Slide 1

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

This video will review common reasons for returning investigational agents, the return process, how to document returns, and strategies to reduce the need for returns.

Slide 2

Reasons for Returning Investigational Agents:

- The study is closed to accrual and all patients have completed therapy
- The study using the agent has closed
- The agent was involved in a temperature excursion during shipping or storage
- The agent has been recalled or is expired

During the course of a clinical trial, it may become necessary to return PMB supplied agents. Common reasons for returning investigational agents when instructed by PMB are:

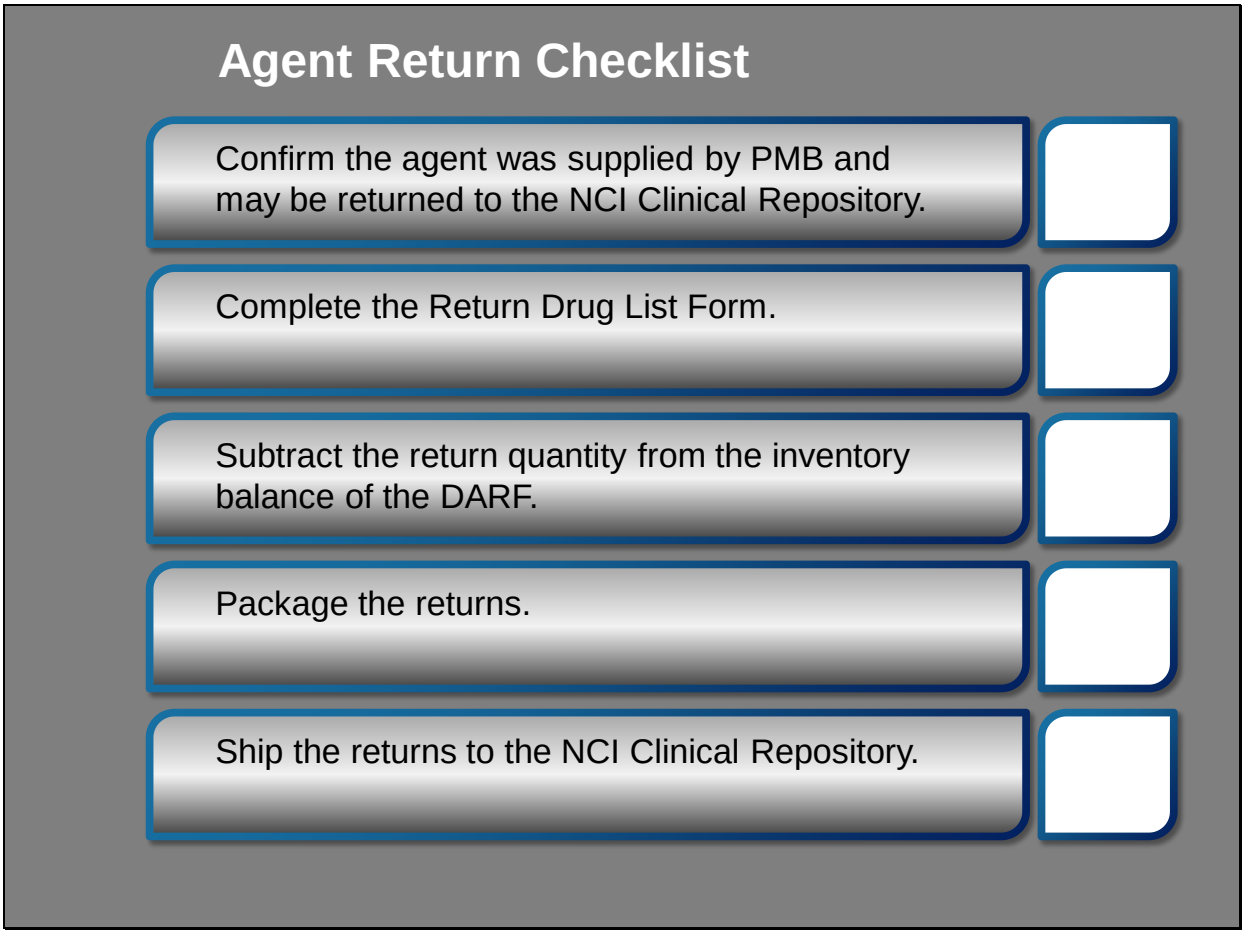
- The study is closed to accrual and all patients have completed therapy.
- The study using the agent has closed.
- The investigational agent was involved in a temperature excursion during shipping or storage.
- The investigational agent has been recalled or is expired.

Slide 3

http://ctep.cancer.gov/forms/

If the excess supply is due to study closure or all patients being off therapy, it may be possible to transfer the supply to another CTEP sponsored IND trial. Refer to the Agent Transfers video for a detailed explanation of the transfer process.

Slide 4

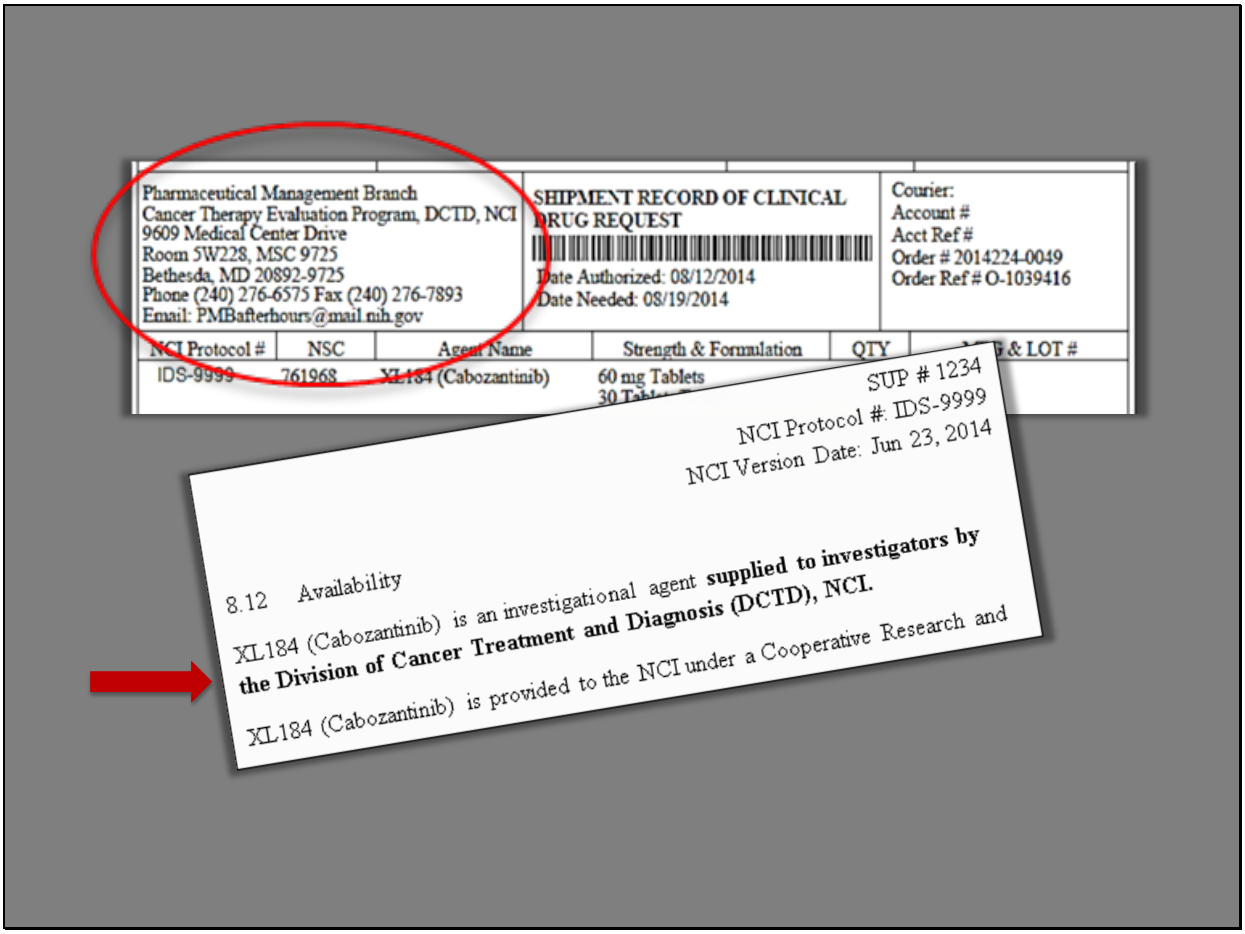


If the excess supply cannot be transferred, it must be returned to the NCI Clinical Repository using the following steps:

- Confirm the agent was supplied by PMB and may be returned to the NCI Clinical Repository.
- Complete the Return Drug List Form.
- Subtract the return quantity from the inventory balance of the DARF.
- Package the returns.
- Ship the returns to the NCI Clinical Repository.

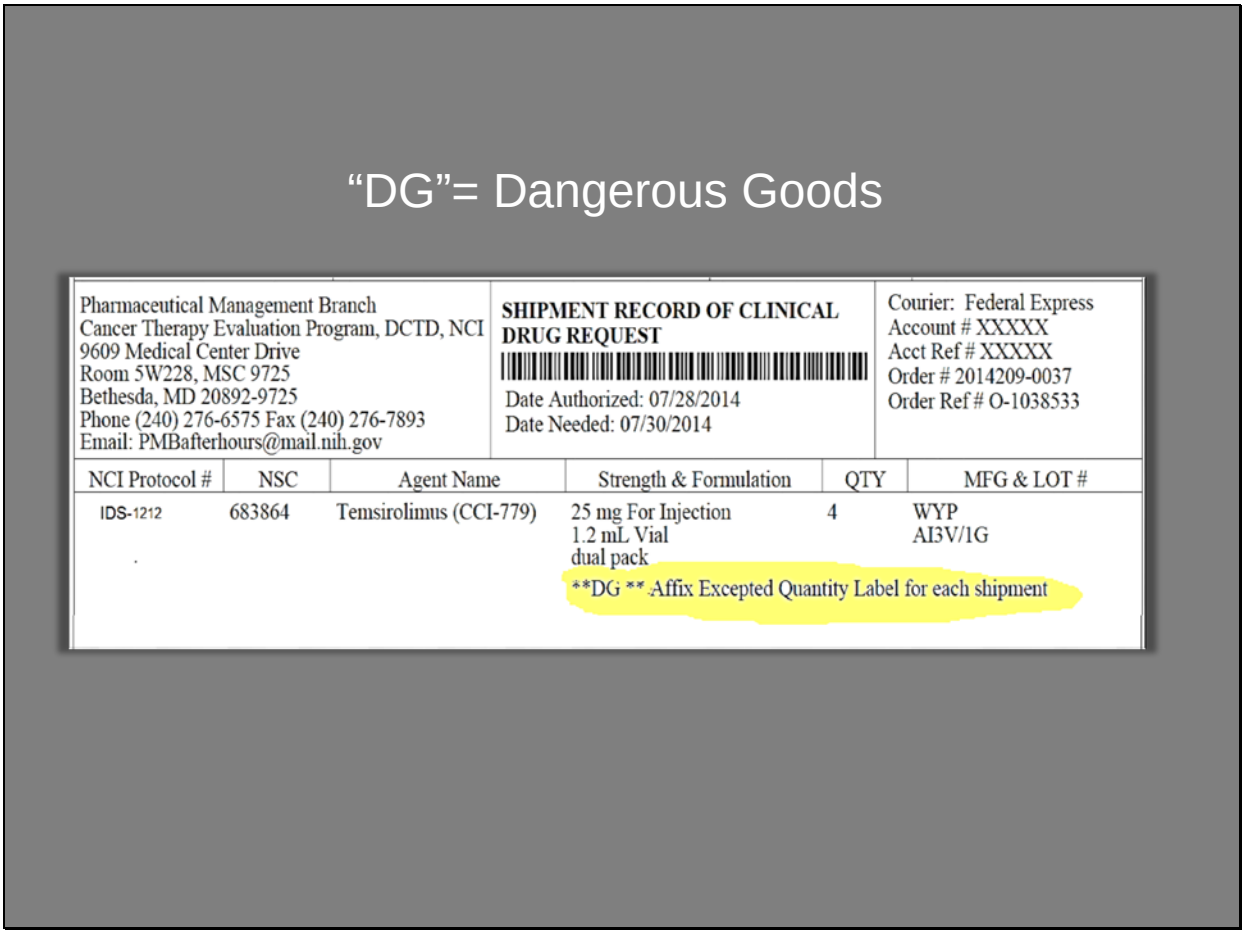
Now let's review each step.

Slide 5



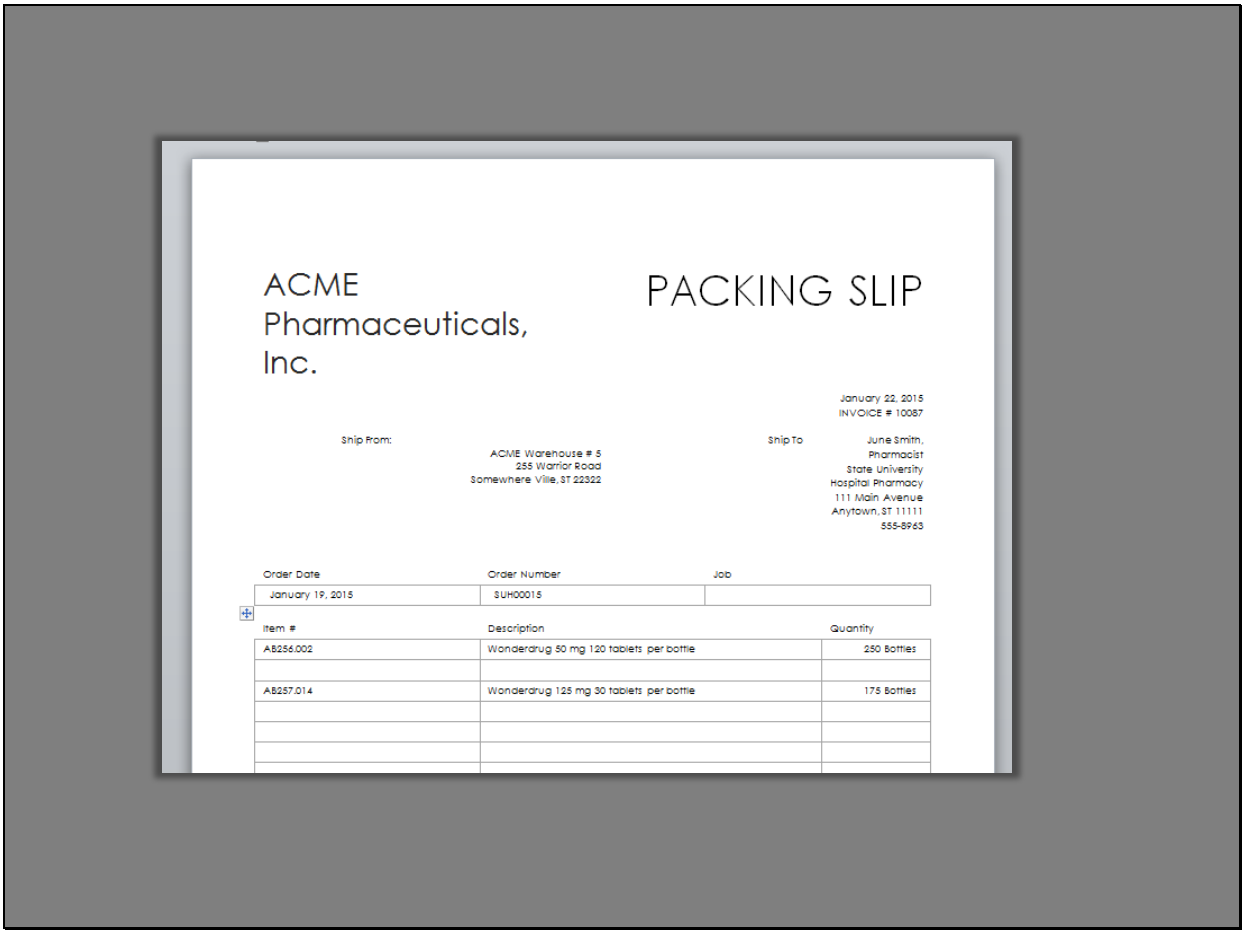
Only un-dispensed PMB supplied agents should be returned to the NCI Clinical Repository. Keep in mind any supplies returned by a patient must be documented and destroyed per your institution's SOPs. Please view the Oral DARF video for specifics.

Slide 6



A Dangerous Good or DG is a compound requiring special labelling and packaging for shipping.
If the agent is a DG, it will be noted on the Shipment Record and stock recovery notices.
If your institution does not have the capability for shipping DGs, approval is required from the PMB for local destruction. This approval must be received prior to destruction.
International sites should request local destruction of all agents.
Refer to the Local Destruction video for more information.

Slide 7



ACME Pharmaceuticals, Inc.

PACKING SLIP

January 22, 2015
INVOICE # 10087

Ship From:

ACME Warehouse # 5
255 Warrior Road
Somewhere Ville, ST 22322

Ship To

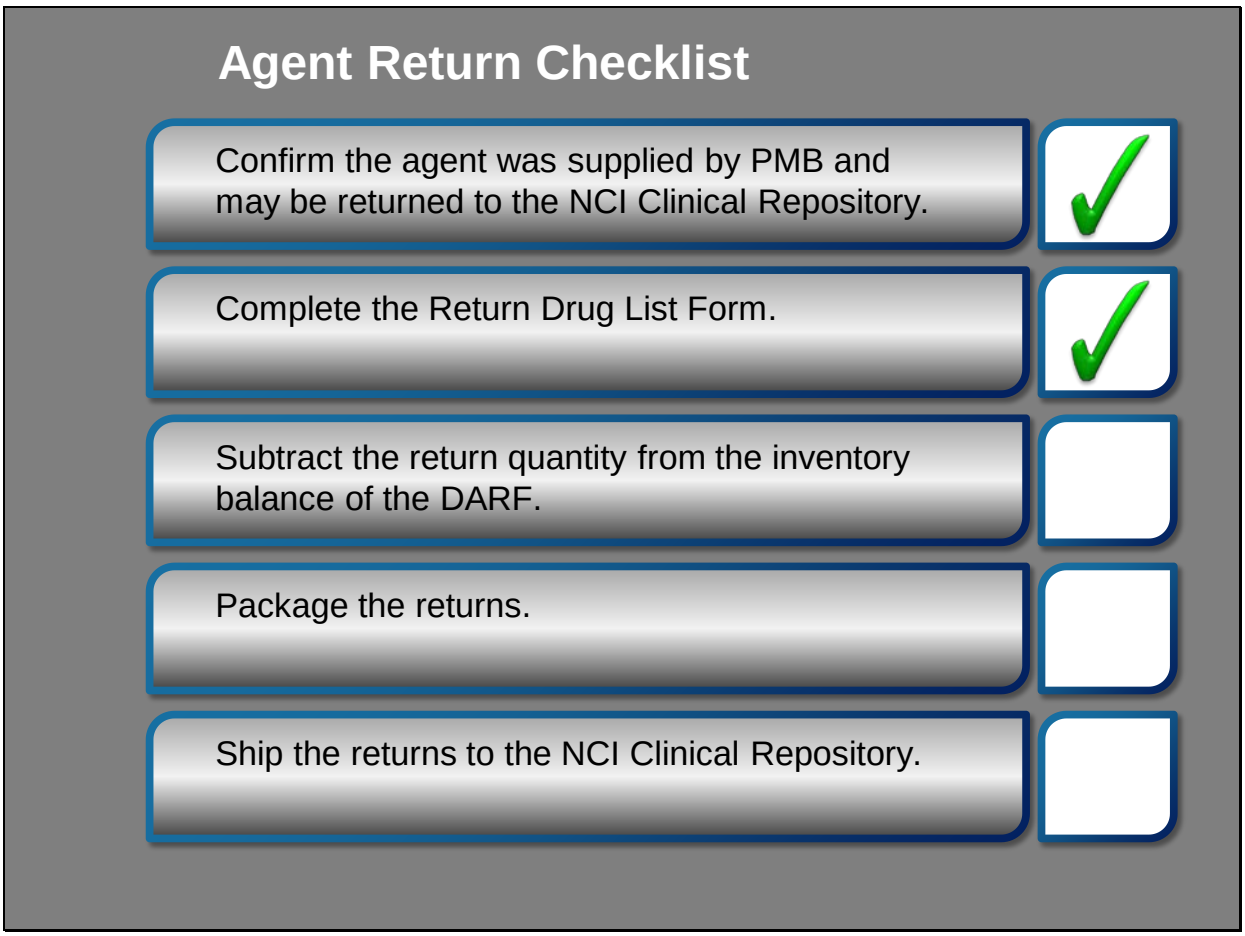
June Smith,
Pharmacist
State University
Hospital Pharmacy
111 Main Avenue
Anytown, ST 11111
555-8963

Order Date	Order Number	Job
January 19, 2015	SUH00015	

Item #	Description	Quantity
AB256.002	Wonderdrug 50 mg 120 tablets per bottle	250 Bottles
AB257.014	Wonderdrug 125 mg 30 tablets per bottle	175 Bottles

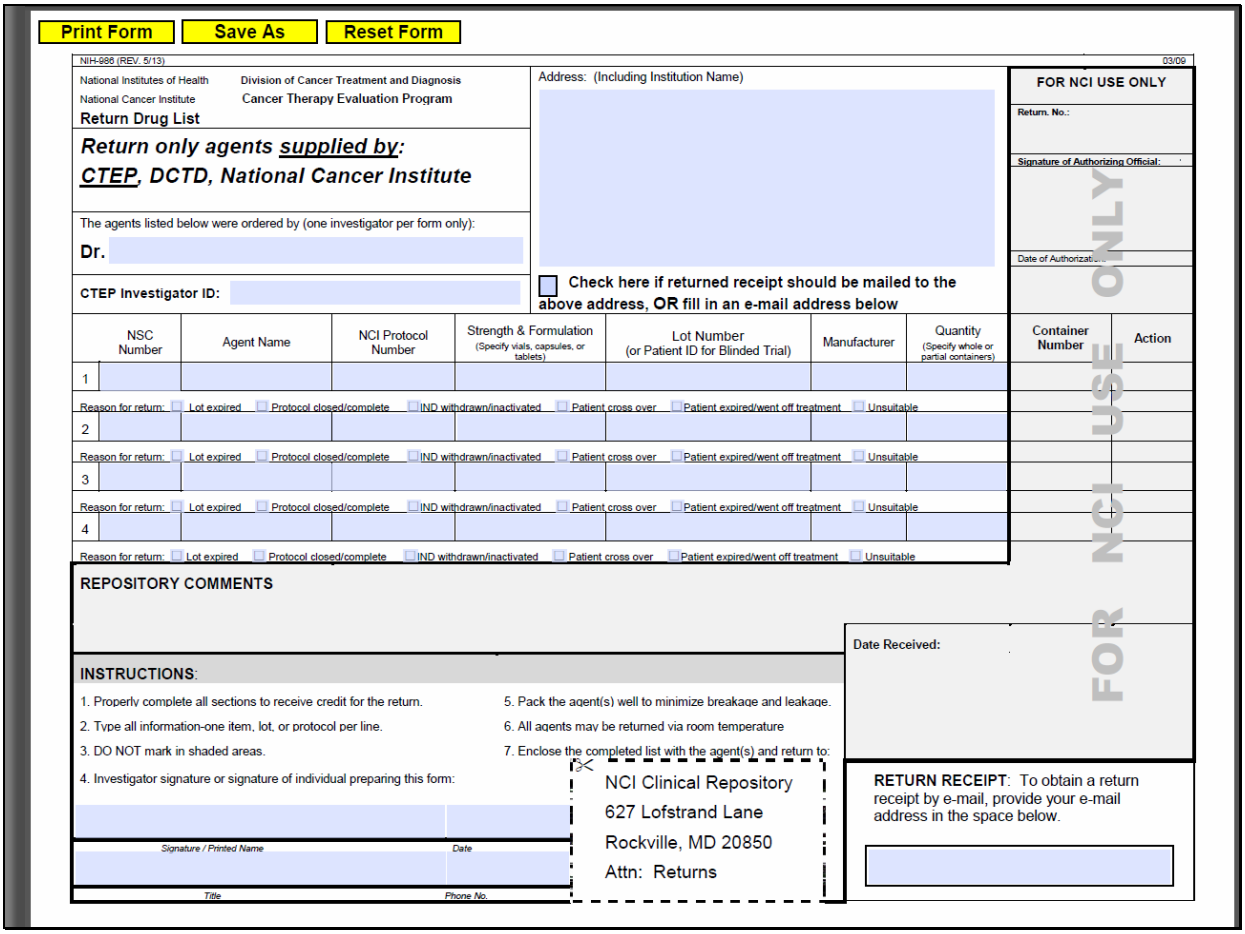
Only those clinical supplies distributed by the PMB are returned to the NCI Clinical Repository. For all other items, refer to the protocol, study sponsor, or supplier for final disposition instructions.

Slide 8



Once you confirm the investigational agent can be returned to the NCI Clinical Repository, complete the Return Drug List Form.

Slide 9



Print Form Save As Reset Form

NIH-986 (REV. 5/13) 03/09

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

Return Drug List

Return only agents supplied by:
CTEP, DCTD, National Cancer Institute

The agents listed below were ordered by (one investigator per form only):

Dr.

CTEP Investigator ID:

Address: (Including Institution Name)

☐ **Check here if returned receipt should be mailed to the above address, OR fill in an e-mail address below**

FOR NCI USE ONLY

Return. No.:

Signature of Authorizing Official:

Date of Authorizat...

	NSC Number	Agent Name	NCI Protocol Number	Strength & Formulation (Specify vials, capsules, or tablets)	Lot Number (or Patient ID for Blinded Trial)	Manufacturer	Quantity (Specify whole or partial containers)	Container Number	Action
1									
	Reason for return: ☐ Lot expired ☐ Protocol closed/complete ☐ IND withdrawn/inactivated ☐ Patient cross over ☐ Patient expired/went off treatment ☐ Unsuitable								
2									
	Reason for return: ☐ Lot expired ☐ Protocol closed/complete ☐ IND withdrawn/inactivated ☐ Patient cross over ☐ Patient expired/went off treatment ☐ Unsuitable								
3									
	Reason for return: ☐ Lot expired ☐ Protocol closed/complete ☐ IND withdrawn/inactivated ☐ Patient cross over ☐ Patient expired/went off treatment ☐ Unsuitable								
4									
	Reason for return: ☐ Lot expired ☐ Protocol closed/complete ☐ IND withdrawn/inactivated ☐ Patient cross over ☐ Patient expired/went off treatment ☐ Unsuitable								

REPOSITORY COMMENTS

Date Received:

FOR NCI USE ONLY

INSTRUCTIONS:

1. Properly complete all sections to receive credit for the return.
2. Type all information-one item, lot, or protocol per line.
3. DO NOT mark in shaded areas.
4. Investigator signature or signature of individual preparing this form:
5. Pack the agent(s) well to minimize breakage and leakage.
6. All agents may be returned via room temperature
7. Enclose the completed list with the agent(s) and return to:

Signature / Printed Name *Date*

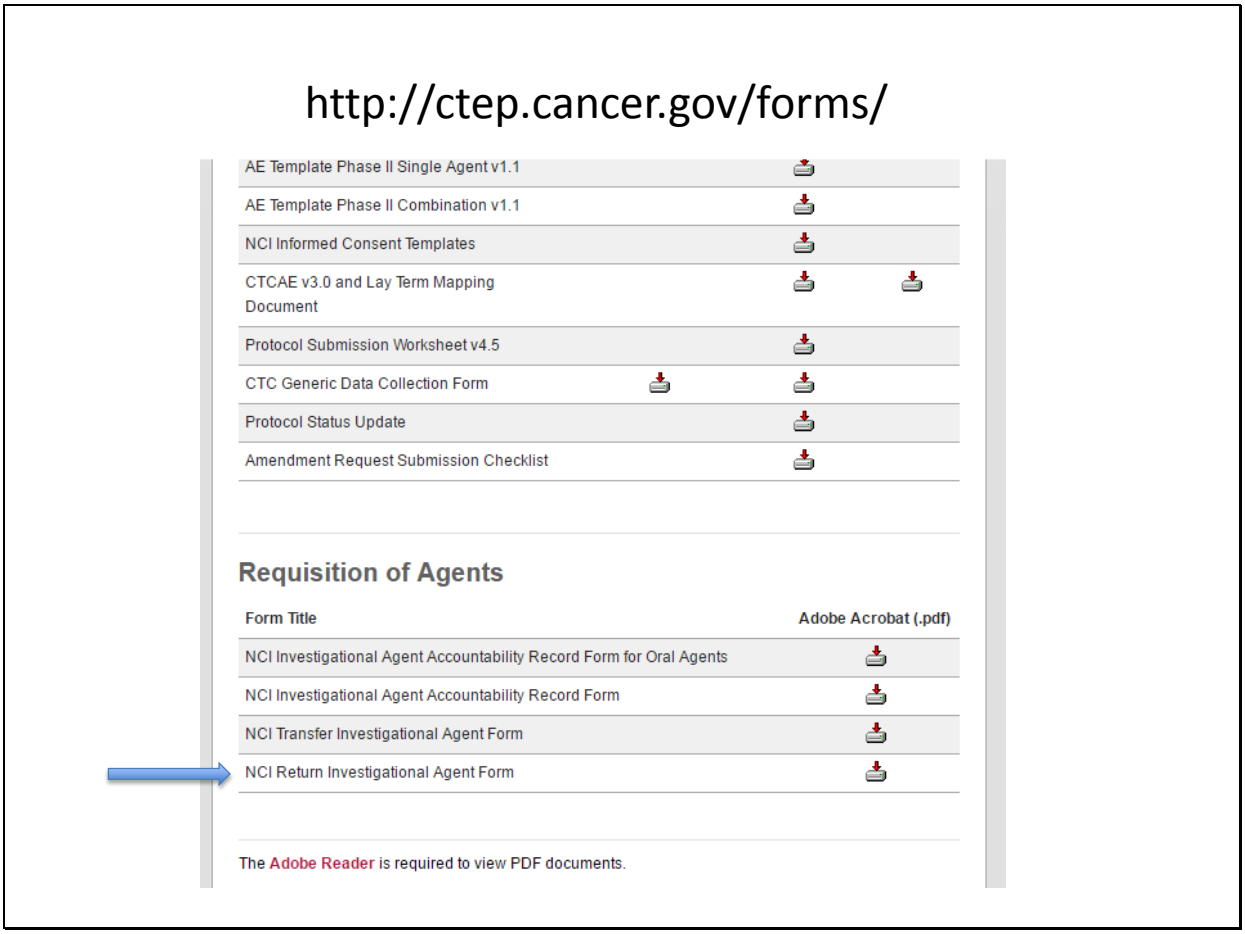
Title *Phone No.*

NCI Clinical Repository
627 Lofstrand Lane
Rockville, MD 20850
Attn: Returns

RETURN RECEIPT: To obtain a return receipt by e-mail, provide your e-mail address in the space below.

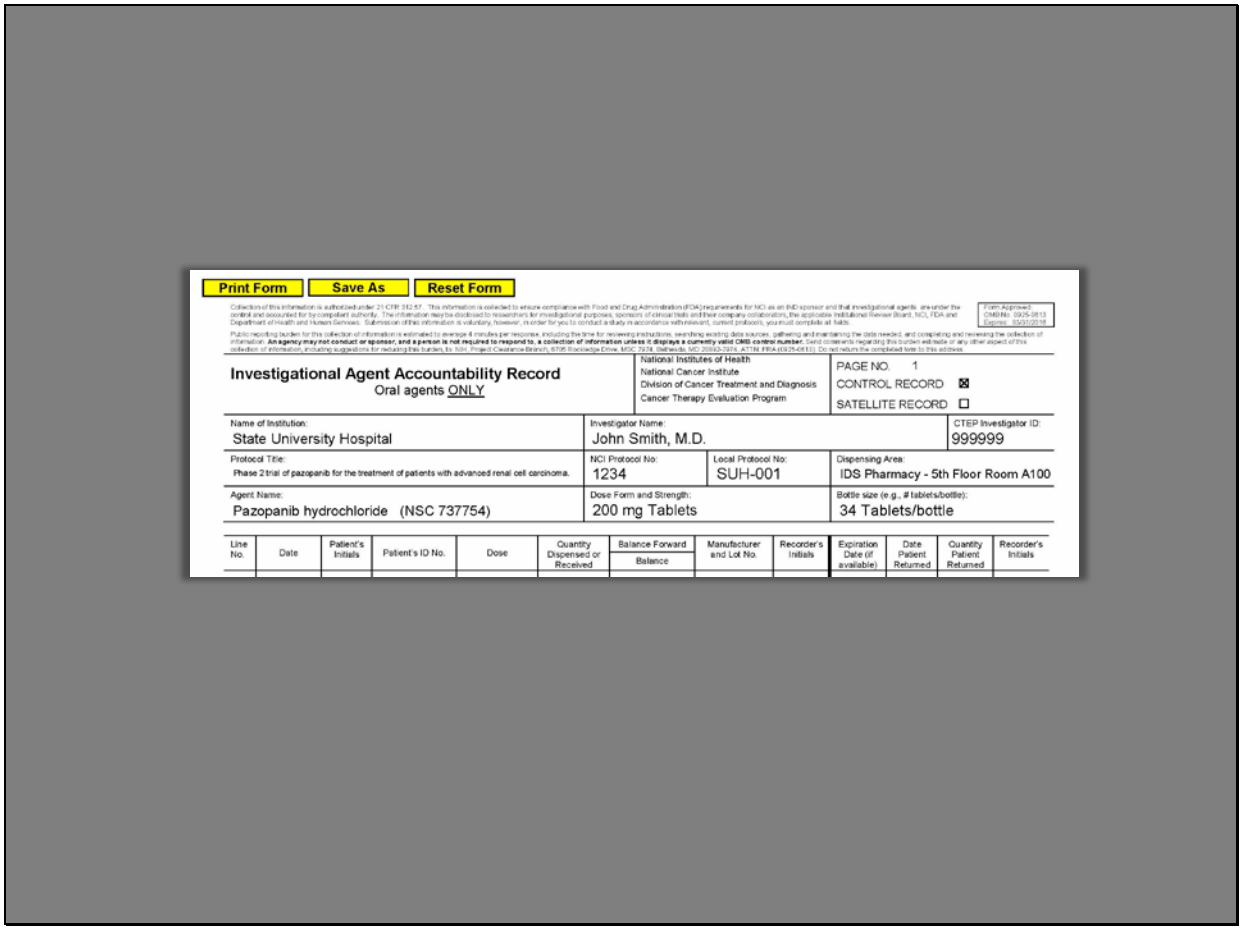
Shown here.

Slide 10



This form is located on the CTEP website and can be completed electronically prior to printing. Let's review the form.

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: 03/31/2018

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

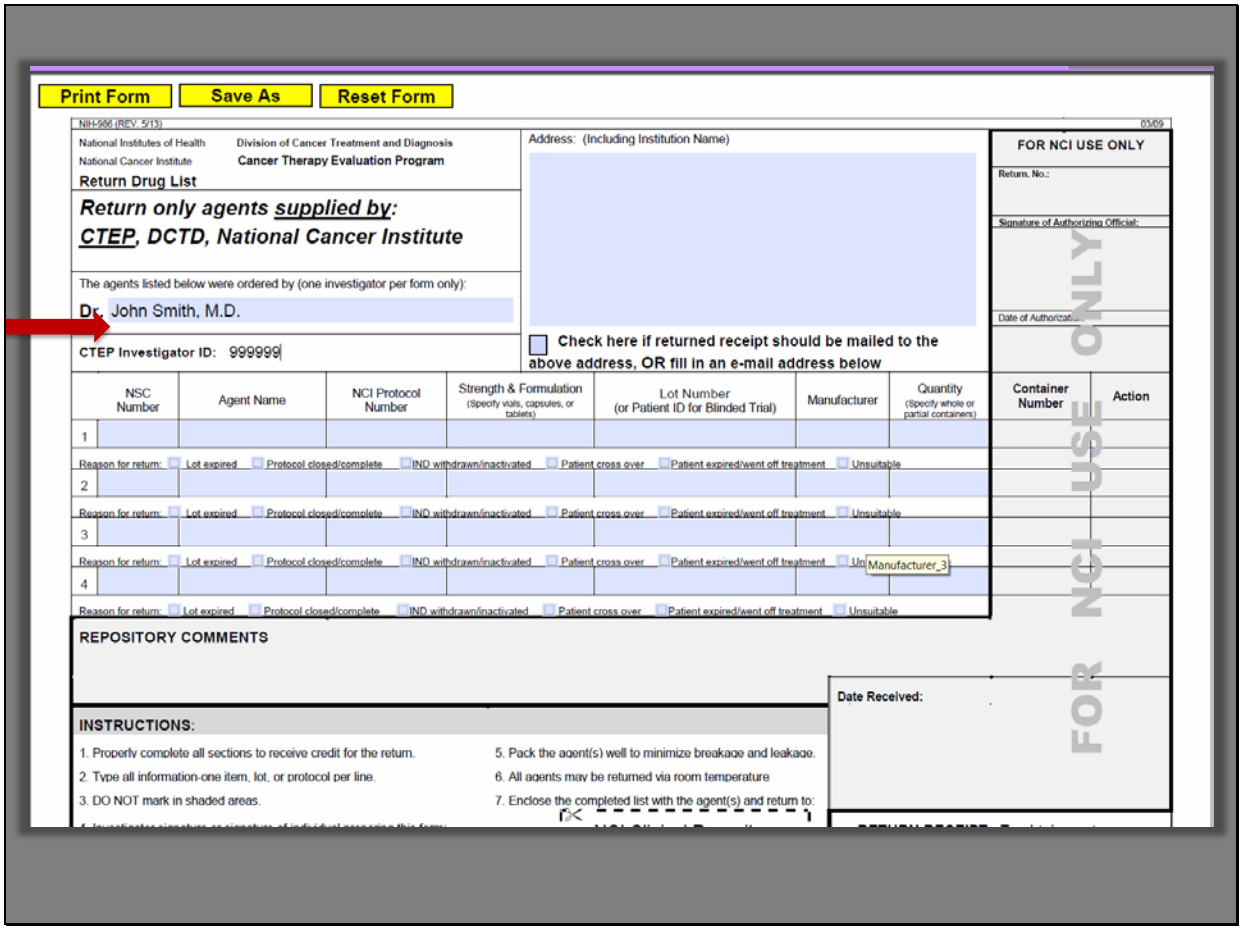
PAGE NO. 1
CONTROL RECORD ☒
SATELLITE RECORD ☐

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

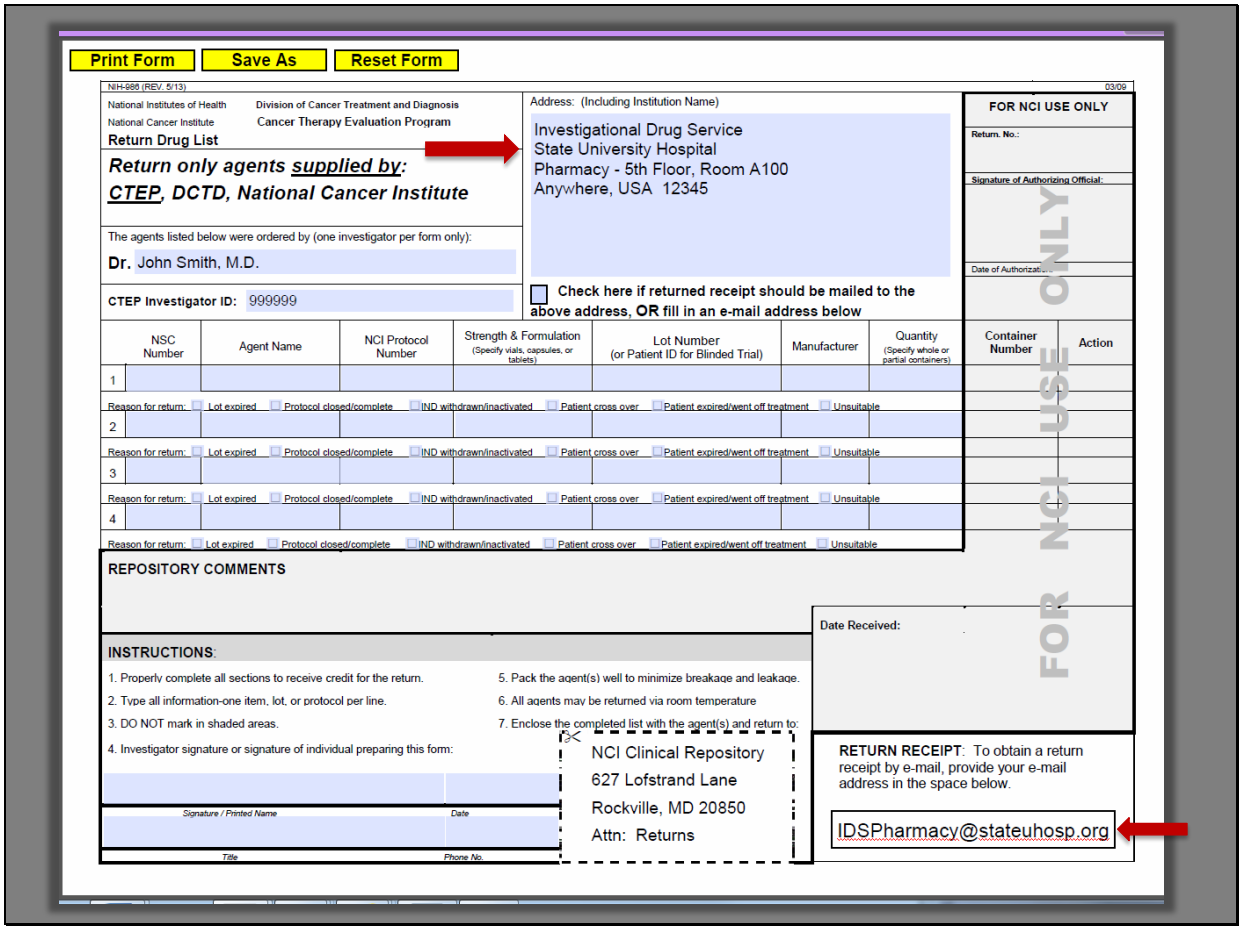
For this example, we will return 4 bottles of 200 mg pazopanib tablets. The CTEP investigator is Dr. John Smith, at State University Hospital. The protocol number is 1234, and the 200 mg pazopanib tablets come in 34 count bottles.

Slide 12



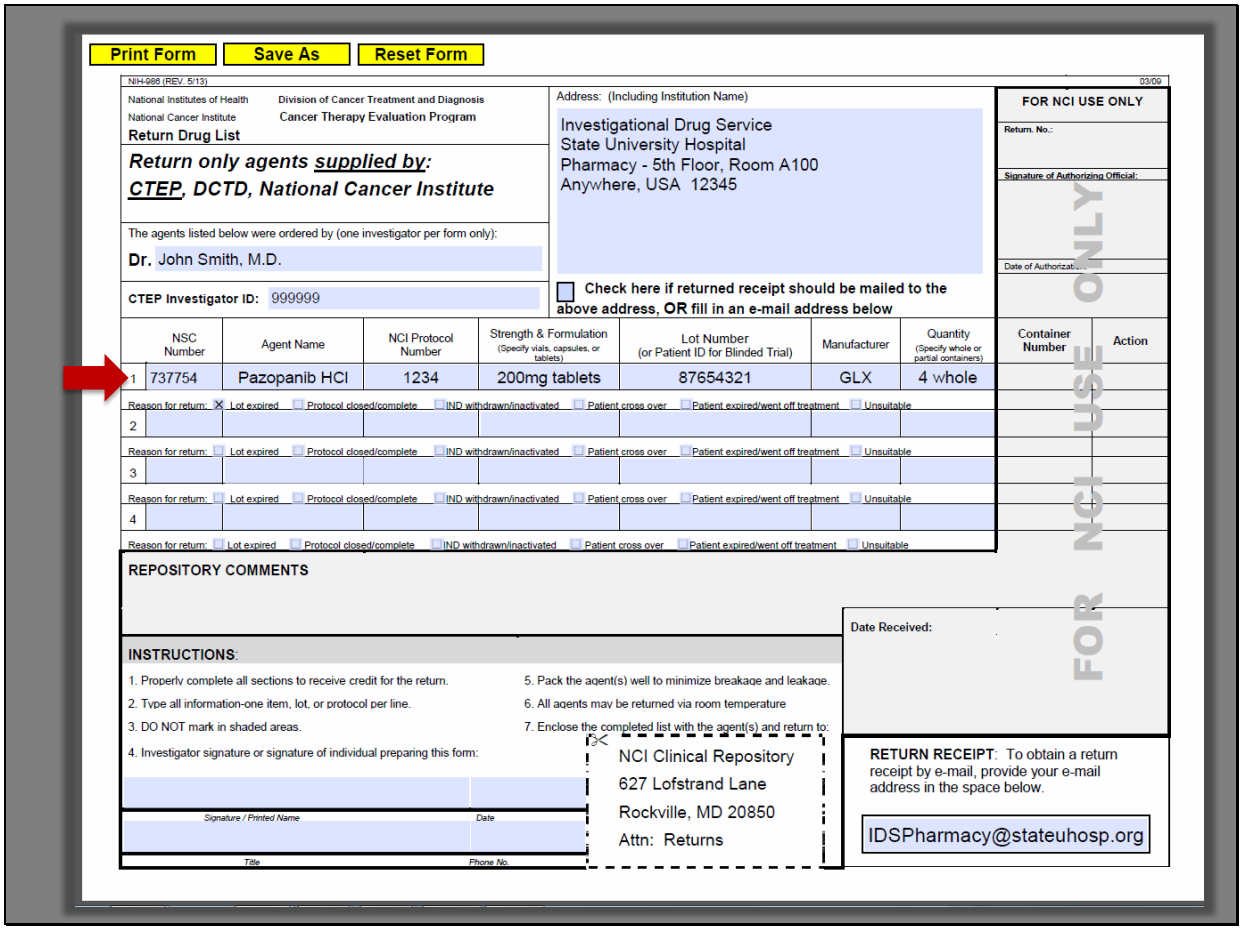
Start by entering the investigator name and CTEP Investigator ID. This will be the investigator noted on the shipping record, unless the agent was transferred. The investigator listed on the DARF will be the same as on the Return Drug List Form.

Slide 13



Next, insert the mailing address, including institution name. Enter an email address in the box at the bottom right of the form to receive a copy of the completed receipt from the NCI Clinical Repository.

Slide 14



Print Form | Save As | Reset Form

NIH-986 (REV. 5/13) 03/09

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

Return Drug List

Return only agents supplied by:
CTEP, DCTD, National Cancer Institute

The agents listed below were ordered by (one investigator per form only):
Dr. John Smith, M.D.

CTEP Investigator ID: 999999

Address: (Including Institution Name)
Investigational Drug Service
State University Hospital
Pharmacy - 5th Floor, Room A100
Anywhere, USA 12345

☐ Check here if returned receipt should be mailed to the above address, OR fill in an e-mail address below

FOR NCI USE ONLY
Return. No.:
Signature of Authorizing Official:
Date of Authorizati

	NSC Number	Agent Name	NCI Protocol Number	Strength & Formulation (Specify vials, capsules, or tablets)	Lot Number (or Patient ID for Blinded Trial)	Manufacturer	Quantity (Specify whole or partial containers)	Container Number	Action
1	737754	Pazopanib HCl	1234	200mg tablets	87654321	GLX	4 whole		
	Reason for return: ☒ Lot expired ☐ Protocol closed/complete ☐ IND withdrawn/inactivated ☐ Patient cross over ☐ Patient expired/went off treatment ☐ Unsuitable								
2									
	Reason for return: ☐ Lot expired ☐ Protocol closed/complete ☐ IND withdrawn/inactivated ☐ Patient cross over ☐ Patient expired/went off treatment ☐ Unsuitable								
3									
	Reason for return: ☐ Lot expired ☐ Protocol closed/complete ☐ IND withdrawn/inactivated ☐ Patient cross over ☐ Patient expired/went off treatment ☐ Unsuitable								
4									
	Reason for return: ☐ Lot expired ☐ Protocol closed/complete ☐ IND withdrawn/inactivated ☐ Patient cross over ☐ Patient expired/went off treatment ☐ Unsuitable								

FOR NCI USE ONLY

REPOSITORY COMMENTS

Date Received:

INSTRUCTIONS:

1. Properly complete all sections to receive credit for the return.
2. Type all information-one item, lot, or protocol per line.
3. DO NOT mark in shaded areas.
4. Investigator signature or signature of individual preparing this form:

Signature / Printed Name — Date
Title — Phone No.

5. Pack the agent(s) well to minimize breakage and leakage.
6. All agents may be returned via room temperature
7. Enclose the completed list with the agent(s) and return to:

NCI Clinical Repository
627 Lofstrand Lane
Rockville, MD 20850
Attn: Returns

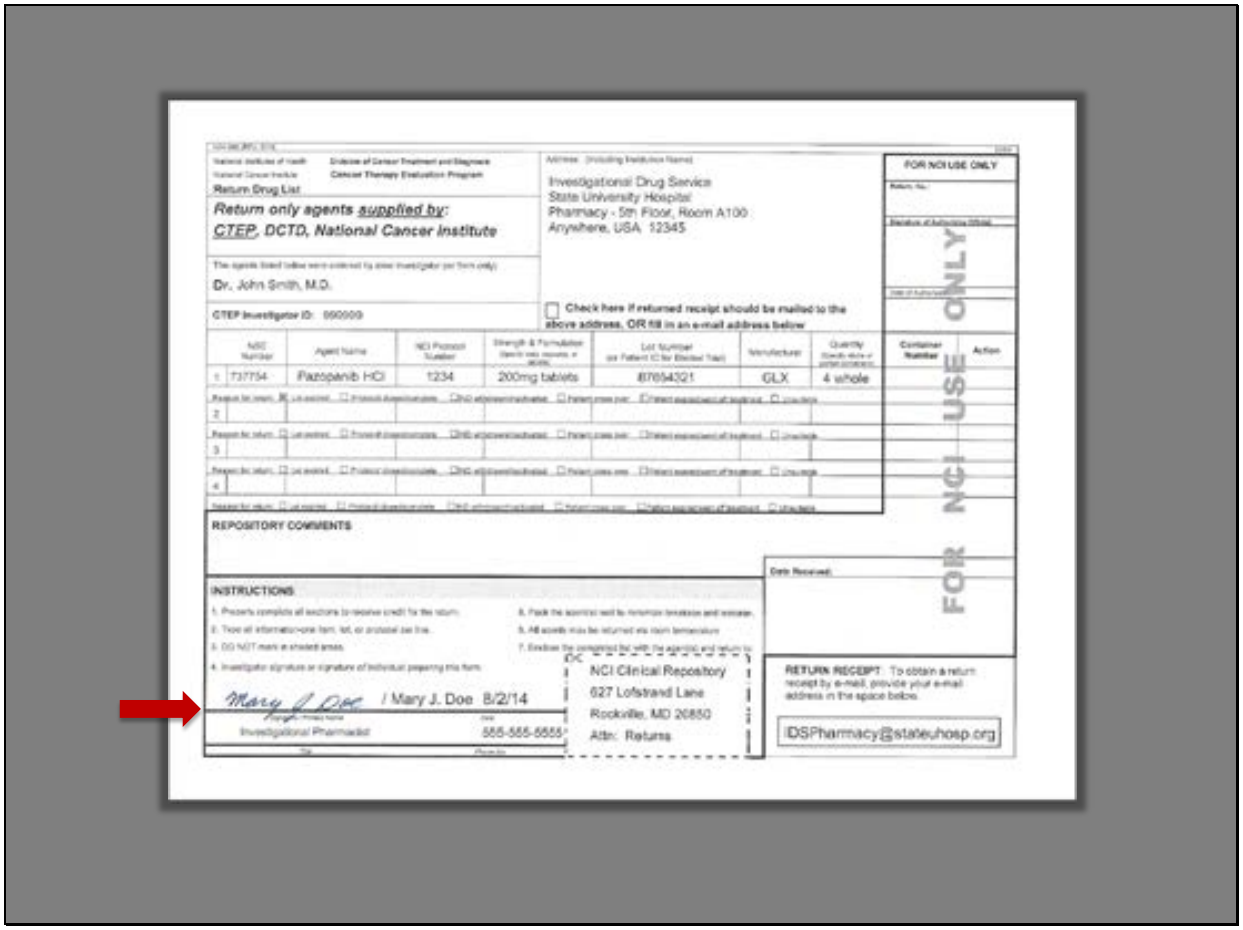
RETURN RECEIPT: To obtain a return receipt by e-mail, provide your e-mail address in the space below.

IDSPharmacy@stateuhosp.org

Now, complete row 1: NSC Number, agent name, NCI Protocol Number, strength & formulation, lot number (or patient ID for patient-specific supplies), manufacturer, quantity including whole or partial containers.
Opened containers with un-dispensed study agent must be returned to the NCI Clinical Repository. Do not return partial injectable vials.

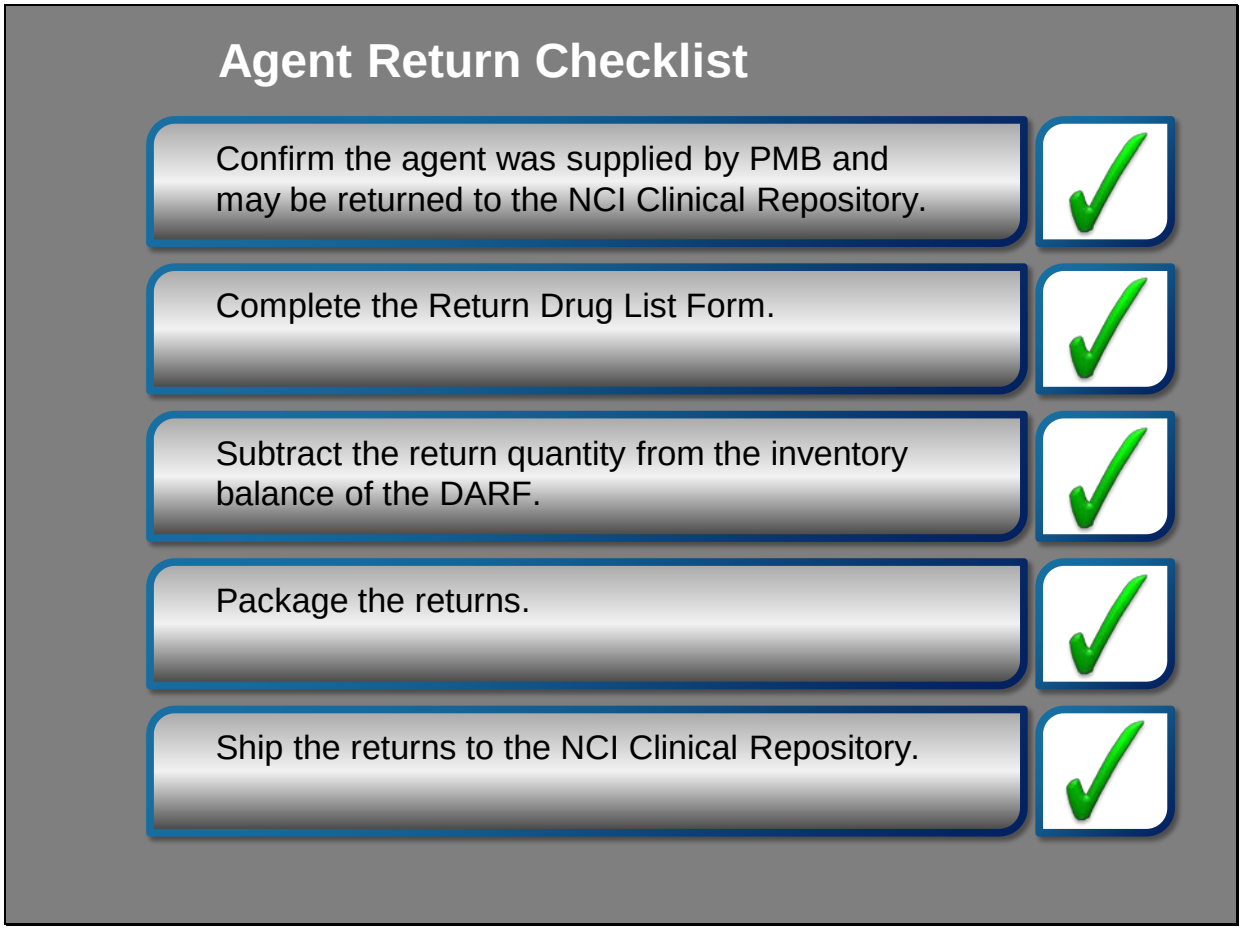
Indicate the reason for the return by checking the appropriate box.
If multiple lots or agents are recorded on the same form, record only 1 lot per row.
All agents on the form must have been ordered by or transferred to the investigator listed at the top of the form.

Slide 15



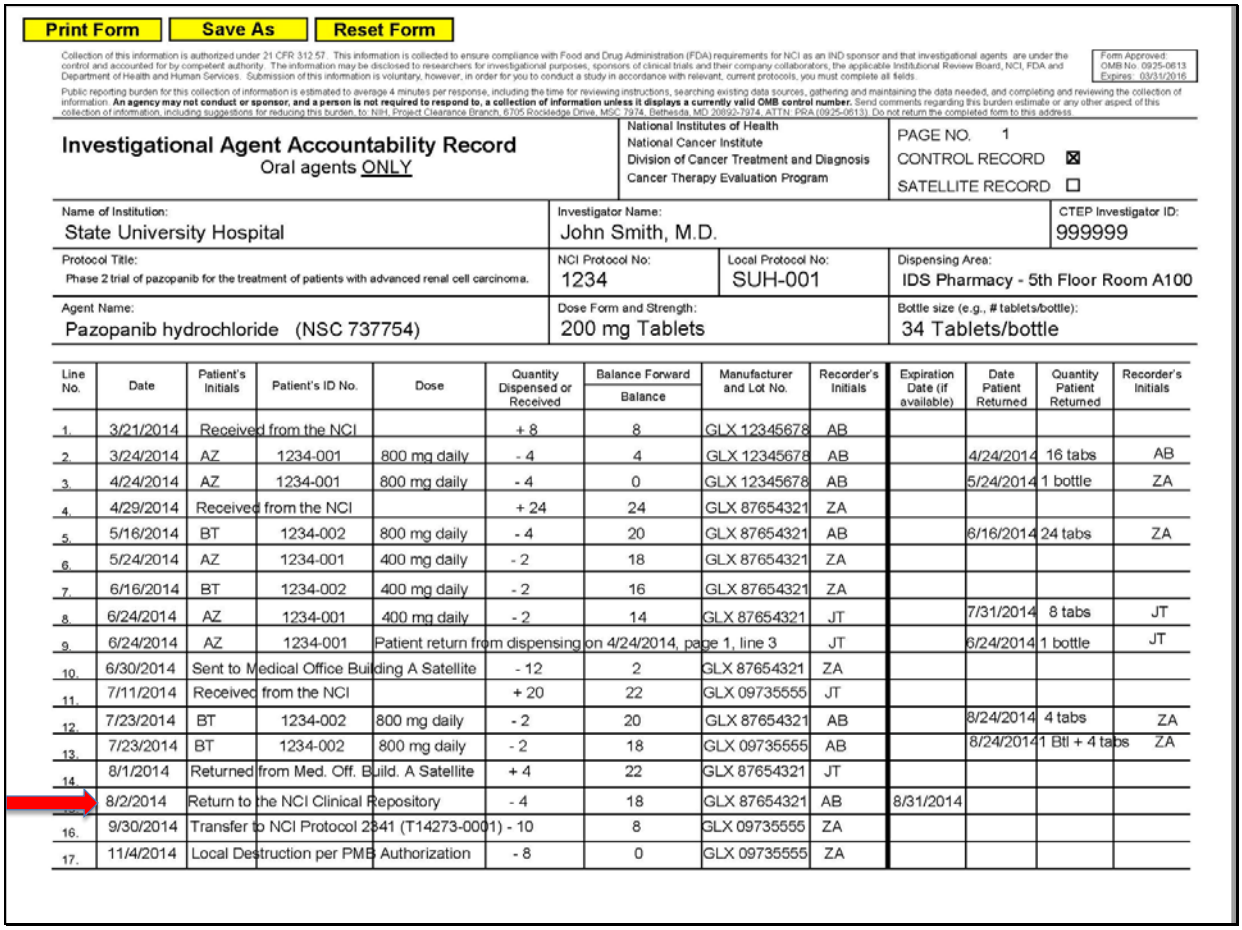
Finally, print, sign and date the form. Include a telephone number in case you need to be contacted.

Slide 16



The agent return can then be completed with appropriate inventory documentation, packaging, and shipping.

Slide 17



Print Form | Save As | Reset Form

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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 2341 (T14273-0001)			- 10	8	GLX 09735555	ZA				
17.	11/4/2014	Local Destruction per PMB Authorization			- 8	0	GLX 09735555	ZA				

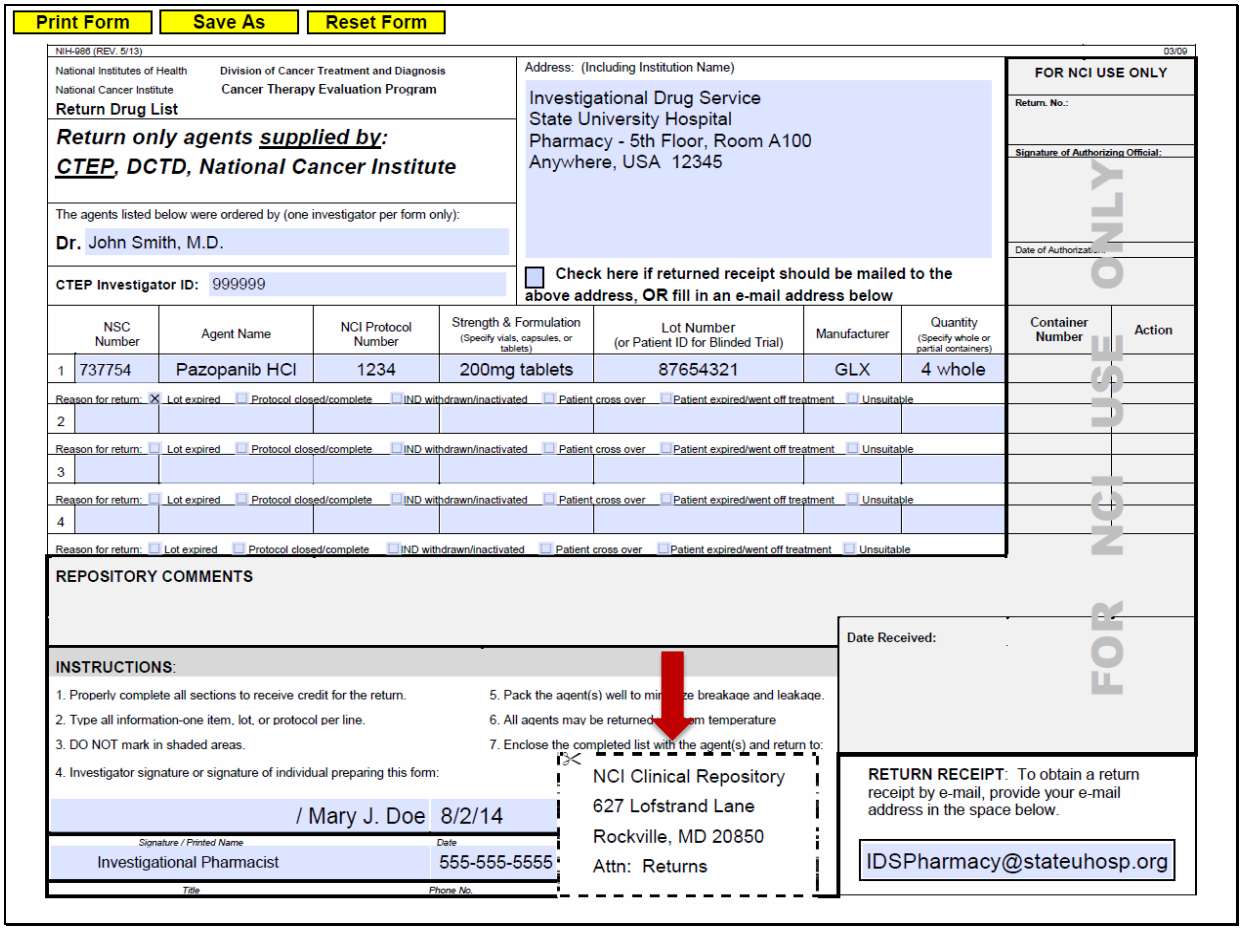
Document returns on the appropriate DARF. The 4 bottles being returned in our example are recorded on line 15 of this Oral DARF.

Agents stored at a satellite location must be returned to the control location, which returns them to the NCI Repository.

Slide 18

Package agents securely to prevent breakage. We recommend double bagging to minimize the risk to couriers and the NCI Clinical Repository staff. Enclose the Return Drug List Form, keeping a copy for your records.
Returns from multiple investigators can be shipped together. However, there must be a separate Return Drug List Form for each investigator. If multiple investigator returns are included in one shipment, please bag returns separately by investigator.
Do not place the Return Drug List form inside of the bag with the returning agent.

Slide 19



Print Form | Save As | Reset Form

NIH-986 (REV. 5/13) 03/09

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

Return Drug List

Return only agents supplied by:
CTEP, DCTD, National Cancer Institute

The agents listed below were ordered by (one investigator per form only):

Dr. John Smith, M.D.

CTEP Investigator ID: 999999

Address: (Including Institution Name)

Investigational Drug Service
State University Hospital
Pharmacy - 5th Floor, Room A100
Anywhere, USA 12345

☐ **Check here if returned receipt should be mailed to the above address, OR fill in an e-mail address below**

FOR NCI USE ONLY

Return. No.:

Signature of Authorizing Official:

Date of Authorizat...

FOR NCI USE ONLY

	NSC Number	Agent Name	NCI Protocol Number	Strength & Formulation (Specify vials, capsules, or tablets)	Lot Number (or Patient ID for Blinded Trial)	Manufacturer	Quantity (Specify whole or partial containers)	Container Number	Action
1	737754	Pazopanib HCl	1234	200mg tablets	87654321	GLX	4 whole		
	Reason for return: ☒ Lot expired ☐ Protocol closed/complete ☐ IND withdrawn/inactivated ☐ Patient cross over ☐ Patient expired/went off treatment ☐ Unsuitable								
2									
	Reason for return: ☐ Lot expired ☐ Protocol closed/complete ☐ IND withdrawn/inactivated ☐ Patient cross over ☐ Patient expired/went off treatment ☐ Unsuitable								
3									
	Reason for return: ☐ Lot expired ☐ Protocol closed/complete ☐ IND withdrawn/inactivated ☐ Patient cross over ☐ Patient expired/went off treatment ☐ Unsuitable								
4									
	Reason for return: ☐ Lot expired ☐ Protocol closed/complete ☐ IND withdrawn/inactivated ☐ Patient cross over ☐ Patient expired/went off treatment ☐ Unsuitable								

REPOSITORY COMMENTS

Date Received:

FOR NCI USE ONLY

INSTRUCTIONS:

1. Properly complete all sections to receive credit for the return.
2. Type all information-one item, lot, or protocol per line.
3. DO NOT mark in shaded areas.
4. Investigator signature or signature of individual preparing this form:
5. Pack the agent(s) well to min...ze breakage and leakage.
6. All agents may be returned ...m temperature
7. Enclose the completed list with the agent(s) and return to:

/ Mary J. Doe 8/2/14

Signature / Printed Name — *Date*

Investigational Pharmacist 555-555-5555

Title — *Phone No.*

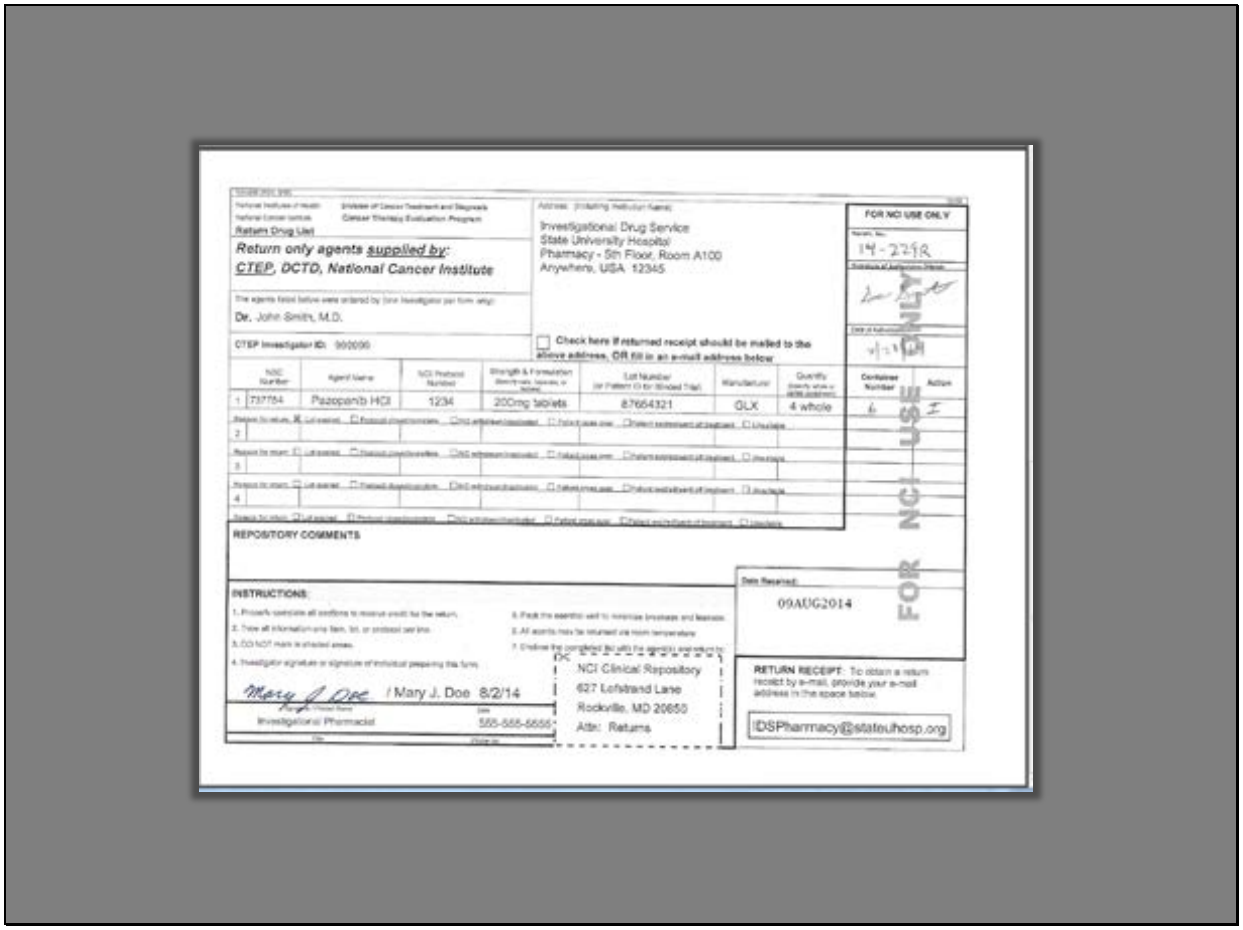
NCI Clinical Repository
627 Lofstrand Lane
Rockville, MD 20850
Attn: Returns

RETURN RECEIPT: To obtain a return receipt by e-mail, provide your e-mail address in the space below.

IDSPharmacy@stateuhosp.org

Ship agent returns to the address on the PMB Return Drug List Form. Room temperature is acceptable for all returns. Express delivery is not necessary. The investigator or designee is responsible for the cost of shipment.

Slide 20



Return Drug List

Return only agents supplied by:
CTEP, DCTD, National Cancer Institute

Dr. John Smith, M.D.

CTEP Investigator ID: 999999

Investigational Drug Service
State University Hospital
Pharmacy - 5th Floor, Room A100
Anywhere, USA 12345

☐ Check here if returned receipt should be mailed to the above address, OR fill in an e-mail address below

FOR NCI USE ONLY

14-2798

NSC Number	Agent Name	NCI Protocol Number	Strength & Formulation	Lot Number	Manufacturer	Quantity	Container Number	Action
1 737754	Pazopanib HCl	1234	200mg tablets	87664321	GLX	4 whole	6	E
2								
3								
4								

REPOSITORY COMMENTS

INSTRUCTIONS

Mary J Doe / Mary J. Doe 8/2/14

Investigational Pharmacist 555-555-5555

NCI Clinical Repository
627 Lofstrand Lane
Rockville, MD 20850
Attn: Returns

Date Received: 09AUG2014

RETURN RECEIPT: To obtain a return receipt by e-mail, provide your e-mail address in the space below.

IDSPharmacy@stateuhosp.org

The NCI Clinical Repository will return the completed Return Drug List Form via email to the address placed in the box in the bottom right-hand corner of the form. Review the form and reconcile any discrepancies noted by the Repository. File the form with your records.

Slide 21

Reducing the need for returns

- Do not order starter supplies
- Restrict requests to an 8 week supply per patient
- Use supplies up to the expiration date, when possible
- Order replacement supplies only if you have active patients
- Transfer excess supplies to another trial, when appropriate

Here are some strategies to reduce the need for returns:

- Do not order starter supplies. At a minimum, there should be a patient in screening before supplies are requested.
- Restrict requests to an 8 week supply per patient.
- Use supplies up to the expiration date, when possible.
- Do not immediately replace supplies on hand when stock recovery letters are received. Order replacement supplies only if you have active patients receiving that strength.
- Transfer excess supplies to another trial when appropriate. Refer to the Agent Transfers video for specifics.

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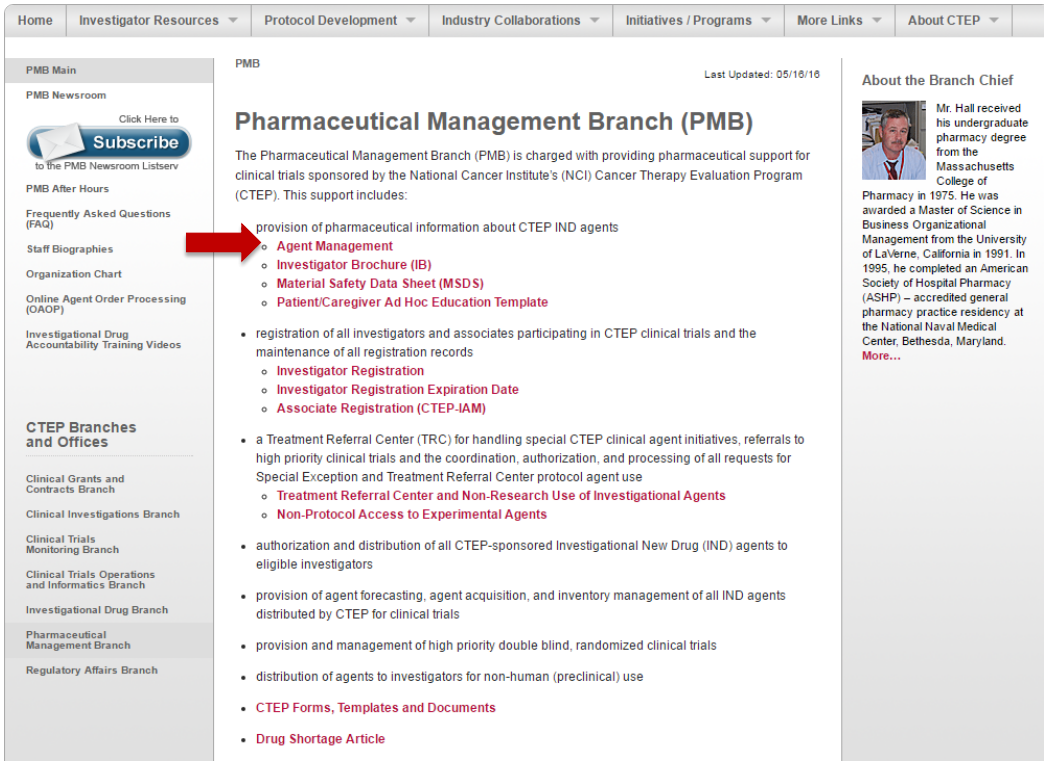
http://ctep.cancer.gov/branches/pmb/defult.htm



The policies and guidelines for agent returns and other topics mentioned in this video can be found on the PMB website under Agent Management. Our FAQs also provide information on related topics.

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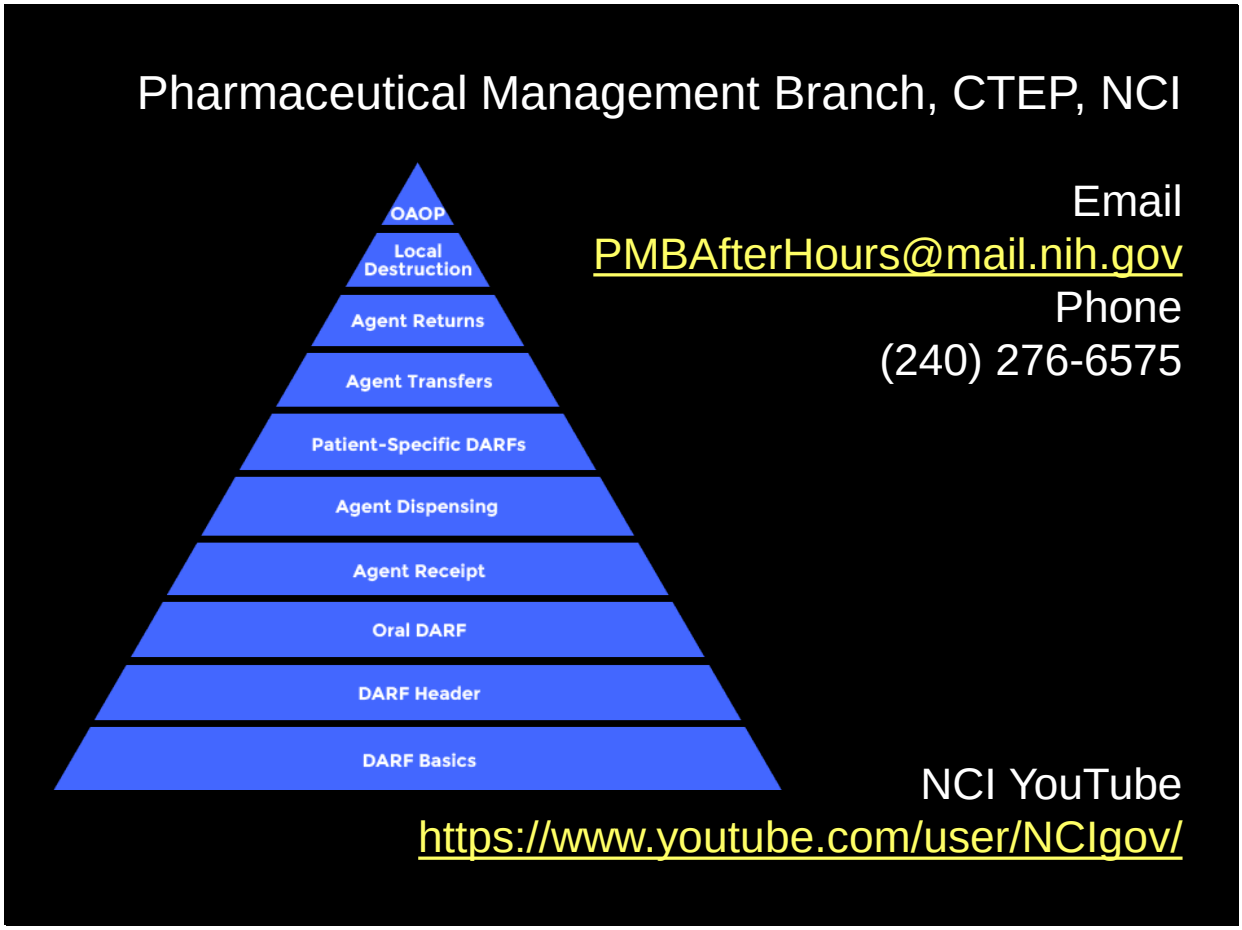

Thank you for watching this video tutorial. Additional PMB Investigational Drug Accountability videos are available through our YouTube Playlist.
Please note that the video and any items displayed within the videos are subject to change. Check back periodically for updates.
Questions can be directed to the Pharmaceutical Management Branch, CTEP, NCI by phone 240-276-6575, Monday through Friday from 8:30am to 4:30pm Eastern Time or by email at PMBAfterhours@mail.nih.gov any time.

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