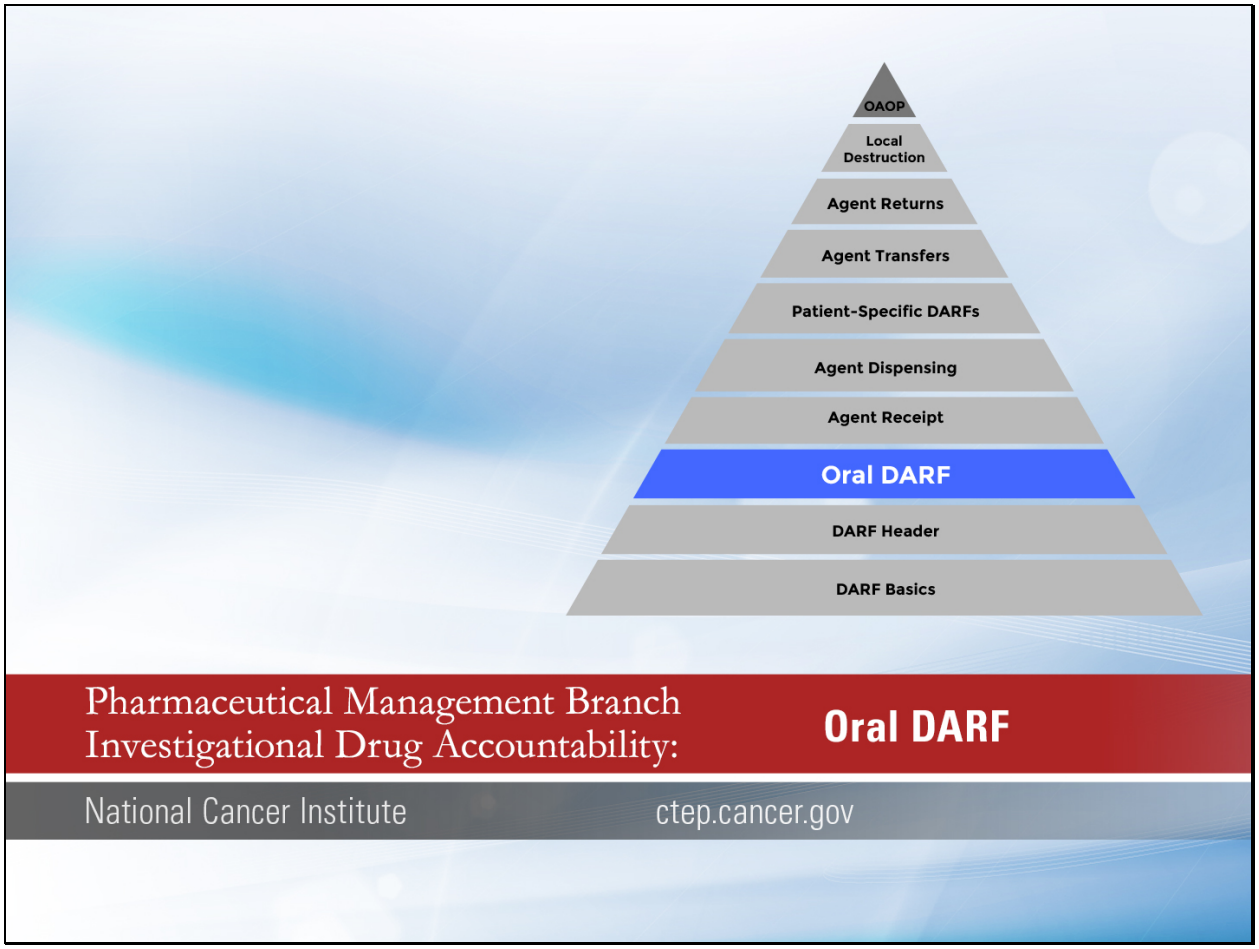
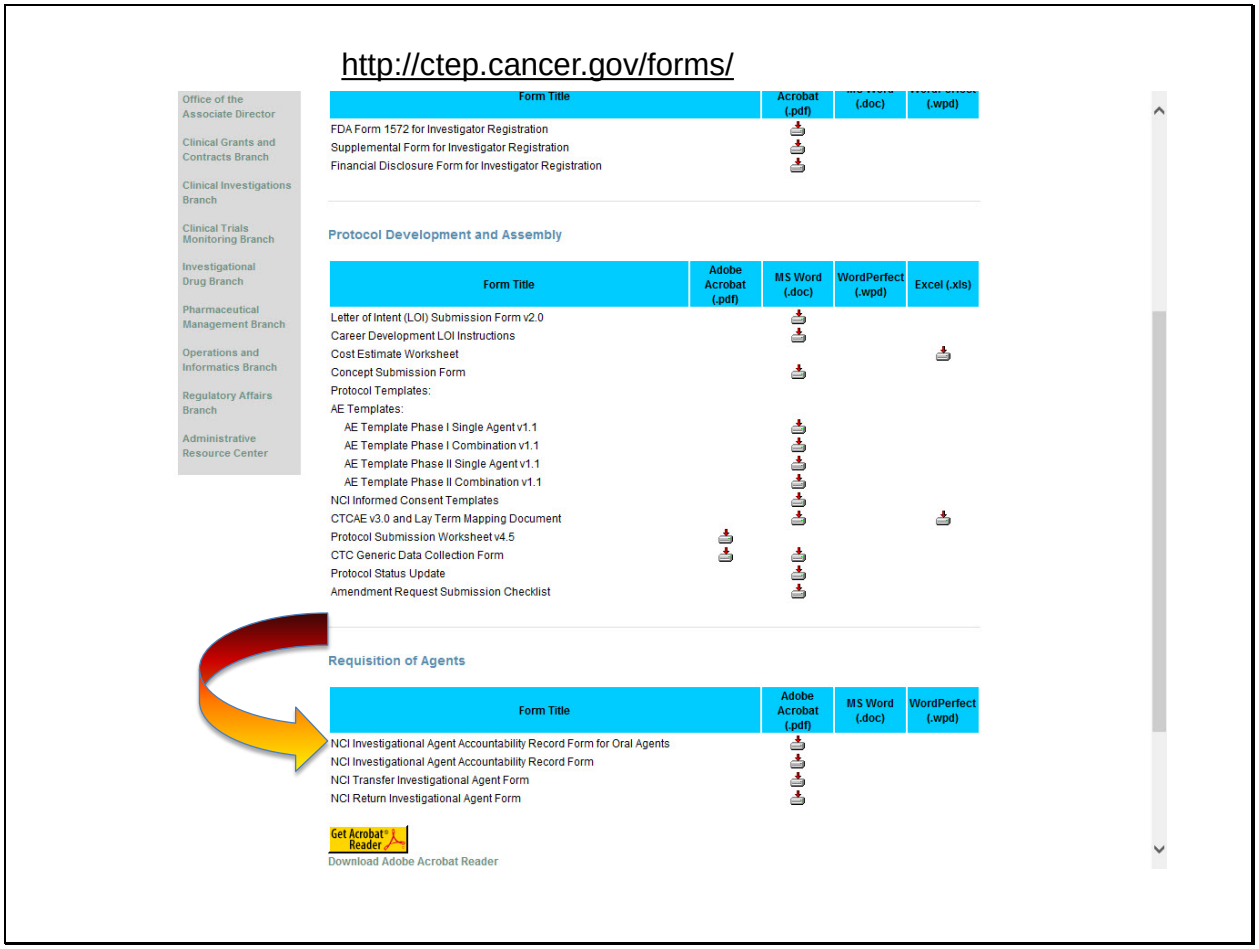
Slide 1



Welcome to this video tutorial on the Oral DARF in the PMB Investigational Drug Accountability series.

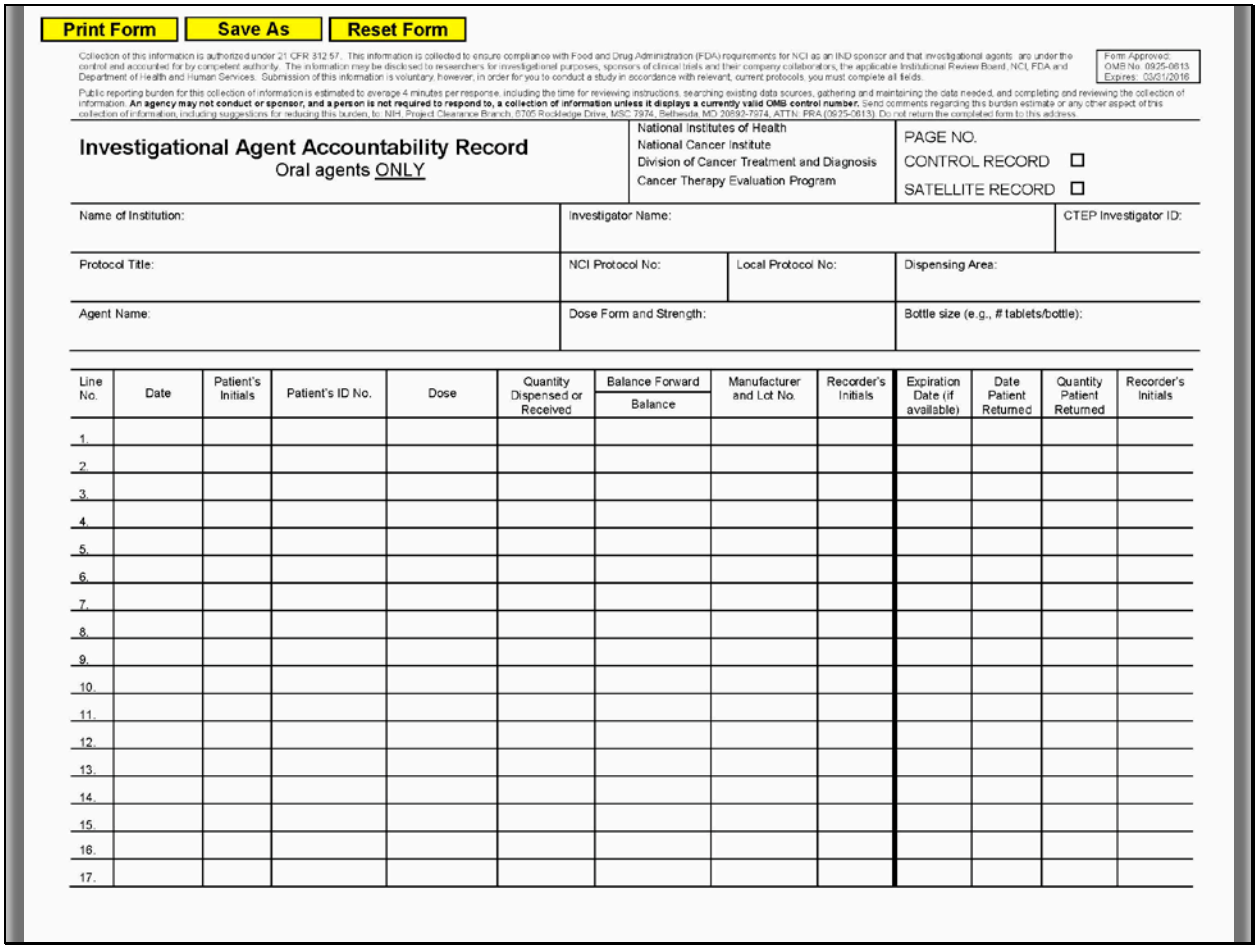
This video will review recording procedures when using the NCI Investigational Agent Accountability Record Form for Oral Agents, or Oral DARF.

Slide 2



You can find the Oral DARF here on the CTEP website, Forms page.

Slide 3



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

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Investigational Agent Accountability Record
Oral agents ONLY

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

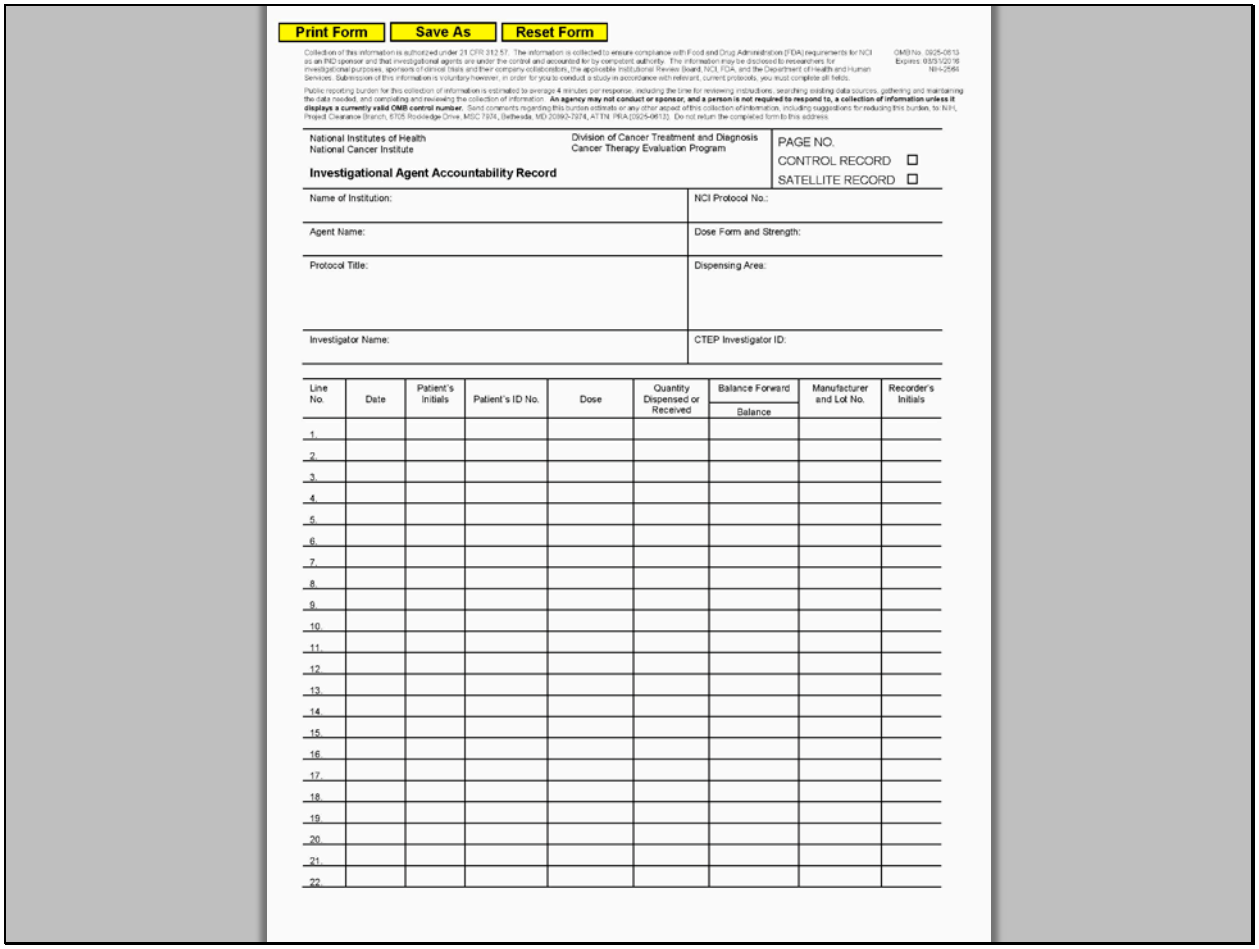
PAGE NO.
CONTROL RECORD ☐
SATELLITE RECORD ☐

Name of Institution:	Investigator Name:		CTEP Investigator ID:
Protocol Title:	NCI Protocol No:	Local Protocol No:	Dispensing Area:
Agent Name:	Dose Form and Strength:		Bottle size (e.g., # tablets/bottle):

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
1.												
2.												
3.												
4.												
5.												
6.												
7.												
8.												
9.												
10.												
11.												
12.												
13.												
14.												
15.												
16.												
17.												

The Oral DARF must be used for NCI studies using an oral agent, either open label, protocol specific, or blinded, patient specific.

Slide 4



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OMB No. 0925-0613
Expires: 03/31/2016
NIH-2584

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National Institutes of Health
National Cancer Institute

Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

PAGE NO.
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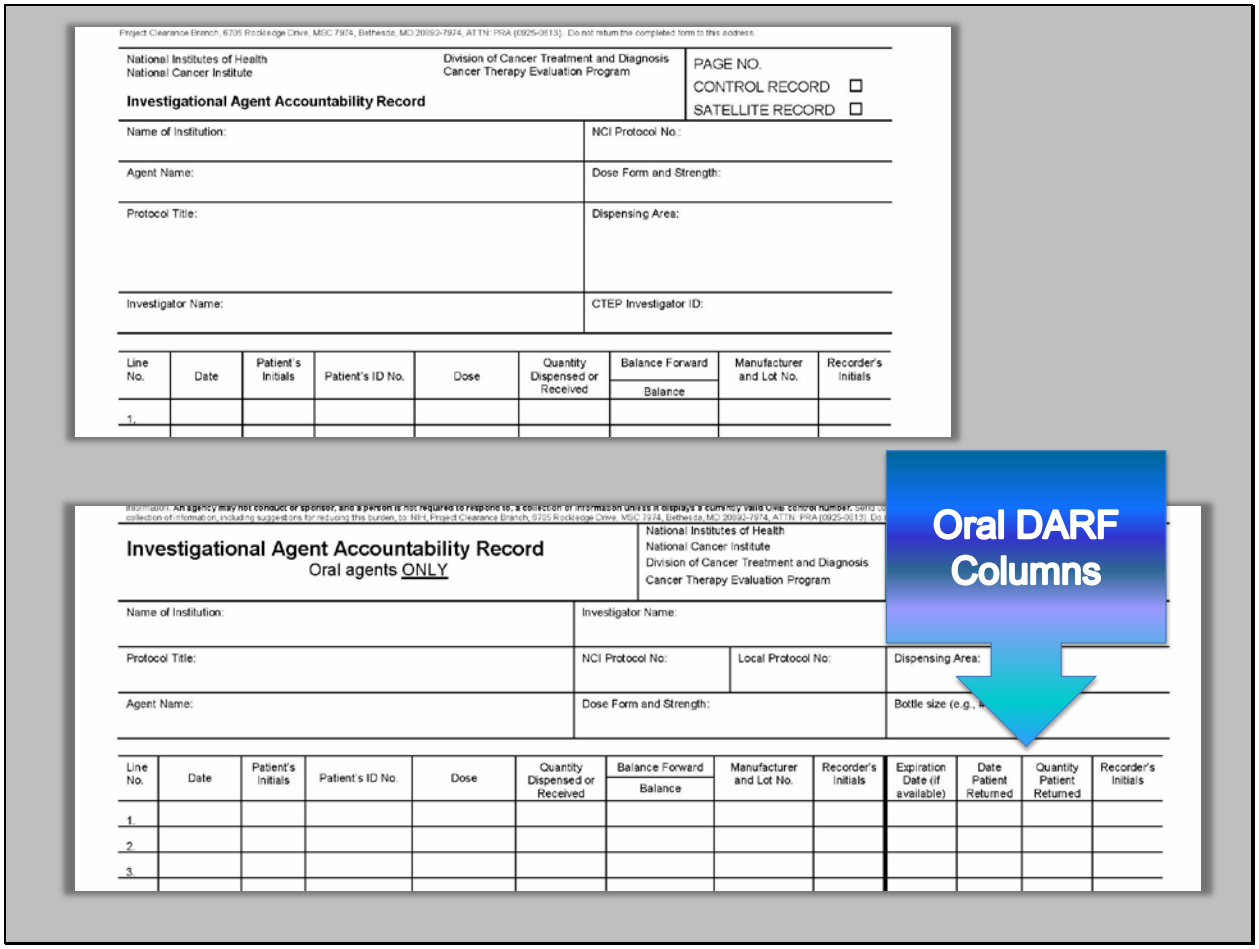
Investigational Agent Accountability Record

Name of Institution:	NCI Protocol No.:
Agent Name:	Dose Form and Strength:
Protocol Title:	Dispensing Area:
Investigator Name:	CTEP Investigator ID:

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials
1.								
2.								
3.								
4.								
5.								
6.								
7.								
8.								
9.								
10.								
11.								
12.								
13.								
14.								
15.								
16.								
17.								
18.								
19.								
20.								
21.								
22.								

Please continue to use the original NCI DARF for all formulations not intended for oral administration.

Slide 5

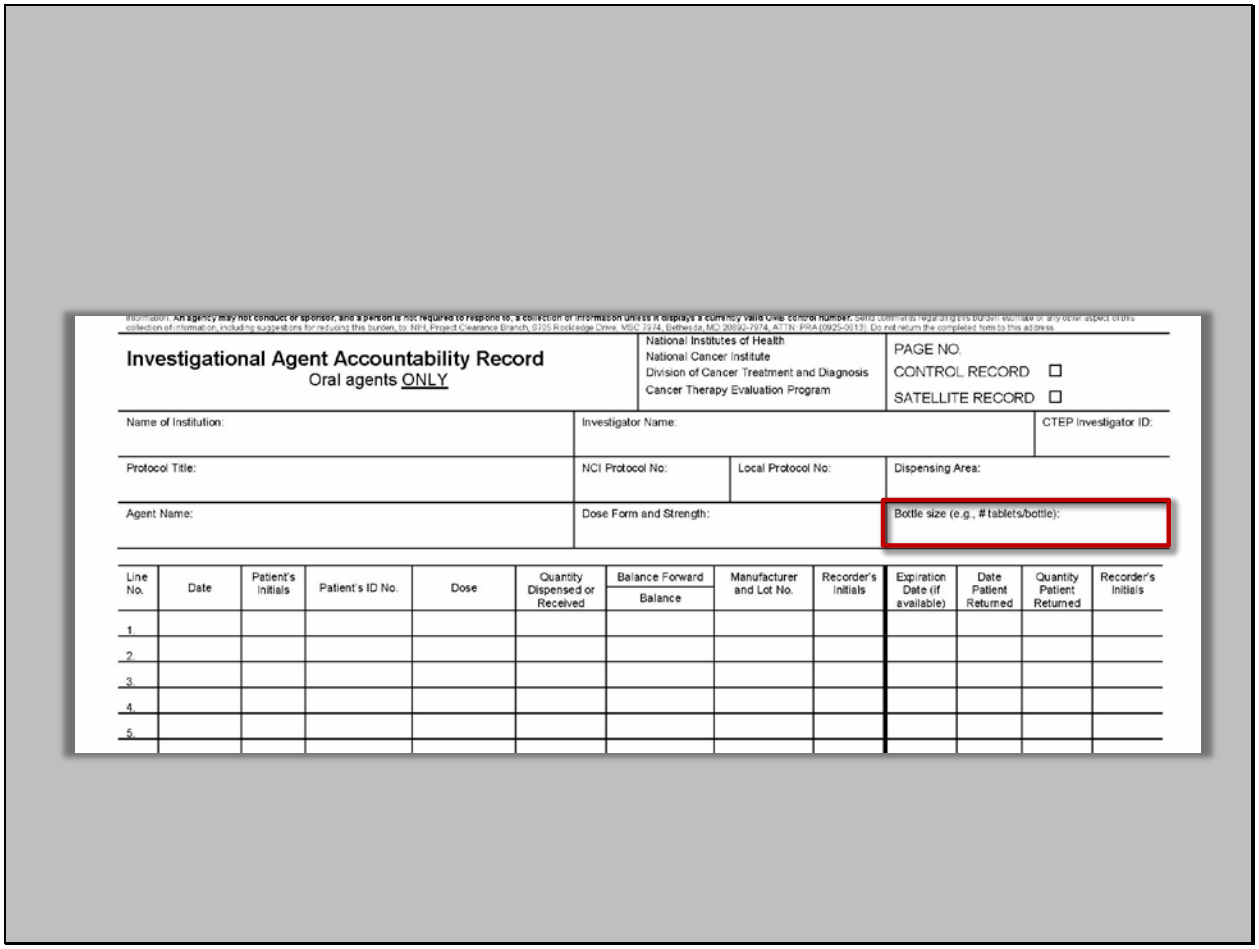


The difference between the two DARFs is that the Oral DARF provides additional columns to document patient returns. These fields provide space for sites to record quantities of oral agents returned by patients.

Sites should not return dispensed oral agents to the NCI Clinical Repository. Patient returns should be destroyed on site in accordance with institutional policy.

Let's review the individual fields unique to the Oral DARF.

Slide 6



Investigational Agent Accountability Record
Oral agents ONLY

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

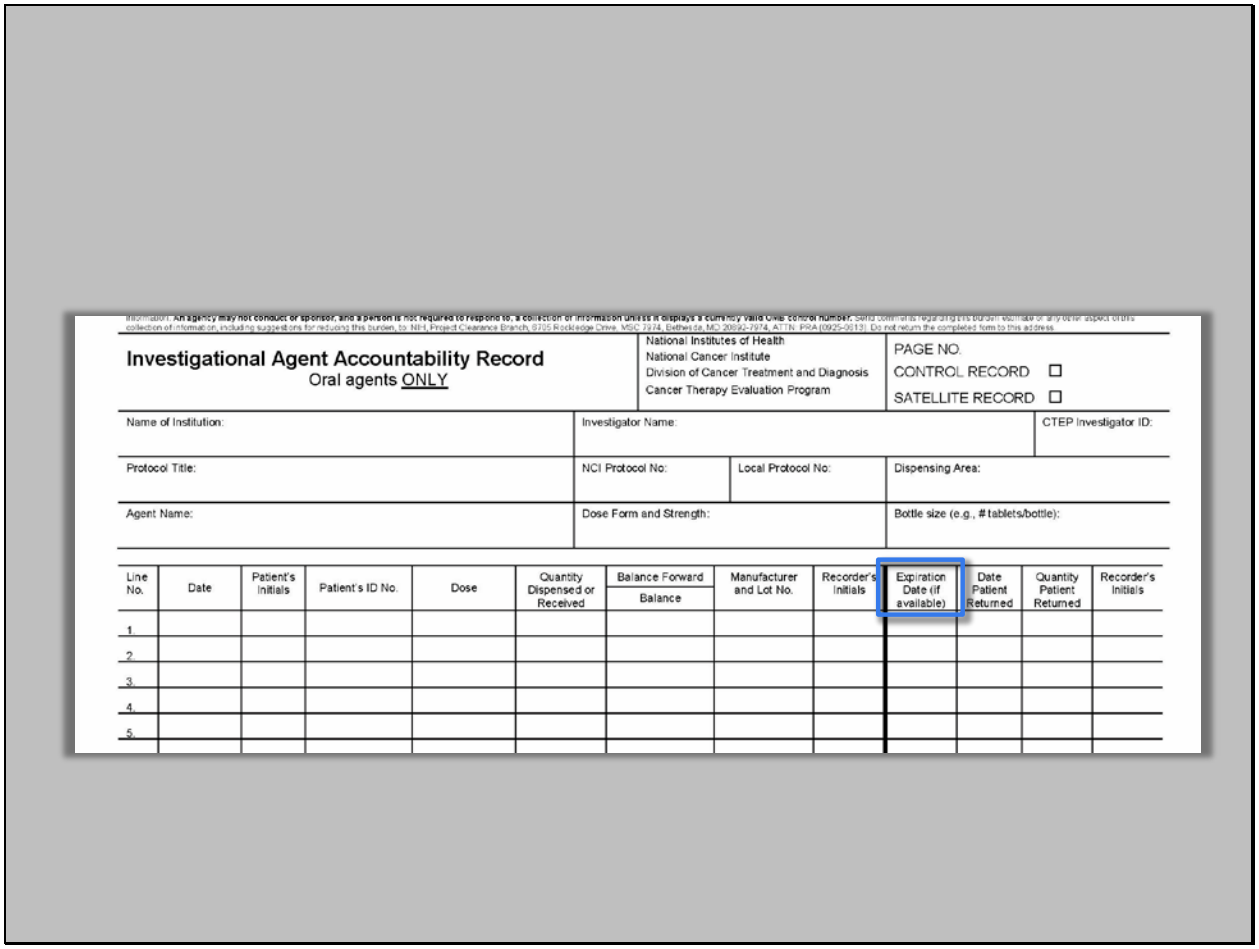
PAGE NO.
CONTROL RECORD ☐
SATELLITE RECORD ☐

Name of Institution:	Investigator Name:		CTEP Investigator ID:
Protocol Title:	NCI Protocol No:	Local Protocol No:	Dispensing Area:
Agent Name:	Dose Form and Strength:		Bottle size (e.g., # tablets/bottle):

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
1.												
2.												
3.												
4.												
5.												

Bottle size is an additional field that appears in the Oral DARF header section. This information is useful as a link between the quantity dispensed and the quantity returned.

Slide 7



Investigational Agent Accountability Record
Oral agents ONLY

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

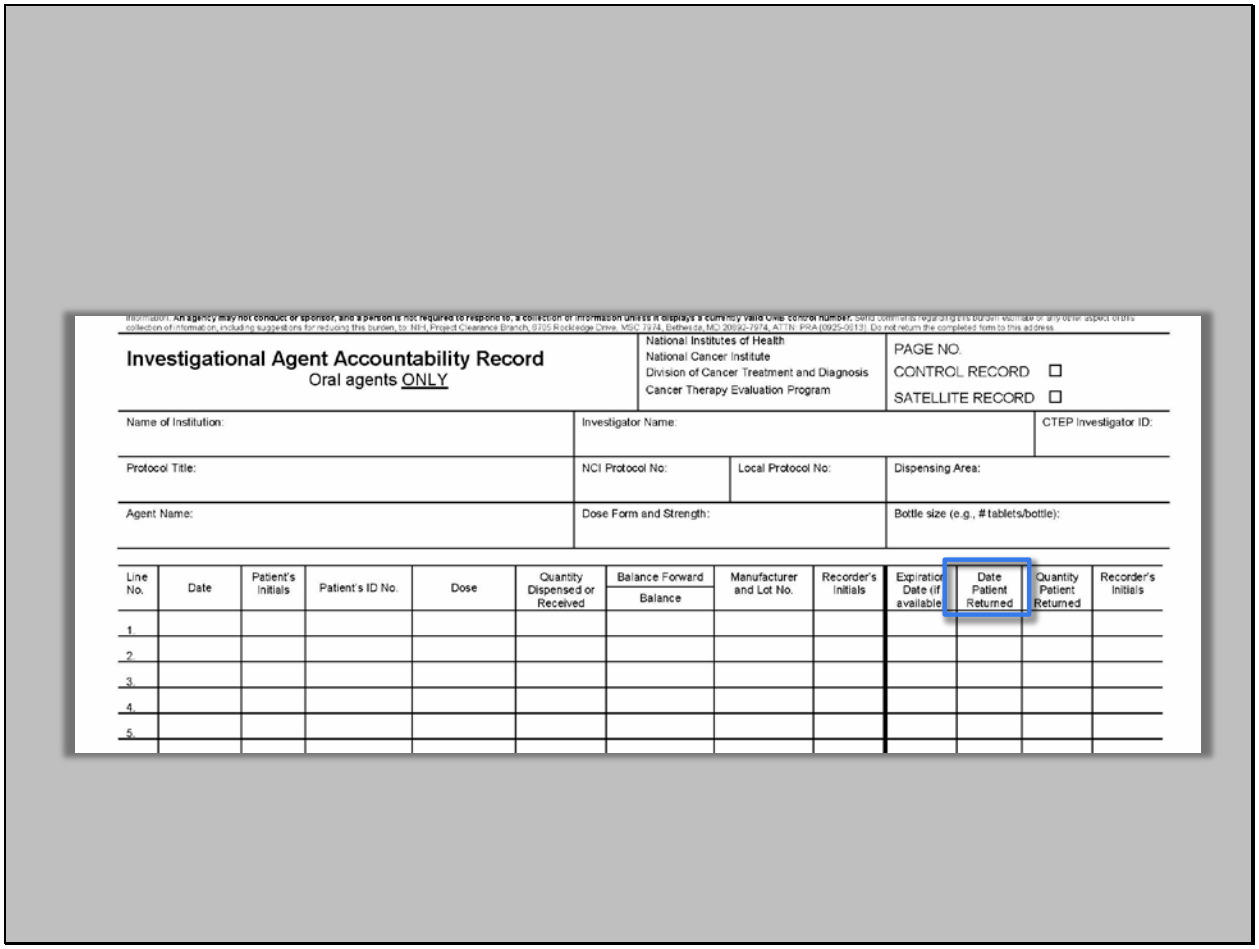
PAGE NO.
CONTROL RECORD ☐
SATELLITE RECORD ☐

Name of Institution:	Investigator Name:		CTEP Investigator ID:
Protocol Title:	NCI Protocol No:	Local Protocol No:	Dispensing Area:
Agent Name:	Dose Form and Strength:		Bottle size (e.g., # tablets/bottle):

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
1.												
2.												
3.												
4.												
5.												

The first additional column is Expiration Date. In many cases this information will not be available. If the expiration date is not available at the time of agent receipt, it is not necessary to add it later to all prior line items where the lot was dispensed or returned. At the time the expiration date is known, it can be added for all lines items recorded for the lot from that point forward.

Slide 8



Investigational Agent Accountability Record
Oral agents ONLY

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

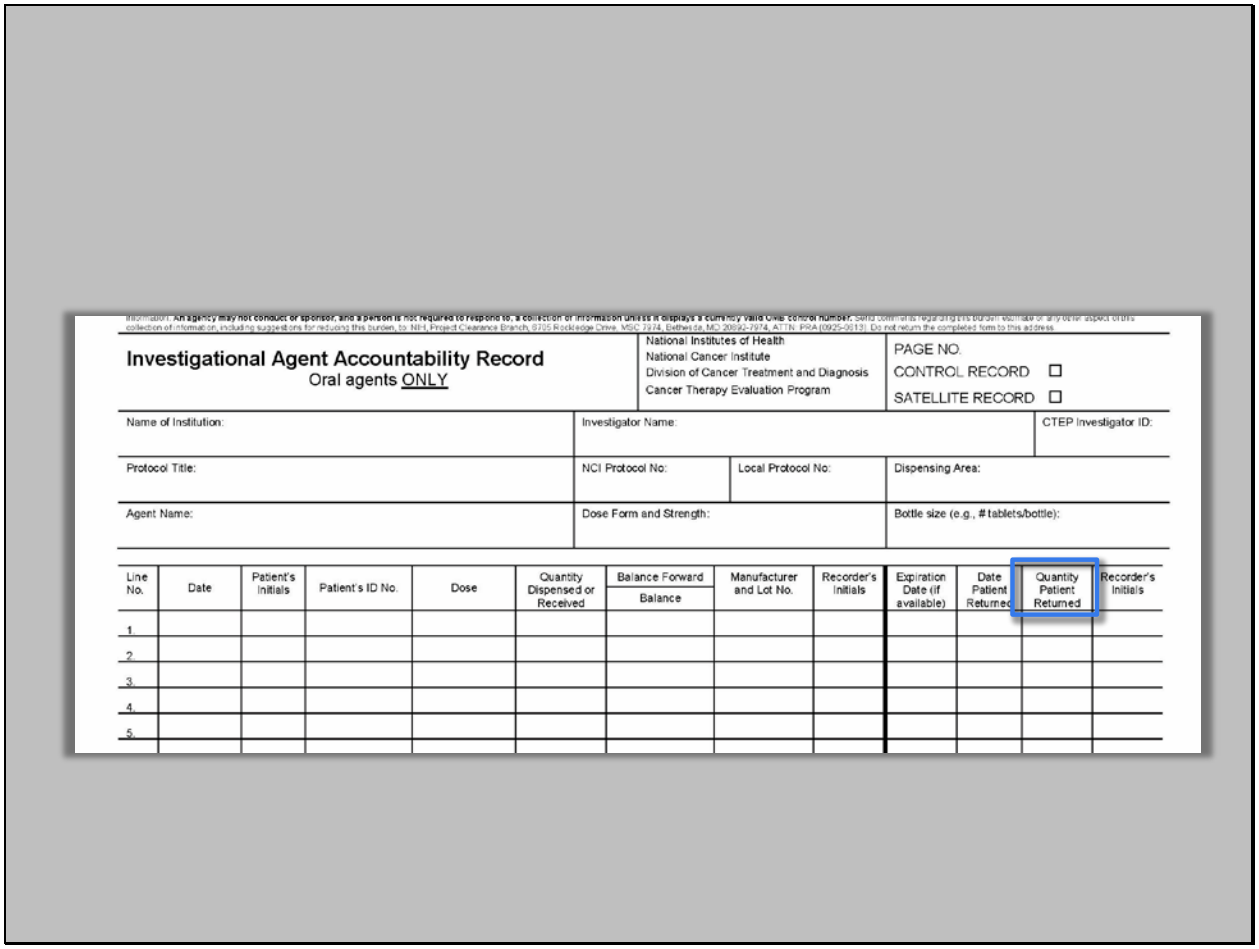
PAGE NO.
CONTROL RECORD ☐
SATELLITE RECORD ☐

Name of Institution:	Investigator Name:		CTEP Investigator ID:
Protocol Title:	NCI Protocol No:	Local Protocol No:	Dispensing Area:
Agent Name:	Dose Form and Strength:		Bottle size (e.g., # tablets/bottle):

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
1.												
2.												
3.												
4.												
5.												

The next column is Date Patient Returned. Record the date received in the dispensing area, it may differ from the actual date received in the clinic.

Slide 9



Investigational Agent Accountability Record
Oral agents ONLY

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

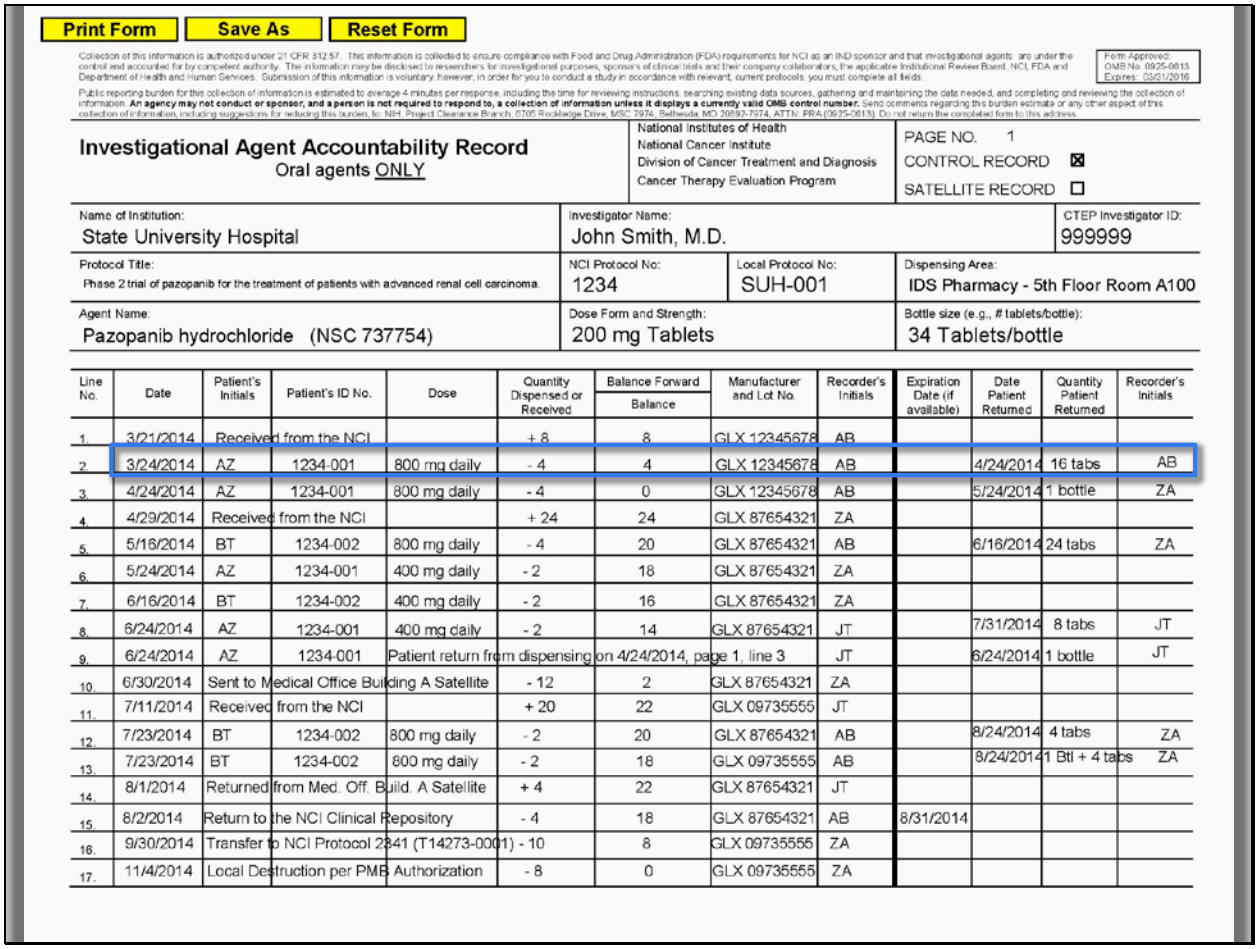
PAGE NO.
CONTROL RECORD ☐
SATELLITE RECORD ☐

Name of Institution:	Investigator Name:		CTEP Investigator ID:
Protocol Title:	NCI Protocol No:	Local Protocol No:	Dispensing Area:
Agent Name:	Dose Form and Strength:		Bottle size (e.g., # tablets/bottle):

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
1.												
2.												
3.												
4.												
5.												

The Quantity Patient Returned is located next to the right. If the quantity returned cannot be easily counted such as suspensions or solutions, you may record returned quantities as full or partial. Returns of sealed bottles do not need to be opened for physical count. Unsealed patient returns should be opened, counted, and recorded. Intact bottles should be recorded as quantity of bottles.

Slide 10



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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

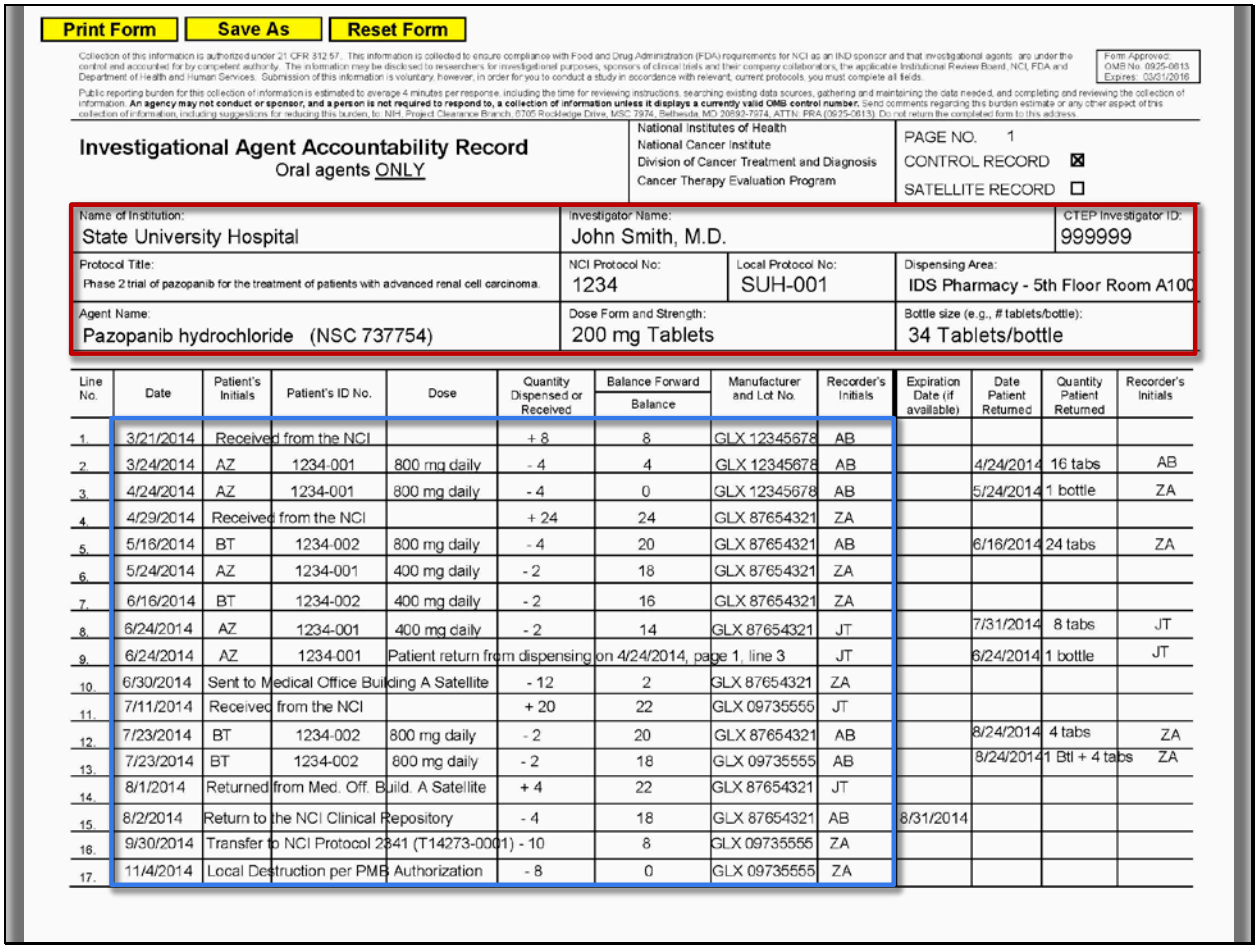
Protocol Title:	NCI Protocol No:	Local Protocol No:	Dispensing Area:
Phase 2 trial of pazopanib for the treatment of patients with advanced renal cell carcinoma.	1234	SUH-001	IDS Pharmacy - 5th Floor Room A100

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				

The Oral DARF is formatted for the dispensing and return information to appear in the same row. When rows of the Oral DARF are used to record activities other than dispensing, the return columns will not be used.

Slide 11



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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: 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

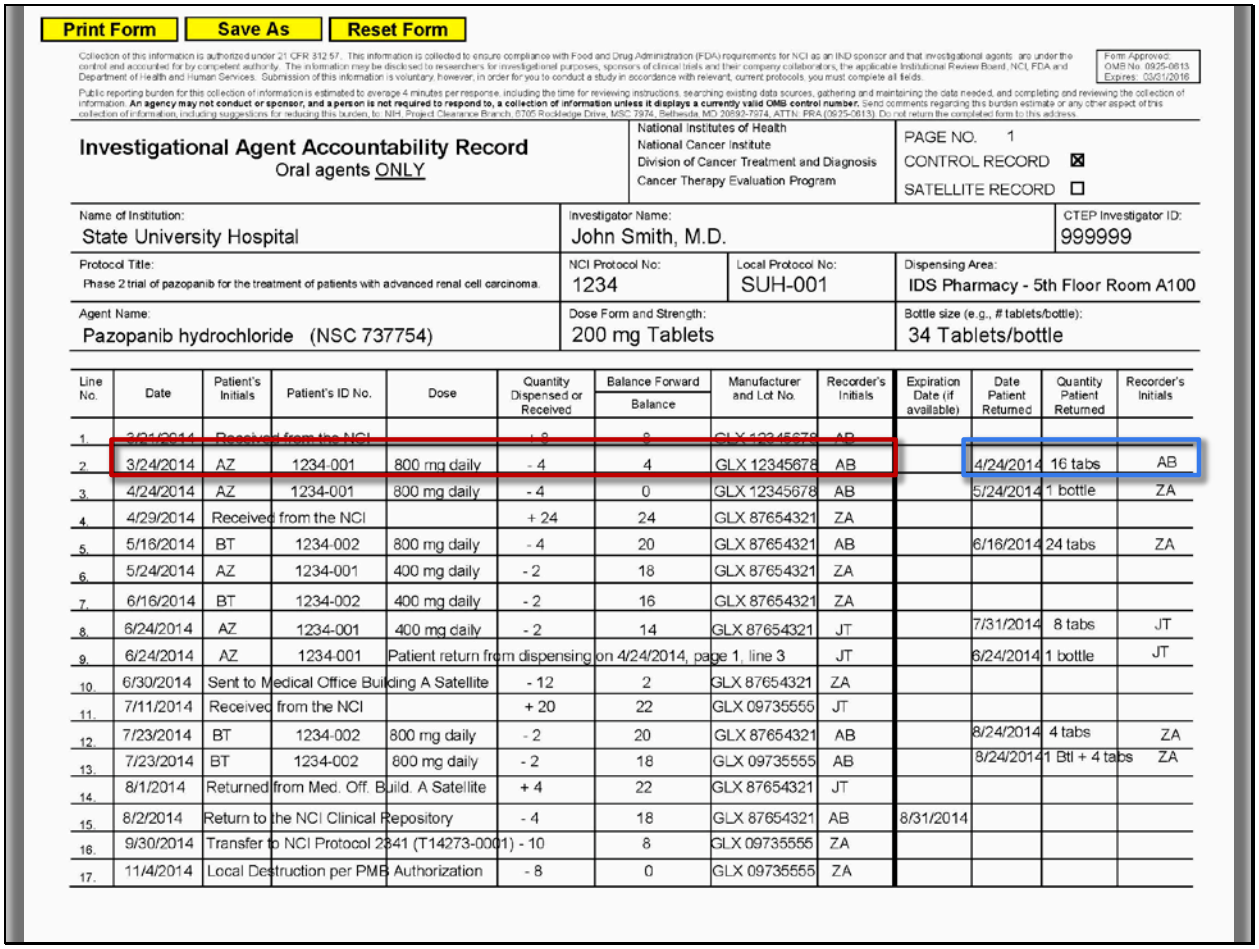
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
1.	3/21/2014	Received from the NCI			+ 8	8	GLX 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				

When a patient return is received, look at the label of the returned agent and find the correct Oral DARF by verifying information in the header section such as the protocol, investigator, agent, formulation, and strength.

Next, locate the correct dispensing row for the returned drug by matching the date dispensed, patient initials, patient ID number, and lot number to the row in which the dispensing was recorded.

Now let's go through some different examples of what steps to take when a patient return is received.

Slide 12



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PAGE NO. 1
CONTROL RECORD ☒
SATELLITE RECORD ☐

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

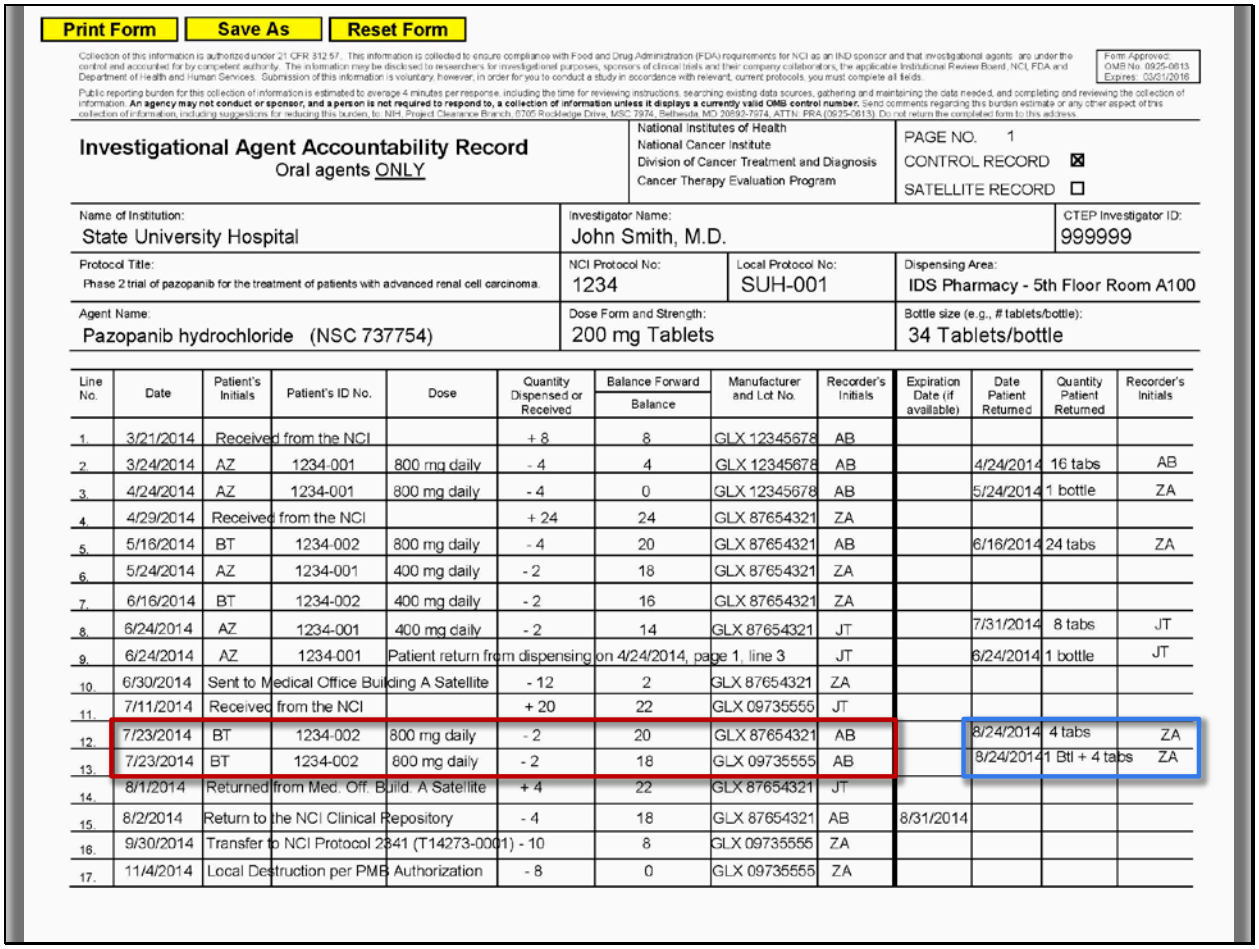
Protocol Title:	NCI Protocol No:	Local Protocol No:	Dispensing Area:
Phase 2 trial of pazopanib for the treatment of patients with advanced renal cell carcinoma.	1234	SUH-001	IDS Pharmacy - 5th Floor Room A100

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				

In the example on line 2, one bottle containing 16 tablets of pazopanib hydrochloride was returned to the dispensing area for patient AZ, 1234-001. The tablets were 200 mg of lot GLX12345678 used in NCI protocol 1234 and dispensed on March 24th, 2014.

Slide 13



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Cancer Therapy Evaluation Program

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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

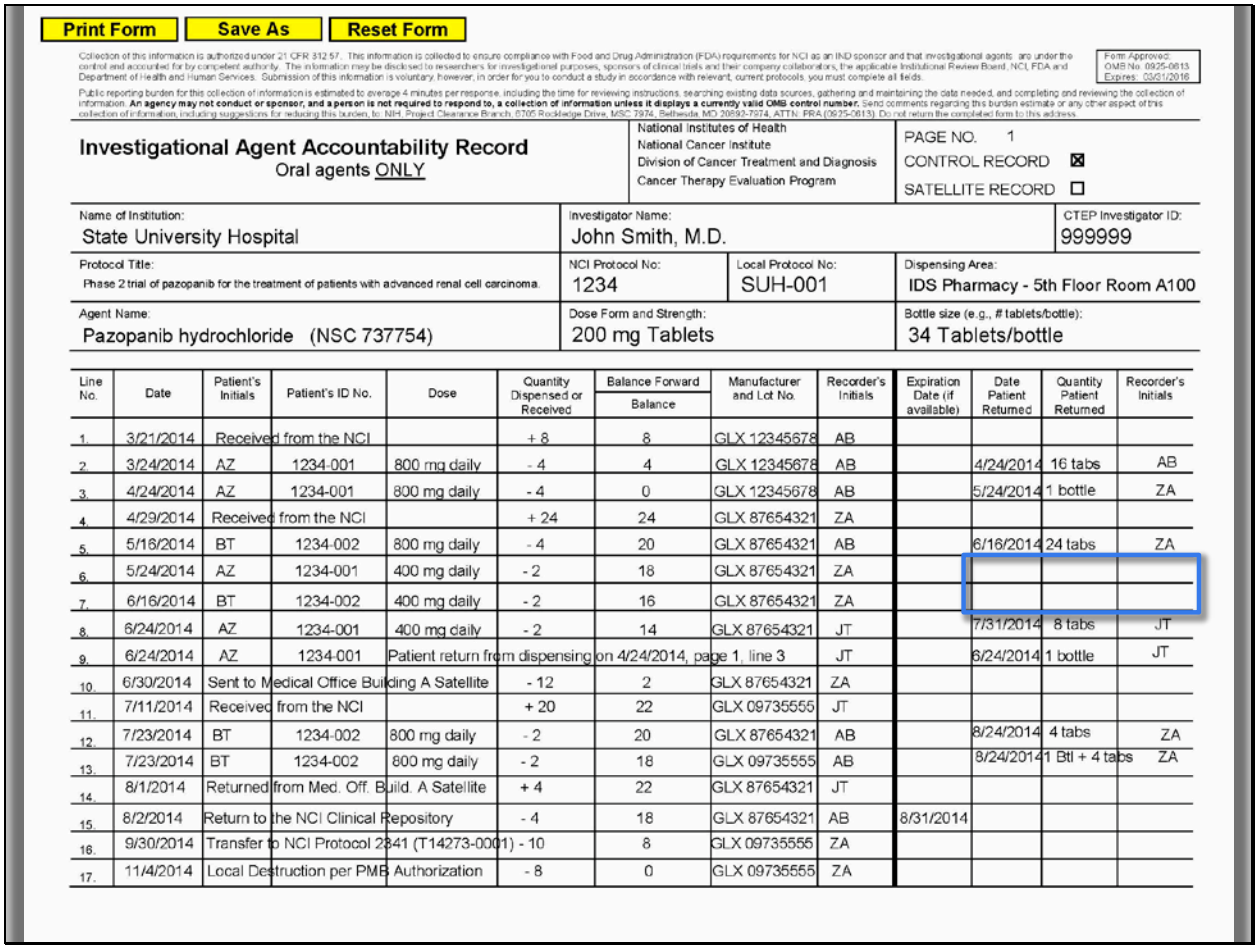
Agent Name:	Dose Form and Strength:	Bottle size (e.g., # tablets/bottle):
Pazopanib hydrochloride (NSC 737754)	200 mg Tablets	34 Tablets/bottle

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				

In the example on lines 12 and 13, two lots were dispensed to patient BT, 1234-002 on July 23rd, 2014. Each dispensing is recorded on a separate line and the return is recorded correctly on the corresponding line for each lot.

Multiple lots of agent dispensed on the same date must be recorded on separate lines of the DARF.

Slide 14



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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

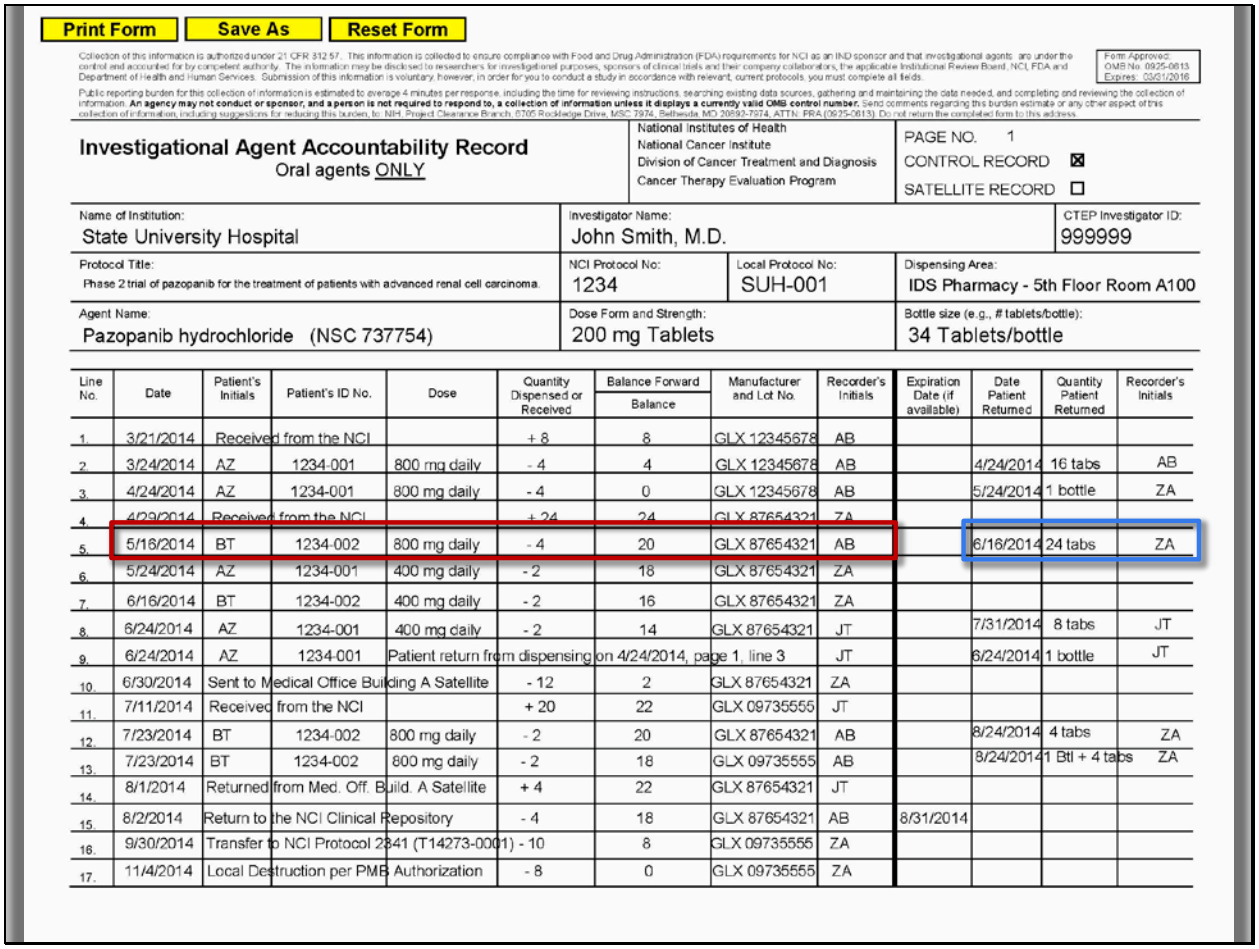
Agent Name:	Dose Form and Strength:	Bottle size (e.g., # tablets/bottle):
Pazopanib hydrochloride (NSC 737754)	200 mg Tablets	34 Tablets/bottle

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				

What if a patient returns an empty bottle? In that case, there is nothing to record such as on line 6 or 7.

Keep in mind that the patient return columns are not intended to document destruction of oral agents or adherence to prescribed therapy. Patient adherence should be measured as described in the protocol.

Slide 15



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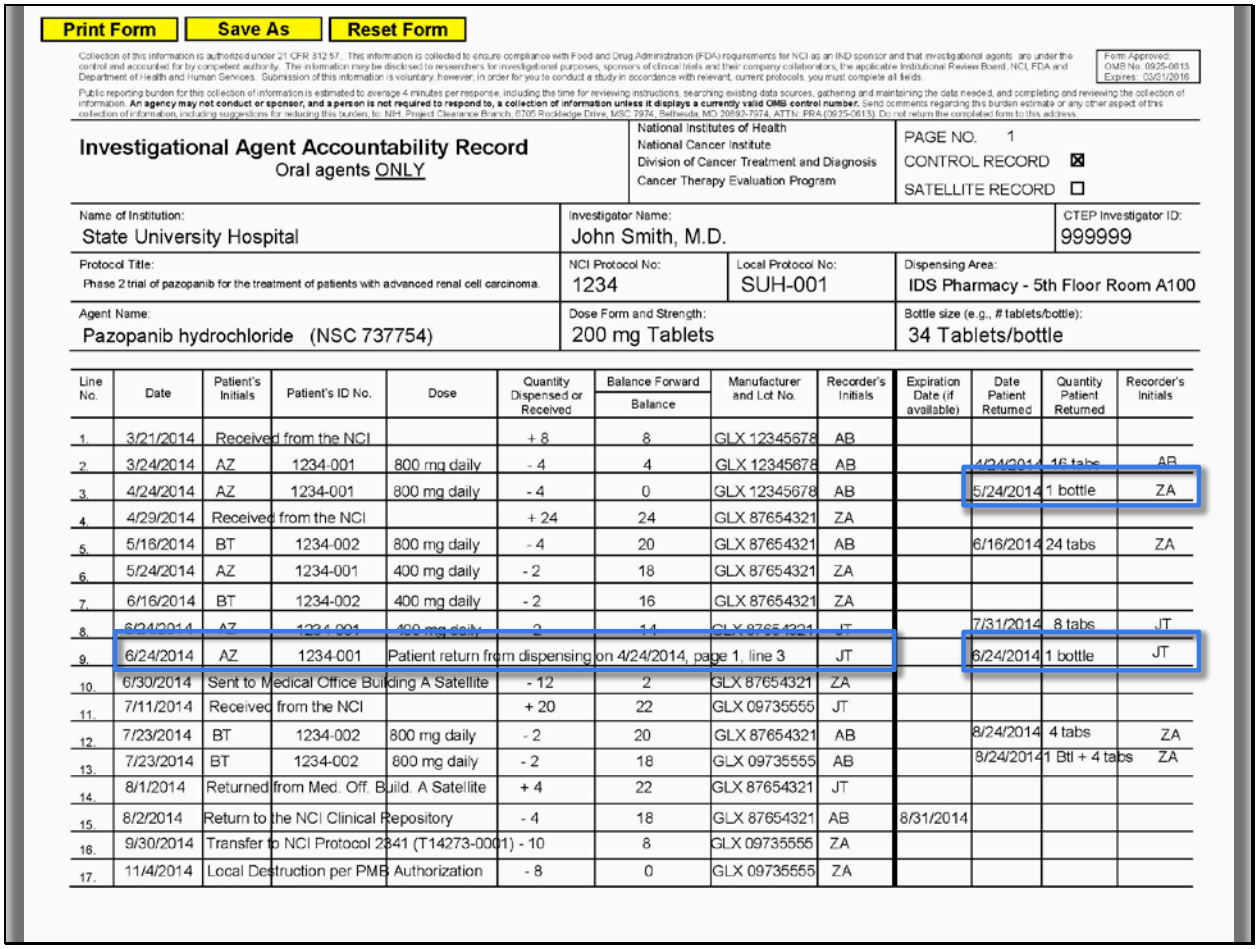
Protocol Title:	NCI Protocol No:	Local Protocol No:	Dispensing Area:
Phase 2 trial of pazopanib for the treatment of patients with advanced renal cell carcinoma.	1234	SUH-001	IDS Pharmacy - 5th Floor Room A100

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				

Let's look at another patient return on line 5. In this case, four partial bottles were returned from a single dispensing on May 16th, 2014. The bottles each contained six tablets. Count and add up the number of tablets from each bottle to record the total quantity returned, which is 24 in this example.

Slide 16



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State University Hospital	John Smith, M.D.	999999

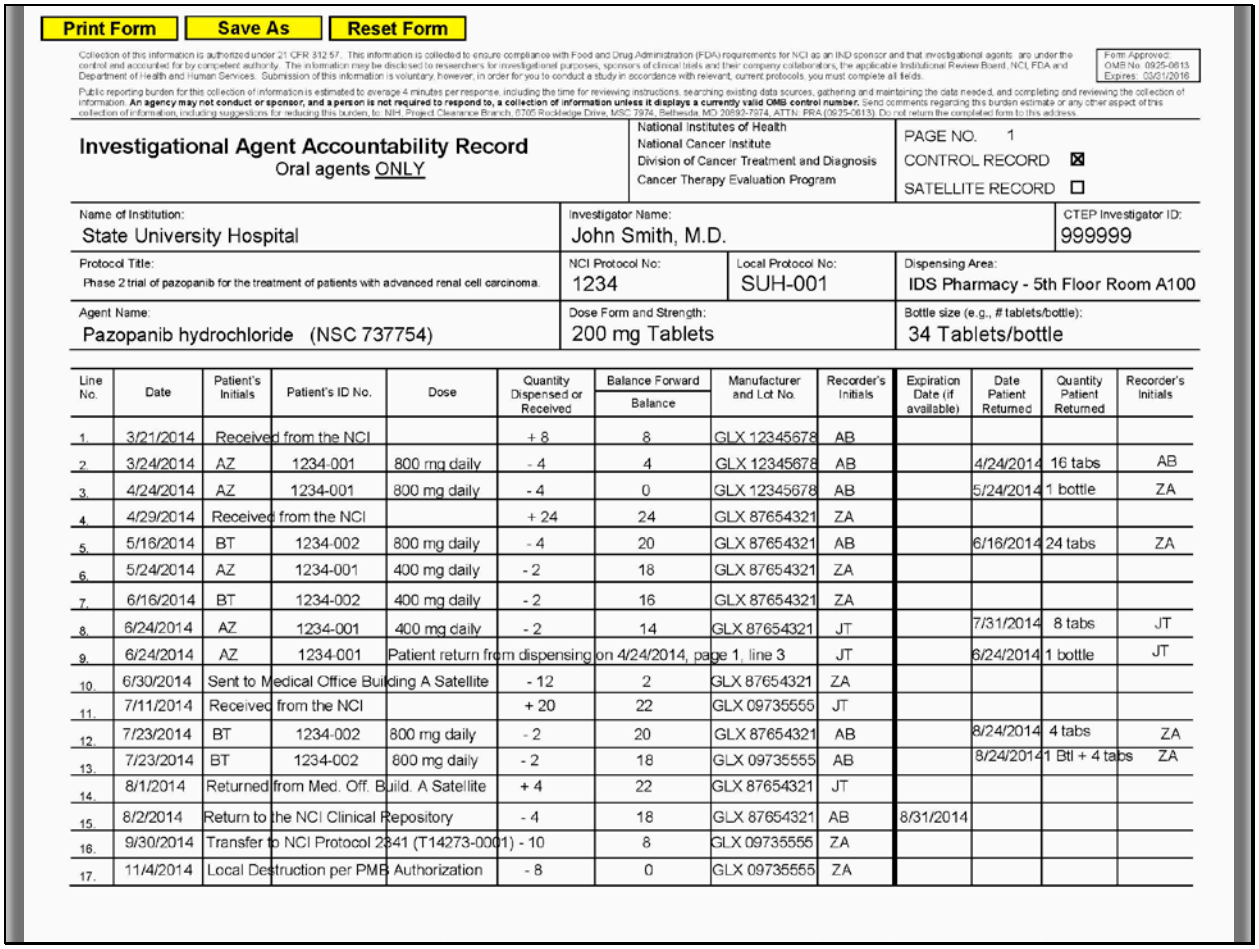
Protocol Title:	NCI Protocol No:	Local Protocol No:	Dispensing Area:
Phase 2 trial of pazopanib for the treatment of patients with advanced renal cell carcinoma.	1234	SUH-001	IDS Pharmacy - 5th Floor Room A100

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				

For the final example let's review the steps to take when additional bottles are returned from a single dispensing but on different dates. The return fields in the dispensing row on line 3 were completed previously, so you'll need to go to a new line. Starting with the next blank row, line 9 in this example; reference the dispensing date, including Oral DARF page number and line number, then record in the return columns.

Slide 17



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Protocol Title:	NCI Protocol No:	Local Protocol No:	Dispensing Area:
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Agent Name:	Dose Form and Strength:	Bottle size (e.g., # tablets/bottle):
Pazopanib hydrochloride (NSC 737754)	200 mg Tablets	34 Tablets/bottle

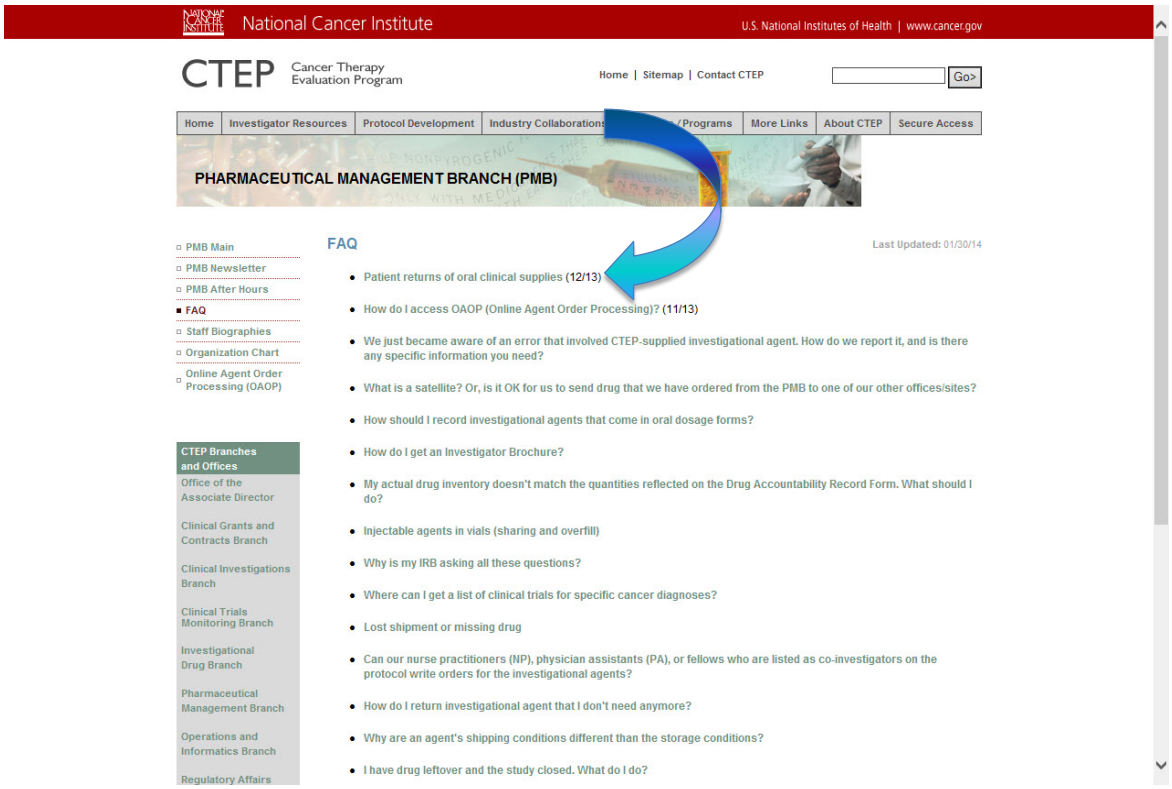
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
1.	3/21/2014	Received from the NCI			+ 8	8	GLX 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				

Lastly, keep in mind if clinical supplies are not returned to the dispensing area, there will be nothing to record in the return columns on the Oral DARF.

And remember the Oral DARF must be used for all NCI studies using oral agents. The same steps described in this video should be taken when recording on a patient specific Oral DARF. The only difference with patient specific supplies is that the Julian date and order number are used as the lot number.

Slide 18

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



Information on patient returns is also available in the PMB FAQ “Patient Returns of Oral Clinical Supplies” available here on the PMB website.

Slide 19

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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.

Slide 20

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1-800-4-CANCER

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