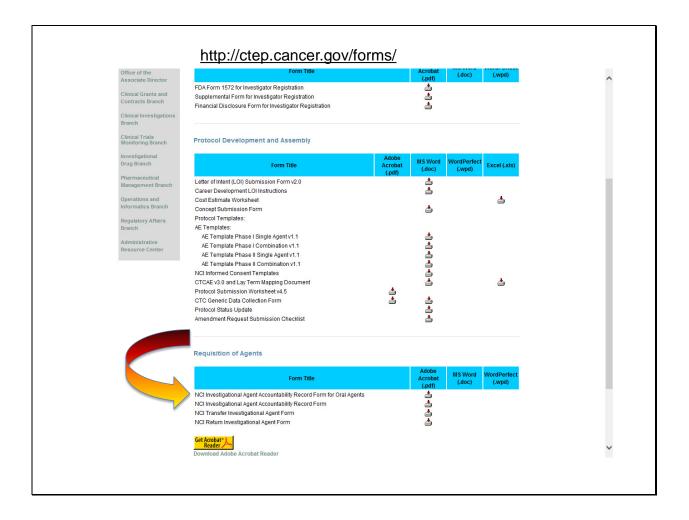
	DAOP Local Destruction Agent Returns Agent Transfers Agent Transfers Agent Dispensing Agent Receipt Oral DARF DARF Header DARF Basics
Pharmaceutical Management Branch Investigational Drug Accountability:	DARF Basics
National Cancer Institute ctep.	cancer.gov

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.

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

Slide 4

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

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Now let's look at the DARF. 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.

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Collection of this information is authorized under 21 CFR 312.57. The information as an IND sponsor and that investigational agents are under the control and acco investigational purposes, sponsors of clinical Intials and their company collaboration Services. Submission of this information is voluntary however, in order for you to Public reporting burden for this collection of information is estimated to average 4 the data needed, and completing and reviewing the collection of information. An displays a currently valid OIMB control number. Send commerts regarding thi Project Clearnos Faron, 610% Rockade, Drow, NSC 7174, Bethetesk, MD 20%	unted for by competent authors rs, the appicable institutional F conduct a study in accordance i minutes per response, includin agency may not conduct or a 5 burden estimate or any other	y. The information may be disclose eview Board, NCI, FDA, and the E with relevant, current protocols, yo g the time for reviewing instruction pensor, and a person is not require spect of this collection of informal	and to researching for the source of the sou
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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.

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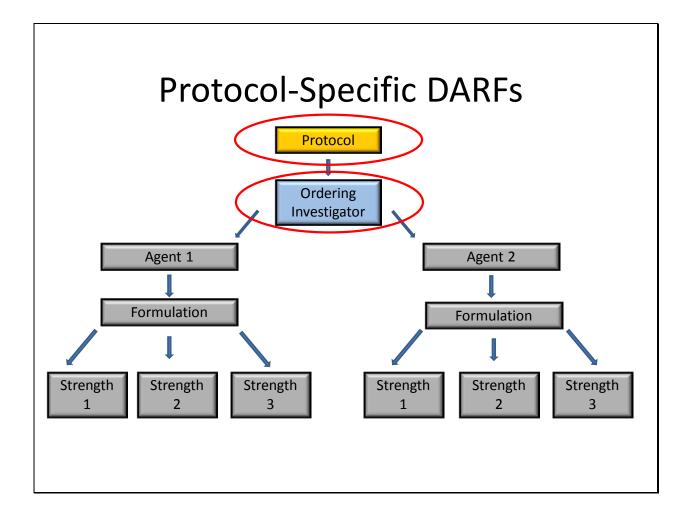
If your institution uses drug accountability software or eDARFs, the database must be able to produce a paper printout that is identical to the NCI DARF. PMB does not endorse any particular eDARF pharmacy package.

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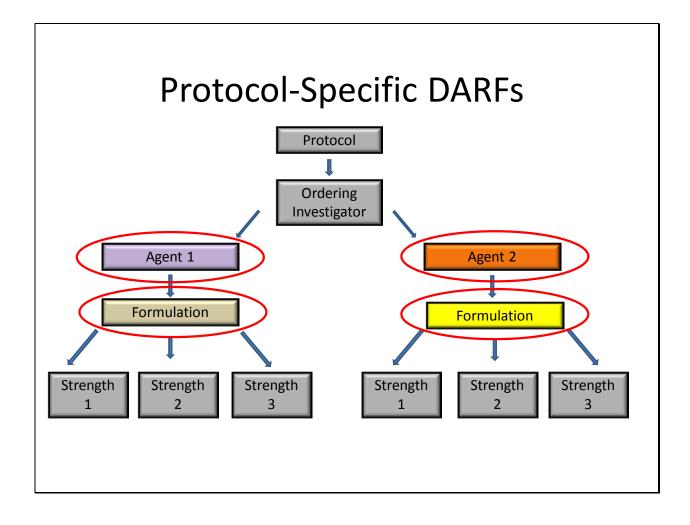
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Corrections made to any paper DARF must be neatly lined out, initialed and dated as in the example on line 14. Erasures or "whiteouts" are not acceptable as shown in the example on line 11.

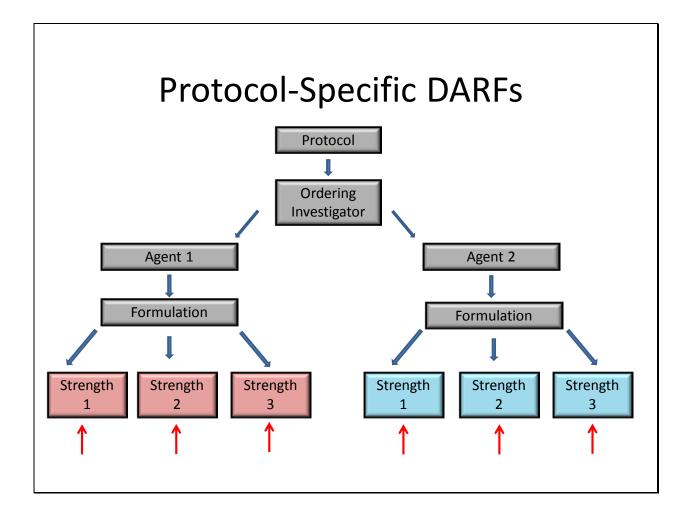
Corrections made in any electronic accountability system also need to be appropriately documented.



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.

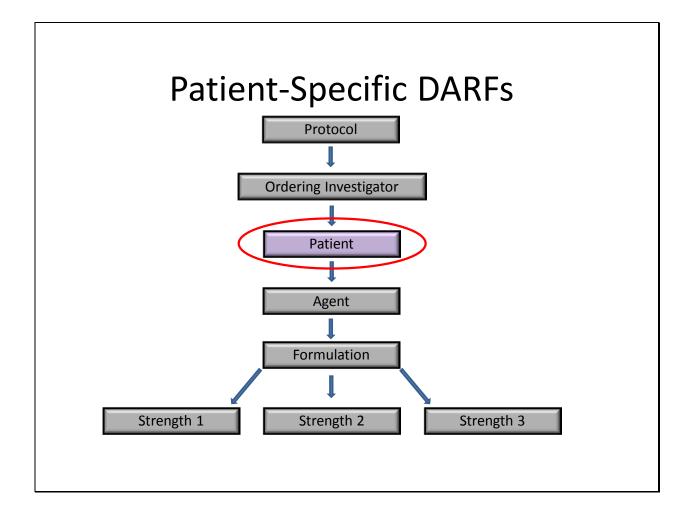
PMB encourages sites to order agents for only one investigator per protocol to minimize the total number of DARFs being maintained.

Control dispensing areas and satellite dispensing areas maintain separate DARFs.

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2.	3/24/2014	AZ	1234-001	800 mg daily	- 4		4	GLX 12345678			4/24/2014	16 tabs	AB
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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 or	n 4/24/2014, p	ge 1, line 3	JT		6/24/2014	1 bottle	JT
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12.	7/23/2014	BT	1234-002	300 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 tab	bs ZA
14.	8/1/2014	Returned	rom Med. Off. B	ild. A Satellite	+ 4		22	GLX 87654321	JT				
15.	8/2/2014	Return to	he NCI Clinical F	epository	- 4		18	GLX 87654321	AB	8/31/2014			
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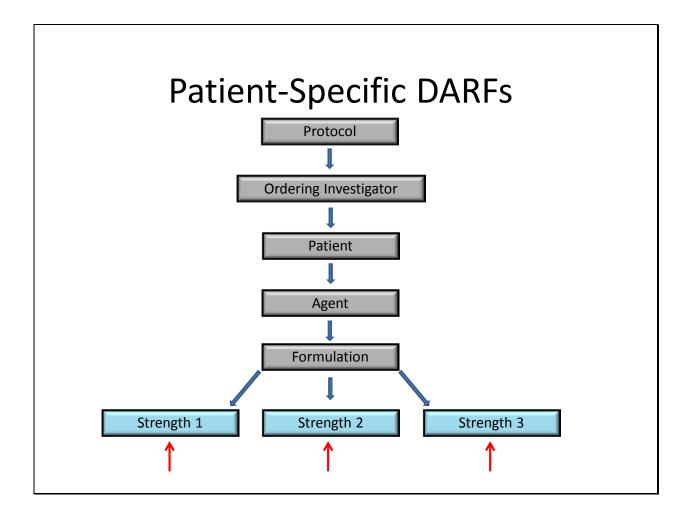
Please note that protocol-specific DARFs are not agent lot specific. Multiple lots of the same strength should be tracked on the same DARF. DARFs are continuous records that may span many pages during the life of a protocol.

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

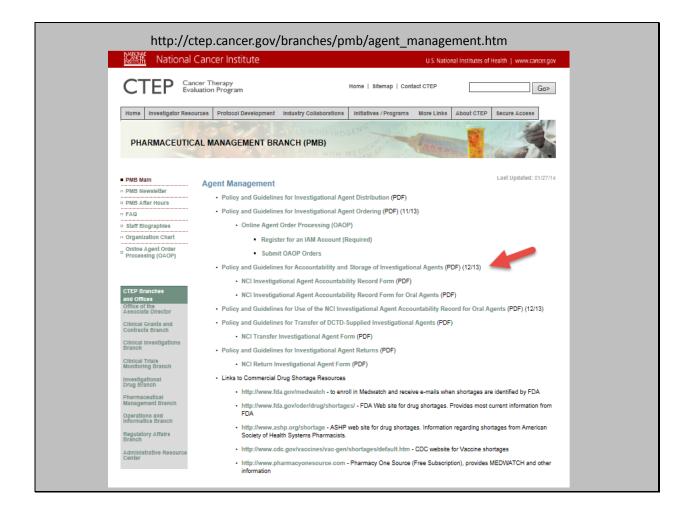


Protocols that use patient-specific supplies (e.g. placebo-controlled studies) are tracked by protocol and by patient. Patient-specific supplies use the Julian date and order number as the lot number.

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



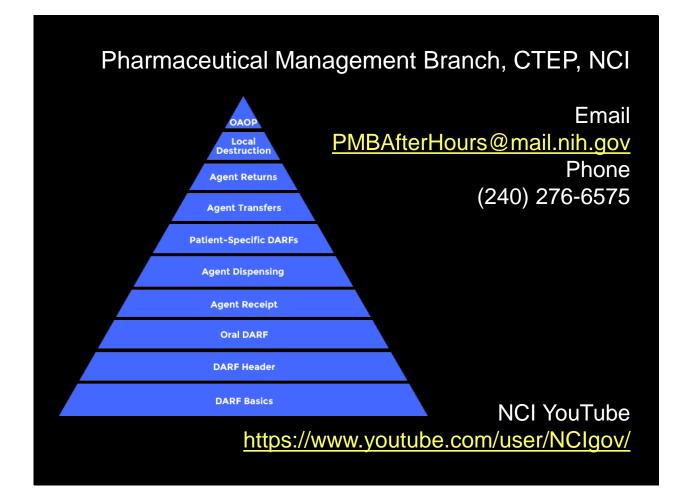
Separate DARFs are required for each patient on that protocol. Each agent formulation for that protocol must have a separate DARF. Additionally, each strength for that particular agent requires a separate DARF.



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.

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Links to CTMB Resources	CTMB Audit Worksheets			
Staff, Picture and Blos	 IRB/ICC Audit Worksheet Pharmacy Audit Worksheet 			
Organization Chart	Patient Case Audit Worksheet			
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and Offices Office of the Associate Director				
Clinical Grants and Contracts Branch				
Clinical Investigations Branch				
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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.



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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