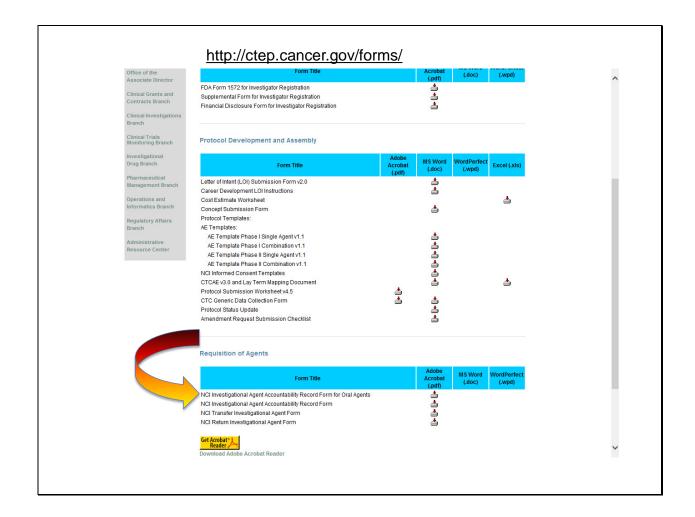


Welcome to this video tutorial on the Oral DARF in the PMB Investigational Drug Accountability series.

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



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

Departm	ment of Health and Hu	luman Services. Su	by. The information may be dubmission of this information	is voluntary, however, in or	order for you to co	conduct a stud	udy in accordance with releva	vant, current protocols, y	you must complete all	Il feids.		Ex	MB No. 0925-061 xpires: 03/31/201
Public re informati collectio	porting burden for the sion. An agency may an of information, incl.	is collection of into y not conduct or si luding suggestions	ormation is estimated to avera sponsor, and a person is no for reducing this burden, to: I	age 4 minutes per respons- at required to respond to, NH, Project Clearance Bo	e, including the to , a collection of anch, 6705 Rock	ime for revie information ledge Drive	awing instructions, searching in unless it displays a curr it, MSC 7974, Bethesda, MD	ig existing data sources, rently valid OMB contr) 20892-7974, ATTN: Pf	gathering and main of number. Send or RA (0925-0613). Do	taining the data ne imments regarding not return the com-	eded, and comple this burden estim- pleted form to this	ting and reviewing rate or any other a raddress.	, the collection of spect of this
							National Institut National Cance	utes of Health		PAGE NO			
liive	esugano	nai Age	ent Account Oral agents O	ADIIII Keo	oru		Division of Can	ncer Treatment an		CONTRO	L RECORE	D 🗖	
			Olai agoino <u>o</u>	142.			Cancer Therap	by Evaluation Prog	ram	SATELLIT	TE RECOR	₹D □	
Name	e of Institution:					Investiç	igator Name:					CTEP Inv	vestigator ID:
Protoc	col Title:					NCI Pre	rotocol No:	Local Protocol	No:	Dispensing /	Area:		
Agent	t Name:					Dose F	Form and Strength:			Bottle size (e.g., # tablets/	/bottle):	
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantit Dispense Receive	ed or	Balance Forward Balance	Manufacturer and Lct No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
4					11022					WYSHIELD,	Notamos	riotamos	
2													
2													
4													
5.													
6.													
7.													
8.													
9.													
10.													
11.													
12.													
13.													
14.													
15.													
16.													
17.		7	7								,		

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

D-i-4 =		Cause *		4.5					
as an IND's investigation Services Si Public recor	of this information is sponsor and that in mal purposes, spor lubmission of this in etino burden for this	restigational agents sens of dimical trials formation is volunts s collection of inform	21 CFR 312 57. The information of the control and a sind their company collaborary however, in order for you nation is estimated to premit a single control of the control	accounted for by competer cretars, the applicable institute conduct a study in accessor 4 minutes per response	nt authority. The in studional Review Bu cordance with refev e, including the time	formation may be disclor sand, NCL FDA, and the C rant, current protocols, ye e for reviewing instruction	ed to researchers for Department of Health ar o must complete all fet as searching misting o	nd Human ids. ata sources.	OMB No. 0925-0813 Expires 08/31/2016 NRI-2564 codering and maintaining
the data no displays a	eded, and completi currently valid Oh	ng and reviewing the	ne collection of information r. Send comments regardir , MSC 7974, Bethesda, ME	An agency may not con to this burden estimate or a	duct or sponsor, any other aspect of	and a person is not requesting collection of into mu	uired to respond to, a tion, including suggesti	collection o ons for rodu	of information unless it sing this burden, to: NIH,
Nationa	al Institutes of all Cancer Institutes	ute	untability Reco	Cancer Thera	noer Treatme py Evaluation	nt and Diagnosis Program	PAGE NO. CONTROL		
	of Institution:	•				NCI Protocol No.:	SATELLITE	RECO	RD 🔲
Agent N	Name:					Dose Form and S	Rrength:		
Protoco	ol Title:					Dispensing Area:			
Investig	gator Name:					CTEP Investigato	r ID:		
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity	or	and L	acturer of No.	Recorder's Initials
1.					Received	d Balance	e		
2.									
3.	1						_		
_4	+	-			-	+-	_		_
6.						+-			_
7.						-			
8.									
9.									
10.	-	-			-	+-	_		
11.					_	+	_		_
13.									
14.									
15.									
16.						\perp			
17.		_			-				
18.	_	_			_	+	_		_
19.						+			
21.									

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

	Institutes of F Cancer Institu			Division of Ca Cancer Thera	ncer Treatm py Evaluation	ent and Diagnosis n Program	PAGE N	NO. NOL RECOF	n П				
Investi	igational A	gent Acco	untability Reco	rd				LITE RECO					
Name of	Institution:					NCI Protocol No.:							
Agent No	ame:					Dose Form and S	trength:			-			
Protocol	Title:					Dispensing Area:							
Investiga	ator Name;					CTEP Investigato	r ID:			-			
										-			
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quanti Dispense Receiv	d or	a	lanufacturer and Lot No.	Recorder's Initials				
										.			
1.	An agency may i	not conduct or sp	consor, and a person is no or reducing this burden, to 1	c required to respond to	a collection or i				number, swita to)ral	DAE)E
		nal Age	onsor, and a person is no reducing this burden, to 1 ont Account Oral agents O	ability Rec		Nationa Nationa Divisio	i Institutes of a Cancer Inst n of Cancer T	of Health	Diagnosis			DAF Jmn:	
Inve		nal Age	nt Account	ability Rec		Nationa Nationa Divisio	i Institutes of a Cancer Inst n of Cancer T	of Health stitute Treatment and	Diagnosis				
Inve	stigatio	nal Age	nt Account	ability Rec		Nations Nations Divisio Cancer	i Institutes of al Cancer Inst n of Cancer T Therapy Eva	of Health stitute Treatment and	Diagnosis		Colu		
Inves	stigation Institution:	nal Age	nt Account	ability Rec		Nation Nation Divisio Cancer Investigator Name:	al Institutes of al Cancer Inst n of Cancer T Therapy Eva	of Health stitute Treatment and raluation Progr	Diagnosis		Colu		
Name of Protocol	stigation Institution:	nal Age	nt Account	ability Rec		Nation Divisio Cancer Investigator Name: NCI Protocol No: Dose Form and Str	al Institutes of all Cancer Institutes of all Cancer Institute of Cancer Therapy Evaluation of Cancer T	of Health stitute Treatment and raluation Progr	Diagnosis	Dispensing	Colu		Record
Name of Protocol Agent Na Line No.	Institution: Title:	Patient's	nt Account Oral agents <u>O</u>	ability Rec	Ouantit Dispense:	Nation Divisio Cancer Investigator Name: NCI Protocol No: Dose Form and Str	al Institutes of all Cancer Institutes of all Cancer Institute of Cancer Therapy Evaluation of Cancer T	of Health stitute Treatment and aluation Progr	Diagnosis am	Dispensing Bottle size (Expiration Date (if	Area:	Quantity	Record
Name of Protocol Agent Na	Institution: Title:	Patient's	nt Account Oral agents <u>O</u>	ability Rec	Ouantit Dispense:	Nation Divisio Cancer Investigator Name: NCI Protocol No: Dose Form and Str	al Institutes of all Cancer Institutes of all Cancer Institute of Cancer Therapy Evaluation of Cancer T	of Health stitute Treatment and aluation Progr	Diagnosis am	Dispensing Bottle size (Expiration Date (if	Area:	Quantity	

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

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

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

			sponsor, and a person is no for reducing this burden, to it			Fintermasion un éledge Drive, MS	National Institut	ites of Health	N number, Sella to A (0925-0613) Do	not return the comp		address.	арма отига
Inve	stigatio	nal Age	ent Account Oral agents O	ability Rec	:ord		National Cance Division of Can	er Institute noer Treatment and	d Diagnosis	10.00). L RECORI	D D	
			Orai agents O	INLT				by Evaluation Prog			TE RECOR		
Name o	of Institution:					Investigato	r Name:					CTEP Inv	vestigator l
Protoco	i Title:					NCI Protoc	ol No:	Local Protocol	No:	Dispensing /	Area:		
Agent h	lame:					Dose Form	n and Strength:			Bottle size (e.g., #tablets	/bottle):	
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quanti Dispense Receiv	ed or	lance Forward Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorde Initial:
1.													
2.		 -'			 	+	\longrightarrow						
3.			\vdash		+	+	\longrightarrow				\vdash		₩
4.			\vdash		+-	+	\longrightarrow				\vdash	—	-
5.		₩	\vdash		+	\pm	\rightarrow						

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

			sponsor, and a person is not for reducing this burden, to his ent Accounta			Information un (edge Drive, MS)	National Institutional Cand	tutes of Health		PAGE NO			speciolis
			Oral agents <u>o</u>	INLT		I		py Evaluation Prog	iram	1	TE RECOR	RD 🗆	
Name	of Institution:					Investigato	or Name:					CTEP Inv	vestigator l
Protoco	d Title:					NCI Protoc	col No:	Local Protocol	No:	Dispensing A	Area:		
Agent 1	Vame:					Dose Form	m and Strength:			Bottle size (e	e.g., #tablets.	/bottle):	
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quanti Dispense Receive	ed or	lance Forward Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Record Initial
1.		-			_	+			1				├
3.						士							
4.					\vdash	\perp							
5.		\pm				土							

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

mormatic	ori. An agency may n of information, incl	y not conduct or r luding suggestions	sponsor, and a person is not ifor reducing this burden, to: N	t required to respond st slH, Project Clearance B	o, a collection of ranch, 8705 Rock	information un deóge Drive, MS	ess in displays a cur C 7974, Bethesda, M	mandy valid UNE cond © 20892-7974, ATTN: Pr	of number, Sells of 6A (0925-0813). Do	not return the com	pers burden esome pleted form to this:	ate or any other a address.	кред отига
Inve	estigatio	onal Age	ent Account	ability Rec	cord		National Cand			PAGE NO		_	
			ent Accounta Oral agents <u>O</u>	NLY				ancer Treatment and apy Evaluation Prog			L RECORE		
Name	of Institution:					Laurationt		,,		SATELLI	TE RECOR		- disaber
Name	of Institution.				,	Investigato	or Name:					CTEP Inv	estigator/
Protoco	ol Title:					NCI Protoc	col No:	Local Protocol	No:	Dispensing	Area:		
Agent I	Name:					Dose Form	n and Strength:			Bottle size ((e.g., #tablets/	bottle):	
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quanti Dispense Receive	ed or	lance Forward Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available	Date Patient Returned	Quantity Patient Returned	Record Initia
1.					$oxed{\Box}$	\perp				•			
2.		<u> </u>	\sqcup		 	+			 		\vdash		↓
3.		 	\longrightarrow		₩	+			 '		\vdash		₩
4.		+	++		+-	+			├ ──'		\vdash		\vdash
5.					\pm	土				<u> </u>			\vdash

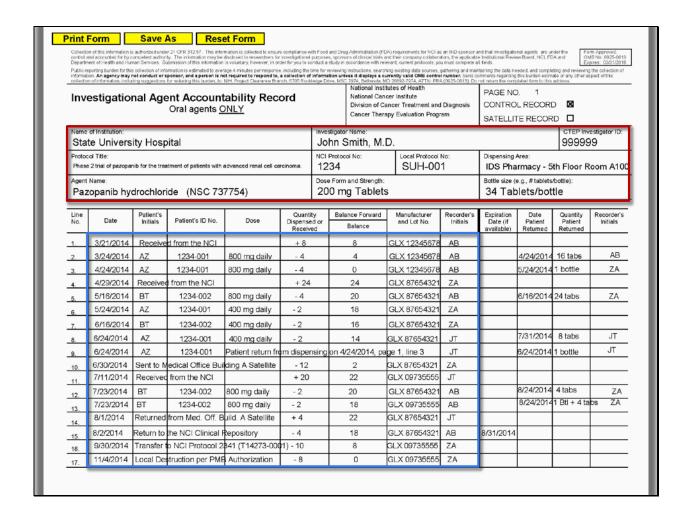
The next column is Date Patient Returned. Record the date received in the dispensing area, it may differ from the actual date received in the clinic.

Investigational Agent Accountability Record Oral agents ONLY														
National Cancer Institute PAGE NO. CONTROL RECORD SATELLITE R														
Name of Institution:	collection	at. An agency may of information, incl	not conduct or a	ponsor, and a person is no for reducing this burden, to 1	c required to respond to NIH, Project Clearance Br	o, a collection of ranch, 8705 Rock	informacion un deóge Crive, MS/	ess it displays a cu C 7974, Bethesda, M	mency valid UNE cond- D 20892-7974, ATTN: PR	or number, Selid to A (0925-0613). Do	not return the come	ers burgen yourn pleted form to this	age or any other a address.	rspect orders
Name of Institution: Investigator Name: NCI Protocol No:	Inve	stigatio	onal Age	ent Account	ability Rec	cord					10.00			
Name of Institution: Investigator Name: NCI Protocol No:				Oral agents O	NLY									
Protocol Title: NCI Protocol No: Local Protocol No: Dispensing Area:							I		py Evaluation	TETT.	SATELLIT	TE RECOR	_	
Agent Name: Dose Form and Strength: Bottle size (e.g., # tablets/bottle):	Name	of Institution:					Investigato	r Name:					CTEP Inv	vestigator I
Line No. Date Patient's ID No. Dose Dispensed or Received Balance Forward Balance and Lot No. Balance Recorder's Initials Returned Patient Returned Recurrence and Lot No. Balance Recorder's Recorder's Recurrence and Lot No. Balance Recorder's Recurrence and Lot No. Balance Returned Returned Returned Returned Returned Returned Returned Returned Returned Recorder Recorder's	Protoco	ol Title:					NCI Protoc	ol No:	Local Protocol	No:	Dispensing A	Area:		
No. Date Initials Patient's ID No. Dose Dispensed or Received Balance and Lot No. Initials Date (if available) Patient Returned 1. 2 3. 3.	Agent I	Name:					Dose Form	n and Strength:			Bottle size (e	e.g., #tablets	/bottle):	
No. Date Initials Patient's ID No. Dose Dispensed or Received Balance and Lot No. Initials Date (if available) Patient Returned 1. 2 3. 3.	1000		Devicers	$\overline{}$				5	Managhatana	Donas de de	Finintial	Dut.	Owner	Tour
2 3		Date		Patient's ID No.	Dose	Dispense	ed or				Date (if	Patient	Patient	Initial
3.	1.					+-	+			-		_		_
3. 4. 5.	2.			\vdash		+-	-							\vdash
5	3.		_			+-	-							\vdash
	4.		-			+-	-							+-
	3.		=				<u> </u>							

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

Collectio	on of this information is	authorized unde	or 21 CFR 312.57. This infor	mation is collected to ensur	re compliance w	th Food and I	Orug Administration (FD	A) requirements for NCI at	an IND spensor a	and that investigation	nal agents are u	nder the For	m Approved: 18 No. 0925-08
Departm	nent of Health and Hun	nan Services. Si	ubmission of this information ormation is estimated to ever	is voluntary, however, in or	der for you to co	indust a study	in accordance with rele	evant, current protocols, yo	u must complete a	I felds.		Ex	pires: 03/31/20
informat	ion. An agency may r	not conduct or s	ponsor, and a person is n for reducing this burden, to:	at required to respond to.	a collection of	information	unless it displays a cu ASC 7974, Bethesda, M	mently valid OMB control D 20892-7974, ATTN: PR	I number. Send o	mments regarding	this burden estim	nate or any other as	pect of this
Inv	estinatio	nal Age	ent Account	ability Rec	ord		National Instit	tutes of Health cer Institute		PAGE NO). 1		
	conguno	iai Age	Oral agents C		oiu			ancer Treatment and		CONTRO	L RECOR	D 🛛	
							Cancer Thera	apy Evaluation Progr	am	SATELLIT	E RECOR	RD 🗖	
	of Institution:						ator Name:						estigator ID:
Sta	te Univers	ity Hosp	oital			John	Smith, M.I					99999	9
	ol Title:	ib for the trees	tment of patients with			NCI Prot		SUH-00		Dispensing /		45 Floor D	046
		nib for the trea	timent of patients with	advanced renai celi ca	rcinoma.	1234		SUN-00	1			th Floor R	oom ATC
-	Name:	drochlor	ide (NSC 73	7754)			rm and Strength: mg Tablets				e.g., # tablets lets/bot		
1 42	opariio riy	arocinor	de (110075	7734)		2001	ing rabics			04 Tab	1013/001	ille	
Line	Date	Patient's	Patient's ID No.	Dose	Quanti		alance Forward	Manufacturer	Recorder's	Expiration	Date	Quantity	Recorder's
No.	Date	Initials	Patient's ID No.	Dose	Dispense Receiv		Balance	and Lot No.	Initials	Date (if available)	Patient Returned	Patient Returned	Initials
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	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 fro	m disper	nsing on	4/24/2014, pa	ge 1, line 3	JT		6/24/2014	1 bottle	JT
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	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	вт	1234-002	800 mg daily	- 2		18	GLX 09735555	AB		8/24/2014	1 Btl + 4 ta	bs ZA
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	841 (T14273-000	1) - 10		8	GLX 09735555	ZA				
17.	11/4/2014	Local Des	truction per PME	Authorization	- 8		0	GLX 09735555	ZA				

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



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

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

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

Public r informa	ment of Health and Hur reporting burden for this tion. An agency may r	man Services. Si s collection of info not conduct or s	ty. The information may be ubmission of this information emation is estimated to ever ponsor, and a person is no for reducing this burden, to:	is voluntary, however, in or rage 4 minutes per response at required to respond to,	der for you to co including the t a collection of	induct a study ime for review information u	in accordance with reli ng instructions, search niess it displays a cu	evant, current protocols, you ning existing data sources, urrently valid OMB contro	u must complete a gathering and main I number. Send o	I fields. Itaining the data ne Imments regarding	eded, and comple this burden estin	eting and reviewing rate or any other as	#B No. 0925-06 pires: C3/31/20 the collection of spect of this
Ima			A	ability Dag			National Insti National Can	tutes of Health		PAGE NO). 1		
inv	esugatio	nai Age	ent Account Oral agents C		ora			ancer Treatment and	Diagnosis	CONTRO	L RECOR	D 🛛	
			Oral agents C	ZINLT			Cancer There	apy Evaluation Progr	am	SATELLIT	E RECOR	RD 🗖	
Name	of Institution:					Investigat	or Name:					CTEP Inv	estigator ID:
Sta	te Univers	ity Hosp	ital			John	Smith, M.	D.				99999	9
	col Title:					NCI Proto	ocol No:	Local Protocol		Dispensing			
Phas	e 2 trial of pazopar	nib for the trea	itment of patients with	advanced renal cell ca	rcinoma.	1234		SUH-00	1			th Floor R	oom A10
-	Name:	des elek	/NO. 70	775.4			m and Strength:				e.g., # tablets		
Pa	zopanib ny	arocnior	ide (NSC 73	7754)		200 F	ng Tablets	5		34 Tab	lets/bot	tie	
Line		Patient's		_	Quantil		lance Forward	Manufacturer	Recorder's	Expiration	Date	Quantity	Recorder's
No.	Date	Initials	Patient's ID No.	Dose	Dispense Receive		Balance	and Lot No.	Initials	Date (if available)	Patient Returned	Patient Returned	Initials
1.	3/21/2014	Receive	d from the NCI					CLV 12245670	ĄĐ				
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 fro	m disper	nsing on	4/24/2014, pa	ge 1, line 3	JT		6/24/2014	1 bottle	JT
10.	6/30/2014	Sent to M	edical Office Buil	ding 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	вт	1234-002	800 mg daily	- 2		18	GLX 09735555	AB		8/24/2014	1 Btl + 4 ta	bs ZA
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		o NCI Protocol 2		1) - 10		8	GLX 09735555	ZA				
17.	11/4/2014		truction per PME		- 8	_	0	GLX 09735555	7A				

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

Public re	norting burden for this	collection of info	brission of this information rmation is estimated to even ponsor, and a person is no for reducing this burden, to	ane 4 minutes per response	including the t	ime for reviewin	ig instructions, search fless it displays a cu IC 7974, Bethesda, M	ing existing data sources.	gathering and mais	teining the date of	eeded, and comple this burden estim pleted form to this	eting and reviewing	pires: 03/31/201 the collection of spect of this
Inv	estinatio	nal Age	ent Account	ability Reco	ord		National Cand			PAGE NO). 1		
	conguno		Oral agents C		J. G			incer Treatment and		CONTRO	L RECOR	D 🛮	
							Cancer Thera	py Evaluation Prog	am	SATELLI	TE RECOR	RD 🗖	
	of Institution:					Investigat							estigator ID:
Sta	te Univers	ity Hosp	ital			John	Smith, M.I	D				99999	9
	ol Title: 2 trial of pazopar	nib for the trea	itment of patients with a	advanced renal cell ca	rcinoma.	NCI Proto 1234	col No:	SUH-00		Dispensing IDS Pha		oth Floor R	oom A10
Agent							n and Strength:			Bottle size (e.g., # tablets	/bottle):	
Paz	opanib hyd	drochlori	de (NSC 73	7754)		200 n	ng Tablets	3		34 Tab	olets/bot	ttle	
					-								
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantit Dispense Receive	d or	lance 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	Receive	d from the NCI		+ 8	\perp	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	$\neg \vdash$	16	GLX 87654321	ZA				
8.	6/24/2014	AZ	1234-001	400 mg daily	- 2			GLX 87654321	JT		7/31/2014	8 tabs	JT
9.	6/24/2014	AZ		Patient return fro		sing on 4			JT		6/24/2014	1 bottle	JT
-	6/30/2014		edical Office Buil		- 12	90.1		GLX 87654321	ZA		5.2 52514	Journe	
10.	7/11/2014		from the NCI	g , , outsine	+ 20			GLX 09735555	JT .				
11.	7/23/2014	BT		800 mg daily	- 2		20	GLX 87654321	AB		8/24/2014	4 tabs	ZA
12.	7/23/2014	BT	1234-002	800 mg daily	- 2			GLX 09735555	AB		8/24/2014	1 Btl + 4 ta	
13.			from Med. Off. B	0 ,	+ 4			GLX 87654321	JT	-			
14.	8/2/2014		the NCI Clinical F		- 4		18	GLX 87654321	AB	8/31/2014			
15.	9/30/2014		o NCI Protocol 2	,		+		GLX 09735555	ZA	5.5 1120 14			
16.	11/4/2014		truction per PME	, , , , , , , , , , , , , , , , , , , ,	- 8	-		GLX 09735555	ZA				

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

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

Public re	eporting burden for this	collection of into	brission of this information rmation is estimated to even ponsor, and a person is no for reducing this burden, to:	age 4 minutes per response	e, including the ti	me for reviewi	ng instructions, search nless it displays a cu SC 7974, Bethesda, M	ing existing data sources, rrently valid OMB contro D 20892-7974, ATTN: PR	gathering and mair	taining the data ne	this burden estim	eting and reviewing	pires: 03/31/201 the collection of pact of this
Inve	estigation	nal Age	ent Account	ability Rece	ord		National Cand	utes of Health cer Institute		PAGE NO). 1		
	conguno		Oral agents C		0.4			ncer Treatment and		CONTRO	L RECOR	D 🛛	
							Cancer Thera	py Evaluation Prog	am	SATELLI	TE RECOR	RD 🗖	
	of Institution:					Investigat		_					estigator ID:
Sta	te Univers	ity Hosp	ital			John	Smith, M.I	D				99999	9
	col Title: e 2 trial of pazopar	nib for the trea	tment of patients with a	advanced renal cell ca	rcinoma.	NCI Proto	col No:	SUH-00		Dispensing IDS Pha		ith Floor R	oom A10
	Name:						m and Strength:	_			e.g., # tablets		
Paz	zopanib hyd	drochlori	de (NSC 73	7754)		200 n	ng Tablets	3		34 Tab	olets/bot	tle	
Line		Patient's			0	Do	lance Forward	Manufacturer	Recorder's	Expiration	Data	Ourantite.	Recorder's
No.	Date	Initials	Patient's ID No.	Dose	Quantit Dispense Receive	d or	Balance	and Lot No.	Initials	Date (if available)	Date Patient Returned	Quantity Patient Returned	Initials
1.	3/21/2014	Receive	d from the NCI		+ 8	\perp	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			GLX 87654321	JT		7/31/2014	8 tabs	JT
9.	6/24/2014	AZ		Patient return fro		sing on 4			JT		6/24/2014	1 bottle	JT
10.	6/30/2014		edical Office Buil		- 12			GLX 87654321	ZA				
11.	7/11/2014		from the NCI		+ 20	\top		GLX 09735555	JT				
	7/23/2014	BT	1234-002	800 mg daily	- 2	\neg	20	GLX 87654321	AB		8/24/2014	4 tabs	ZA
12.	7/23/2014	BT	1234-002	800 mg daily	- 2	+		GLX 09735555	AB		8/24/2014	1 Btl + 4 ta	bs ZA
13.	8/1/2014	Returned	from Med. Off. B		+ 4			GLX 87654321	JT				
14.	8/2/2014		the NCI Clinical F		- 4		18	GLX 87654321	AB	8/31/2014			
15.	9/30/2014		o NCI Protocol 2			+		GLX 09735555	ZA	5.0 1120 14			
16.	11/4/2014		truction per PME	,	- 8	_		GLX 09735555	ZA				

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

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

Departro Public re informati	end accounted for by onent of Health and Hun eporting burden for this ion. An agency may n	ompetent authori nan Services. Su collection of info not conduct or s	or 21 CFR 312.57. This infor- ty. The information may be abmission of this information armation is estimated to ever ponsor, and a person is no	disclosed to researchers for is voluntary, however, in or age 4 minutes per response at required to respond to.	investigational der for you to co a including the t a collection of	purposes, sp induct a stud ime for review information	ponsors of clinical trials a dy in accordance with rele twing instructions, search a unless it displays a cu	nd their company collabors evant, current protocols, you sing existing data sources, arrently valid OMB contro	tors, the applicable u must complete a gathering and main I number. Send or	e Institutional Revie I fields. Itaining the data ne Imments regarding	w Board, NCI, FI eded, and compli this burden estin	OA and OM Exp eting and reviewing sate or any other as	m Approved: B No. 0925-06 ires: 03/31/20 the collection o pect of this
			ent Account Oral agents C	ability Rec		edge Drive, I	National Instit National Can Division of Ca	tutes of Health	l Diagnosis	PAGE NO CONTRO		D 🛛	
	of Institution: te Univers	ity Hosp	pital			-	nator Name: n Smith, M.I	D.				99999 99999	estigator ID: 9
	col Title: e 2 trial of pazopar	iib for the trea	atment of patients with a	advanced renal cell ca	rcinoma.	NCI Pro 1234	tocol No:	Local Protocol SUH-00		Dispensing IDS Pha		ith Floor R	oom A10
	Name: zopanib hyd	drochlori	ide (NSC 73	7754)			orm and Strength: mg Tablets	3			e.g., #tablets lets/bot		
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quanti Dispense Receive	d or	Balance Forward Balance	Manufacturer and Lct No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
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	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	7A				
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 fro	m disper	sing on	1 4/24/2014, pa	ge 1, line 3	JT		6/24/2014	1 bottle	JT
10.	6/30/2014	Sent to M	edical Office Buil	ding A Satellite	- 12		2	GLX 87654321	ZA				
11.	7/11/2014	Received	from the NCI		+ 20		22	GLX 09735555	1				
12.	7/23/2014	BT	1234-002	800 mg daily	- 2		20	GLX 87654321	AB		8/24/2014		ZA
13.	7/23/2014	BT	1234-002	800 mg daily	- 2		18	GLX 09735555	AB		8/24/2014	1 Btl + 4 ta	os ZA
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	Repository	- 4		18	GLX 87654321	AB	8/31/2014			
16.	9/30/2014	Transfer t	o NCI Protocol 2	841 (T14273-000	1) - 10		8	GLX 09735555	ZA				
17.	11/4/2014	Local Des	truction per PME	Authorization	- 8	\neg	0	GLX 09735555	ZA				

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

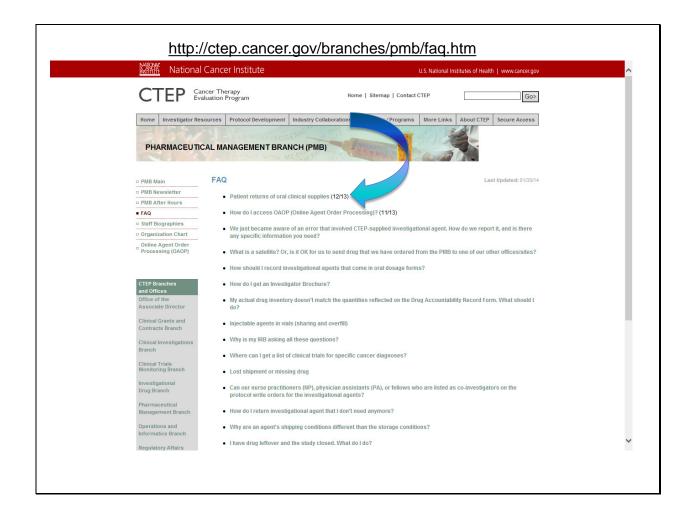
Collectio	on of this information is	authorized unde	or 21 CFR 312.57. This infor	mation is collected to ensur	e compliance w	th Food and D	Orug Administration (FD	A) requirements for NCI a	an IND sponsor a	and that investigation	nal agents are u	nderthe For	m Approved: 18 No. 0925-081		
Departm	ent of Health and Hun	nan Services. Si	ubmission of this information ormation is estimated to ever	is voluntary, however, in or	der for you to co	ndust a study	in accordance with rele	evant, current protocols, yo	u must complete a	I felds.		Exp	pires: 03/31/201		
informati	ion. An agency may r	not conduct or s	ponsor, and a person is n for reducing this burden, to:	at required to respond to.	a collection of	information u	unless it displays a cu	mently valid OMB contro	number. Send o	mments regarding	this burden estim	ate or any other as	pect of this		
Investigational Agent Accountability Record							National Institutes of Health National Cancer Institute				PAGE NO. 1				
IIIV	esugatio	iai Age	Oral agents C					CONTROL RECORD							
			Oral agents <u>e</u>	21421			Cancer Therapy Evaluation Program				SATELLITE RECORD				
Name	Name of Institution:							vestigator Name:				CTEP Investigator ID:			
State University Hospital							John Smith, M.D.				999999				
							ocol No:		Local Protocol No:		Dispensing Area:				
						1234				IDS Pharmacy - 5th Floor Room A10					
							Dose Form and Strength: 200 mg Tablets				Bottle size (e.g., # tablets/bottle): 34 Tablets/bottle				
Paz	opanio nyo	arocnior	ide (NSC/3	(1754)		2001	ng rabiets	•		34 Tab	nets/bot	.tie			
Line	Date	Patient's Initials	Patient's ID No.	Dose	Quanti		alance Forward	Manufacturer	Recorder's Initials	Expiration	Date	Quantity	Recorder's		
No.					Dispense Receive		Balance	and Lot No.		Date (if available)	Patient Returned	Patient Returned	Initials		
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		424201	16 tabe	AR		
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	Receive	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	Δ7	1234 004	400 mg daily	2		11	CLV 97654324	J.T.		7/31/2014	8 tabs	JT		
9.	6/24/2014	AZ	1234-001	Patient return fro	m disper	sing on	4/24/2014, pa	ge 1, line 3	JT		6/24/2014	1 bottle	JT		
10.	6/30/2014	Sent to N	edical Office Bui	ding A Satellite	- 12		2	GLX 87654321	ZA						
11.	7/11/2014	Received	from the NCI		+ 20		22	GLX 09735555	1						
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 ta	bs ZA		
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	Repository	- 4	\top	18	GLX 87654321	AB	8/31/2014					
16.	9/30/2014	Transfer	o NCI Protocol 2	841 (T14273-000	1) - 10	\top	8	GLX 09735555	ZA						
17.	11/4/2014	Local Des	truction per PME	Authorization	- 8		0	GLX 09735555	ZA						

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

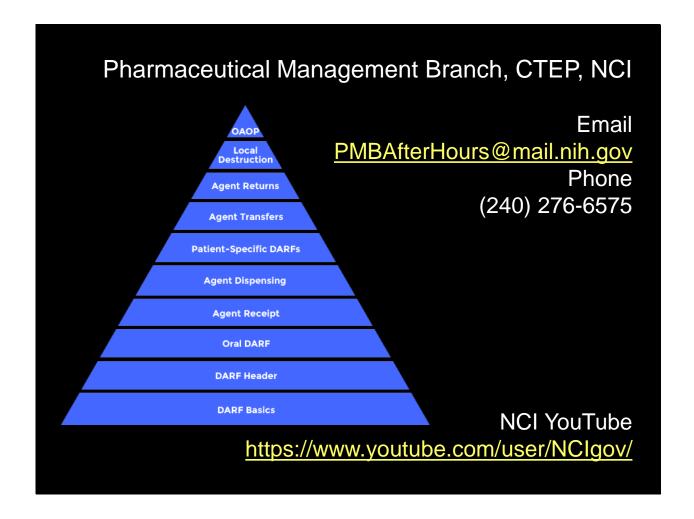
Publicing	morting burden for this	collection of info	bmission of this information rmation is estimated to even ponsor, and a person is no for reducing this burden, to	ace 4 minutes per response	including the tim	ne for reviewin	ng instructions, search niess it displays a cu IC 7974, Bethesda, M	ing existing data sources, irrently valid OMB control D 20892-7974, ATTN: PR	gathering and main	taining the data ne	eded, and comple this burden estimated form to this	eting and reviewing	pires: 03/31/201 the collection of spect of this		
							National Institutes of Health				PAGE NO. 1				
Investigational Agent Accountability Record Oral agents ONLY							National Cancer Institute Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program				CONTROL RECORD SATELLITE RECORD				
							ohn 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.							SUH-001			IDS Pharmacy - 5th Floor Room A10					
The state of the s							n and Strength:	Bottle size (e.g., # tablets/bottle):							
Paz	opanib hyd	drochlori	de (NSC 73	7754)		200 n	ng Tablets	3		34 Tab	lets/bot	tle			
Line		Patient's			Quantity	/ Bai	lance Forward	Manufacturer	Recorder's	Expiration	Date	Quantity	Recorder's		
No.	Date	Initials	Patient's ID No.	Dose	Dispensed	or Delever	and Lot No.	Initials	Date (if available)	Patient Returned	Patient Returned	Initials			
1	3/21/2014	Receive	d from the NCI		+ 8	_	8	GLX 12345678	AB	available)	Retuined	Recuired			
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	\top	0	GLX 12345678	AB		5/24/2014		ZA		
4.	4/29/2014		from the NCI	ooo mg dany	+ 24	\top	24	GLX 87654321	ZA		0/2-4/201-				
5.	5/16/2014	BT	1234-002	800 mg daily	- 4	\top	20	GLX 87654321	AB		6/16/2014	24 tabs	ZA		
6.	5/24/2014	AZ	1234-001	400 mg daily	- 2	\top	18	GLX 87654321	ZA						
	6/16/2014	BT	1234-002	400 mg daily	- 2	\top	16	GLX 87654321	ZA						
7.	6/24/2014	AZ	1234-001	400 mg daily	- 2	\top		GLX 87654321	JT		7/31/2014	8 tabs	JT		
8.	6/24/2014	AZ		Patient return fro		sing on 4			JT		6/24/2014	1 bottle	JT		
9.	6/30/2014		edical Office Buil			g 011-		GLX 87654321	ZA		5.2-32014	. Dollic			
10.	7/11/2014		from the NCI	ag ri outoille	+ 20	+		GLX 09735555	JT						
11.	7/23/2014	BT	1234-002	800 mg daily	- 2		20	GLX 87654321	AB		8/24/2014	4 tabs	ZA		
12.	7/23/2014	BT	1234-002	800 mg daily	- 2	+		GLX 09735555	AB		8/24/2014	1 Btl + 4 ta			
13.	8/1/2014	Returned	from Med. Off. B		+ 4	+	22	GLX 87654321	JT						
14.	8/2/2014	Return to	the NCI Clinical F	Repository	- 4		18	GLX 87654321	AB	8/31/2014					
15.	9/30/2014		o NCI Protocol 2	,	-	+		GLX 09735555	ZA	5.0 HE014					
16.	11/4/2014		truction per PME		- 8	-		GLX 09735555	ZA						

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

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



Information on patient returns is also available in the PMB FAQ "Patient Returns of Oral Clinical Supplies" 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

Produced September 2014