



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.

## 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.

<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.

## Agent Return Checklist

Confirm the agent was supplied by PMB and may be returned to the NCI Clinical Repository.	<input type="checkbox"/>
Complete the Return Drug List Form.	<input type="checkbox"/>
Subtract the return quantity from the inventory balance of the DARF.	<input type="checkbox"/>
Package the returns.	<input type="checkbox"/>
Ship the returns to the NCI Clinical Repository.	<input type="checkbox"/>

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.

Pharmaceutical Management Branch  
Cancer Therapy Evaluation Program, DCTD, NCI  
9609 Medical Center Drive  
Room 5W228, MSC 9725  
Bethesda, MD 20892-9725  
Phone (240) 276-6575 Fax (240) 276-7893  
Email: PMBafterhours@mail.nih.gov

SHIPMENT RECORD OF CLINICAL  
DRUG REQUEST

Courier:  
Account #  
Acct Ref #  
Order # 2014224-0049  
Order Ref # O-1039416

Date Authorized: 08/12/2014  
Date Needed: 08/19/2014


NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	LOT #
IDS-9999	761968	XL184 (Cabozantinib)	60 mg Tablets 30 Tablets		

SUP # 1234  
NCI Protocol #: IDS-9999  
NCI Version Date: Jun 23, 2014

8.12 Availability  
XL184 (Cabozantinib) is an investigational agent **supplied to investigators by the Division of Cancer Treatment and Diagnosis (DCTD), NCI.**  
XL184 (Cabozantinib) is provided to the NCI under a Cooperative Research and

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.

## “DG”= Dangerous Goods

Pharmaceutical Management Branch Cancer Therapy Evaluation Program, DCTD, NCI 9609 Medical Center Drive Room 5W228, MSC 9725 Bethesda, MD 20892-9725 Phone (240) 276-6575 Fax (240) 276-7893 Email: PMBAfterhours@mail.nih.gov		<b>SHIPMENT RECORD OF CLINICAL                  DRUG REQUEST</b>  Date Authorized: 07/28/2014 Date Needed: 07/30/2014		Courier: Federal Express Account # XXXXX Acct Ref # XXXXX Order # 2014209-0037 Order Ref # O-1038533	
NCI Protocol #	NSC	Agent Name	Strength & Formulation	QTY	MFG & LOT #
IDS-1212	683864	Temsirolimus (CCI-779)	25 mg For Injection 1.2 mL Vial dual pack	4	WYP AI3V/1G
<b>**DG** Affix Excepted Quantity Label for each shipment</b>					

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.

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
A8256.002	Wonderdrug 50 mg 120 tablets per bottle	250 Bottles
A8257.014	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.

### Agent Return Checklist

Confirm the agent was supplied by PMB and may be returned to the NCI Clinical Repository.	<input checked="" type="checkbox"/>
Complete the Return Drug List Form.	<input checked="" type="checkbox"/>
Subtract the return quantity from the inventory balance of the DARF.	<input type="checkbox"/>
Package the returns.	<input type="checkbox"/>
Ship the returns to the NCI Clinical Repository.	<input type="checkbox"/>

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



**Print Form**
**Save As**
**Reset Form**

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NIH-889 (REV. 5/13)

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.** \_\_\_\_\_

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

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

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**REPOSITORY COMMENTS**

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**INSTRUCTIONS:**

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

Signature / Printed Name \_\_\_\_\_ Date \_\_\_\_\_

Title \_\_\_\_\_ Phone No. \_\_\_\_\_

Date Received: \_\_\_\_\_

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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.





FOR NCI USE ONLY

Shown here.

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

AE Template Phase II Single Agent v1.1	
AE Template Phase II Combination v1.1	
NCI Informed Consent Templates	
CTCAE v3.0 and Lay Term Mapping Document	 
Protocol Submission Worksheet v4.5	
CTC Generic Data Collection Form	 
Protocol Status Update	
Amendment Request Submission Checklist	

**Requisition of Agents**

Form Title	Adobe Acrobat (.pdf)
NCI Investigational Agent Accountability Record Form for Oral Agents	
NCI Investigational Agent Accountability Record Form	
NCI Transfer Investigational Agent Form	
NCI Return Investigational Agent Form	

The **Adobe Reader** is required to view PDF documents.

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

Collection of this information is authorized under 21 CFR 312.61. This information is collected to ensure compliance with Food and Drug Administration (FDA) requirements for NCI as an IRB sponsor and IRB investigator agents, and under the control and oversight of the appropriate authority. The information may be disclosed to researchers for investigational purposes, sponsors of clinical trials and their company collaborators, the appropriate Institutional Review Board (IRB), 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 protocol, you must complete all fields. Public meeting notices 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 the burden, to: Mail Stop 0188, Washington, DC 20503-0188, or to the Office of Management and Budget, Paperwork Project Director, Washington, DC 20503-9000. Do not return this collection form to the address.

Form Approved OMB No. 0925-0113 Expires 03/31/2014

**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

CTEP Investigator ID: 999999

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

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
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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.

NIH-896 (REV. 5/13) 8305  
 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  Check here if returned receipt should be mailed to the above address, OR fill in an e-mail address below

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: <input type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Unsuitable								
2								
Reason for return: <input type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Unsuitable								
3								
Reason for return: <input type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Un[Manufacturer 3]								
4								
Reason for return: <input type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Unsuitable								

**REPOSITORY COMMENTS**

**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 required on individual containers of 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:
 

NCI, Division of Cancer Treatment and Diagnosis  
 Cancer Therapy Evaluation Program  
 301 Rockville Pike  
 Bethesda, MD 20895

Date Received:

FOR NCI USE ONLY

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.

Print Form Save As Reset Form

NH-985 (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

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: <input type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Unsuitable								
2								
Reason for return: <input type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Unsuitable								
3								
Reason for return: <input type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Unsuitable								
4								
Reason for return: <input type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Unsuitable								

**REPOSITORY COMMENTS**

**INSTRUCTIONS:**

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

Signature / Printed Name \_\_\_\_\_ Date \_\_\_\_\_  
 Title \_\_\_\_\_ Phone No. \_\_\_\_\_

Date Received: \_\_\_\_\_

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.

[IDSParmacy@stateuhosp.org](mailto:IDSParmacy@stateuhosp.org)

FOR NCI USE ONLY

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.

Print Form Save As Reset Form

NH-088 (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

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: <input checked="" type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Unsuitable								
Reason for return: <input type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Unsuitable								
Reason for return: <input type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Unsuitable								
Reason for return: <input type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Unsuitable								

REPOSITORY COMMENTS

INSTRUCTIONS:

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

Signature / Printed Name \_\_\_\_\_ Date \_\_\_\_\_

Title \_\_\_\_\_ Phone No. \_\_\_\_\_

Date Received: \_\_\_\_\_

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.

[IDSParmacy@stateuhosp.org](mailto:IDSParmacy@stateuhosp.org)

FOR NCI USE ONLY

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.

National Institutes of Health National Cancer Institute Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program Return Drug List		Address (Including Institution Name) Investigational Drug Service State University Hospital Pharmacy - 5th Floor, Room A100 Anywhere, USA 12345		FOR NCI USE ONLY Return No. Division of Cancer Therapy Date of Submission					
Return only agents <u>supplied by:</u> <b>CTEP, DCTD, National Cancer Institute</b>		The agents listed below were ordered by site investigator (or form only) Dr. John Smith, M.D.		FOR NCI USE ONLY					
CTEP Investigator ID: 000000		<input type="checkbox"/> Check here if returned receipt should be mailed to the above address. OR fill in an e-mail address below							
NCI Number	Agent Name	NCI Product Number	Strength & Formulation (Specify dose, route, or other)	Lot Number (or Patient ID for Blinded Trial)	Manufacturer	Quantity (Specify units or other)	Container Number	Action	
1	T37734	Pazopanib HCl	200mg tablets	87854321	GLX	4 whole			
2									
3									
4									
REPOSITORY COMMENTS								Date Received:	
INSTRUCTIONS 1. Preserve complete all sections to receive credit for the return. 2. Type all information on form, left, or attached to file. 3. DO NOT mark or check dates. 4. Investigator signature or signature of individual preparing this form.								5. Pack the agent(s) well to minimize leakage and exposure. 6. All agents must be returned via room temperature. 7. Enclose the completed form with the agent(s) and return to: NCI Clinical Repository 627 Loftstrand Lane Rockville, MD 20850 Attn: Returns	
Mary J. Doe / Mary J. Doe B/2/14 Investigational Pharmacist 555-555-5555								RETURN RECEIPT: To obtain a return receipt by e-mail, provide your e-mail address in the space below. IDSParmacy@state.hosp.org	

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

## Agent Return Checklist

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.	

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

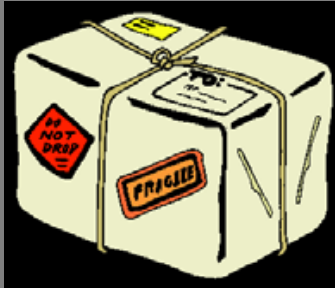


<b>Print Form</b>		<b>Save As</b>		<b>Reset Form</b>										
<small>Collection of this information is authorized under 21 CFR 312.57. This information is collected to ensure compliance with Food and Drug Administration (FDA) requirements for NCI as an IND sponsor and that investigational agents are under the control and accounted for by complete authority. The information may be disclosed to researchers for investigational purposes, sponsors of clinical trials and their company collaborators, the applicable Institutional Review Board, NCI, FDA and Department of Health and Human Services. Submission of this information is voluntary, however, in order for you to conduct a study in accordance with relevant, current protocols, you must complete all fields.</small>											<small>Form Approved OMB No. 0925-0613 Expires: 03/31/2016</small>			
<b>Investigational Agent Accountability Record</b> Oral agents <u>ONLY</u>											National Institutes of Health National Cancer Institute Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program		PAGE NO. 1 CONTROL RECORD <input checked="" type="checkbox"/> SATELLITE RECORD <input type="checkbox"/>	
Name of Institution: State University Hospital				Investigator Name: John Smith, M.D.				CTEP Investigator ID: 999999						
Protocol Title: Phase 2 trial of pazopanib for the treatment of patients with advanced renal cell carcinoma.				NCI Protocol No: 1234		Local Protocol No: SUH-001		Dispensing Area: IDS Pharmacy - 5th Floor Room A100						
Agent Name: Pazopanib hydrochloride (NSC 737754)				Dose Form and Strength: 200 mg Tablets				Bottle size (e.g., # tablets/bottle): 34 Tablets/bottle						
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials		
1.	3/21/2014	Received from the NCI			+ 8	8	GLX 12345678	AB						
2.	3/24/2014	AZ	1234-001	800 mg daily	- 4	4	GLX 12345678	AB		4/24/2014	16 tabs	AB		
3.	4/24/2014	AZ	1234-001	800 mg daily	- 4	0	GLX 12345678	AB		5/24/2014	1 bottle	ZA		
4.	4/29/2014	Received from the NCI			+ 24	24	GLX 87654321	ZA						
5.	5/16/2014	BT	1234-002	800 mg daily	- 4	20	GLX 87654321	AB		6/16/2014	24 tabs	ZA		
6.	5/24/2014	AZ	1234-001	400 mg daily	- 2	18	GLX 87654321	ZA						
7.	6/16/2014	BT	1234-002	400 mg daily	- 2	16	GLX 87654321	ZA						
8.	6/24/2014	AZ	1234-001	400 mg daily	- 2	14	GLX 87654321	JT		7/31/2014	8 tabs	JT		
9.	6/24/2014	AZ	1234-001	Patient return from dispensing on 4/24/2014, page 1, line 3				JT		6/24/2014	1 bottle	JT		
10.	6/30/2014	Sent to Medical Office Building A Satellite			- 12	2	GLX 87654321	ZA						
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.

## Package agents securely to prevent breakage



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.

<b>Print Form</b>		<b>Save As</b>		<b>Reset Form</b>				
NIH-998 (REV. 5/13) National Institutes of Health National Cancer Institute <b>Return Drug List</b>						Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program		
Address: (Including Institution Name) Investigational Drug Service State University Hospital Pharmacy - 5th Floor, Room A100 Anywhere, USA 12345						<b>FOR NCI USE ONLY</b> Return No.: Signature of Authorizing Official: Date of Authorization:		
<b>Return only agents <u>supplied by:</u></b> <b><u>CTEP, DCTD, National Cancer Institute</u></b>								
The agents listed below were ordered by (one investigator per form only): Dr. John Smith, M.D.								
CTEP Investigator ID: 999999						<input type="checkbox"/> Check here if returned receipt should be mailed to the above address, OR fill in an e-mail address below		
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: <input checked="" type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Unsuitable								
Reason for return: <input type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Unsuitable								
Reason for return: <input type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Unsuitable								
Reason for return: <input type="checkbox"/> Lot expired <input type="checkbox"/> Protocol closed/complete <input type="checkbox"/> IND withdrawn/inactivated <input type="checkbox"/> Patient cross over <input type="checkbox"/> Patient expired/went off treatment <input type="checkbox"/> Unsuitable								
<b>REPOSITORY COMMENTS</b>						Date Received:		
<b>INSTRUCTIONS:</b> 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 at room temperature. 7. Enclose the completed list with the agent(s) and return to:		
Signature / Printed Name: / Mary J. Doe Date: 8/2/14 Title: Investigational Pharmacist Phone No.: 555-555-5555						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. IDSParmacy@stateuosp.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.

**NCI RETURN DRUG LIST**

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

**Return Drug List**

**Return only agents supplied by:**  
**CTEP, OCTO, National Cancer Institute**

The agents listed below were ordered by your Investigator per form only:  
 Dr. John Smith, M.D.

CTEP Investigator ID: 900090

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

**FOR NCI USE ONLY**

Return No: 14-279R  
 Signature of Institution Representative: [Signature]  
 Date of Return: 8/2/14

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

NCI Number	Agent Name	NCI Protocol Number	Strength & Formulation (mg/ml, tablets, etc.)	Lot Number (or Pattern ID for Shaded Flap)	Manufacturer	Quantity (units, vials, etc.)	Container Number	Action
1 737704	Pazopanib HCl	1234	200mg tablets	87664321	GLX	4 whole		RETURN
2								
3								
4								

**REPOSITORY COMMENTS**

**INSTRUCTIONS:**

1. Please complete all sections to receive credit for the return.
2. Type all information on this form, in or outside the lines.
3. DO NOT mark in shaded areas.
4. Investigator signature or signature of institutional preparing this form.
5. Pack the material well to minimize breakage and leakage.
6. All agents may be returned at room temperature.
7. Enclose the completed (to allow for accurate tracking by NCI) Clinical Repository.

Date Received: 09AUG2014

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

NCI Clinical Repository  
 627 Loftland Lane  
 Rockville, MD 20850  
 Attn: Returns  
 IDSParmacy@stateuhosp.org

Mary J. Doe / Mary J. Doe 8/2/14  
 Investigational Pharmacist 555-555-5555

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 and notes by the Repository. File the form with your records.

## 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.

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

Home Investigator Resources Protocol Development Industry Collaborations Initiatives / Programs More Links About CTEP

PMB Main PMB Newsroom PMB After Hours Frequently Asked Questions (FAQ) Staff Biographies Organization Chart Online Agent Order Processing (OAOP) Investigational Drug Accountability Training Videos

CTEP Branches and Offices

Clinical Grants and Contracts Branch

Clinical Investigations Branch

Clinical Trials Monitoring Branch

Clinical Trials Operations and Informatics Branch

Investigational Drug Branch

Pharmaceutical Management Branch

Regulatory Affairs Branch

PMB

Last Updated: 05/16/16

### Pharmaceutical Management Branch (PMB)

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

- provision of pharmaceutical information about CTEP IND agents
  - Agent Management
  - Investigator Brochure (IB)
  - Material Safety Data Sheet (MSDS)
  - Patient/Caregiver Ad Hoc Education Template
- registration of all investigators and associates participating in CTEP clinical trials and the maintenance of all registration records
  - Investigator Registration
  - Investigator Registration Expiration Date
  - Associate Registration (CTEP-IAM)
- a Treatment Referral Center (TRC) for handling special CTEP clinical agent initiatives, referrals to high priority clinical trials and the coordination, authorization, and processing of all requests for Special Exception and Treatment Referral Center protocol agent use
  - Treatment Referral Center and Non-Research Use of Investigational Agents
  - Non-Protocol Access to Experimental Agents
- authorization and distribution of all CTEP-sponsored Investigational New Drug (IND) agents to eligible investigators
- provision of agent forecasting, agent acquisition, and inventory management of all IND agents distributed by CTEP for clinical trials
- provision and management of high priority double blind, randomized clinical trials
- distribution of agents to investigators for non-human (preclinical) use
- CTEP Forms, Templates and Documents
- Drug Shortage Article

About the Branch Chief

Mr. Hall received his undergraduate pharmacy degree from the Massachusetts College of Pharmacy in 1975. He was awarded a Master of Science in Business Organizational Management from the University of LaVerne, California in 1991. In 1995, he completed an American Society of Hospital Pharmacy (ASHP) – accredited general pharmacy practice residency at the National Naval Medical Center, Bethesda, Maryland.

More...

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.

Pharmaceutical Management Branch, CTEP, NCI



OAOP  
Local Destruction  
Agent Returns  
Agent Transfers  
Patient-Specific DARFs  
Agent Dispensing  
Agent Receipt  
Oral DARF  
DARF Header  
DARF Basics

Email  
[PMBAfterHours@mail.nih.gov](mailto:PMBAfterHours@mail.nih.gov)  
Phone  
(240) 276-6575

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

Thank you for watching this video tutorial. Additional PMB Investigational Drug Accountability videos are available through our YouTube Playlist.

Please note that the video and any items displayed within the videos are subject to change. Check back periodically for updates.

Questions can be directed to the Pharmaceutical Management Branch, CTEP, NCI by phone 240-276-6575, Monday through Friday from 8:30am to 4:30pm Eastern Time or by email at [PMBAfterhours@mail.nih.gov](mailto:PMBAfterhours@mail.nih.gov) any time.

U.S. Department of Health and Human Services  
National Institutes of Health | National Cancer Institute

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

1-800-4-CANCER

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