

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.

<http://ctep.cancer.gov/forms/>

Form Title	Acrobat (.pdf)	MS Word (.doc)	WordPerfect (.wpd)
FDA Form 1572 for Investigator Registration			
Supplemental Form for Investigator Registration			
Financial Disclosure Form for Investigator Registration			

**Protocol Development and Assembly**

Form Title	Adobe Acrobat (.pdf)	MS Word (.doc)	WordPerfect (.wpd)	Excel (.xls)
Letter of Intent (LOI) Submission Form v2.0				
Career Development LOI Instructions				
Cost Estimate Worksheet				
Concept Submission Form				
Protocol Templates:				
AE Templates:				
AE Template Phase I Single Agent v1.1				
AE Template Phase I Combination v1.1				
AE Template Phase II Single Agent v1.1				
AE Template Phase II Combination v1.1				
NCI Informed Consent Templates				
CTCAE v3.0 and Lay Term Mapping Document				
Protocol Submission Worksheet v4.5				
CTC Generic Data Collection Form				
Protocol Status Update				
Amendment Request Submission Checklist				

**Requisition of Agents**

Form Title	Adobe Acrobat (.pdf)	MS Word (.doc)	WordPerfect (.wpd)
NCI Investigational Agent Accountability Record Form for Oral Agents			
NCI Investigational Agent Accountability Record Form			
NCI Transfer Investigational Agent Form			
NCI Return Investigational Agent Form			

Download Adobe Acrobat Reader

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.

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

Collection of this information is authorized under 21 CFR 312.57. This 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 competent authority. The information may be disclosed to researchers for investigational purposes, sponsors of clinical trials and their company collaborators, the applicable Institutional Review Board, NCI, FDA and Department of Health and Human Services. Submission of this information is voluntary. However, in order for you to conduct a study in accordance with relevant, current protocols, you must complete all fields.

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Form Approved  
 OMB No. 0925-0013  
 Expires: 03/31/2016

**Investigational Agent Accountability Record**  
Oral agents ONLY

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

PAGE NO. \_\_\_\_\_

CONTROL RECORD

SATELLITE RECORD

Name of Institution: \_\_\_\_\_ Investigator Name: \_\_\_\_\_ CTEP Investigator ID: \_\_\_\_\_

Protocol Title: \_\_\_\_\_ NCI Protocol No: \_\_\_\_\_ Local Protocol No: \_\_\_\_\_ Dispensing Area: \_\_\_\_\_

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

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
						Balance						
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

Print Form
Save As
Reset Form

Collection of this information is authorized under 21 CFR 312.57. The information collected to ensure compliance with Food and Drug Administration (FDA) requirements for NCI as an IND sponsor and trial investigational agents are under the control and accounted for by computer authority. The information may be disclosed to researchers for investigational purposes, sponsors of clinical trials and their company collaborators, the applicable Institutional Review Board, NCI, FDA, and the Department of Health and Human Services. Submission of this information is voluntary however, in order for you to conduct a study in accordance with relevant, current protocols, you must complete all items.

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National Institutes of Health  
 National Cancer Institute

Division of Cancer Treatment and Diagnosis  
 Cancer Therapy Evaluation Program

OMB No. 0925-0013  
 Expires 03/31/2010  
 HSA 2568

**Investigational Agent Accountability Record**

PAGE NO. \_\_\_\_\_  
 CONTROL RECORD   
 SATELLITE RECORD

Name of Institution: \_\_\_\_\_ NCI Protocol No.: \_\_\_\_\_  
 Agent Name: \_\_\_\_\_ Dose Form and Strength: \_\_\_\_\_  
 Protocol Title: \_\_\_\_\_ Dispensing Area: \_\_\_\_\_  
 Investigator Name: \_\_\_\_\_ CTEP Investigator ID: \_\_\_\_\_

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
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
21								
22								

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

\*Disclaimer: 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 this collection of information, including suggestions for reducing this burden, to: NH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0613). Do not return the completed form to this address.

<b>Investigational Agent Accountability Record</b> Oral agents <u>ONLY</u>		National Institutes of Health National Cancer Institute Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program	PAGE NO. CONTROL RECORD <input type="checkbox"/> SATELLITE RECORD <input type="checkbox"/>
Name of Institution:		Investigator Name:	CTEP Investigator ID:
Protocol Title:		Dispensing Area:	
Agent Name:		Dose Form and Strength:	Bottle size (e.g., # tablets/bottle):

Writable fields

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.												

Handwrite individual entries

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.

Print Form
Save As
Reset Form

OMB No. 0925-0613  
 Expires: 03/31/2016  
 NIH-2564

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

Print Form
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Form Approved:  
 OMB No. 0925-0613  
 Expires: 03/31/2016

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<b>Investigational Agent Accountability Record</b> Oral agents <u>ONLY</u>	National Institutes of Health National Cancer Institute Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program	PAGE NO. CONTROL RECORD <input type="checkbox"/> SATELLITE RECORD <input type="checkbox"/>
Name of Institution:	Investigator Name:	CTEP Investigator ID:
Protocol Title:	NCI Protocol No.:	Local Protocol No.:
		Dispensing Area:

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=

<b>Print Form</b>		<b>Save As</b>		<b>Reset Form</b>	
<p>Collection of this information is authorized under 21 CFR 312.57. This 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 competent authority. The information may be disclosed to researchers for investigational purposes, sponsors of clinical trials and their company collaborators, the applicable Institutional Review Board, NCI, FDA, and the Department of Health and Human Services. Submission of this information is voluntary however, in order for you to conduct a study in accordance with relevant, current protocols, you must complete all fields.</p> <p>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 completing and reviewing the collection of information. <b>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.</b> 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, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0613). Do not return the completed form to this address.</p>					
National Institutes of Health National Cancer Institute				Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program	
<b>Investigational Agent Accountability Record</b>				PAGE NO. CONTROL RECORD <input type="checkbox"/> SATELLITE RECORD <input type="checkbox"/>	
Name of Institution:			NCI Protocol No.:		
Agent Name:			Dose Form and Strength:		

<b>Print Form</b>		<b>Save As</b>		<b>Reset Form</b>	
<p>Collection of this information is authorized under 21 CFR 312.57. This 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 competent authority. The information may be disclosed to researchers for investigational purposes, sponsors of clinical trials and their company collaborators, the applicable Institutional Review Board, NCI, FDA and Department of Health and Human Services. Submission of this information is voluntary, however, in order for you to conduct a study in accordance with relevant, current protocols, you must complete all fields.</p> <p>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 completing and reviewing the collection of information. <b>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.</b> 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, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0613). Do not return the completed form to this address.</p>					
<b>Investigational Agent Accountability Record</b> Oral agents <u>ONLY</u>				National Institutes of Health National Cancer Institute Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program	
Name of Institution:				Investigator Name:	
Protocol Title:				CTEP Investigator ID:	
NCI Protocol No.:		Local Protocol No.:		Dispensing Area:	

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.

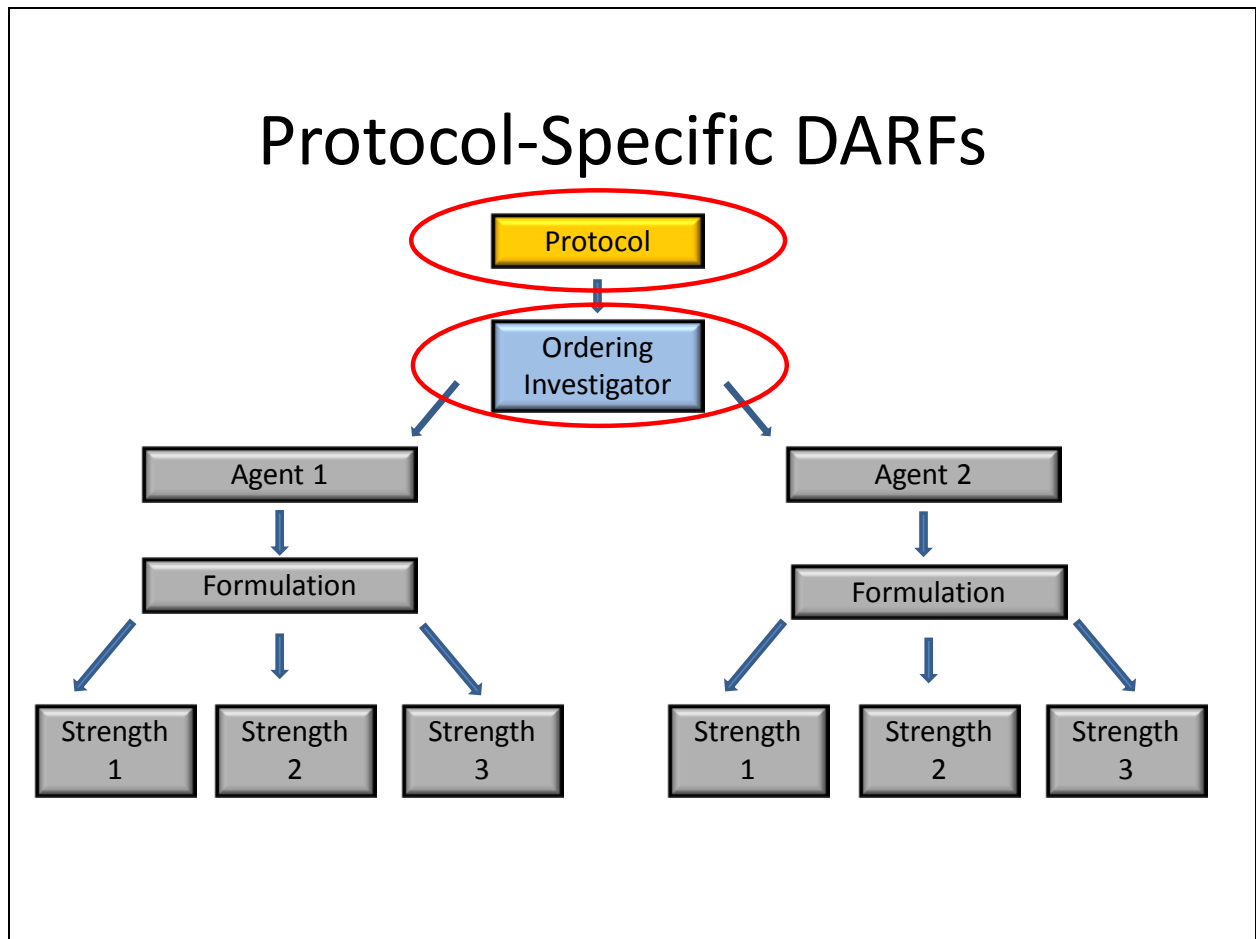
## Corrections Made on the DARF

11.	7/11/2014	Received from the NCI		+ 20	22	GLX 0973555	JK				
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 tabs	ZA
14.	<del>8/4/2014</del> 8/2/2014	Returned from Med. Off. Bldg. A Satellite		+ 4	22	GLX 87654321	JT				
	8/2/2014	Return to the NCI Clinical Repository		- 4	18	GLX 87654321	AB	8/31/2014			

Corrections made to any NCI 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.

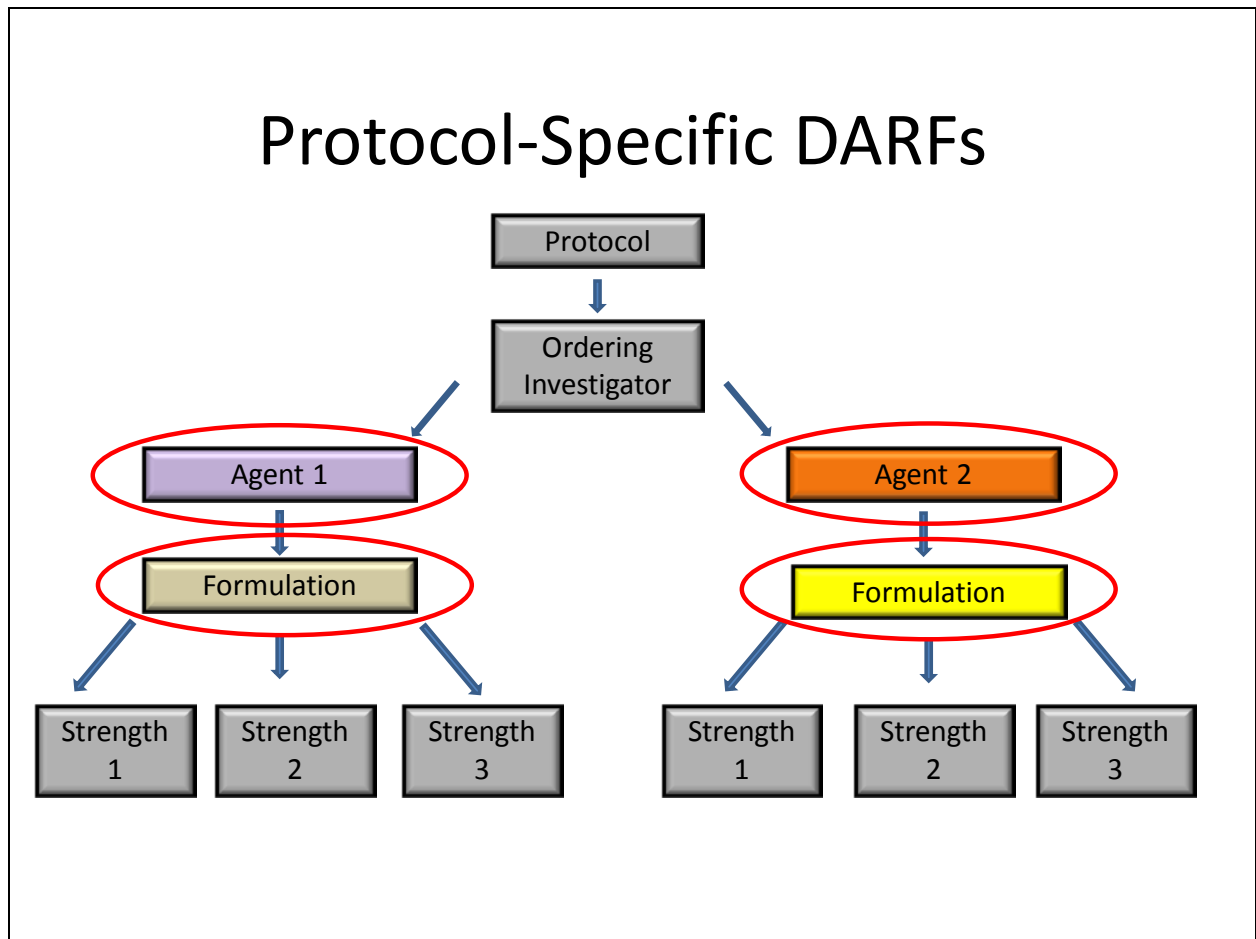
Corrections made in any electronic accountability system also need to be appropriately documented.



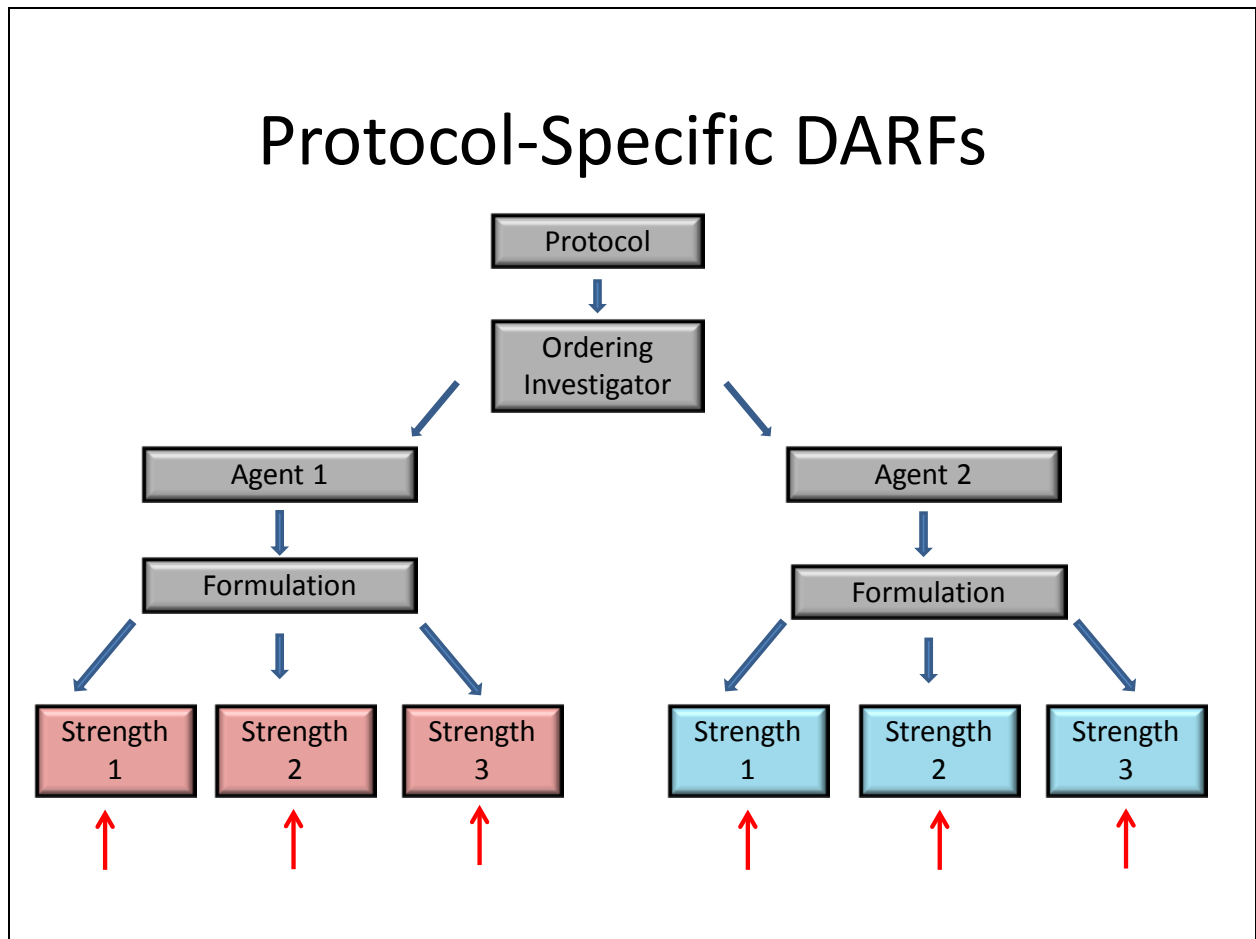


Separate DARFs are required for each protocol and for each ordering investigator.

## Protocol-Specific DARFs



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.

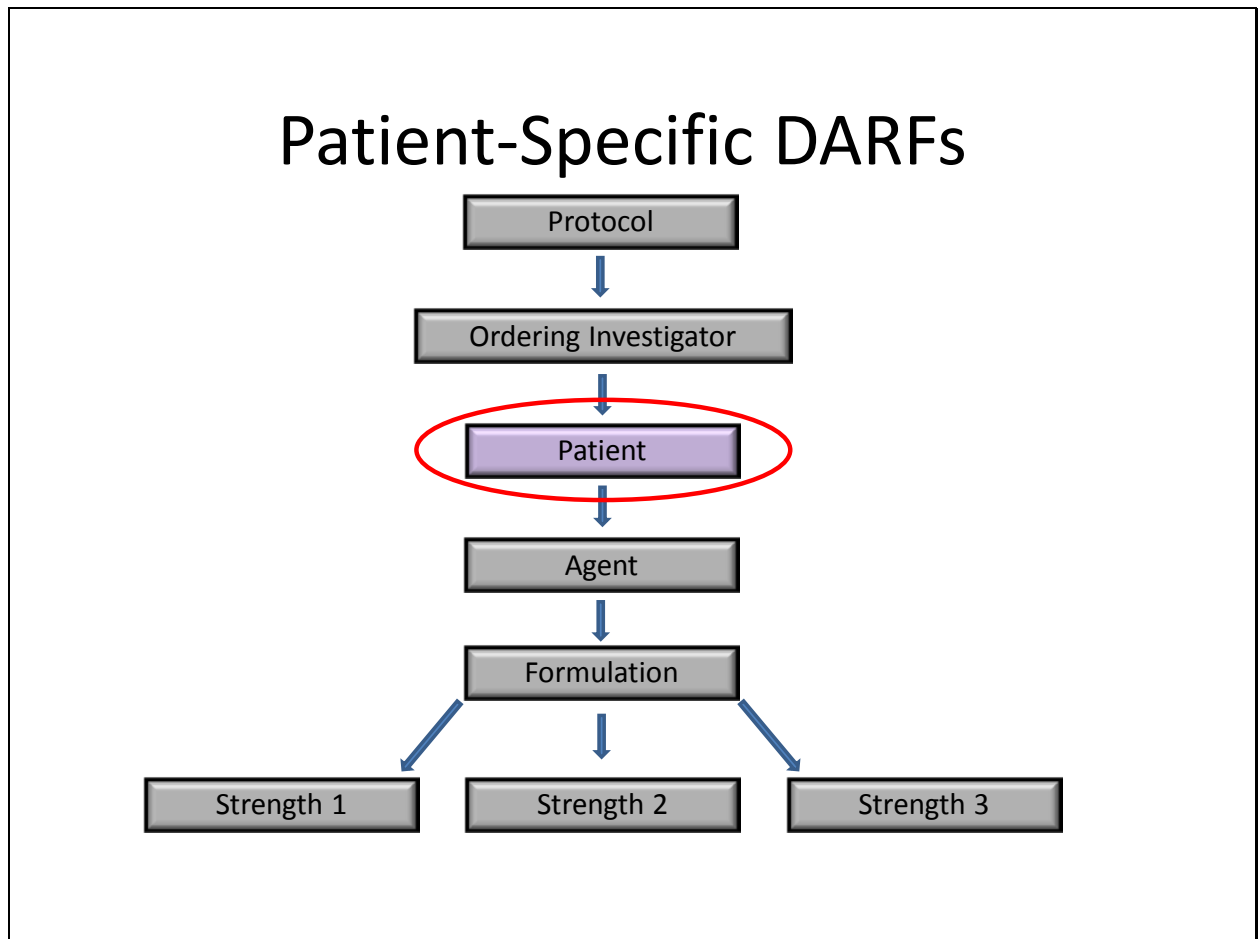
PMB encourages sites to order agents for only one investigator per protocol to minimize the total number of DARFs being maintained.

Control dispensing areas and satellite dispensing areas maintain separate DARFs.

<b>Print Form</b>		<b>Save As</b>		<b>Reset Form</b>								
<small>Collection of this information is authorized under 21 CFR 312.57. This 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 competent authority. The information may be disclosed to researchers for investigational purposes, sponsors of clinical trials and their company collaborators, the applicable Institutional Review Board, NCI, FDA and Department of Health and Human Services. Submission of this information is voluntary. However, in order for you to conduct a study in accordance with relevant, current protocols, you must complete all fields.</small>										<small>Form Approved OMB No. 0925-0013 Expires: 03/31/2016</small>		
<small>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 completing 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 this collection of information, including suggestions for reducing this burden, to: NIH Project Clearance Branch, 6705 Rockledge Drive, MSC 7924, Bethesda, MD 20895-7774, ATTN: PRA (3025-0013). Do not return the completed form to this address.</small>												
<b>Investigational Agent Accountability Record</b> <b>Oral agents ONLY</b>						National Institutes of Health National Cancer Institute Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program		PAGE NO. 1 CONTROL RECORD <input checked="" type="checkbox"/> SATELLITE RECORD <input type="checkbox"/>				
Name of Institution: <b>State University Hospital</b>				Investigator Name: <b>John Smith, M.D.</b>				CTEP Investigator ID: <b>999999</b>				
Protocol Title: Phase 2 trial of pazopanib for the treatment of patients with advanced renal cell carcinoma.				NCI Protocol No: <b>1234</b>		Local Protocol No: <b>SUH-001</b>		Dispensing Area: <b>IDS Pharmacy - 5th Floor Room A100</b>				
Agent Name: <b>Pazopanib hydrochloride (NSC 737754)</b>				Dose Form and Strength: <b>200 mg Tablets</b>				Bottle size (e.g., # tablets/bottle): <b>34 Tablets/bottle</b>				
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		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 from dispensing on 4/24/2014, page 1, line 3				JT		6/24/2014	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 Btl + 4 tabs	ZA
14	8/1/2014	Returned	from Med. Off. Bldg. A Satellite		+ 4	22	GLX 87654321	JT				
15	8/2/2014	Return to	the NCI Clinical Repository		- 4	18	GLX 87654321	AB		8/31/2014		
16	9/30/2014	Transfer to	NCI Protocol 241 (T14273-0001)		- 10	8	GLX 09735555	ZA				
17	11/4/2014	Local Dispensing	in per PMB Authorization		- 8	0	GLX 09735555	ZA				

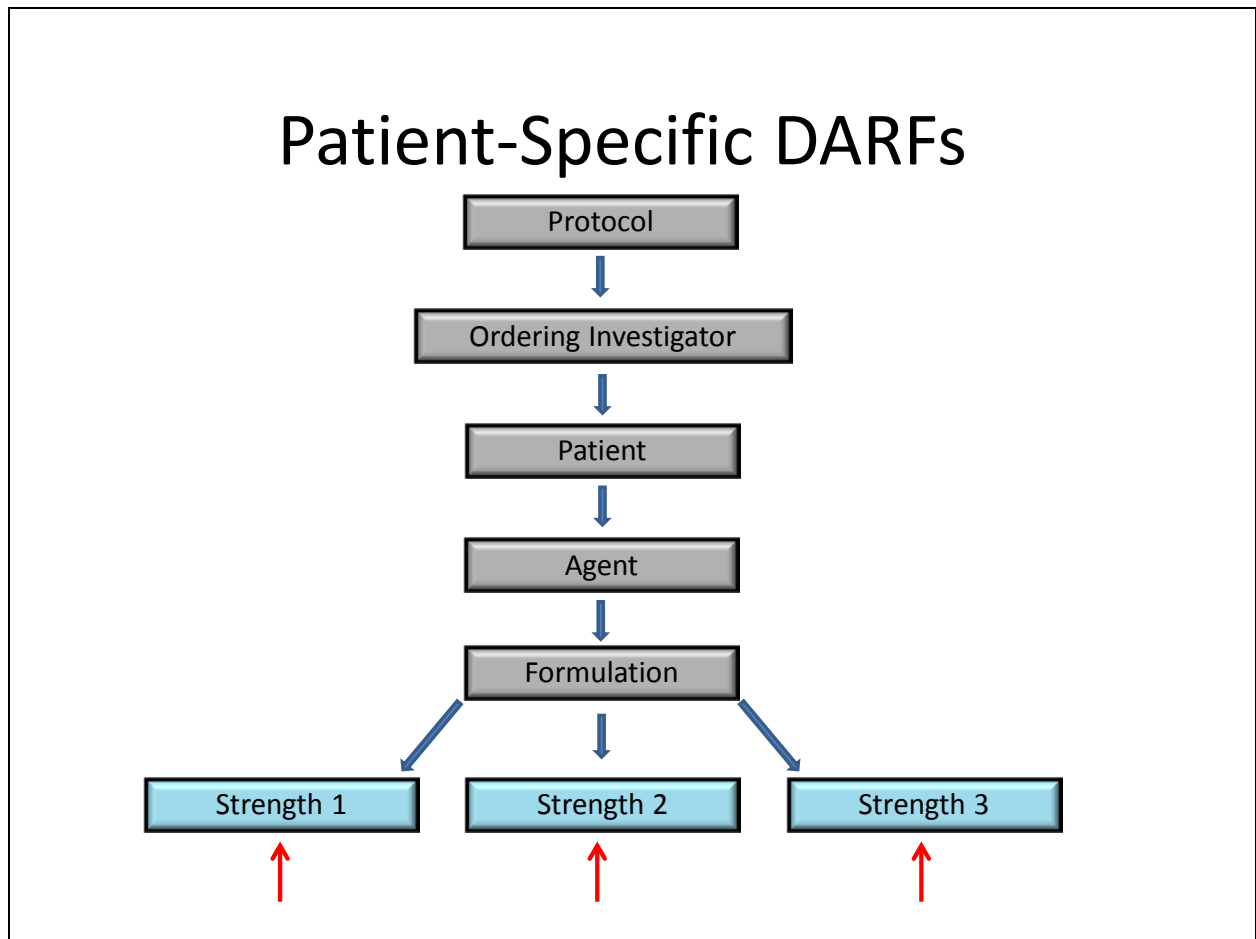
Please note that protocol-specific DARFs are not agent lot specific. Multiple lots of the same strength should be tracked on the same DARF. DARFs are continuous records that may span many pages during the life of a protocol.

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

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**PHARMACEUTICAL MANAGEMENT BRANCH (PMB)**

Last Updated: 01/27/14

**Agent Management**

- Policy and Guidelines for Investigational Agent Distribution (PDF)
- Policy and Guidelines for Investigational Agent Ordering (PDF) (11/13)
  - Online Agent Order Processing (OAOP)
    - Register for an IAM Account (Required)
    - Submit OAOP 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 DCTD-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/cder/drug/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 Systems Pharmacists.
  - <http://www.cdc.gov/vaccines/vac-gen/shortages/default.htm> - CDC website for Vaccine shortages
  - <http://www.pharmacyonesource.com> - Pharmacy One Source (Free Subscription), provides MEDWATCH and other information

**PMB Main**

- ▢ PMB Newsletter
- ▢ PMB After Hours
- ▢ FAQ
- ▢ Staff Biographies
- ▢ Organization Chart
- ▢ Online Agent Order Processing (OAOP)

**CTEP Branches and Offices**

- Office of the Associate Director
- Clinical Grants and Contracts Branch
- Clinical Investigations Branch
- Clinical Trials Monitoring Branch
- Investigational Drug Branch
- Pharmaceutical Management Branch
- Operations and Informatics Branch
- Regulatory Affairs Branch
- Administrative Resource Center

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.

http://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring.htm

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CLINICAL TRIALS MONITORING BRANCH (CTMB)

CTMB Main

- CTMB Documents / Guidances
- Joan K. Mauer Memorial Award
- Links to CTMB Resources
- Staff, Picture and Bios
- Organization Chart

CTMB Documents / Guidances Last Updated: 04/04/14

- NCI Guidelines for Auditing Clinical Trials for the National Clinical Trials Network (NCTN) Program, Community Clinical Oncology Program (CCOP)/NCI Community Oncology Research Program (NCORP) and Research Bases
- NCI Guidelines for Auditing Clinical Trials for the Experimental Therapeutics Clinical Trials Network (ETCTN)
- CTMB Audit Worksheets
  - IRB/CC Audit Worksheet
  - Pharmacy Audit Worksheet
  - Patient Case Audit Worksheet
- NCTN Program Guidelines [Revised 12/2012]
- Good Clinical Practices (GCP) Guidance Document

CTEP Branches and Offices

- Office of the Associate Director
- Clinical Grants and Contracts Branch
- Clinical Investigations Branch
- Clinical Trials Monitoring Branch
- Investigational

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  
[PMBAfterHours@mail.nih.gov](mailto:PMBAfterHours@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

Produced September 2014