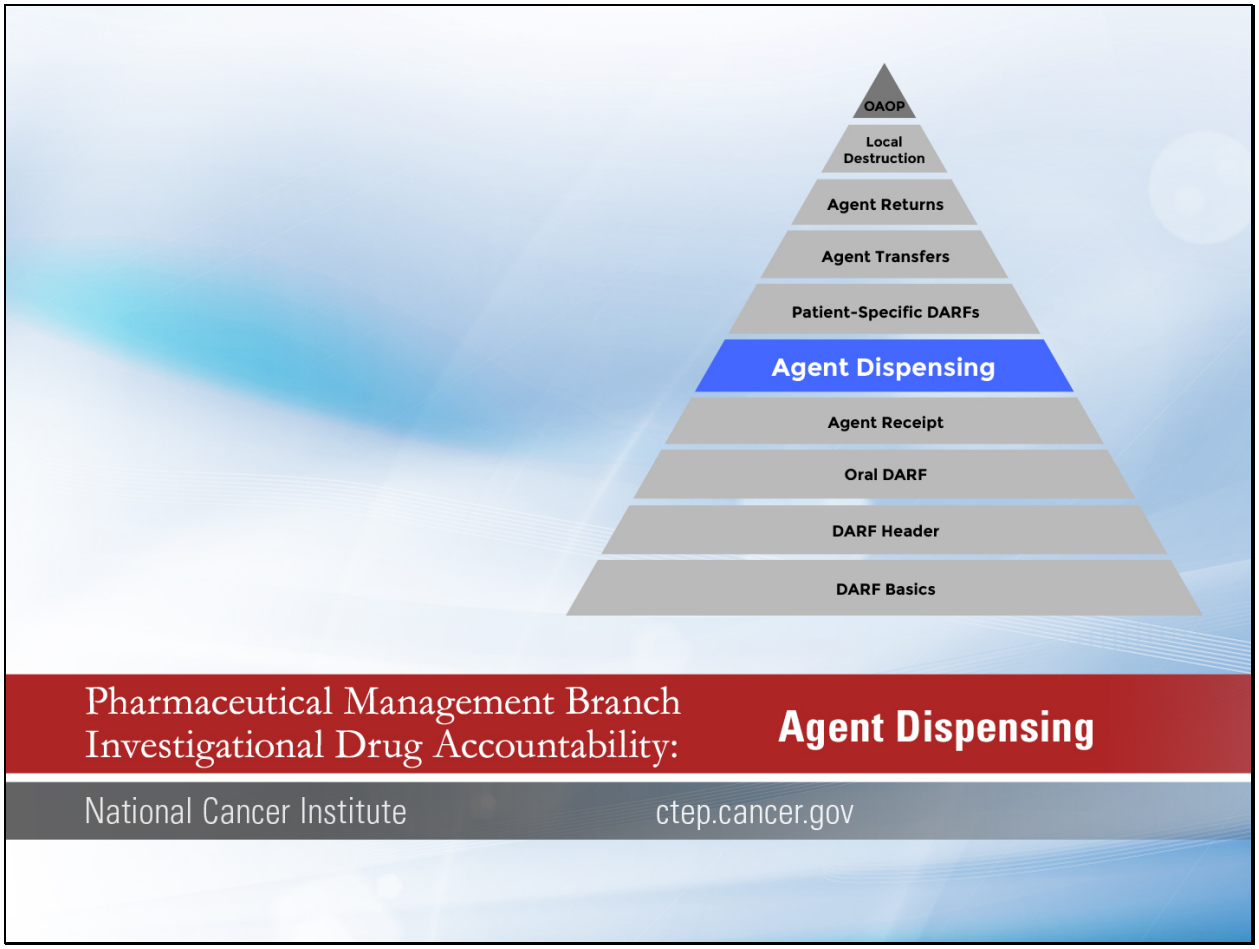
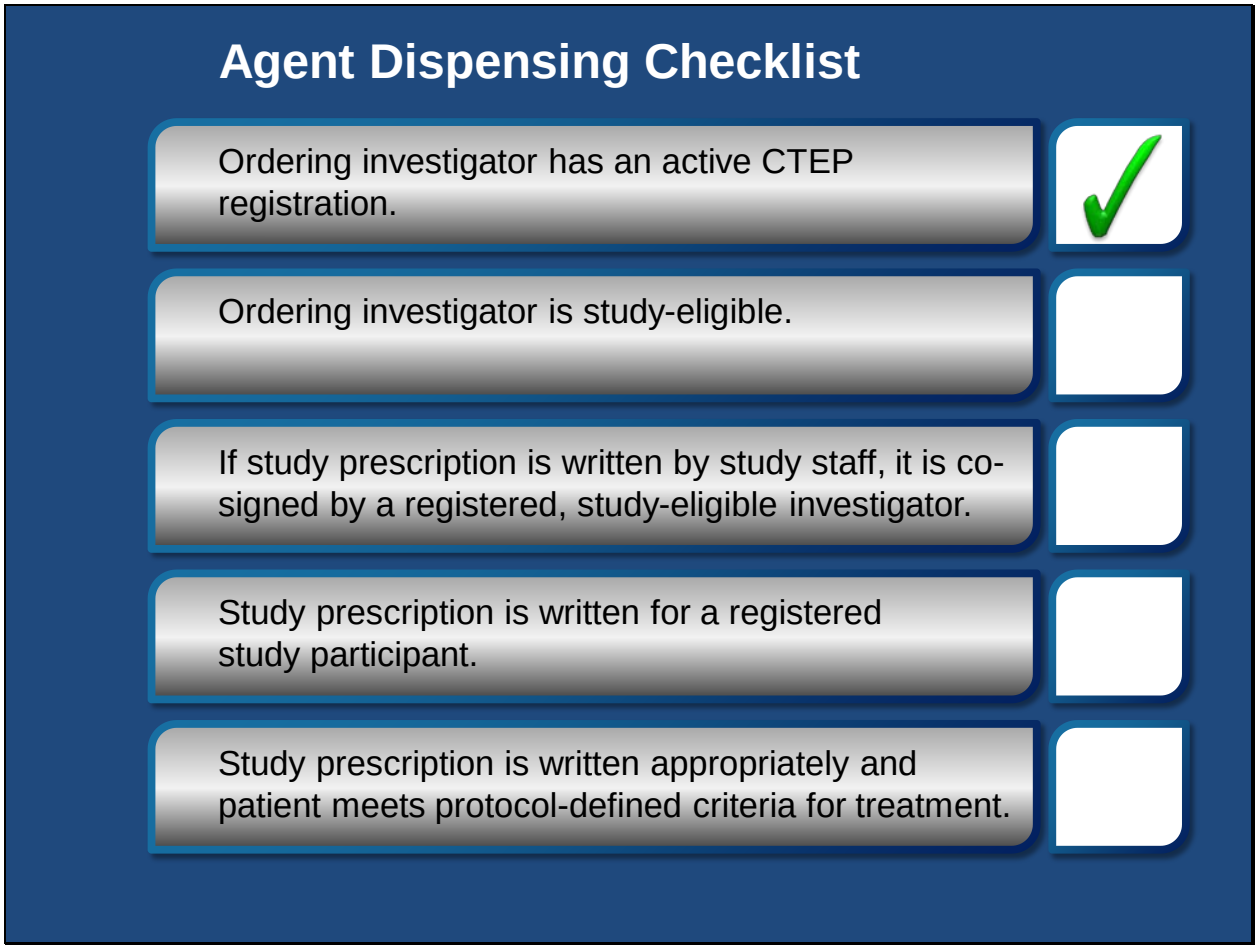
Slide 1



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.

Slide 2



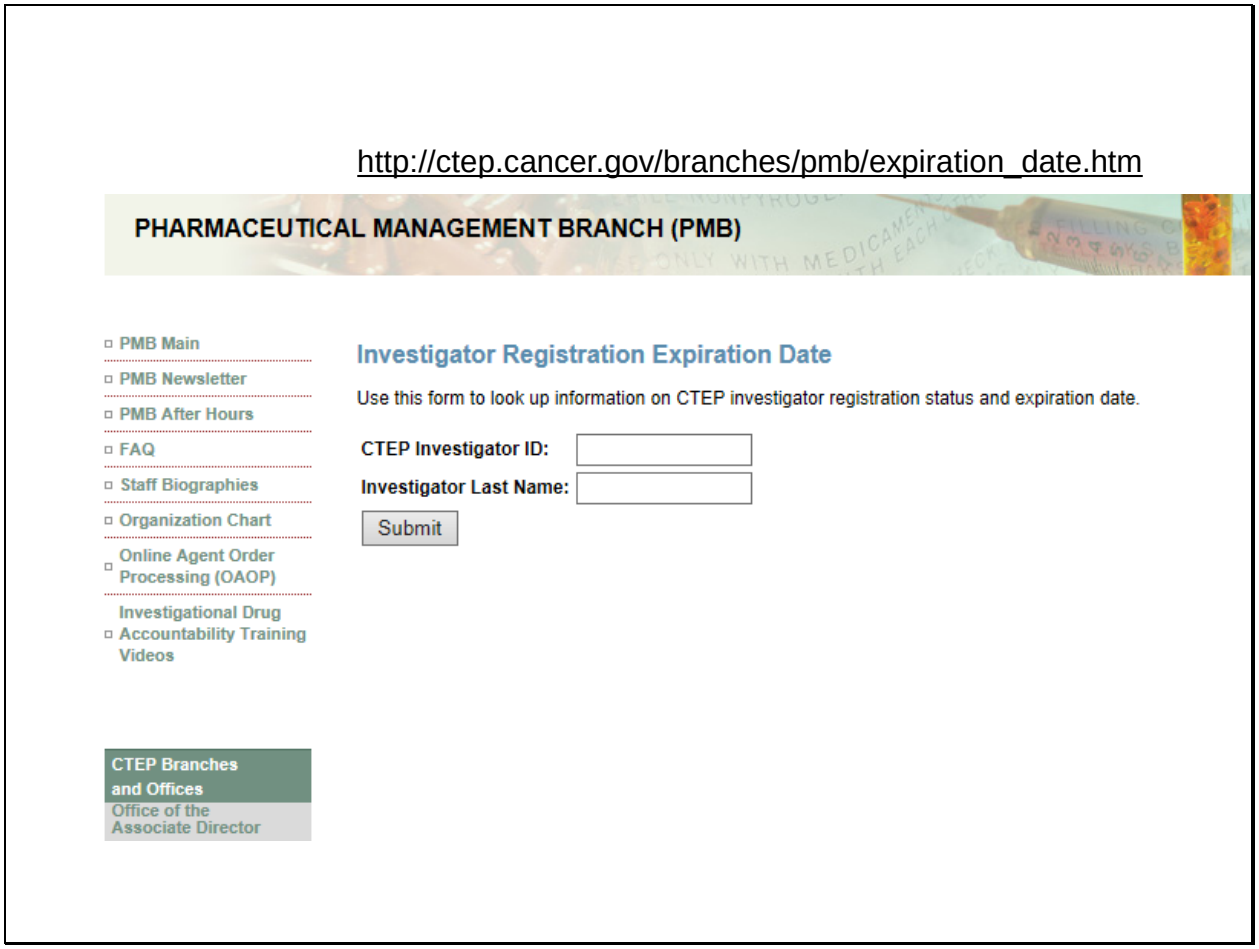
Upon receiving a prescription for study agent for use in an NCI approved protocol, first verify that the ordering investigator has an active CTEP registration.

Slide 3

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

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

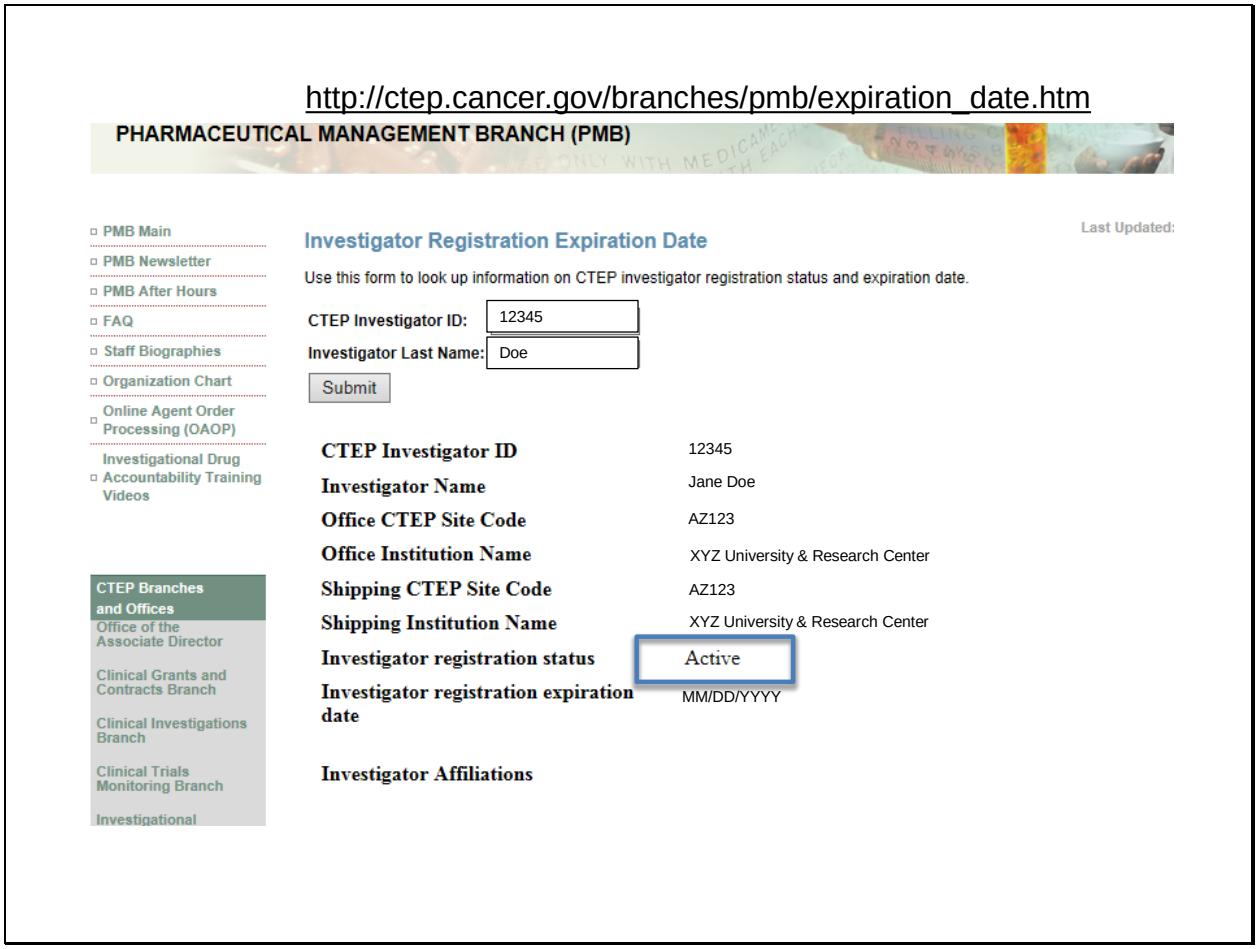
Slide 4



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

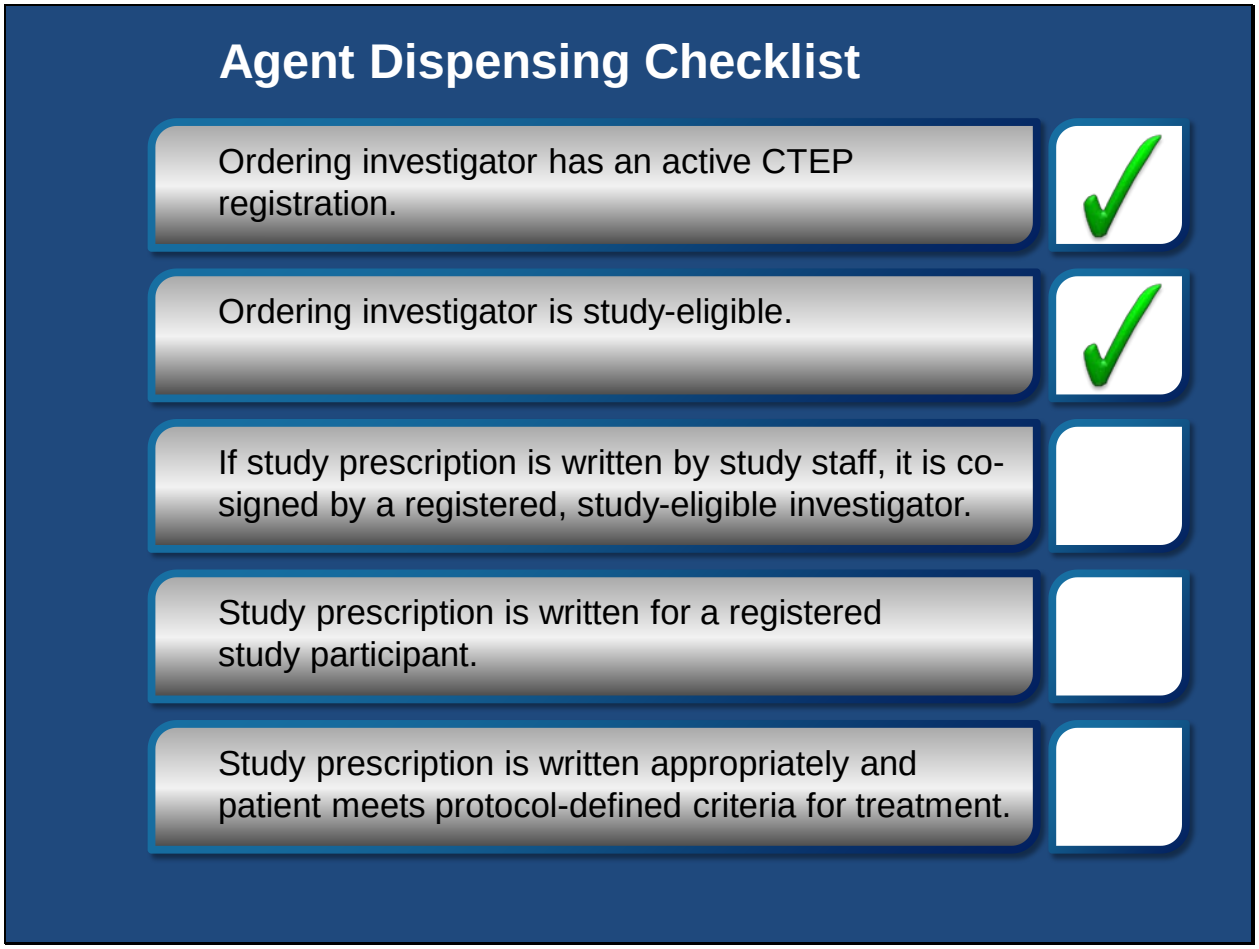
If the CTEP Investigator ID is unknown, you can look it up in OAOP or check with your research coordinator. The CTSU website can also be used if you have access to it. The Regulatory tab provides a list of all investigators at a site with their registration status and CTEP Investigator ID.

Slide 5



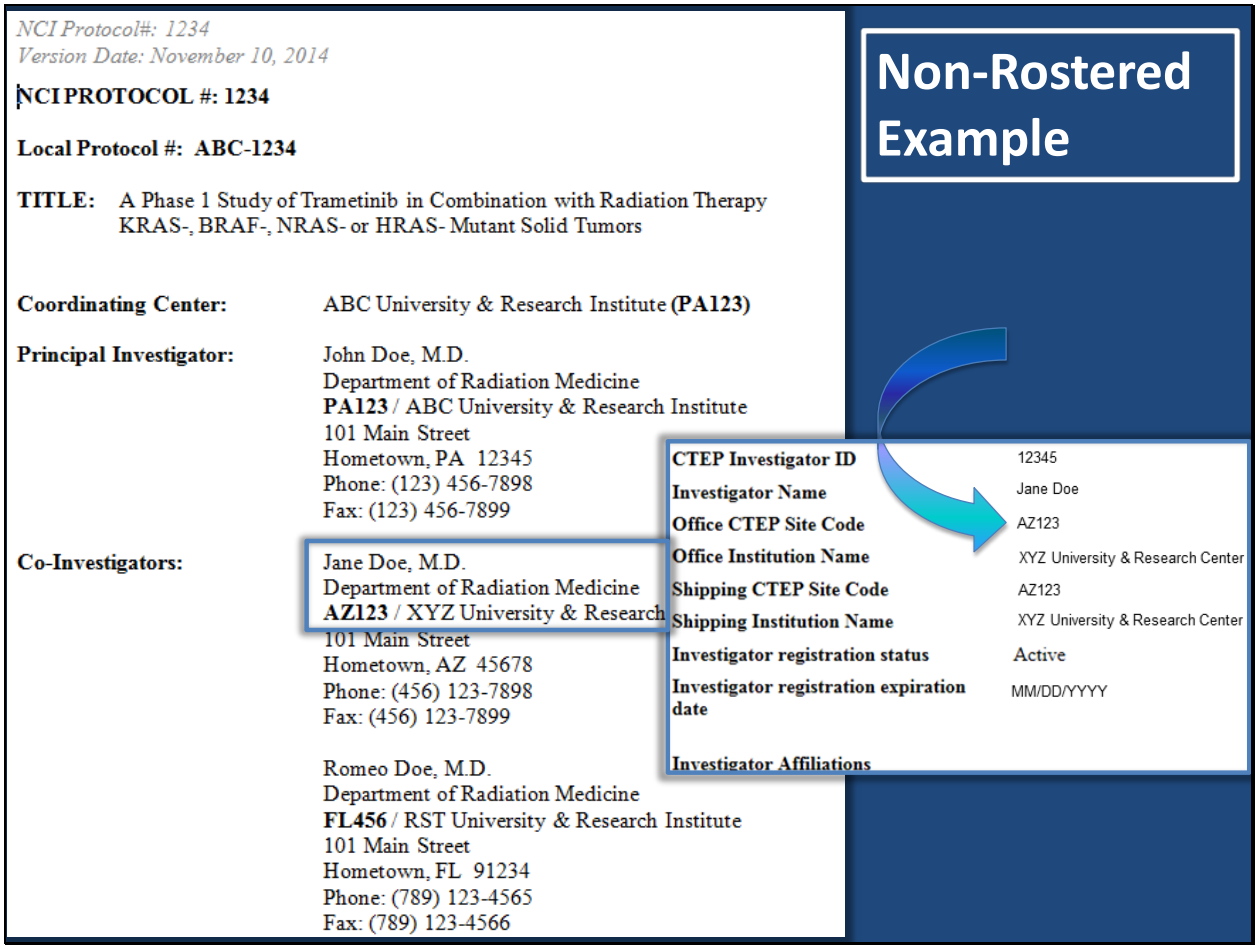
This is an example of an investigator with an active CTEP registration status. Note that this investigator does not have any current affiliations. Investigator affiliations indicate eligibility to participate on rostered participant protocols.

Slide 6



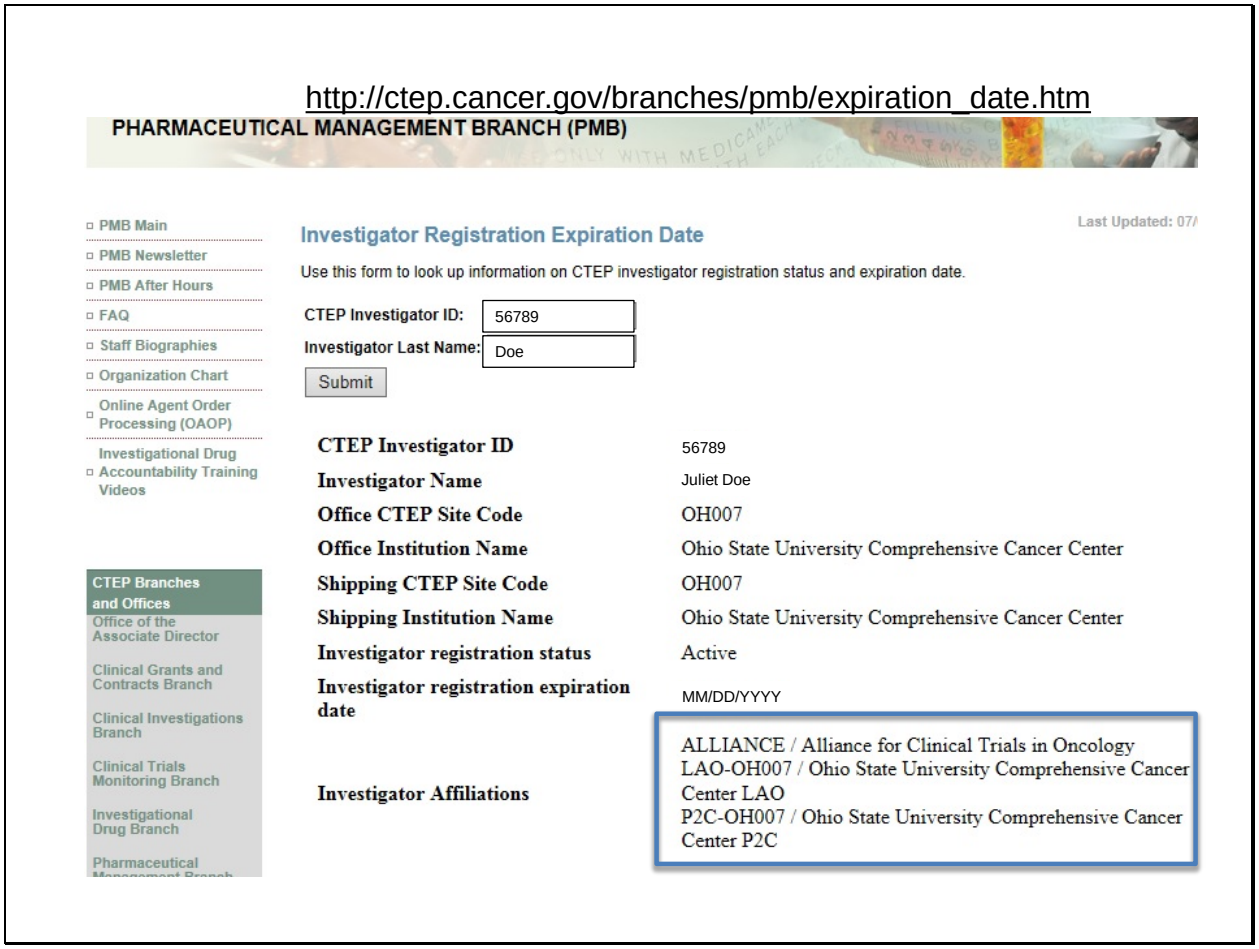
The next step requires a copy of the current version of the protocol, in addition to the investigator registration status search results, in order to verify that the ordering investigator is study-eligible to participate on the trial. Let's review a couple examples.

Slide 7



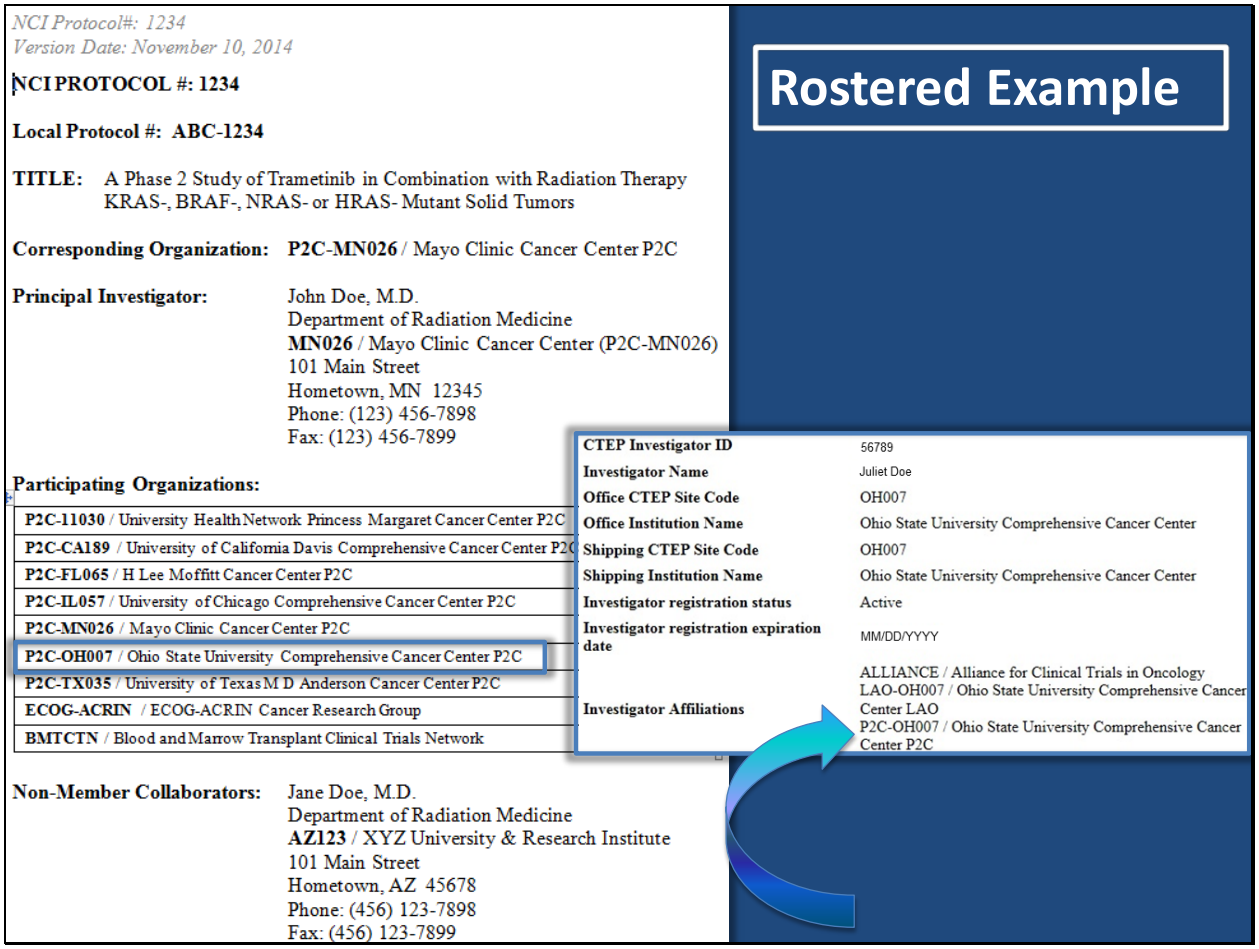
For non-rostered single or multicenter studies, each study eligible institution and ordering investigator must be listed on the protocol title page. In this example of a multi-center study we've verified the investigator name, institution, and CTEP site code on the title page with the investigator registration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

Slide 8



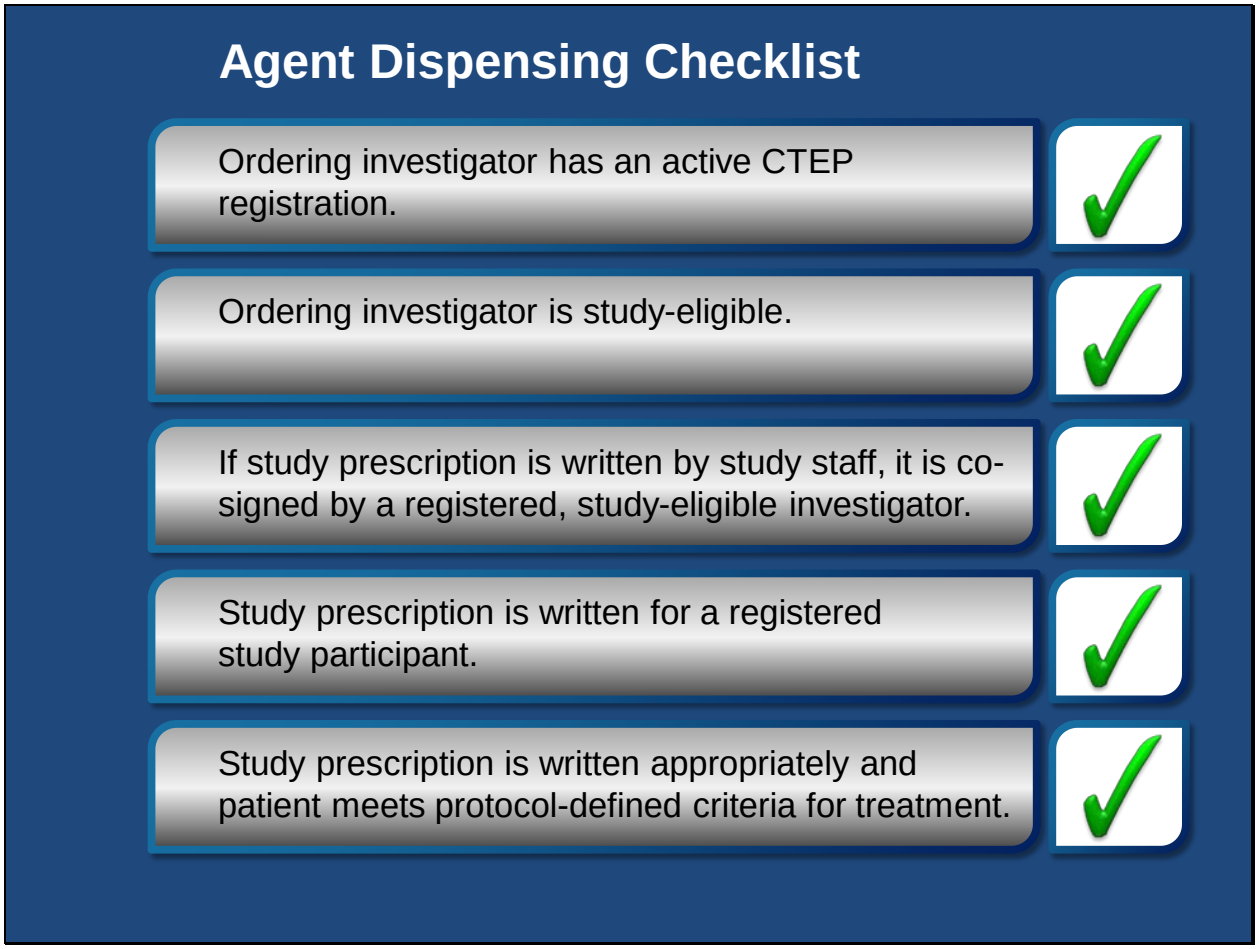
To check study eligibility of an ordering investigator for a rostered participant protocol, utilize the investigator affiliations in the investigator registration status search results when referring to the protocol title page. In this example, the investigator has affiliations with ALLIANCE, a Lead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

Slide 9



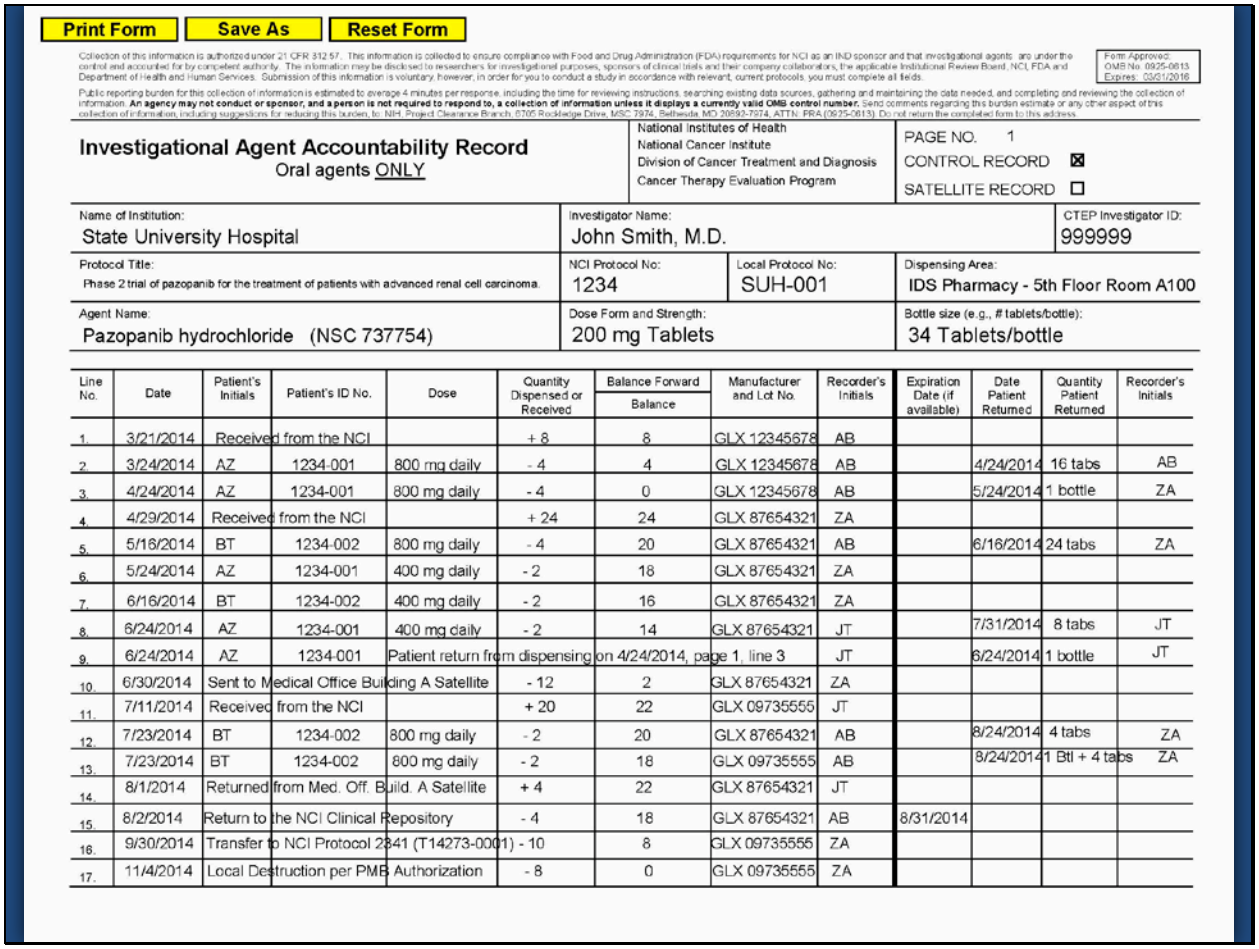
Now refer to the participating organizations on the title page. For rostered studies each study-eligible investigator is NOT listed on the title page. The P2C that this investigator is affiliated with appears on the title page so the investigator is study-eligible for this rostered participant protocol.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

Slide 10



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.

Slide 11



Print Form | Save As | Reset Form

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.

Form Approved: OMB No. 0925-0613 Expires: 03/31/2016

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.

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 ☒
SATELLITE RECORD ☐

Name of Institution:	Investigator Name:	CTEP Investigator ID:
State University Hospital	John Smith, M.D.	999999

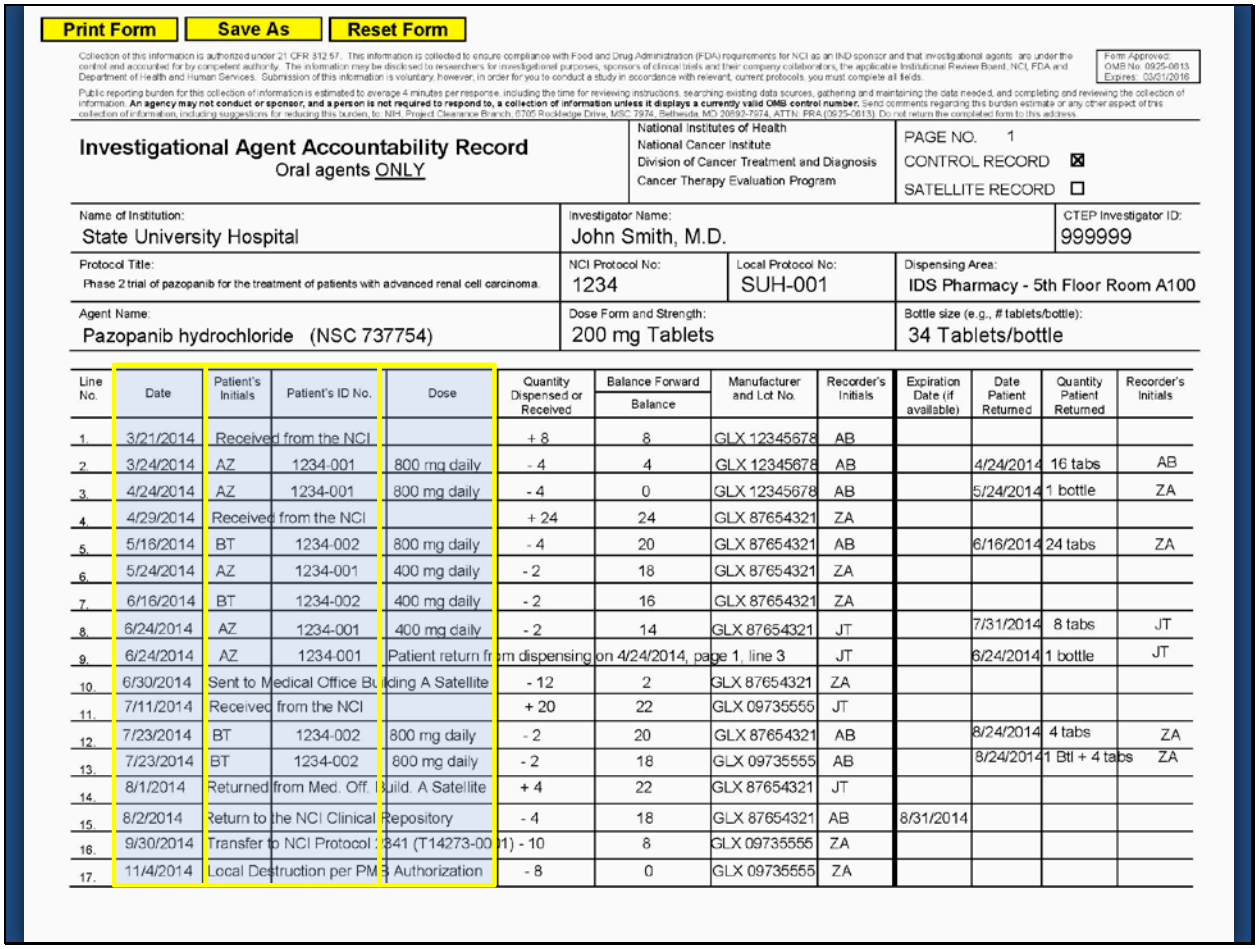
Protocol Title:	NCI Protocol No:	Local Protocol No:	Dispensing Area:
Phase 2 trial of pazopanib for the treatment of patients with advanced renal cell carcinoma.	1234	SUH-001	IDS Pharmacy - 5th Floor Room A100

Agent Name:	Dose Form and Strength:	Bottle size (e.g., # tablets/bottle):
Pazopanib hydrochloride (NSC 737754)	200 mg Tablets	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.

Slide 12



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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.

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 ☒
SATELLITE RECORD ☐

Name of Institution:	Investigator Name:	CTEP Investigator ID:
State University Hospital	John Smith, M.D.	999999

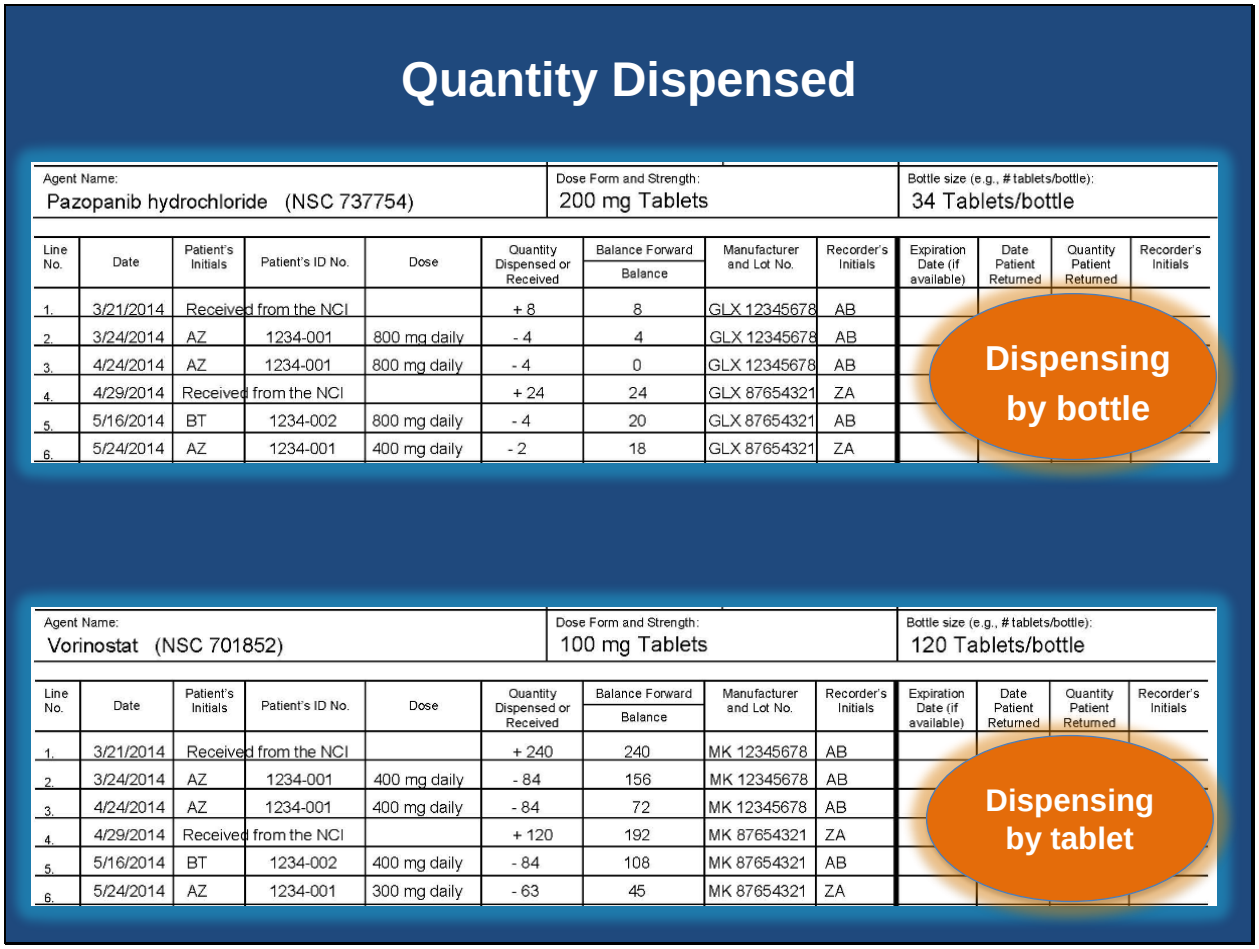
Protocol Title:	NCI Protocol No:	Local Protocol No:	Dispensing Area:
Phase 2 trial of pazopanib for the treatment of patients with advanced renal cell carcinoma.	1234	SUH-001	IDS Pharmacy - 5th Floor Room A100

Agent Name:	Dose Form and Strength:	Bottle size (e.g., # tablets/bottle):
Pazopanib hydrochloride (NSC 737754)	200 mg Tablets	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 7841 (T14273-01)			- 10	8	GLX 09735555	ZA				
17.	11/4/2014	Local Destruction per PMB Authorization			- 8	0	GLX 09735555	ZA				

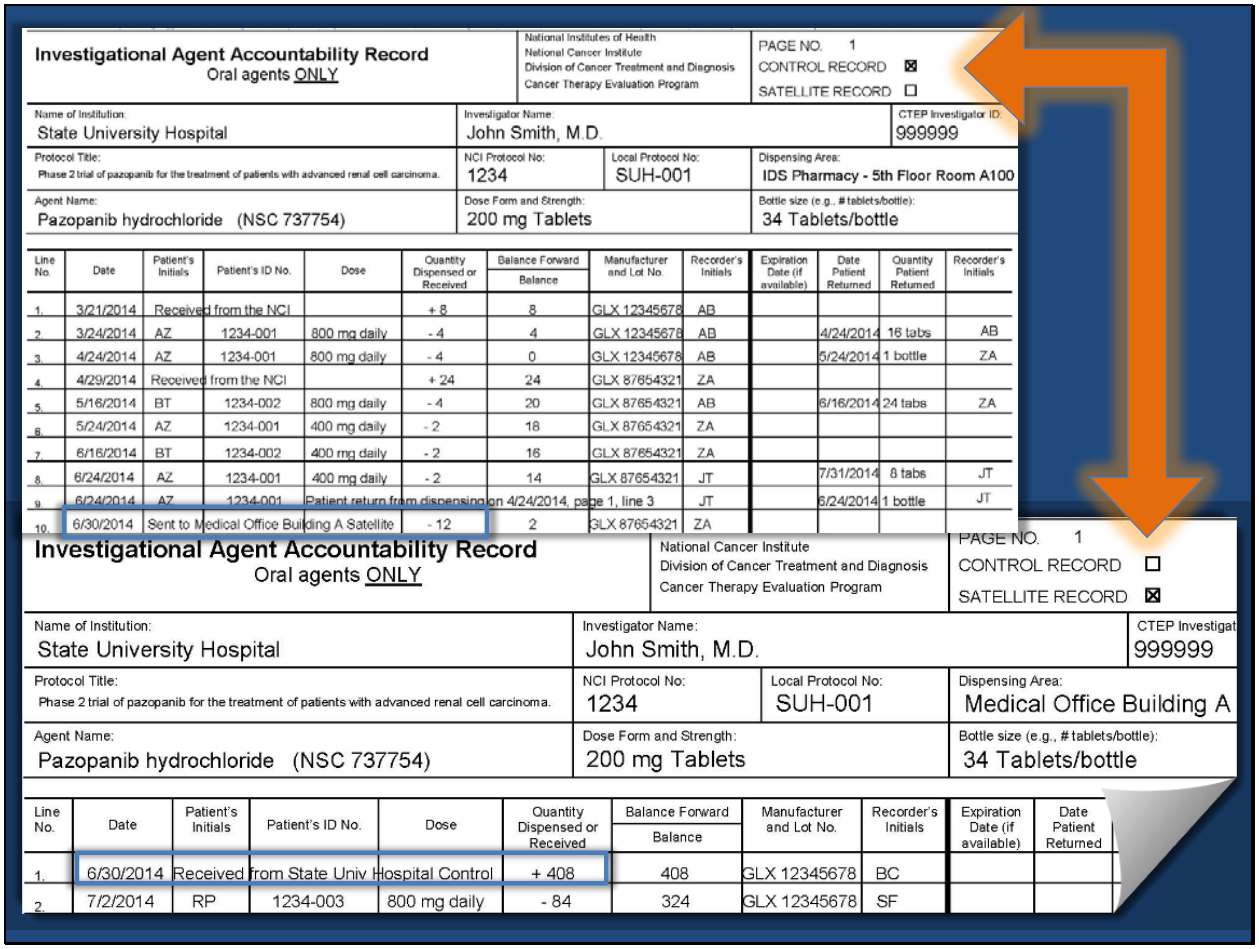
Record the date that the agent is prepared for dispensing. It may differ from the date it is provided to the patient or the date the patient begins treatment. Record the patient's initials and patient's ID number. In the dose field, record the prescribed dose. There can be different approaches to recording 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.

Slide 13



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.

Slide 14



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 ☒
SATELLITE RECORD ☐

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 ONLY

National Cancer Institute
Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

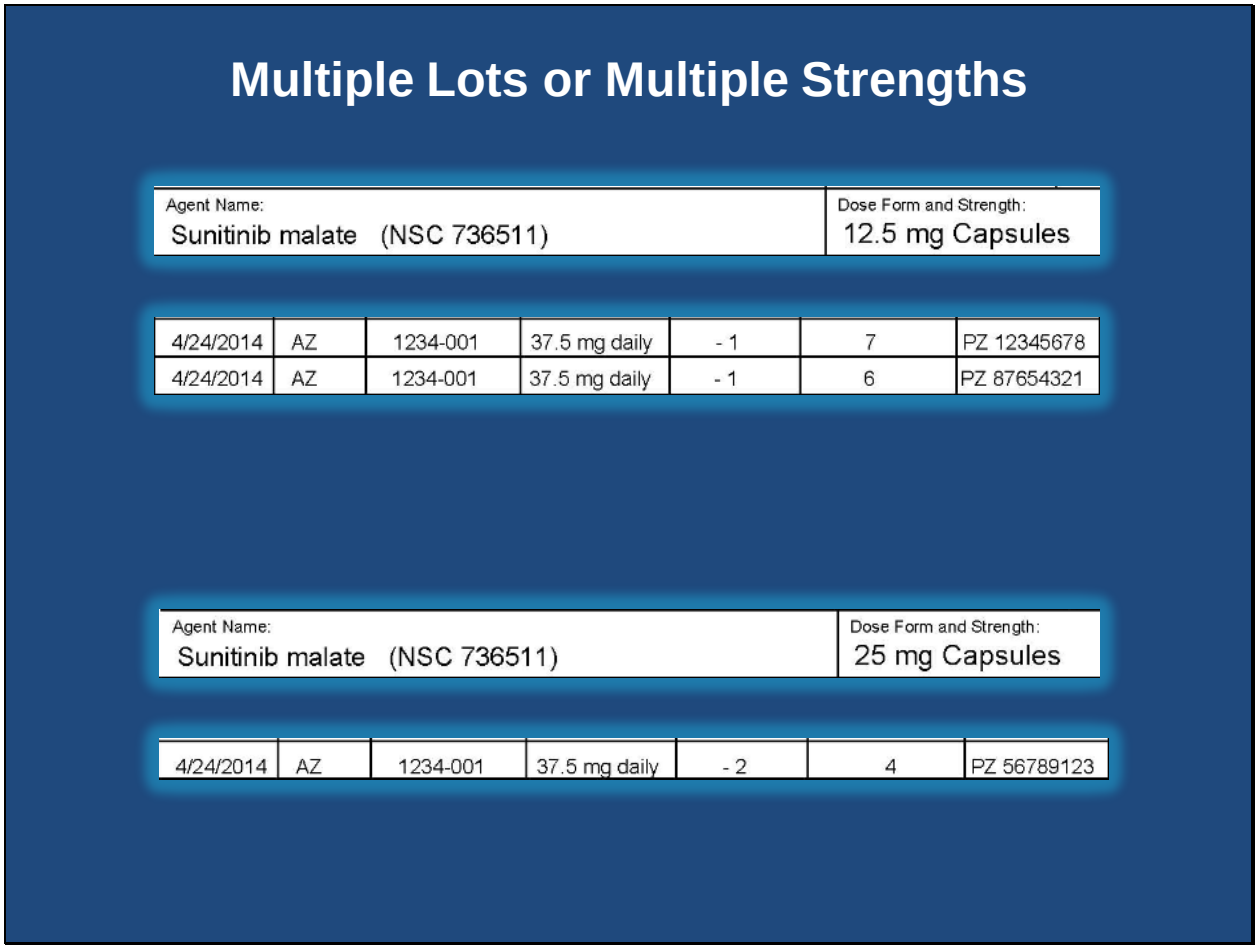
PAGE NO. 1
CONTROL RECORD ☐
SATELLITE RECORD ☒

Name of Institution: State University Hospital
Investigator Name: John Smith, M.D.
CTEP Investigat: 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.

Slide 15



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.

Slide 16

Single-use Vials

National Institutes of Health
National Cancer Institute

Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

Investigational Agent Accountability Record

PAGE NO. *1*
CONTROL RECORD ☒
SATELLITE RECORD ☐

Name of Institution:	NCI Protocol No.:
State University Hospital	2468
Agent Name:	**Dose Form and Strength:**
Ziv-Aflibercept (VEGF-Trap, AVE 0005), NSC 724770	200 mg / 8 mL vial; 25 mg/mL
Protocol Title:	**Dispensing Area:**
Phase II Study of Ziv-Aflibercept in Metastatic Colon Cancer	IDS Pharmacy - 5th Floor Room A100
Investigator Name:	**CTEP Investigator ID:**
John Smith, M.D.	999999

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward *0* / Balance	Manufacturer and Lot No.	Recorder's Initials
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 DARF, 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 DARF. Do not document destruction of agent remaining in single-use vials following dose preparation.

Slide 17

Multi-dose Vials

Tracking by milligram

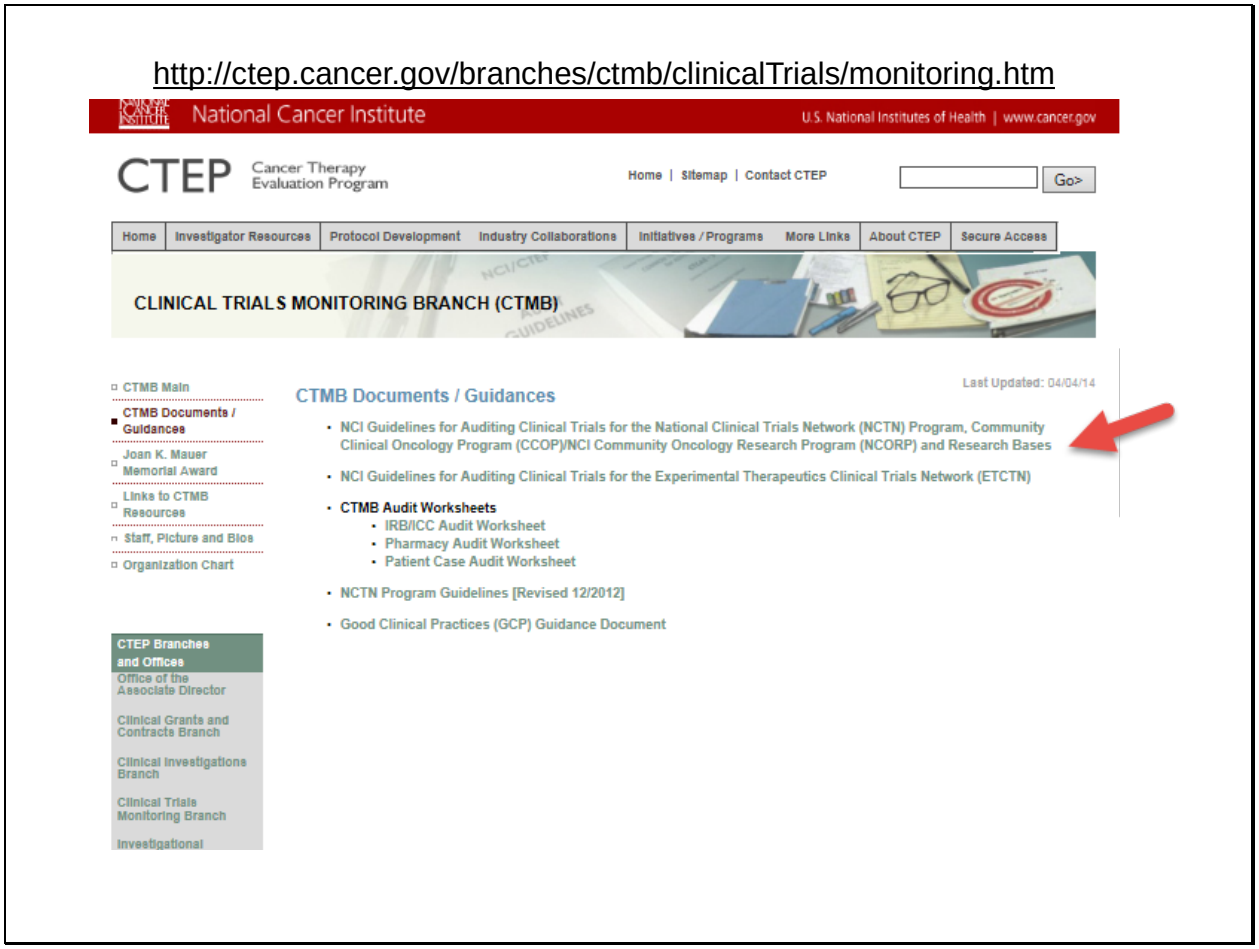
Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward 0
				Balance
Received from the NCI			10 vials	10 X 440 mg
AS	12345	288 mg	288 mg	9 vials + 152 mg
BT	12346	320 mg	320 mg	8 vials + 272 mg

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

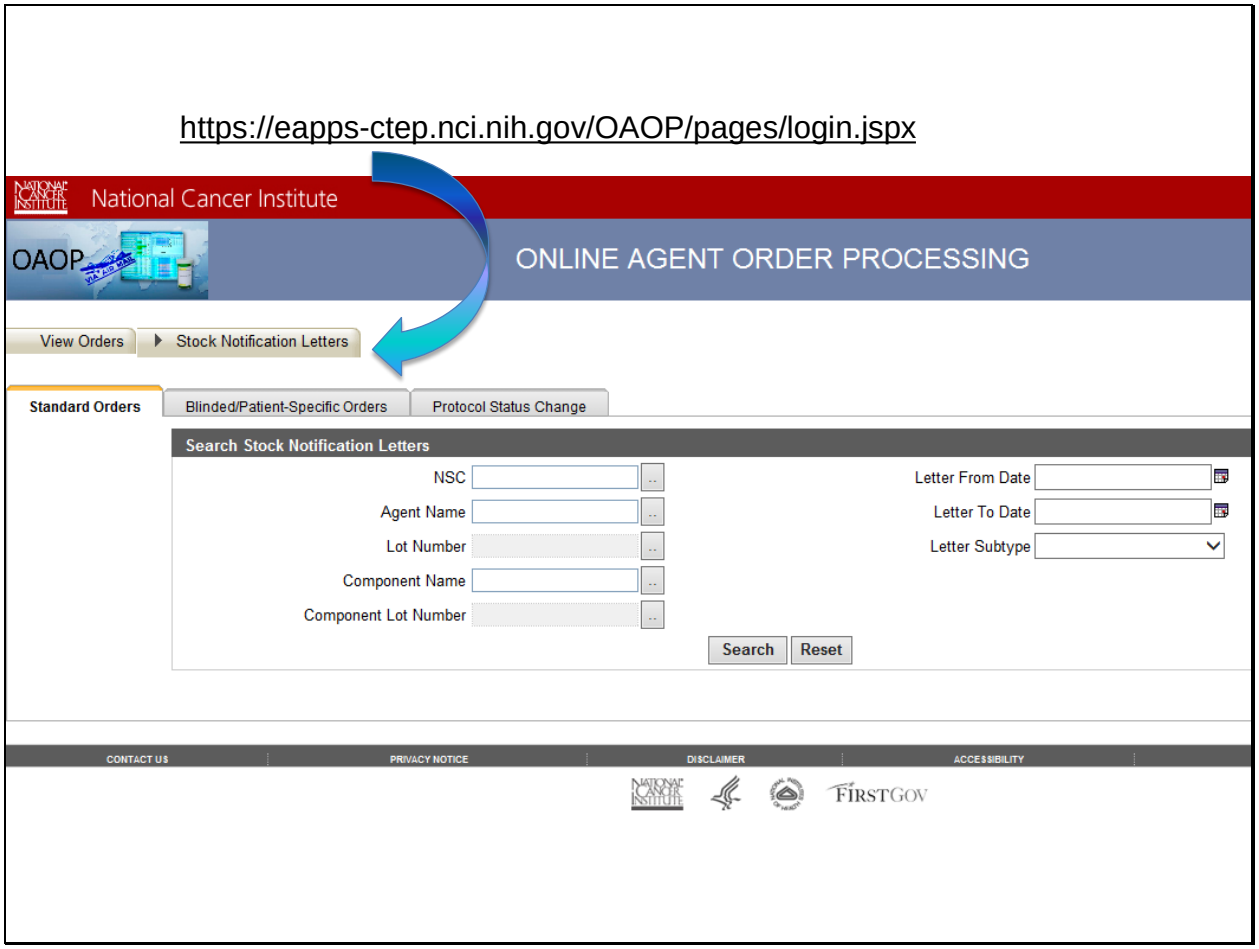
If dispensing from a multi-dose vial, PMB recommends tracking inventory either by milligram or by vial. Tracking by milligram involves more calculations whereas the term partial can be used when tracking by vial. Record either the number of vials plus the word partial when using the vial method, or the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

Slide 18



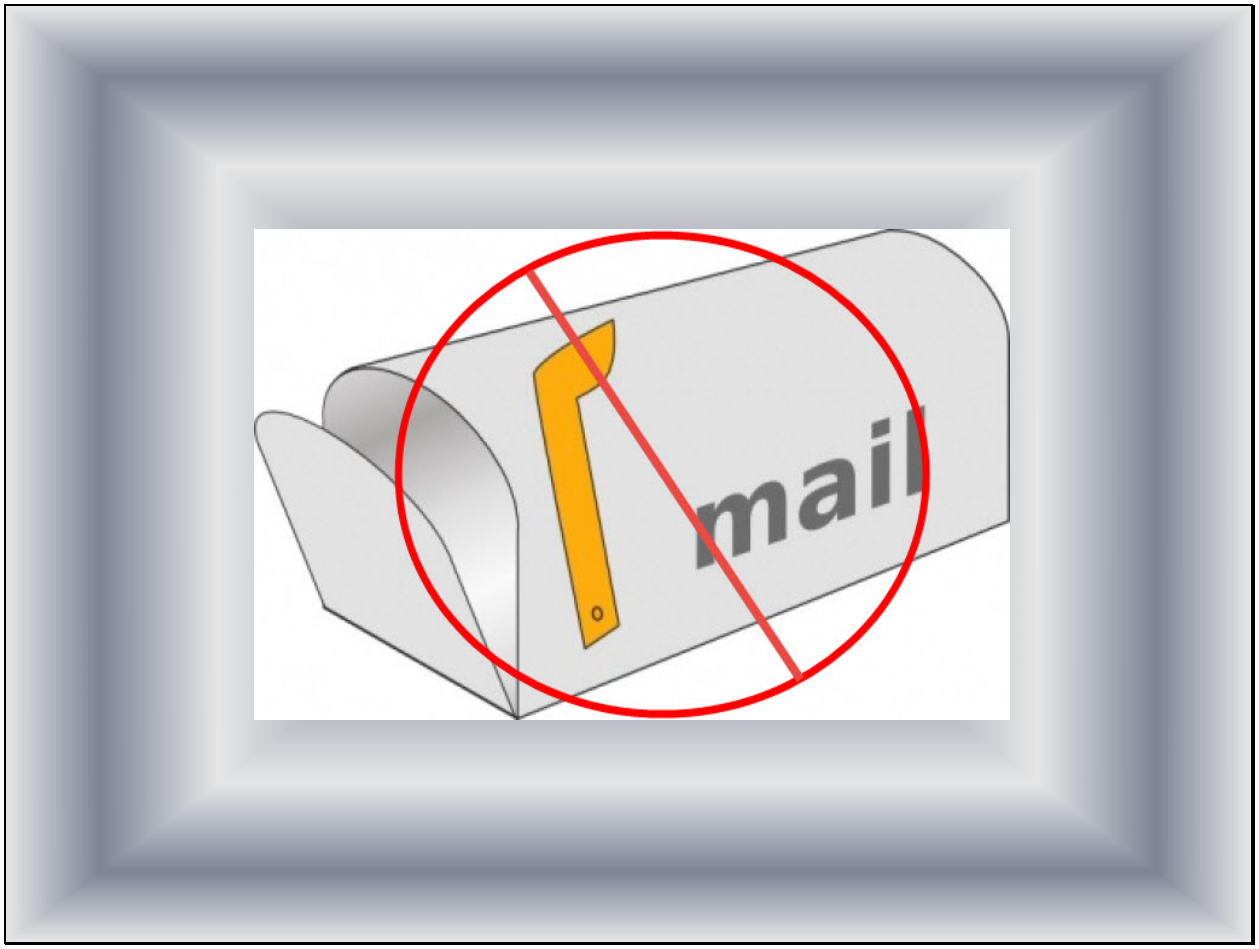
We've reviewed the agent dispensing checklist and examples of accountability procedures. Another helpful resource is Section 5.3 Agent Accountability and Pharmacy Operations of the NCI Guidelines for Auditing Clinical Trials for the NCTN found on the Clinical Trials Monitoring Branch website. Institution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

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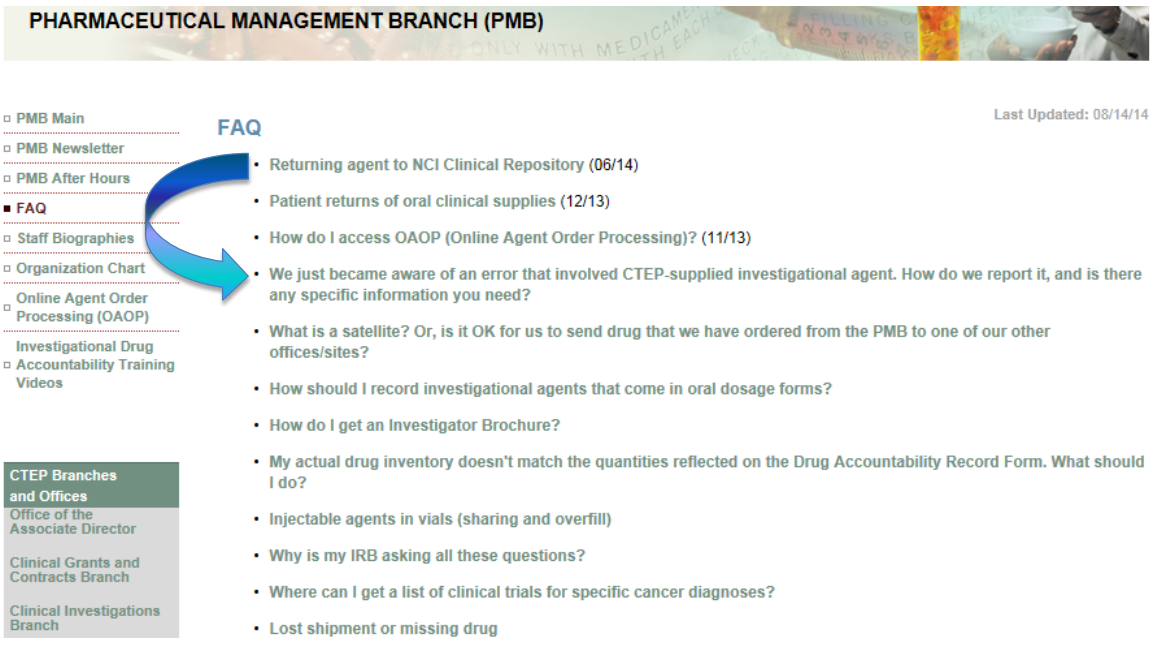
http://ctep.cancer.gov/branches/pmb/faq.htm



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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