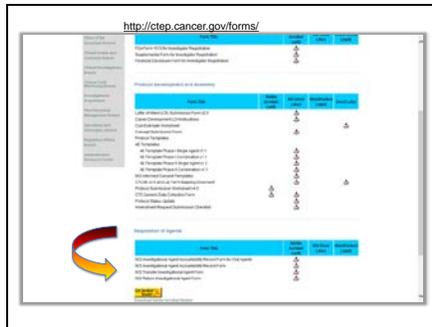


Slide 1



Welcome to this video tutorial on Agent Transfers in the PMB Investigational Drug Accountability series. This video will review when and how to perform an agent transfer of PMB-supplied agents for DCTD-sponsored trials.

Slide 2



You can find the agent transfer form and other forms on the CTEP website.

Slide 3

PMB-supplied agents may be transferred from a DCTD-sponsored protocol to another DCTD-sponsored protocol for the same investigator or between eligible investigators within the same institution, also called an intra-institutional transfer. Transferring agents is not the same as transporting, which is moving agents back and forth between the control dispensing area and the satellite dispensing area, which does not require a formal transfer request. A transfer request between DCTD-sponsored protocols can only be considered if the protocols utilize the same agent, strength and formulation

supplied by PMB. Except in situations of urgent medical need when PMB is not available, agent transfers require prior approval from PMB before the actual transfer occurs.

Slide 4

**Transfer Investigational Agent Form**

This form is to be used for all intra-institutional transfer, inter-institutional.

**TRANSFER FROM:**

Investigator transferring agent: \_\_\_\_\_ CTSP Investigator ID: \_\_\_\_\_ Date of transfer: \_\_\_\_\_

Name of institution: \_\_\_\_\_

Street Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_

Reason for transfer request:  Protocol closed/complete  Shared agent obtained for Special Exception  Agent has short supply  Other\*

(\*Requires verbal confirmation with PMB before approval)

**TRANSFER TO:**

Agent receiving agent: \_\_\_\_\_ CTSP Investigator ID: \_\_\_\_\_

The following CTSP receiving agent has NOT obtained approval in writing to participate in REC approved protocol:

Receiving site	Investigator	REC Number	Agent Name	Strength and Dosage	Quantity	Requisition and REC Number

**\*Additional Signature (Investigator or Designer)**

Printed Name: \_\_\_\_\_

Signature Number: \_\_\_\_\_ PIN Number: \_\_\_\_\_

Phone Number: \_\_\_\_\_

FAX: 240-276-7893

See <http://www.fda.gov/oc/ohrt/ohrtfaq.html> for further information.  
All requested information MUST be supplied for form to be valid.

The form contains writable sections that may be typed out prior to printing for handwritten signature. Let’s discuss the three major portions of the form and what is required to successfully complete it from top to bottom.

Slide 5

**Agent Transfer Form: Top Section Containing Transfer From Investigator and Transfer Reason**

**Transfer Investigational Agent Form**

This form is to be used for all intra-institutional transfer, inter-institutional.

**TRANSFER FROM:**

Investigator transferring agent: \_\_\_\_\_ CTSP Investigator ID: \_\_\_\_\_ Date of transfer: \_\_\_\_\_

Name of institution: \_\_\_\_\_

Street Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_

Reason for transfer request:  Protocol closed/complete  Shared agent obtained for Special Exception  Agent has short supply  Other\*

(\*Requires verbal confirmation with PMB before approval)

The top portion lists information about the investigator who is transferring the agent. The “Transfer From” investigator must be the investigator who either 1) originally ordered the agent or 2) was the “Transfer To” investigator on a previously PMB-approved transfer.

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**Agent Transfer Form: Top Section Containing Transfer From Investigator and Transfer Reason**

Clinical Therapeutics Program  
 Division of Cancer Treatment and Diagnosis  
 National Cancer Institute  
 National Institutes of Health

**Transfer Investigational Agent Form**

This form is to be used for an inter-institutional transfer, see instructions.

---

**TRANSFER FROM**

Investigator transferring agent	CTSP Investigator ID	Date of transfer
Dr. _____		
Name of institution		
Street Address		
City	State	Zip Code
Reason for transfer request: <input type="checkbox"/> Protocol closed/completed <input type="checkbox"/> Unused agent obtained for Special Exception <input type="checkbox"/> Agent has short dating <input type="checkbox"/> Other*		

\*Requires verbal clarification with PMB before approval

PMB-supplied agents may be transferred for various reasons. The more commonly accepted reasons are that:

1. The protocol is closed or completed and excess quantity of unused agent can be dispensed for another DCTD-sponsored protocol. This includes special exception protocols.
2. An agent with short dating can be used prior to the expiration date for another protocol.

Reasons that fall into the “other” category should be clarified with PMB before transfer request and may include the following:

1. A patient needs to be treated now and there is insufficient protocol supply to dispense or prepare a dose.
2. The control pharmacy or dispensing area relocates.
3. The responsible investigator at the site changes.

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**Agent Transfer Form: Middle Section Containing Transfer To Investigator and Agent Information**

**TRANSFER TO**

Investigator receiving agent	CTSP Investigator ID
Dr. _____	

The following CTSP-supplied agent for NCI approved protocol is being transferred to NCI approved protocol:

Received on	Transferred to	Agent Name	Strength/Concentration	Quantity	Manufacturer and Lot Number
NCI Protocol Number	NCI Protocol Number	NCI Number			

The middle portion lists information about the investigator to whom agent is being transferred. The remaining portion contains information about the protocols involved in the transfer and the agent that is being transferred. The agent being transferred must not be expired at the time of transfer. Only intact or whole units may be transferred. Check the shipment receipt for the specific unit or package multiplier information.

Slide 8

**Agent Transfer Form: Bottom Section Containing Signature and Instructions for Submission to PMB**

Authorized Signatory (Investigator or Designee) \_\_\_\_\_

Printed Name \_\_\_\_\_

Telephone Number \_\_\_\_\_ Fax Number \_\_\_\_\_

Email Address \_\_\_\_\_

Return form to:  
Pharmaceutical Management Bureau, CTSP, DCTD  
100 Shady Grove  
Room 5B123, MSC #725  
Bethesda, MD 20894-0725  
PMB@hcthorus@mail.nih.gov  
FAX: 240-276-7893

See <http://www.fda.gov/oc/ohrt/ohrt-agent-transfer.html> for further information.  
All requested information MUST be supplied for form to be valid.

The bottom portion of the form requires an authorized signature from either the investigator or designee of the investigator, either shipping or ordering designee. Transfer forms must be completely filled out to be considered for approval.

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**Agent Transfer Form: Bottom Section Containing Signature and Instructions for Submission to PMB**

Authorized Signatory (Investigator or Designee) \_\_\_\_\_

Printed Name \_\_\_\_\_

Telephone Number \_\_\_\_\_ Fax Number \_\_\_\_\_

Email Address \_\_\_\_\_

Return form to:  
Pharmaceutical Management Bureau, CTSP, DCTD  
100 Shady Grove  
Room 5B123, MSC #725  
Bethesda, MD 20894-0725  
PMB@hcthorus@mail.nih.gov  
FAX: 240-276-7893

See <http://www.fda.gov/oc/ohrt/ohrt-agent-transfer.html> for further information.  
All requested information MUST be supplied for form to be valid.

Completed forms must be submitted by fax or by email. Requests are usually responded to in the same business day. Mailing forms to PMB through the postal service is not recommended.

Slide 10

**Transfer Investigational Agent Form**

This form is to be used to obtain approval for transfer of an investigational agent.

TRANSFER FORM

Investigator (Name, Title)  
Dr. John Smith

CTSP Investigator ID: 000000 Date of Transfer: 3/30/2014

Reason for transfer request:  Protocol closed/terminated  Investigator transferred to another institution  Agent not used during study  Other \_\_\_\_\_

TRANSFER TO:  
Investigator (Name, Title)  
Dr. John Smith

CTSP Investigator ID: 000000

The receiving institution must agree to hold the agent product in strict accordance to ICH guidelines.

Product Name	Investigator	CTSP Investigator ID	Agent Name	Strength and Dosage	Quantity	Manufacturer and Lot Number
1234	0001	000000	pazopanib	400mg tablets	10 bottles	GLA 00788888

Authorized Signatory (Investigator or Designee) \_\_\_\_\_

Printed Name \_\_\_\_\_

Telephone Number \_\_\_\_\_ Fax Number \_\_\_\_\_

Email Address \_\_\_\_\_

Return form to:  
Pharmaceutical Management Bureau, CTSP, DCTD  
100 Shady Grove  
Room 5B123, MSC #725  
Bethesda, MD 20894-0725  
PMB@hcthorus@mail.nih.gov  
FAX: 240-276-7893

See <http://www.fda.gov/oc/ohrt/ohrt-agent-transfer.html> for further information.  
All requested information MUST be supplied for form to be valid.

Here is a completed transfer form for Dr. John Smith. The request is made because NCI protocol 1234 closed and remaining pazopanib 200 mg tablets can be used on NCI protocol 2341.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Date: September 30, 2014  
 To: Dr. John Smith, et al, J.A.  
 Fax: (321) 436-7009  
 From: J.S. Inventory Management Specialist  
 Re: Transfer # T14273-0001

There are 2 pages in this transmission (including the cover sheet)

The Pharmaceutical Management Branch has **APPROVED** the following agent transfer request that was received on 09/30/2014.

Transfer #: T14273-0001  
 From Investigator: Smith, John  
 Investigator ID: 1009799  
 Institution: State University Hospital  
 Protocol: 1234

PMB action date: 09/30/2014  
 To Investigator: Smith, John  
 Investigator ID: 1009799  
 Institution: State University Hospital  
 Protocol: 2345

Agent Name	NDC	Lot Number	Quantity	Strength/Unit Factor
Pazopanib 200 mg tablets	747774	107741310	10 bottles/24	200 mg/tablet

Protocol 1234 is closed at this site.

Please retain a copy of this form with your accountability records. If you have any questions or comments, please call (247) 276-6777 or contact us via email at P33@hhs.gov/industrial@hhs.gov.

Thank you.

The transfer request is approved because Dr. Smith is an active registered investigator at State University Hospital and both studies utilize PMB-supplied pazopanib 200 mg tablets. Here is the transfer approval letter from PMB that must be retained with the appropriate agent accountability records.

Slide 12

**Transfer From: Protocol 1234**

**Investigational Agent Accountability Record**  
 Oral agents 255.2

Name of institution: State University Hospital  
 Investigator Name: John Smith, M.D.  
 NCI Protocol No.: 1234  
 Last Protocol No.: 0124-001  
 Issuing Area: 000 Pharmacy  
 Site Protocol: 100566

Product Name: Pazopanib hydrochloride (NDC 73775-04)  
 Date Form used through: 200 mg tablets  
 Same unit as Agent Accountability: 24 Tablets/Bottle

Trans. No.	Date	Quantity	Patent's Lot No.	Case	Quantity (Number of Bottles)	Balance/Forward	Transfer From	Transfer To	Quantity (Number of Bottles)	Balance/Forward	Transfer From	Transfer To
1	01/15/2014	Received from the NCI			+ 8	8	OLK 0124001	AB				
2	04/28/2014	AN	1234-001	400 mg daily	-2	6	OLK 0124001	AB		04/28/2014	10 bottles	
3	04/28/2014	AN	1234-001	400 mg daily	-2	4	OLK 0124001	AB		05/02/2014	4 bottles	
4	02/28/2014	Returned from the NCI			+ 24	24	OLK 0124001	EA				
5	04/28/2014	BT	1234-001	400 mg daily	-4	20	OLK 0124001	AB		05/02/2014	24 bottles	
6	04/28/2014	AN	1234-001	400 mg daily	-2	18	OLK 0124001	EA				
7	04/28/2014	BT	1234-001	400 mg daily	-2	16	OLK 0124001	EA				
8	04/28/2014	AN	1234-001	400 mg daily	-2	14	OLK 0124001	EA		10/01/2014	8 bottles	
9	04/28/2014	AN	1234-001	Returned return from (Investigator) 01/24/2014, page 3, line 3						05/02/2014	1 bottles	
10	01/15/2014	Returned from the NCI			+ 20	20	OLK 0124001	EA				
11	02/28/2014	BT	1234-001	400 mg daily	-2	20	OLK 0124001	AB		05/02/2014	4 bottles	
12	12/03/2014	BT	1234-001	400 mg daily	-2	18	OLK 0124001	AB		05/02/2014	8 bottles	
13	01/15/2014	Returned from Med. CR. (Lot: A) Satellite			+ 4	22	OLK 0124001	EA				
14	02/28/2014	Returned to the NCI-Clinical Research			-4	18	OLK 0124001	AB		05/02/2014		
15	02/28/2014	Transfer to NCI Protocol 2345 (12/15/2013)			-18	0	OLK 0124001	EA				
16	11/02/2014	Local Distribution per PMB Authorization			-8	0	OLK 0124001	EA				

Approved transfers should be documented on the two DARFs that are involved in the transfer. The assigned transfer number can be recorded on the DARF for reference.

Note the transfer must be made from the control record. Transfers cannot be documented on satellite records. For more about the responsibilities of control dispensing areas, refer to PMB's "Policy and Guidelines for Investigational Agent Distribution."

On the DARF for protocol 1234, line 16 shows documentation of an agent transfer made to NCI protocol 2341 for 10 bottles of pazopanib 200 mg tablets. Transfer number T14273-0001 was documented on the DARF and 10 bottles were subtracted from the balance for NCI protocol 1234.

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**Transfer To: Protocol 2341**

Investigational Agent Accountability Record		National Cancer Institute Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program		PMB# NO: 1					
Drug Agent: QSLC				CONTROL RECORD: 00					
Name of Institution: State University Hospital		Investigator Name: John Smith, M.D.		Control Number: 099999					
Protocol Title: Phase I trial of pazopanib for the treatment of patients with advanced breast		NCI Protocol No: 2341		Local Protocol No: SUNP-022					
Agent Name: Pazopanib hydrochloride (NDC 737754)		Drug Form and Strength: 200 mg Tablets		Dispensing Area: GDC Pharmacy - 5th Floor Room A					
				Units per vial / Package: 34 Tablets/Bottle					
Line	Date	Quantity	Received	Released	Balance	Units	Balance	Units	Balance
1.	8/22/2014	100	100						
2.	8/22/2014	100	100						
3.	8/27/2014	100	100						
4.	8/29/2014	100	100						

On the DARF for protocol 2341, line 4 shows documentation of a transfer of 10 bottles pazopanib 200 mg tablets from protocol 1234. Notice that Dr. Smith was already the ordering investigator on study 2341 and a new DARF was not required. If Dr. Smith were not an ordering investigator for study 2341 previously, a new DARF would need to be created.

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Circumstances may arise when a transfer is needed and PMB is not open for business. In these urgent cases, the transfer can be made without prior PMB approval. Transfer forms for urgent medical need should be submitted within 72 hours of the actual transfer. There is always a risk that the transfer will not be approved retroactively because it was not a valid transfer. Denied transfer requests should be documented on the DARF and kept with the appropriate agent accountability records.

Other special cases that are not urgent require prior PMB approval. Please call for transfer requests that include the following:

1. Transfer of agent between institutions (also known as inter-institutional transfer)
2. Relocation of control dispensing area
3. Patient-specific supplies

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**Examples of Non-Valid Transfer Requests**

1. Agent being transferred is not the same strength or formulation between protocols
2. The "Transfer To" investigator does not have an active registration
3. The "Transfer To" investigator is not an eligible participant on the study
4. PMB-supplied agent is transferred to a non-DCTD-sponsored protocol
5. PMB-supplied agent is transferred for commercial use
6. Commercial agents are transferred to a DCTD-sponsored protocol
7. Borrowing from one protocol to supply another without an approved transfer
8. Transfer of partial containers
9. Transfer of patient-specific agents without prior PMB approval
10. Transfer requests to retrospectively correct errors in accountability

Examples of instances when agent transfer is NOT valid include:

1. Agent being transferred is not the same strength or formulation between protocols
2. The "Transfer To" investigator does not have an active registration
3. The "Transfer To" investigator is not an eligible participant on the study
4. PMB-supplied agent is transferred to a non-DCTD-sponsored protocol
5. PMB-supplied agent is transferred for commercial use
6. Commercial agents are transferred to a DCTD-sponsored protocol
7. Borrowing from one protocol to supply another without an approved transfer
8. Transfer of partial containers
9. Transfer of patient-specific agents without prior PMB approval
10. Transfer requests to retrospectively correct errors in accountability

Slide 16

Examples of Non-Valid Transfer Requests

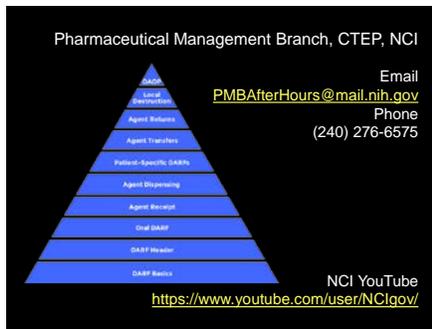
1. Agent being transferred is not the same strength or formulation between protocols
2. The "Transfer To" investigator does not have an active registration
3. The "Transfer To" investigator is not an eligible participant on the study
4. PMB-supplied agent is transferred to a non-DCTD-sponsored protocol
5. PMB-supplied agent is transferred for commercial use
6. Commercial agents are transferred to a DCTD-sponsored protocol
7. Borrowing from one protocol to supply another without an approved transfer
8. Transfer of partial containers
9. Transfer of patient-specific agents without prior PMB approval
10. Transfer requests to retrospectively correct errors in accountability

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To learn more, please refer to the “Pharmaceutical Management Branch Policy and Guidelines for Investigational Agent Transfers” available here on the PMB website.

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

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