

Slide 1

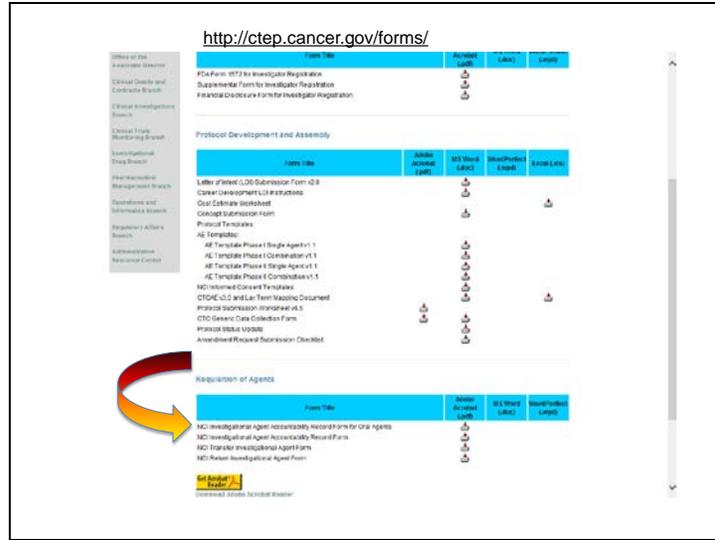


Welcome to this video tutorial on DARF Basics in the PMB Investigational Drug Accountability series.

The video will review the basics of using the NCI Investigational Agent Accountability Record Form, commonly referred to as the Drug Accountability Record Form (DARF).

Any references to the Investigational Agent Accountability Record in this presentation apply exclusively to the NCI DARF.

Slide 2



You can find the DARF and other forms on the CTEP website at <http://ctep.cancer.gov/forms>.

You will notice there are two forms, the original DARF and the Oral DARF.

DARFs must be maintained to track the disposition of all study-supplied agents for NCI clinical trials.

Slide 3

Caution: This information is submitted under 21 CFR 312.63. This information is submitted in strict confidence with Food and Drug Administration (FDA) requirements for NCI as an NCI sponsor and that investigational agents are under the control and protection of the sponsor's authority. This information may be disclosed to members for investigational purposes, sponsor of clinical trials and their company contractors, the appropriate Institutional Review Board, NCI, FDA and Department of Health and Human Services. Submission of this information is voluntary, however, in order to participate in studies or treatment with investigational agents, patients, and their caregivers at NCI.

Public reporting burden for this collection of information is estimated to average 15 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 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 Washington Headquarters Office, Paperwork Project, (202) 953-7021. Send comments to the Office of Management and Budget, Paperwork Project, (202) 953-3021.

Investigational Agent Accountability Record
Oral agents ONLY

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

Name of Institution: _____ Investigator Name: _____

NCI Protocol No: _____ Local Protocol No: _____ Dispensing Area: _____

Agent Name: _____ Dose Form and Strength: _____ Bottle size (e.g., # tablets/bottle): _____

PAGE NO: _____
 CONTROL RECORD
 SATELLITE RECORD

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												
2												
3												
4												
5												
6												
7												
8												
9												
10												
11												
12												
13												
14												
15												
16												
17												

The Oral DARF must be used for NCI studies using an oral agent.

Slide 4

The image shows a screenshot of a web-based form titled "Investigational Agent Accountability Record". At the top, there are buttons for "Print Form", "Save As", and "Reset Form". Below these are several lines of small text providing instructions and contact information. The form is divided into several sections:

- Form Header:** Includes "National Institutes of Health" and "Division of Cancer Treatment and Diagnosis".
- Form Title:** "Investigational Agent Accountability Record" is highlighted with a red box.
- Form Fields:** Includes "Agent Name", "Patient's Name", "Dispensing Area", and "Investigator Name".
- Form Controls:** Includes checkboxes for "CONTROL RECORD" and "SATELLITE RECORD".
- Table:** A table with columns for "Line No.", "Date", "Patient's ID No.", "Dose", "Quantity Dispensed or Received", "Batch/Forward", "Manufacture", and "Residual". The table has 20 rows.

The original DARF must be used for all NCI studies using formulations not intended for oral administration. Examples include injectable, topical and imaging agents.

Slide 5

The image shows a form titled "Investigational Agent Accountability Record" for "Oral agents ONLY". The form is divided into several sections:

- Header:** Contains the title, "National Institutes of Health", "National Cancer Institute", "Division of Cancer Treatment and Diagnosis", and "Cancer Therapy Evaluation Program". It also includes checkboxes for "CONTROL RECORD" and "SATELLITE RECORD".
- Form Fields:** A section with a light blue background containing fields for "Name of Institution", "Investigator Name", "CTEP Investigator ID", "Protocol Title", "Protocol No.", "Dispensing Area", "Agent Name", "Dose Form and Strength", and "Bottle size (e.g., # tablets/bottle)". A large blue text overlay "Writable fields" is centered over this section.
- Table:** A table with a light red background for data entry. The columns are: 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, and Recorder's Initials. A large red text overlay "Handwrite individual entries" is centered over the table.

Now let's look at the DARE. Notice that within the electronic form available from the CTEP website, the header contains writable fields. The remaining fields are not writable, but are locked for change control and require handwritten entry.

Once the header fields are completed for a specific protocol, the form may be saved to generate additional accountability pages. The edited form may be saved to the user's computer if proper Adobe® software is available.

Slide 6

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

Collection of this information is authorized under 21 CFR 312.63. The information is collected to ensure compliance with Food and Drug Administration (FDA) requirements for New Active Ingredient (NAI) and Investigational Agents (IA) under the Center for Drug Evaluation and Research (CDER). This information may be disclosed to other FDA offices, including the Center for Drug Evaluation and Research (CDER), the Center for Drug Evaluation and Research (CDER), the Center for Drug Evaluation and Research (CDER), and the Center for Drug Evaluation and Research (CDER). Submission of this information is voluntary however, in order for you to conduct a study in accordance with relevant, current products, we must complete all fields.

Public reporting burden for this collection of information is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and reviewing 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 the collection of information, including suggestions for reducing the burden, to Washington Headquarters Service, Paperwork Project (0704-0188), ATTN: Paperwork Project Director, Washington, DC 20503-2922. Send all requests for change of form to this address.

OMB No. 0925-0010
Expires: 03/31/2010
Rev: 03/2009

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

Investigational Agent Accountability Record

Name of Institution: _____ NCI Protocol No.: _____

Agent Name: _____ Dose Form and Strength: _____

PAGE NO.
CONTROL RECORD
SATELLITE RECORD

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

Collection of this information is authorized under 21 CFR 312.63. The information is collected to ensure compliance with Food and Drug Administration (FDA) requirements for New Active Ingredient (NAI) and Investigational Agents (IA) under the Center for Drug Evaluation and Research (CDER). This information may be disclosed to other FDA offices, including the Center for Drug Evaluation and Research (CDER), the Center for Drug Evaluation and Research (CDER), the Center for Drug Evaluation and Research (CDER), and the Center for Drug Evaluation and Research (CDER). Submission of this information is voluntary however, in order for you to conduct a study in accordance with relevant, current products, we must complete all fields.

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OMB No. 0925-0010
Expires: 03/31/2010
Rev: 03/2009

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

Investigational Agent Accountability Record
Oral agents ONLY

Name of Institution: _____ Investigator Name: _____ CTF Investigator ID: _____

Protocol Title: _____ NCI Protocol No.: _____ Local Protocol No.: _____ Dispensing Area: _____

PAGE NO.
CONTROL RECORD
SATELLITE RECORD

If the specific protocol DARF is saved or printed for future use, check the expiration date in the upper right-hand corner to be sure the document is still in date prior to use.

eDARF=

Print Form
Save As
Reset Form

Collection of this information is authorized under 21 CFR 31.337. The 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 the intended authority. The information may be disclosed by researchers for investigational purposes, sponsors of clinical trials and their company collaborators, the appropriate Institutional Review Board (IRB), FDA, and the Department of Health and Human Services. Submission of this information is voluntary however, a number for you to contact a statistician, pharmacist, or other personnel, as needed, is provided.

Public reporting burden for this collection of information is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and reviewing and reviewing the collection of information. **Do not send comments on this collection of information, including suggestions for reducing this burden, to NIH.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to NIH, Project Clearance Branch, 1015 LBJ Building, Room 3036, Bethesda, MD 20892-7004, or to the Office of Management and Enterprise Services, Paperwork Project Director, Paperwork Project, Washington, DC 20503-0001. Do not return this collection of information to this address.

National Institutes of Health National Cancer Institute Investigational Agent Accountability Record Name of Institution: _____ Agent Name: _____	Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program PAGE NO: _____ CONTROL RECORD <input type="checkbox"/> SATELLITE RECORD <input type="checkbox"/> NCI Protocol No.: _____ Dose Form and Strength: _____
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Print Form
Save As
Reset Form

Collection of this information is authorized under 21 CFR 31.337. The 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 the intended authority. The information may be disclosed by researchers for investigational purposes, sponsors of clinical trials and their company collaborators, the appropriate Institutional Review Board (IRB), FDA, and the Department of Health and Human Services. Submission of this information is voluntary however, a number for you to contact a statistician, pharmacist, or other personnel, as needed, is provided.

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National Institutes of Health National Cancer Institute Investigational Agent Accountability Record Oral agents <u>ONLY</u> Name of Institution: _____ Protocol Title: _____	Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program PAGE NO: _____ CONTROL RECORD <input type="checkbox"/> SATELLITE RECORD <input type="checkbox"/> NCI Protocol No.: _____ Local Protocol No.: _____ Dispensing Area: _____ CTEP Investigator ID: _____
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If your institution uses drug accountability software or eDARFs, the database must be able to produce a paper printout that is identical to the NCI DARF. PMB does not endorse any particular eDARF pharmacy package.

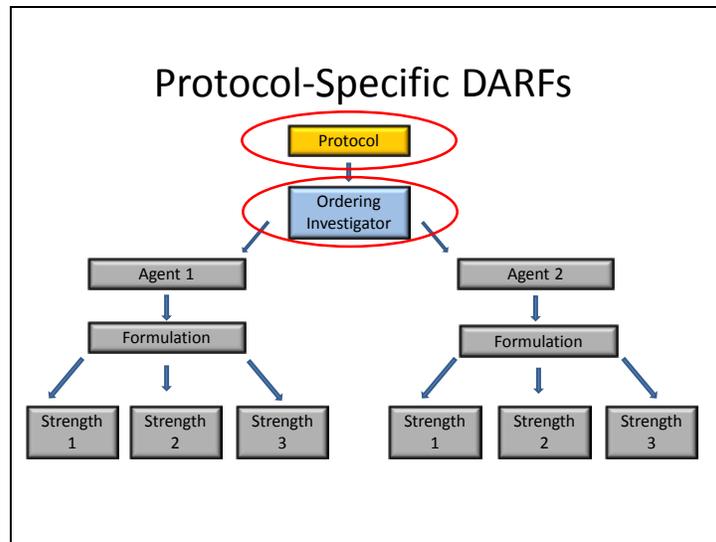
Slide 8

Corrections Made on the DARF

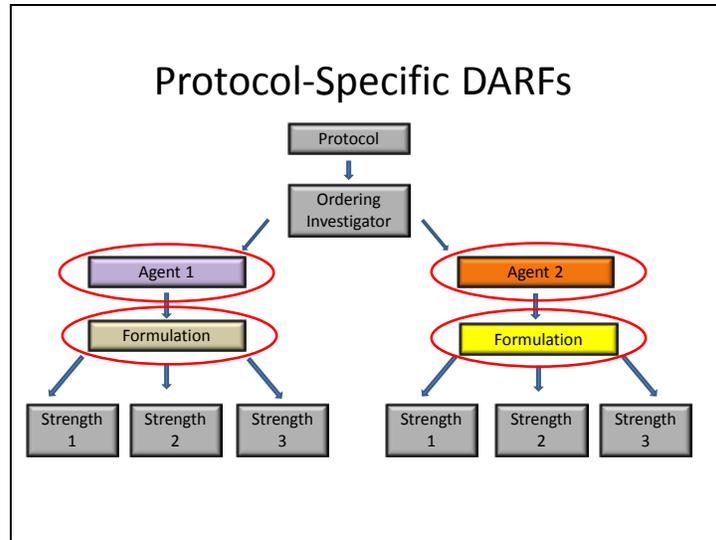
11	7/11/2014	Received from the NCI		+ 20	22	GLX 0973555	AK						
12	7/23/2014	BT	1234-002	800 mg daily	-2	20	GLX 87654321	AB		8/24/2014	4 tabs		ZA
13	7/23/2014	BT	1234-002	800 mg daily	-2	18	GLX 0973555	AB		8/24/2014	4 tabs		ZA
14	7/23/2014	Returned from Med. Off. Bldg. A Satellite		+ 4	22	GLX 87654321	JT						
15	8/22/2014	Return to the NCI Clinical Repository		-4	16	GLX 87654321	AB		8/31/2014				

Corrections made to any paper DARF must be neatly lined out, initialed and dated as in the example on line 14. Erasures or “whiteouts” are not acceptable as shown in the example on line 11.

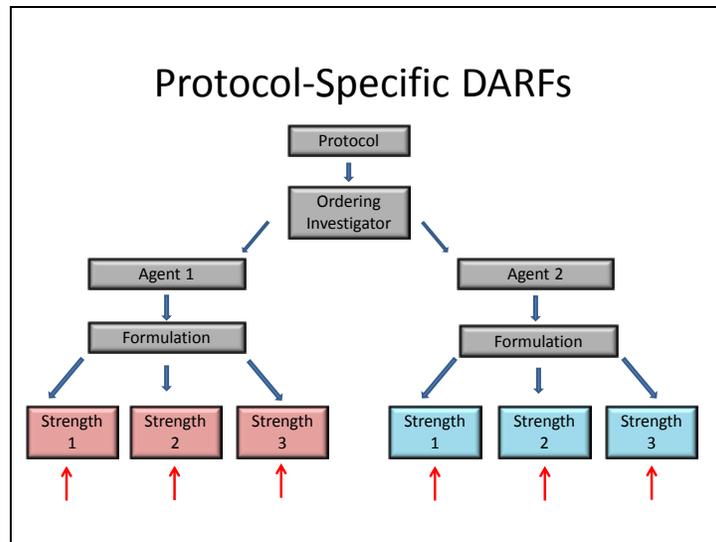
Corrections made in any electronic accountability system also need to be appropriately documented.



Separate DARFs are required for each protocol and for each ordering investigator.



Each agent formulation for that protocol must have a separate DARF. Additionally, each strength for that particular agent requires a separate DARF.



In the example, six DARFs are required, one for each strength.

PMB encourages sites to order agents for only one investigator per protocol to minimize the total number of DARFs being maintained.

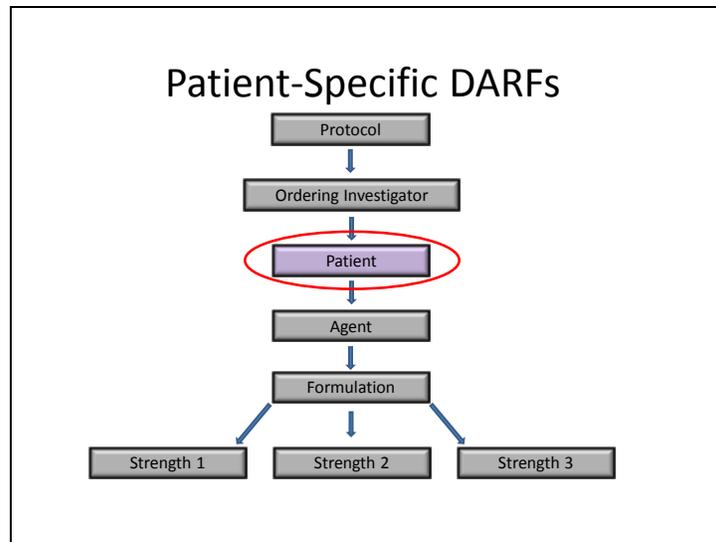
Control dispensing areas and satellite dispensing areas maintain separate DARFs.

Slide 12

Print Form		Save As		Reset Form									
<small>Caution: This information is classified under 21 CFR 312.61. This information is controlled under conditions with Food and Drug Administration (FDA) requirements for NCI as an ND sponsor and that investigational agents are under the control and protection of the sponsor's facility. This information may be disclosed to members of the investigational protocol, sponsor of clinical trials and their designees, the appropriate Institutional Review Board, NCI, FDA and Department of Health and Human Services. Submission of this information is voluntary, however, it is required to participate in a study or experiment with research, control patients, and their families at NCI.</small>													
<small>Public reporting burden for this collection of information is estimated to average 15 minutes per response, including 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 a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Washington Headquarters Office of Management and Budget, Paperwork Project Collection (0707-0188), Washington, DC 20503.</small>													
Investigational Agent Accountability Record Oral agents ONLY				National Institutes of Health National Cancer Institute Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program									
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.				CTEP Investigator ID: 999999									
NCI Protocol No: 1234		Local Protocol No: SUH-001		PAGE NO. 1 CONTROL RECORD <input checked="" type="checkbox"/> SATELLITE RECORD <input type="checkbox"/>									
Agent Name: Pazopanib hydrochloride (NSC 737754)				Dispensing Area: IDS Pharmacy - 5th Floor Room A100									
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		8/16/2014		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			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 BE + 4 tabs	ZA
14	8/1/2014		Returned from Med. Off. Building A Satellite			+ 4	22	GLX 87654321	JT				
15	8/2/2014		Return to NCI Clinical Repository			- 4	18	GLX 87654321	AB	8/31/2014			
16	9/30/2014		Transfer to NCI Protocol 2 (114273-0001)			- 10	8	GLX 09735555	ZA				
17	11/4/2014		Local Dispensing per PMS Authorization			- 8	0	GLX 09735555	ZA				

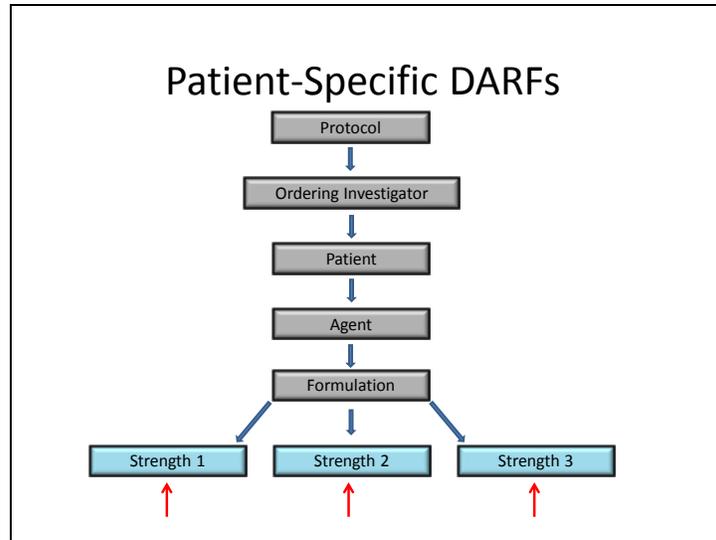
Please note that protocol-specific DARFs are not agent lot specific. Multiple lots of the same strength should be tracked on the same DARF. DARFs are continuous records that may span many pages during the life of a protocol.

Protocol-specific DARFs are used to track agent disposition for multiple patients on the same study.



Protocols that use patient-specific supplies (e.g. placebo-controlled studies) are tracked by protocol and by patient. Patient-specific supplies use the Julian date and order number as the lot number.

Refer to the protocol document if you are unsure whether agent supplies are patient-specific.



Separate DARFs are required for each patient on that protocol. Each agent formulation for that protocol must have a separate DARF. Additionally, each strength for that particular agent requires a separate DARF.

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

The screenshot shows the National Cancer Institute (NCI) website for the Cancer Therapy Evaluation Program (CTEP). The page is titled 'Agent Management' and is part of the Pharmaceutical Management Branch (PMB). A red arrow points to the link 'Policy and Guidelines for Accountability and Storage of Investigational Agents (PDF) (12/13)'. The page also includes a navigation menu, a search bar, and a list of links to various documents and resources.

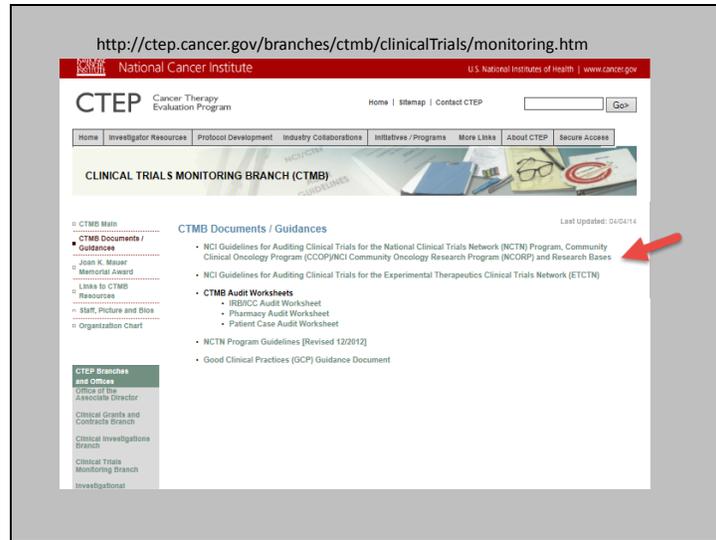
CTEP Cancer Therapy Evaluation Program

PHARMACEUTICAL MANAGEMENT BRANCH (PMB)

Agent Management Last updated: 11/12/13

- Policy and Guidelines for Investigational Agent Distribution (PDF)
- Policy and Guidelines for Investigational Agent Ordering (PDF) (11/13)
 - Online Agent Order Processing (OAOPI)
 - Register for an IAM Account (Required)
 - Submit OAOPI Orders
- Policy and Guidelines for Accountability and Storage of Investigational Agents (PDF) (12/13)
- NCI Investigational Agent Accountability Record Form (PDF)
- NCI Investigational Agent Accountability Record Form for Oral Agents (PDF)
- Policy and Guidelines for Use of the NCI Investigational Agent Accountability Record for Oral Agents (PDF) (12/13)
- Policy and Guidelines for Transfer of DCCT-Supplied Investigational Agents (PDF)
 - NCI Transfer Investigational Agent Form (PDF)
- Policy and Guidelines for Investigational Agent Returns (PDF)
 - NCI Return Investigational Agent Form (PDF)
- Links to Commercial Drug Shortage Resources
 - <http://www.fda.gov/medwatch> - to enroll in MedWatch and receive e-mails when shortages are identified by FDA
 - <http://www.fda.gov/drugs/shortages/> - FDA Web site for drug shortages. Provides most current information from FDA
 - <http://www.ashp.org/shortage/> - ASHP web site for drug shortages. Information regarding shortages from American Society of Health System Pharmacists
 - <http://www.cdc.gov/ncidod/diseases/genitourinary/shortages/default.htm> - CDC website for Vaccine shortages
 - <http://www.pharmacyone.com> - Pharmacy One Source (Free Subscription), provides MEDWATCH and other information

To recap, DARFs track the disposition of investigational agents used for NCI clinical trials. To learn more, please refer to the “Pharmaceutical Management Branch Policy and Guidelines for Accountability and Storage of Investigational Agents” available here on the PMB website.



Another helpful resource is Section 5.3 (agent accountability and pharmacy operations) of the “NCI Guidelines for Auditing Clinical Trials for the NCTN” found on the Clinical Trials Monitoring Branch (CTMB) website.

Pharmaceutical Management Branch, CTEP, NCI



Email
PMBAAfterHours@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 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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