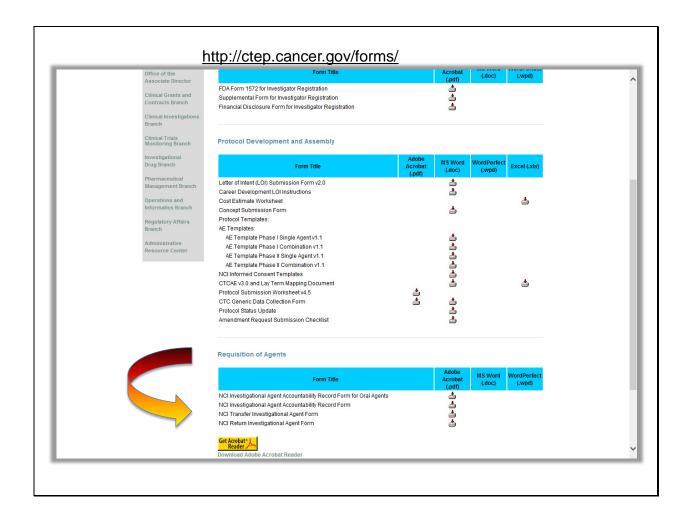


Welcome to this video tutorial on Agent Transfers in the PMB Investigational Drug Accountability series. This video will review when and how to perform an agent transfer of PMB-supplied agents for DCTD-sponsored trials.



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

This form is to be used for a	vestigational intra-institutional transfer, o	_	m		National Ca	Cancer Treatment a ncer Institute titutes of Health	and Diagnosis	
TRANSFER FROM:								
Investigator transferring age	ent:		CTEP Investigator ID:		Date of transfe	er:		
Dr. Name of institution:								
			-				T	
Street Address:			City:	City: State:			Zip Code:	
Reason for transfer requ TRANSFER TO:	est: Protocol clased/ca	mplete 🔲 Unused a	gent obtained for Special Exc	xeption ∐ Agentha	as short dati		on with PMB before approval)	
Investigator receiving agent Dr.			CTEP Investigator ID:					
The following CTEP-sup Received on	plied agent for NCI-approv Transferred to	ed protocol is being tra	insferred to NCI-approved pro	otocol:			Manufacturer and	
NCI Protocol Number	NCI Protocol Number	NSC Number	Agent Name	Strength and Fe	ormulation	Quantity	Lot Number	
Authorized Signature (investigator or Designee			Return form to Pharmaceutic NCI Shady Gr Room 5W228 9609 Medical Bethesda, Mi	cal Managem rove 8, MSC 9725 Center Drive		P, DCTD	
Telephone Number	F	ax Number		PMBAfterhours@mail.nih.gov				
				FAX: 240-	-276-7893			
Email Address								

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.

	vestigational an intra-institutional transfer, o	_	orm			Division of National C	nerapy Evaluation Prof Cancer Treatment a Cancer Institute Institutes of Health		
TRANSFER FROM:									
estigator transferring age	ant:			CTEP Investigator ID:		Date of trans	ifer:		
Dr. Name of institution:									
						T		T	
Street Address:				City:		State:		Zip Code:	
Reason for transfer requirements TRANSFER TO:	uest: Protocol closed/co	mplete Unus	ed agent obt	ntained for Special Exc	æption 🗌 Agent	has short dat		on with PMB before approval	
estigator receiving agent	t:			CTEP Investigator ID:					
Dr.									
The following CTEP-sup	oplied agent for NCI-approv	ed protocol is beir	ng transferre	d to NCI-approved pr	otocol:				
Received on NCI Protocol Number	Transferred to NCI Protocol Number	NSC Number		Agent Name	Strength and	Formulation	Quantity	Manufacturer and Lot Number	
<u> </u>									
Authorized Signature (Investigator or Designee) Printed Name					Return form to: Pharmaceutical Management Branch, CTEP, DCTD NCI Shady Grove Room 5W228, MSC 9725 9609 Medical Center Drive Bethesda, MD 20892-9725				
Telephone Number	F	ax Number			<u>PMBAfter</u>	rhours@ma	ail.nih.gov		
					FAX: 24	0-276-789	76-7893		
Email Address		vanagement htm fr	or further info	ormation.					
See http://ctep.cancer.co	ov/branches/pmb/agent_m	anagement num	or raidior iiii						

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.

Transfer Investigational Agent Form		Cancer Therapy Evaluation Pr Division of Cancer Treatment National Cancer Institute	
This form is to be used for an intra-institutional transfer, one transfer/form.		National Institutes of Health	
TRANSFER FROM: Investigator transferring agent:	CTEP Investigator ID:	Date of transfer:	
Dr.			
Name of institution:			
Street Address:	City:	State:	Zip Code:
Reason for transfer request: Protocol closed/complete Unused agent o	btained for Special Exception Agent	has short dating Other*	*
		(ttDawwissawashalalasifaat	ion 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.

Transfer Investigational Agent Form This form is to be used for an intra-institutional transfer, one transfer/form.		Cancer Therapy Evaluation Pr Division of Cancer Treatment National Cancer Institute National Institutes of Health	
TRANSFER FROM: Investigator transferring agent:	CTEP Investigator ID:	Date of transfer:	
Dr.			
Name of institution:			
Street Address:	City:	State:	Zip Code:
Reason for transfer request: Protocol closed/complete Unused agent of	otained for Special Exception Agent	has short dating Other*	•
		(**Requires verbal clarificati	on 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.

Agent Transfer Form: Middle Section Containing Transfer To Investigator and Agent Information TRANSFER TO: Investigator receiving agent: CTEP Investigator ID: Dr. The following CTEP-supplied agent for NCI-approved protocol is being transferred to NCI-approved protocol: Received on Transferred to Manufacturer and NCI Protocol Number NCI Protocol Number NSC Number Agent Name Strength and Formulation Quantity Lot 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.

Agent Transfer Form: Bottom Section Containing Signature and Instructions for Submission to PMB Return form to: Authorized Signature (Investigator or Designee) Pharmaceutical Management Branch, CTEP, DCTD NCI Shady Grove Room 5W228, MSC 9725 Printed Name 9609 Medical Center Drive Bethesda, MD 20892-9725 Telephone Number Fax Number PMBAfterhours@mail.nih.gov FAX: 240-276-7893 Email Address See http://ctep.cancer.gov/branches/pmb/agent management.htm 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.

Authorized Signature (Investigato	r or Designee)	Return form to: Pharmaceutical Management Branch, CTEP, DCTD NCI Shady Grove Room 5W228, MSC 9725
Printed Name		9609 Medical Center Drive Bethesda, MD 20892-9725
Telephone Number	Fax Number	PMBAfterhours@mail.nih.gov
Email Address		FAX: 240-276-7893
See http://ctep.cancer.gov/branches	/omb/agent_management.htm for further information.	
	Vomb/agent management.htm for further 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.

	vestigational an intra-institutional transfer, o		orm			Division of National Co	erapy Evaluation Prog Cancer Treatment an ancer Institute stitutes of Health		
TRANSFER FROM:									
Investigator transferring ag	ent:			CTEP Investigator ID: Date of transfer:					
Dr. John Smith				999999		9/30/201	4		
Name of institution: State University H	lospital								
Street Address: 10 Mair				City:		State:		Zip Code:	
011001710010001				Nowhere		USA		54321	
Reason for transfer red	uest: Protocol closed/co	mplete Unus	ed agent obt	tained for Special Exc	eption Agent	has short dat	ing Other**_		
reason for transfer req								with PMB before approve	
TRANSFER TO:						(require	o verbai ciarmoanoi	Tillian in Decision approximation	
Investigator receiving ager	nt:			CTEP Investigator ID:					
Dr. John Smith					999999				
	plied agent for NCI-approve	d protocol is being	g transferred	to NCI-approved pro	ocol:				
Received on	Transferred to						0	Manufacturer and Lot Number	
NCI Protocol Number	NCI Protocol Number	NSC Number		Agent Name	Strength and		Quantity	GLX 09735555	
1234	2341	737754	pazopanit	0	200mg tabi	200mg tablets		GLX 09733333	
1. ~/	1				Return form	ı to:			
1 41	(Investigator or Designee)			Pharmaceu	tical Manager	ment Branch, CTEF	P, DCTD	
Authorized Signature						NCI Shady Grove Room 5W228, MSC 9725			
Authorized Signature						al Center Driv			
1/						MD 20892-97	25		
ZA Printed Name 123-456-7890		23-456-7899			Bethesda,	MD 20892-97			
ZA Printed Name 123-456-7890 Telephone Number		23-456-7899 ax Number			Bethesda,				
ZA Printed Name 123-456-7890 Telephone Number za@nowhere.edu			_		Bethesda,	MD 20892-97	ail.nih.gov		
ZA Printed Name 123-456-7890 Telephone Number			-		Bethesda,	MD 20892-97	ail.nih.gov		
ZA Printed Name 123-456-7890 Telephone Number za@nowhere.edu Email Address		ax Number	- or further info	ormation.	Bethesda,	MD 20892-97	ail.nih.gov		

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.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health National Cancer Institute Cancer Therapy Evaluation Progr Bethesda, Maryland 20892

Date: September 30, 2014

To: Dr. John Smith, c/o ZA

Fax: (123) 456-7899

From: FS, 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 PMB action date: 09/30/2014 From Investigator: Smith, John To Investigator: Smith, John Investigator ID: 999999 Investigator ID: 999999

Institution: State University Hospital Institution: State University Hospital

Protocol: 1234

Agent Name:	NSC:	Lot Number:	Quantity:	Strength/Unit/Form:
Pazopanib 200 mg tablets	737754	09735555	10 bottles (34 tabs/bottle)_	200/mg/tablet

Protocol: 2341

Protocol 1234 is closed at the site.

Please retain a copy of this form with your accountability records. If you have any questions or comments, please call (240) 276-6575 or contact us via e-mail at PMBafterhours@mail.nih.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.

Investigational Agent Accountability Record Oral agents ONLY						National Cancer Institute Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program					PAGE NO. 1 CONTROL RECORD ☑ SATELLITE RECORD □			
	of Institution: te Univers	ity Hosp	ital				gator Name: n Smith, M.I	D.				стер 999		
	ol Title: 2 trial of pazopa	nib for the trea	tment of patients with	advanced renal cell ca	rcinoma.	NCI Protocol No: Local Protocol No: SUH-001				Dispensing Area: IDS Pharmacy - 5th Floo				
	Name: copanib hy	drochlori	de (NSC 73	7754)			orm and Strength: mg Tablets	·			e.g., #tablets olets/bot			
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantit Dispense Receive	d or	Balance Forward Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantit Patient Returne		
1.	3/21/2014	Receive	d 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		
3.	4/24/2014	AZ	1234-001	800 mg daily	- 4		0	GLX 12345678	AB		5/24/2014	1 bottle		
4.	4/29/2014	Received	from the NCI		+ 24		24	GLX 87654321	ZA					
5.	5/16/2014	вт	1234-002	800 mg daily	- 4		20	GLX 87654321	AB		6/16/2014	24 tabs		
6.	5/24/2014	AZ	1234-001	400 mg daily	- 2		18	GLX 87654321	ZA					
7.	6/16/2014	вт	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		
9.	6/24/2014	AZ	1234-001	Patient return fro	m disper	sing or	n 4/24/2014, pa	ge 1, line 3	JT		6 <i>1</i> 24/2014	1 bottle		
10.	6/30/2014	Sent to M	edical Office Bui	ding A Satellite	- 12		2	GLX 87654321	ZA					
11.	7/11/2014	Received	from the NCI		+ 20		22	GLX 09735555	ı					
12.	7/23/2014	BT	1234-002	800 mg daily	- 2		20	GLX 87654321	AB		8/24/2014	4 tabs		
13.	7/23/2014	BT	1234-002	800 mg daily	- 2		18	GLX 09735555	AB		8/24/2014	1 Btl + 4		
14.	8/1/2014	Returned	from Med. Off. B	uild. A Satellite	+ 4		22	GLX 87654321	JT					
15	8/2/2014	Return to	the NCI Clinical F	epository	- 4		18	GLX 87654321	AB	8/31/2014				
16.	9/30/2014	Transfer t	o NCI Protocol 2	341 (T14273-000	1) - 10		8	GLX 09735555	ZA					
17.	11/4/2014	Local Des	truction per PME	Authorization	- 8	\neg	0	GLX 09735555	ZA					

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.

Transfer To: Protocol 2341 PAGE NO. Investigational Agent Accountability Record National Cancer Institute CONTROL RECORD Division of Cancer Treatment and Diagnosis Oral agents ONLY Cancer Therapy Evaluation Program SATELLITE RECORD □ Name of Institution: Investigator Name CTEP Investigator State University Hospital John Smith, M.D. 999999 NCI Protocol No: Local Protocol No: Dispensing Area: Phase 1 trial of pazopanib for the treatment of patients with advanced tumors 2341 SUH-002 IDS Pharmacy - 5th Floor Room A Dose Form and Strength: Pazopanib hydrochloride (NSC 737754) 200 mg Tablets 34 Tablets/bottle Line Balance Forward Expiration Date (if available) Quantity Manufacturer Recorder's Date Quantity Patient Record-Initial Dispensed or Received Patient's ID No. and Lot No. 6/23/2014 Received from the NCI + 12 12 GLX 12345678 6/24/2014 2341-001 8 GLX 12345678 8/27/2014 2341-002 400 mg daily GLX 8765432 9/30/2014 Transfer from NCI Protoco 1234 (T14273-0001) + 10 16 GLX 09735555

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.



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

Examples of Non-Valid Transfer Requests

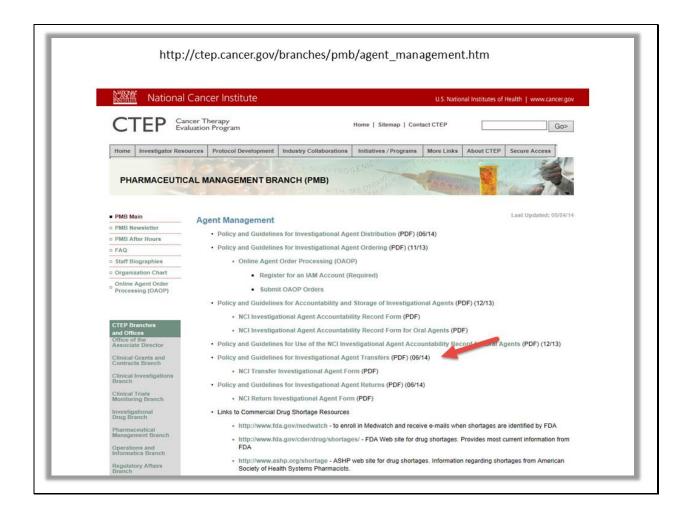
- 1. Agent being transferred is not the same strength or formulation between protocols
- 2. The "Transfer To" investigator does not have an active registration
- 3. The "Transfer To" investigator is not an eligible participant on the study
- 4. PMB-supplied agent is transferred to a non-DCTD-sponsored 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:

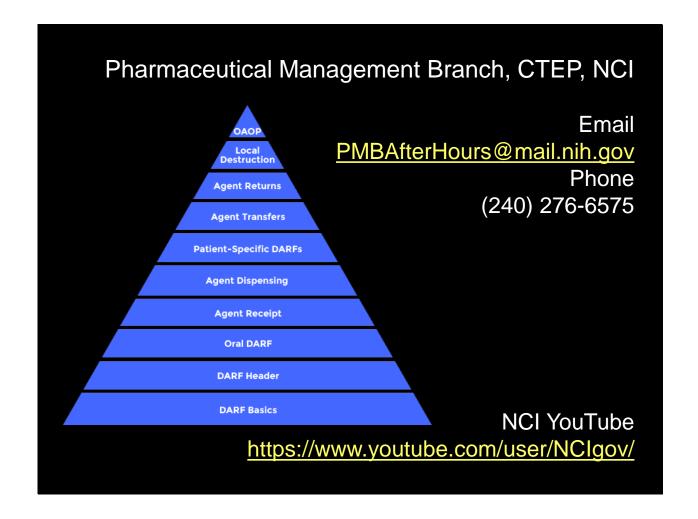
- 1. Agent being transferred is not the same strength or formulation between protocols
- 2. The "Transfer To" investigator does not have an active registration
- 3. The "Transfer To" investigator is not an eligible participant on the study
- 4. PMB-supplied agent is transferred to a non-DCTD-sponsored 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

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 restriction
- 3. The "Transfer To" investigator is not are the participant on the study
- 4. PMB-supplied agent is transfer to a M-ECTD-sponsored protocol
- 5. PMB-supplied age of the for commercial use
- 6. Commercia agents in transferred to a DCTD-sponsored protocol
- 7. Borrov 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



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



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.

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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