Name</b>	Julie Doe
<b>Office CTEP Site Code</b>	AC101
<b>Office Institution Name</b>	XYZ University & Research Center
<b>Shipping CTEP Site Code</b>	AC101
<b>Shipping Institution Name</b>	XYZ University & Research Center
<b>Investigator registration status</b>	Active
<b>Investigator registration expiration date</b>	06/30/2015
<b>Institution Affiliation</b>	

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.

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PHARMACEUTICAL MANAGEMENT BRANCH (PMB)	
<b>Investigator Registration Expiration Date</b>	
Use this form to look up information on CTEP investigator registration dates and expiration dates.	
CTEP investigator ID	0570
Investigator Last Name	Doe
<input type="button" value="Submit"/>	
<b>CTEP Investigator ID</b>	0570
<b>Investigator Name</b>	Julie Doe
<b>Office CTEP Site Code</b>	OH007
<b>Office Institution Name</b>	Ohio State University Comprehensive Cancer Center
<b>Shipping CTEP Site Code</b>	OH007
<b>Shipping Institution Name</b>	Ohio State University Comprehensive Cancer Center
<b>Investigator registration status</b>	Active
<b>Investigator registration expiration date</b>	06/30/2015
<b>Investigator Affiliations</b>	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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**Rostered Example**

NCI Protocol # 1214  
 Local Protocol # ABC1234

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

**Corresponding Organization:** P2C MMSB - Mayo Clinic Cancer Center P2C

**Principal Investigator:** John Doe, MD  
 Department of Radiation Medicine  
 MMSB - Mayo Clinic Cancer Center (P2C-MMSB)  
 123 Main Street  
 Rochester, MN 55905  
 Phone: (555) 123-4567  
 Fax: (555) 456-7890

**Participating Organizations:**

P2C Name	Investigator Name	Office CTEP Site Code
P2C ALB1 - University of Alabama Cancer Center P2C	John Doe	000001
P2C ALB2 - University of Alabama Cancer Center P2C	John Doe	000001
P2C ALB3 - University of Alabama Cancer Center P2C	John Doe	000001
P2C ALB4 - University of Alabama Cancer Center P2C	John Doe	000001
P2C ALB5 - University of Alabama Cancer Center P2C	John Doe	000001
P2C ALB6 - University of Alabama Cancer Center P2C	John Doe	000001
P2C ALB7 - University of Alabama Cancer Center P2C	John Doe	000001
P2C ALB8 - University of Alabama Cancer Center P2C	John Doe	000001
P2C ALB9 - University of Alabama Cancer Center P2C	John Doe	000001
P2C ALB10 - University of Alabama Cancer Center P2C	John Doe	000001
P2C ALB11 - University of Alabama Cancer Center P2C	John Doe	000001
P2C ALB12 - University of Alabama Cancer Center P2C	John Doe	000001
P2C ALB13 - University of Alabama Cancer Center P2C	John Doe	000001
P2C ALB14 - University of Alabama Cancer Center P2C	John Doe	000001
P2C ALB15 - University of Alabama Cancer Center P2C	John Doe	000001
P2C ALB16 - University of Alabama Cancer Center P2C	John Doe	000001
P2C ALB17 - University of Alabama Cancer Center P2C	John Doe	000001
P2C ALB18 - University of Alabama Cancer Center P2C	John Doe	000001
P2C ALB19 - University of Alabama Cancer Center P2C	John Doe	000001
P2C ALB20 - University of Alabama Cancer Center P2C	John Doe	000001

**Non-Member Collaborators:** Jane Doe, MD  
 Department of Radiation Medicine  
 AZ123 - XYZ University Research Institute  
 456 Main Street  
 University, AZ 45678  
 Phone: (555) 123-4567  
 Fax: (555) 456-7890

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.

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**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.

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Date	Time	Initials	Quantity	Balance	Lot	Expiry	Recorder	Checked	Checked Date	Checked By	Checked By Initials	Checked By Date
11/01/2014	08:00	SM	1	29	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	28	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	27	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	26	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	25	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	24	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	23	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	22	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	21	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	20	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	19	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	18	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	17	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	16	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	15	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	14	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	13	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	12	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	11	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	10	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	9	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	8	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	7	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	6	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	5	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	4	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	3	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	2	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	1	BLX12045012	08/14	SM					

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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Date	Time	Initials	Quantity	Balance	Lot	Expiry	Recorder	Checked	Checked Date	Checked By	Checked By Initials	Checked By Date
11/01/2014	08:00	SM	1	29	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	28	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	27	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	26	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	25	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	24	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	23	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	22	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	21	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	20	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	19	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	18	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	17	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	16	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	15	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	14	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	13	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	12	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	11	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	10	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	9	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	8	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	7	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	6	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	5	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	4	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	3	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	2	BLX12045012	08/14	SM					
11/01/2014	08:00	SM	1	1	BLX12045012	08/14	SM					

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.



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**Multiple Lots or Multiple Strengths**

Agent Name: Sunitinib malate (NSC 736511)		Dose Form and Strength: 12.5 mg Capsules	
4540314	AZ	1254-001	37.5 mg daily
4540314	AZ	1254-004	37.5 mg daily
Agent Name: Sunitinib malate (NSC 736511)		Dose Form and Strength: 25 mg Capsules	
4540314	AZ	1254-001	37.5 mg daily

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.

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**Single-use Vials**

National Institute of Health National Cancer Institute		Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program		PAGE NO. 7				
Investigational Agent Accountability Record				CONTROL RECORD <input checked="" type="checkbox"/>				
				SATELLITE RECORD <input type="checkbox"/>				
Name of Institution: State University Hospital		NCI Protocol No: 2493						
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.		CIER Investigator ID: 989999						
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward or Balance	Manufacturer and Lot No.	Pharmacy Notes
1	12/22/14	Received	From NCI		+12	12	S3712345678	KJB
2	12/22/14	JT	1234-001	254 mg	-2	10	S3712345678	JL
3	12/22/14	BT	1234-002	238 mg	-2	8	S3712345678	KJB
4	12/26/14	JT	1234-001	177 mg	-1	7	S3712345678	AC
5	12/26/14	BT	1234-002	329 mg	-2	5	S3712345678	KJB

When dispensing injectable agents on the original NCI DARF, often the dose dispensed is intended for a single administration. If the dose requires calculations, for example  $\text{mg}/\text{m}^2$ , 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 DARF. Do not document destruction of agent remaining in single-use vials following dose preparation.

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**Multi-dose Vials**

**Tracking by milligram**

Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward
Dispensed from the Vial				10 vials
AS	12345	200 mg	200 mg	9 vials = 180 mg
BT	12345	200 mg	200 mg	8 vials = 160 mg

**Tracking by vial**

Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward
Dispensed from the Vial				10 vials
AS	12345	200 mg	1 vial	9 vials
BT	12345	200 mg	1 vial	8 vials

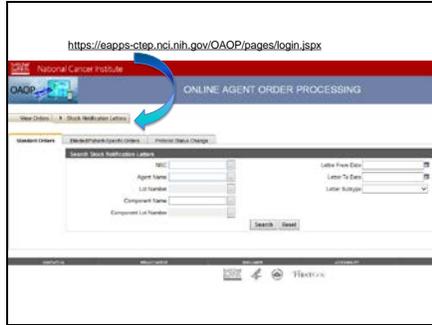
If dispensing from a multi-dose vial, PMB recommends tracking inventory either by milligram or by vial. Tracking by milligram involves more calculations whereas the term partial can be used when tracking by vial. Record either the number of vials plus the word partial when using the vial method, or the 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.

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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.

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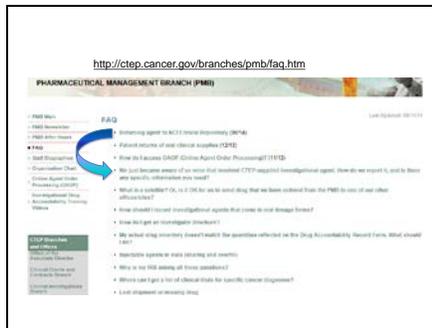
Dispensing areas should have procedures in place for ensuring the agent is suitable for clinical use. Once an expiration date is known, PMB will issue notification to each ordering investigator and all shipping and ordering designees at each institution. Access PMB stock notification letters through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

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Dispensing areas should not mail investigational medications to study subjects.

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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.

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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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