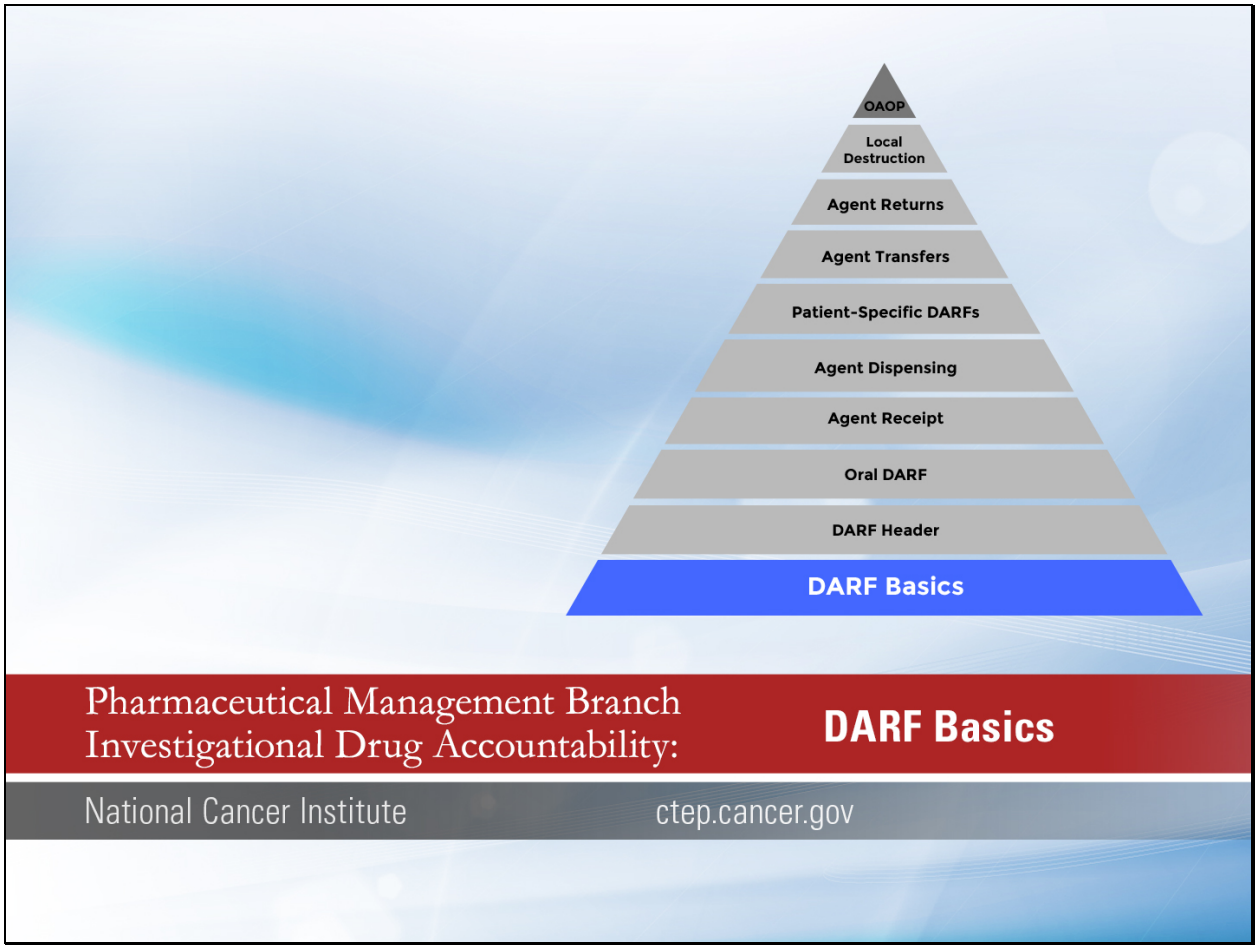
Slide 1

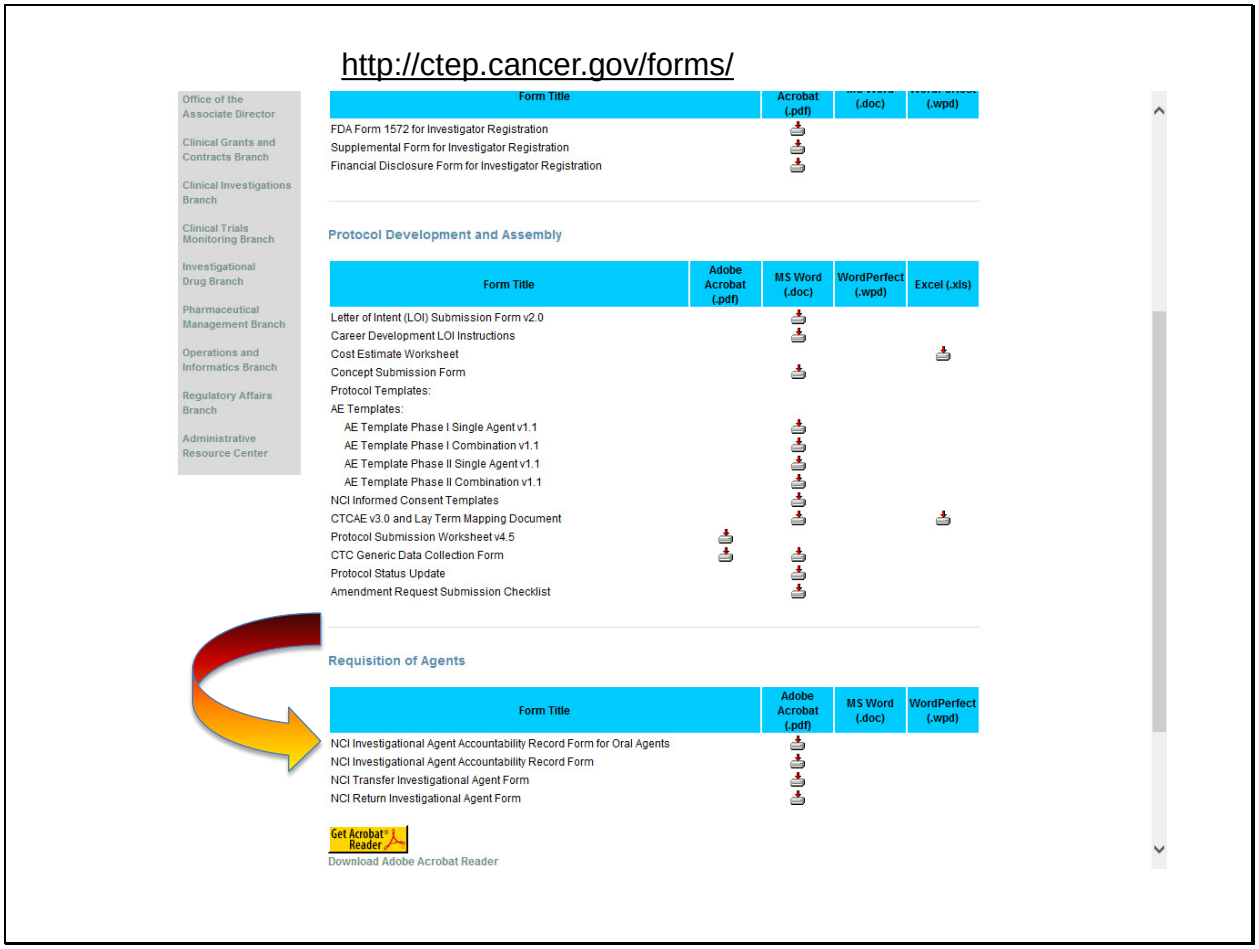


Welcome to this video tutorial on DARF Basics in the PMB Investigational Drug Accountability series.

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

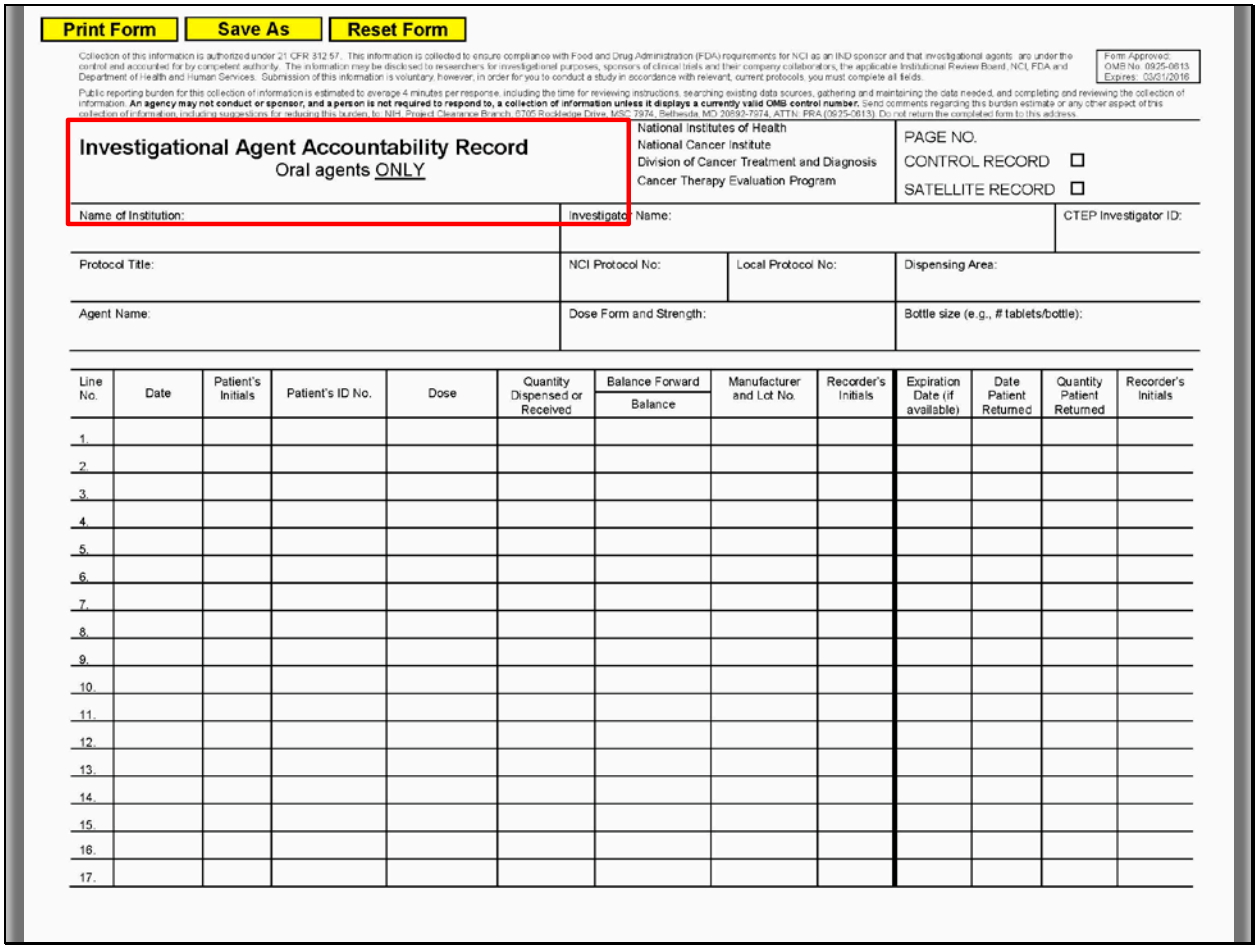


You can find the DARF and other forms on the CTEP website at http://ctep.cancer.gov/forms.

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



Print Form | Save As | Reset Form

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

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 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0613). Do not return the completed form to this address.

Investigational Agent Accountability Record
Oral agents ONLY

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

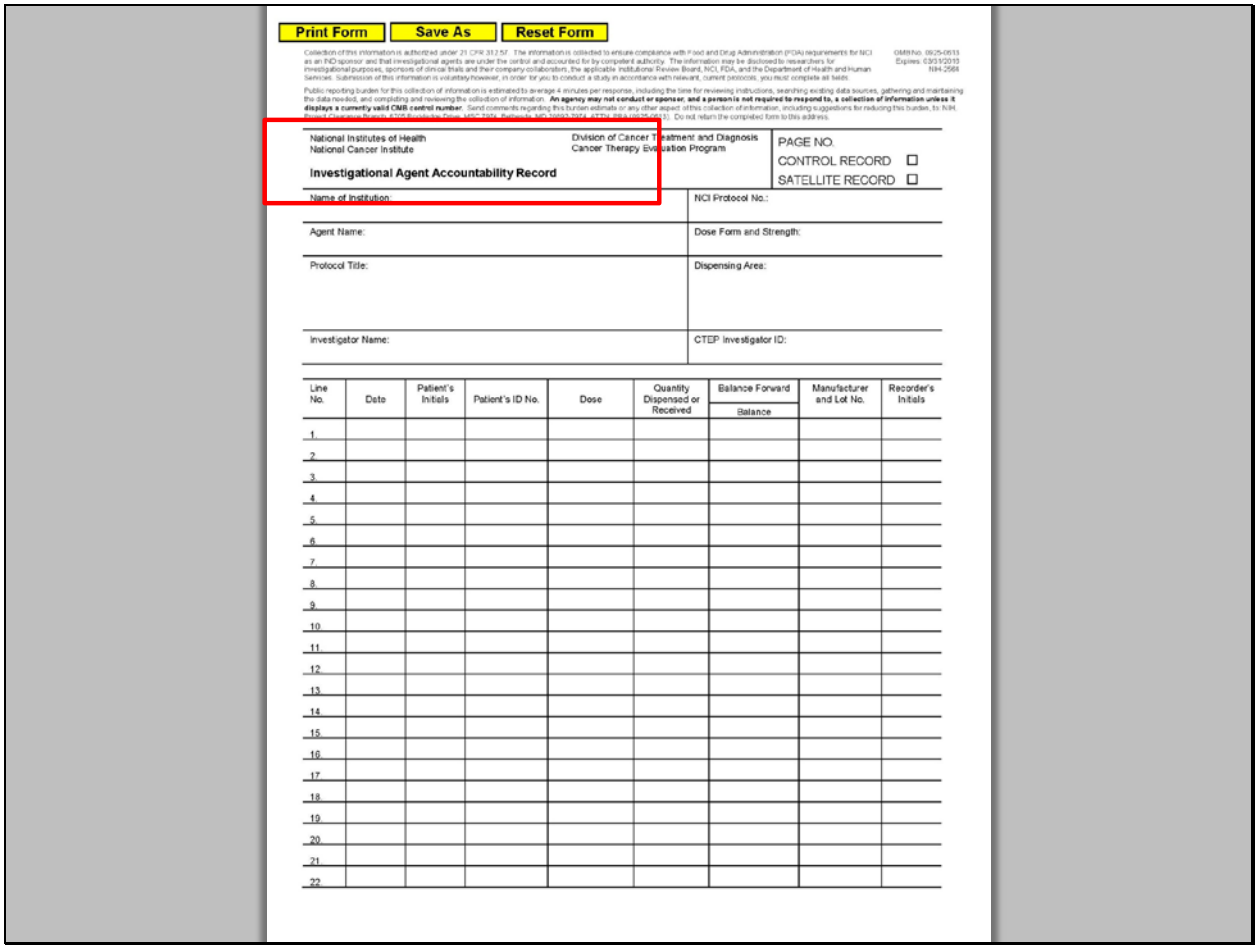
PAGE NO.
CONTROL RECORD ☐
SATELLITE RECORD ☐

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 / 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



Print Form Save As Reset Form

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Expires: 03/31/2013
NIH-2584

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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 ☐
SATELLITE RECORD ☐

Investigational Agent Accountability Record

Name of Institution:

NCI Protocol No.:

Agent Name:

Dose Form and Strength:

Protocol Title:

Dispensing Area:

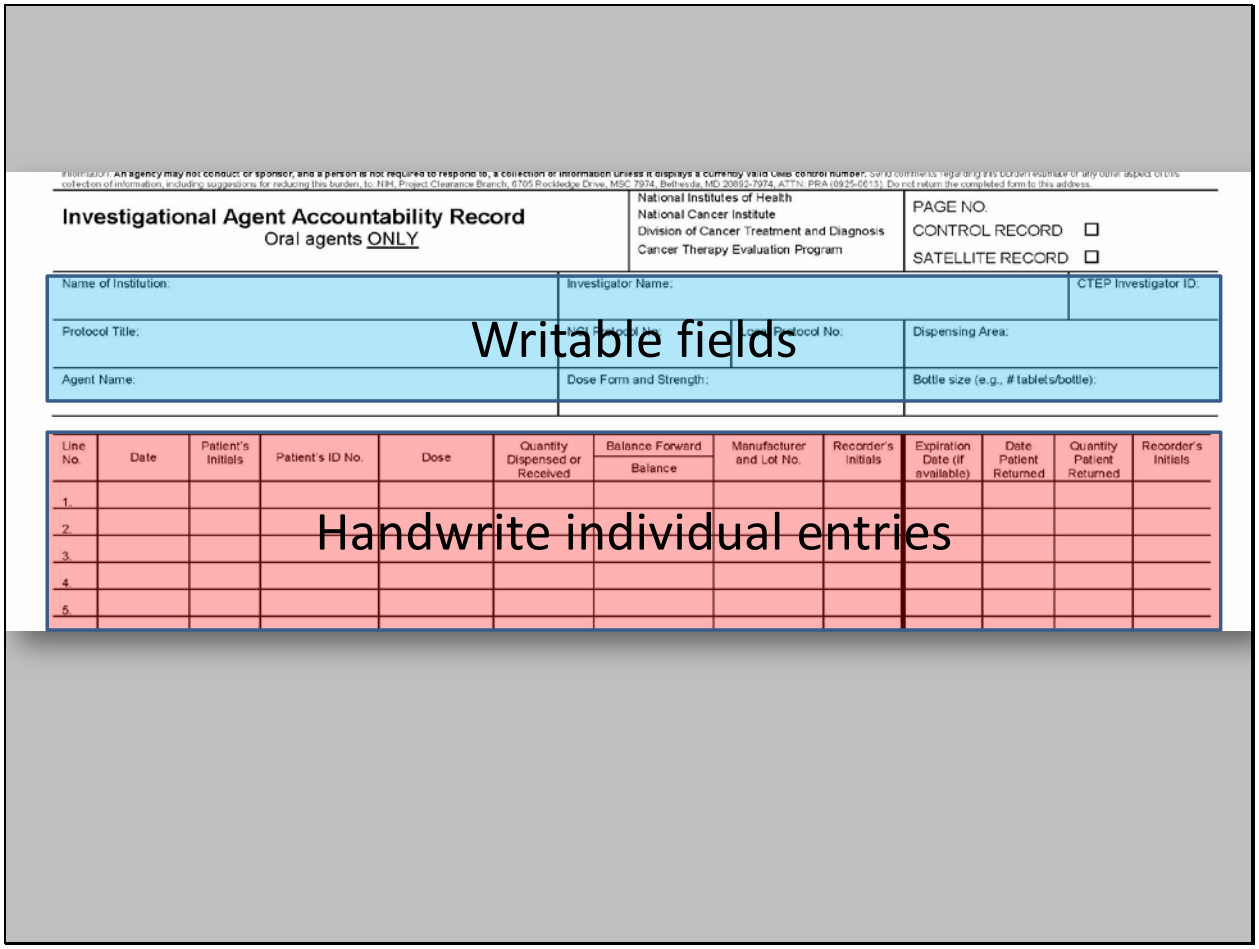
Investigator Name:

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.

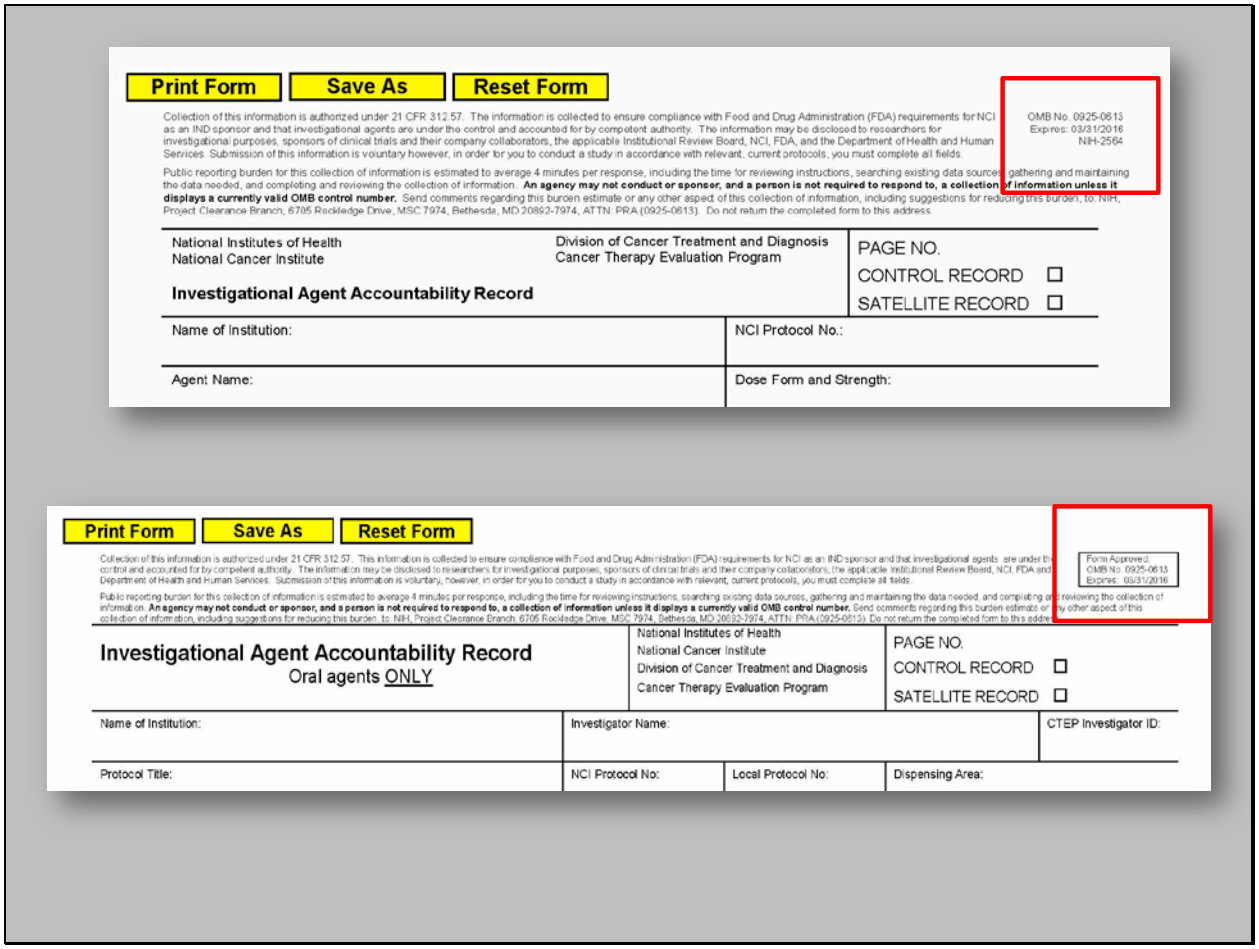
Slide 5



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.

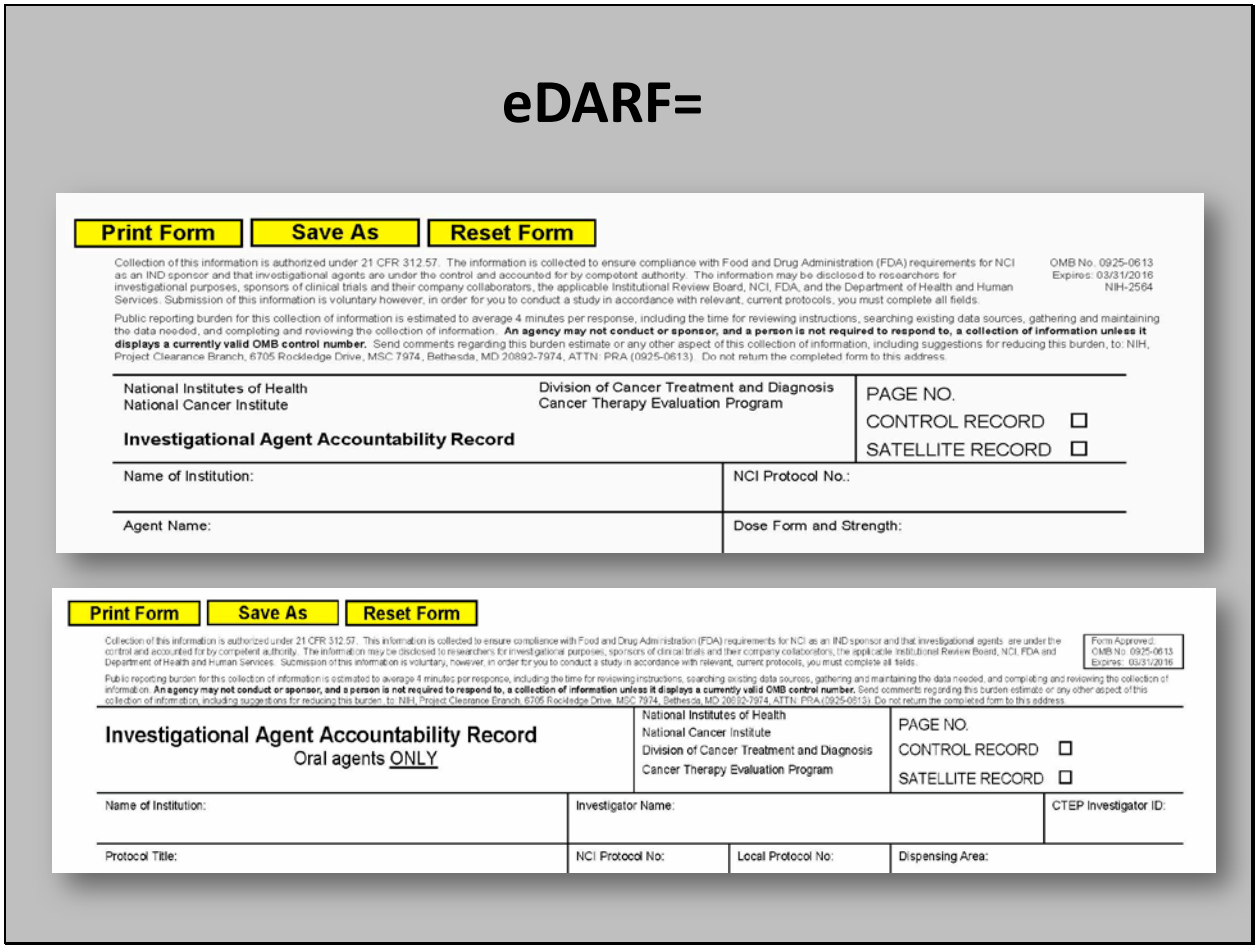
Slide 6



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.

Slide 7

eDARF=



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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 ☐
SATELLITE RECORD ☐

Investigational Agent Accountability Record

Name of Institution:

NCI Protocol No.:

Agent Name:

Dose Form and Strength:

Print Form Save As Reset Form

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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:

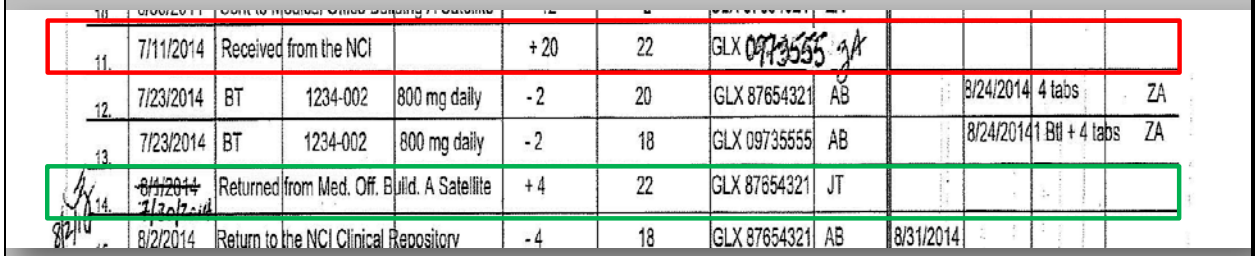
Local Protocol No:

Dispensing Area:

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

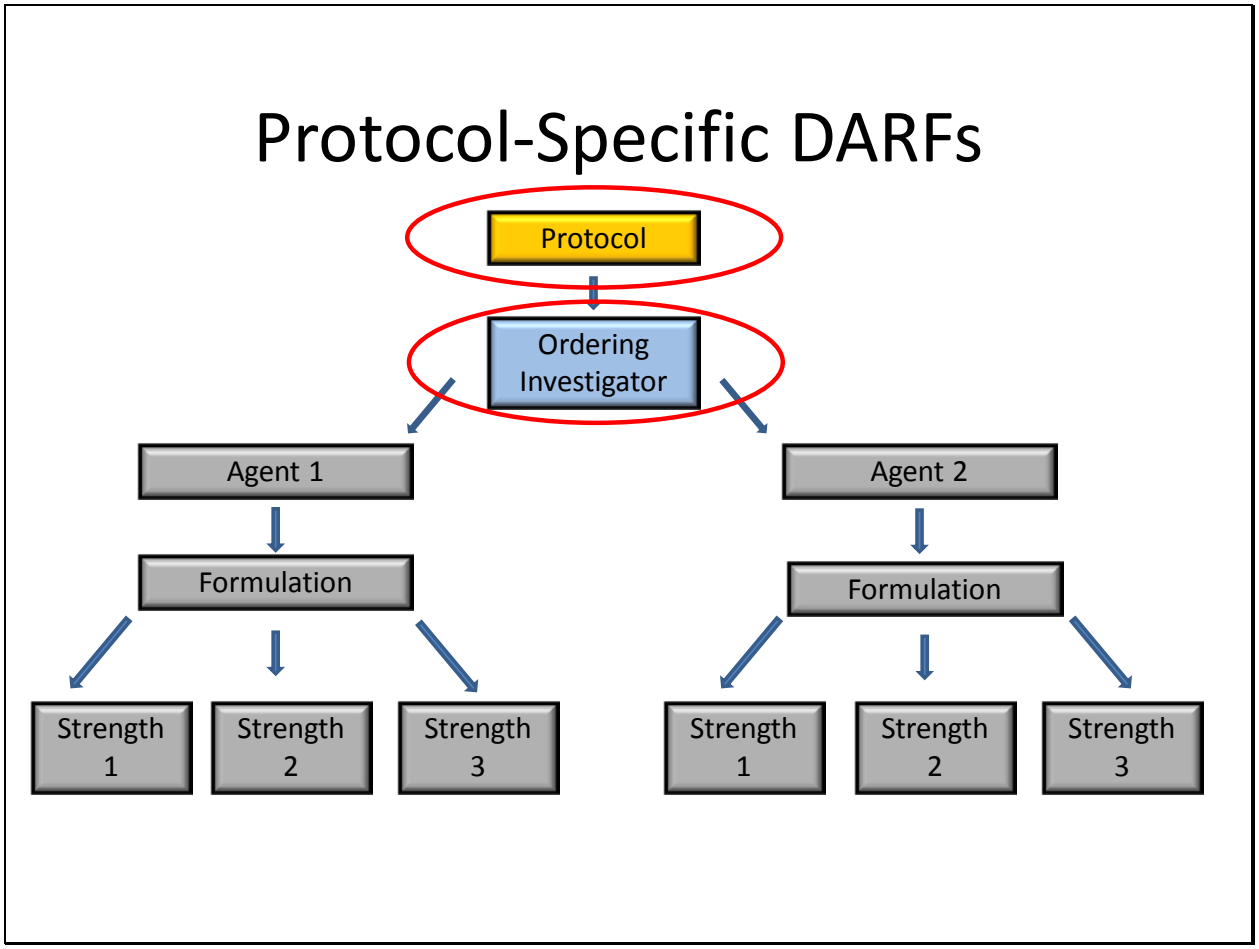


11.	7/11/2014	Received from the NCI			+ 20	22	GLX 09735555 gk					
12.	7/23/2014	BT	1234-002	800 mg daily	- 2	20	GLX 87654321	AB		8/24/2014	4 tabs	ZA
13.	7/23/2014	BT	1234-002	800 mg daily	- 2	18	GLX 09735555	AB		8/24/2014	1 Btl + 4 tabs	ZA
14.	~~8/1/2014~~ 8/2/2014 gk	Returned from Med. Off. Build. 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 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.

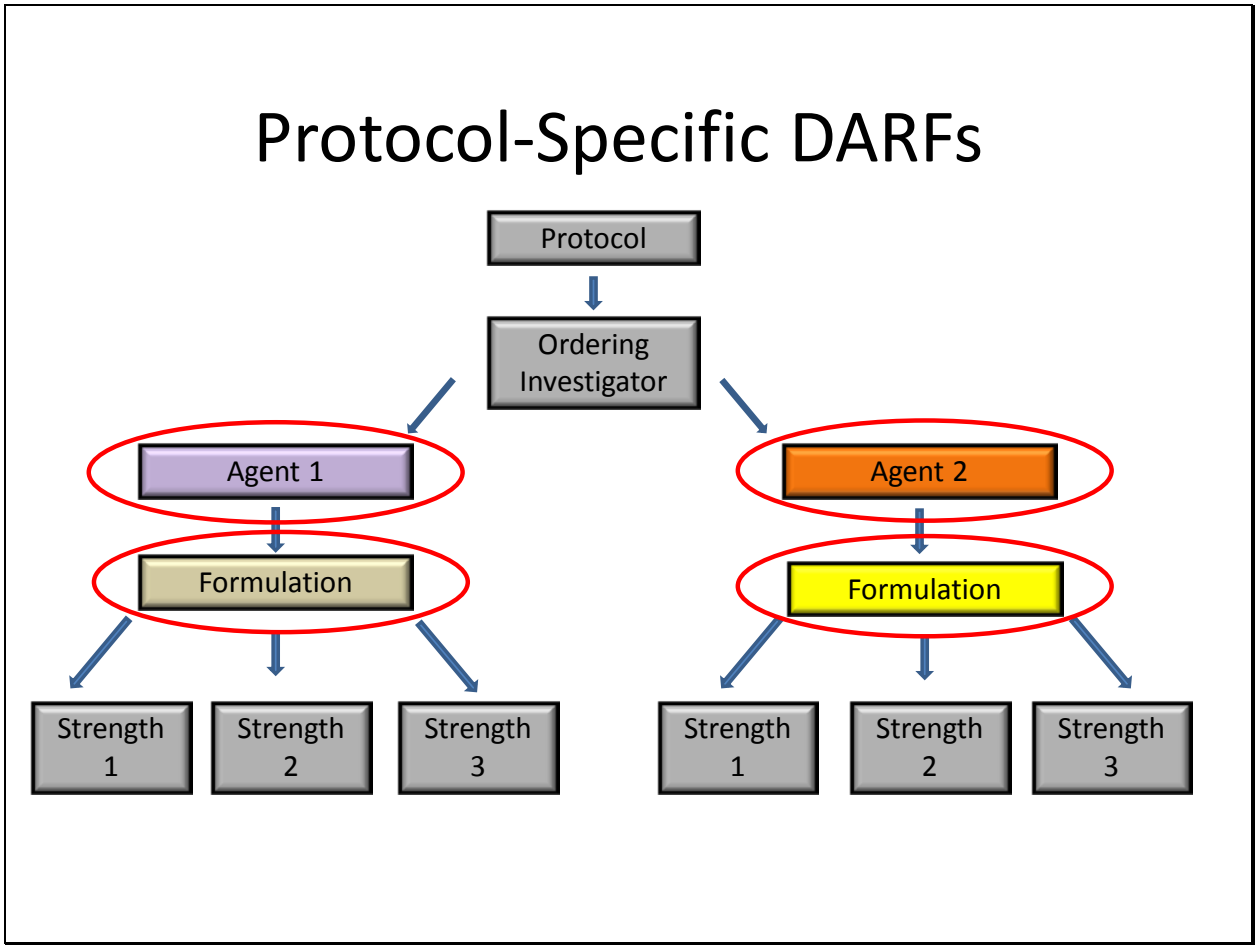
Corrections made in any electronic accountability system also need to be appropriately documented.

Slide 9



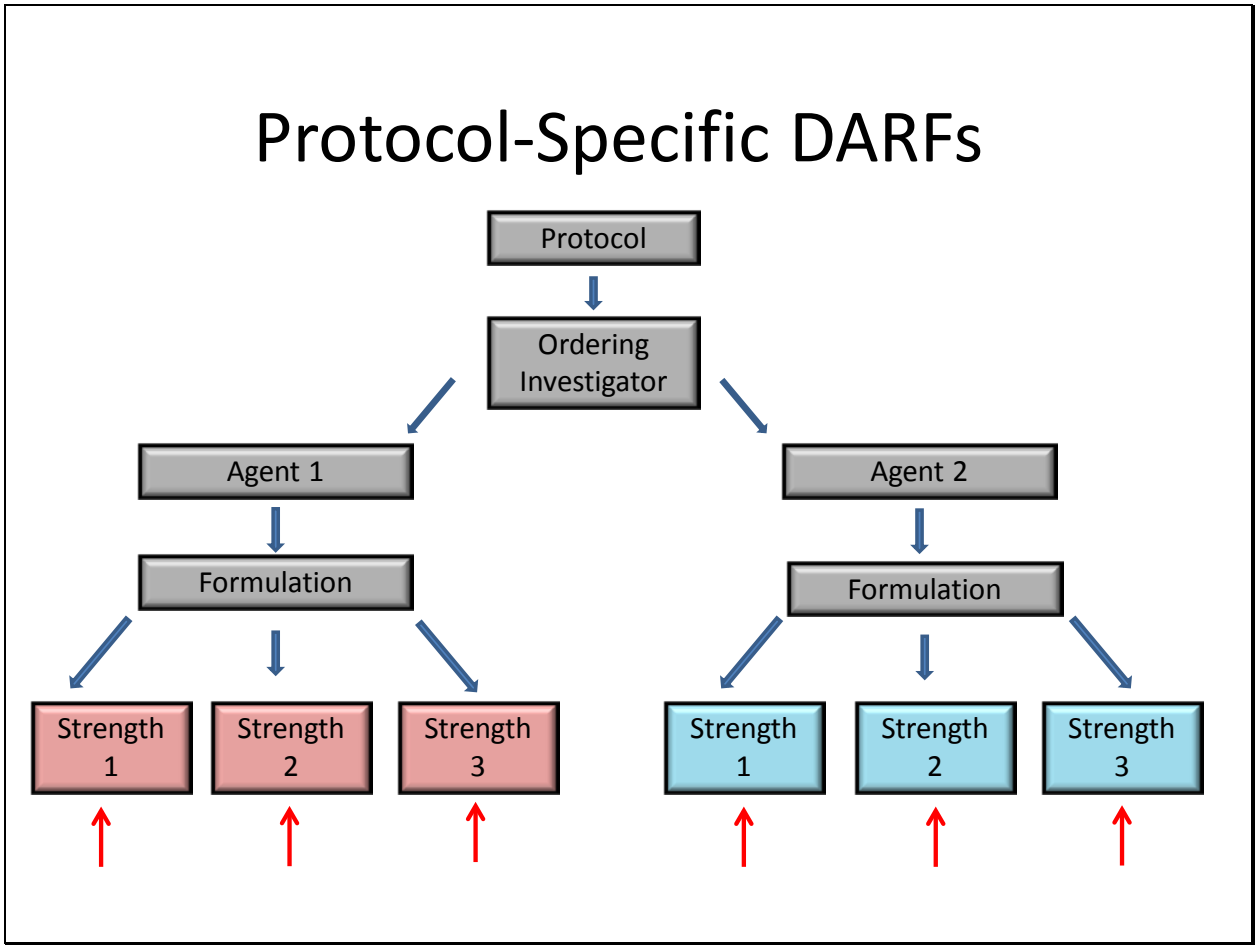
Separate DARFs are required for each protocol and for each ordering investigator.

Slide 10



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

Slide 11

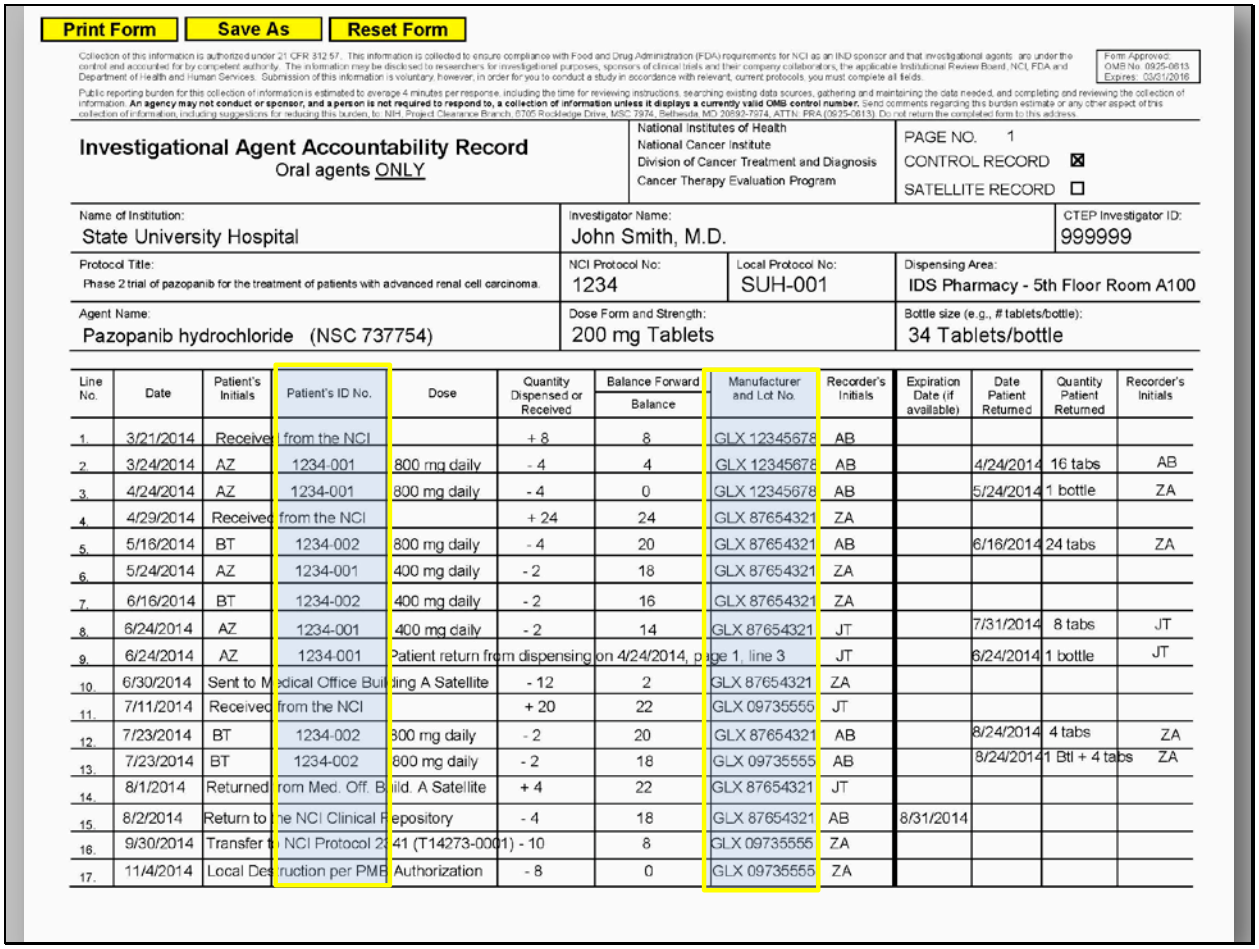


In the example, six DARFs are required, one for each strength.

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



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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. 1
CONTROL RECORD ☒
SATELLITE RECORD ☐

Name of Institution:	Investigator Name:	CTEP Investigator ID:
State University Hospital	John 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.	1234	SUH-001	IDS Pharmacy - 5th Floor Room A100

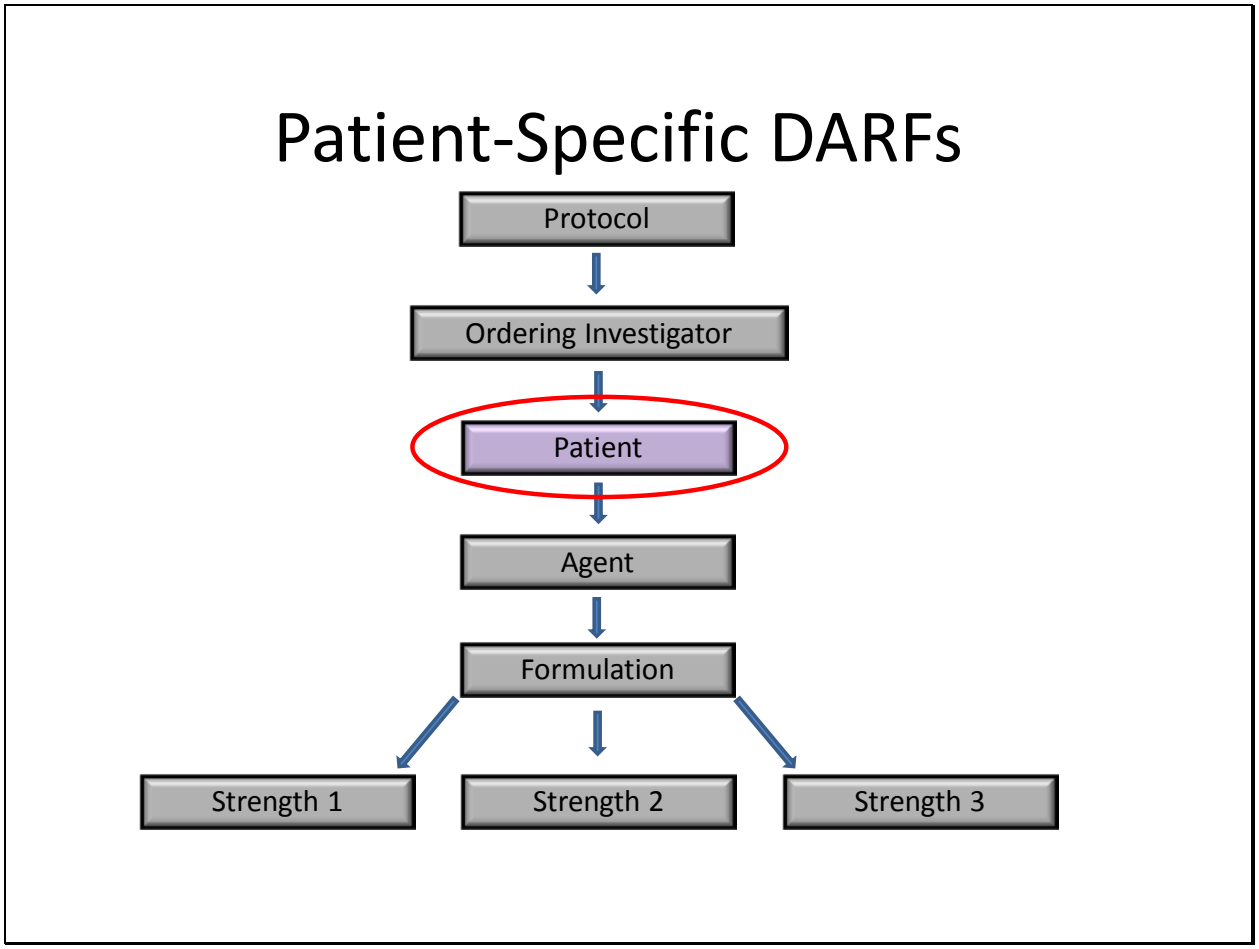
Agent Name:	Dose Form and Strength:	Bottle size (e.g., # tablets/bottle):
Pazopanib hydrochloride (NSC 737754)	200 mg Tablets	34 Tablets/bottle

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		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. Bild. 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 2241 (T14273-0001)			- 10	8	GLX 09735555	ZA				
17.	11/4/2014	Local Destruction 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.

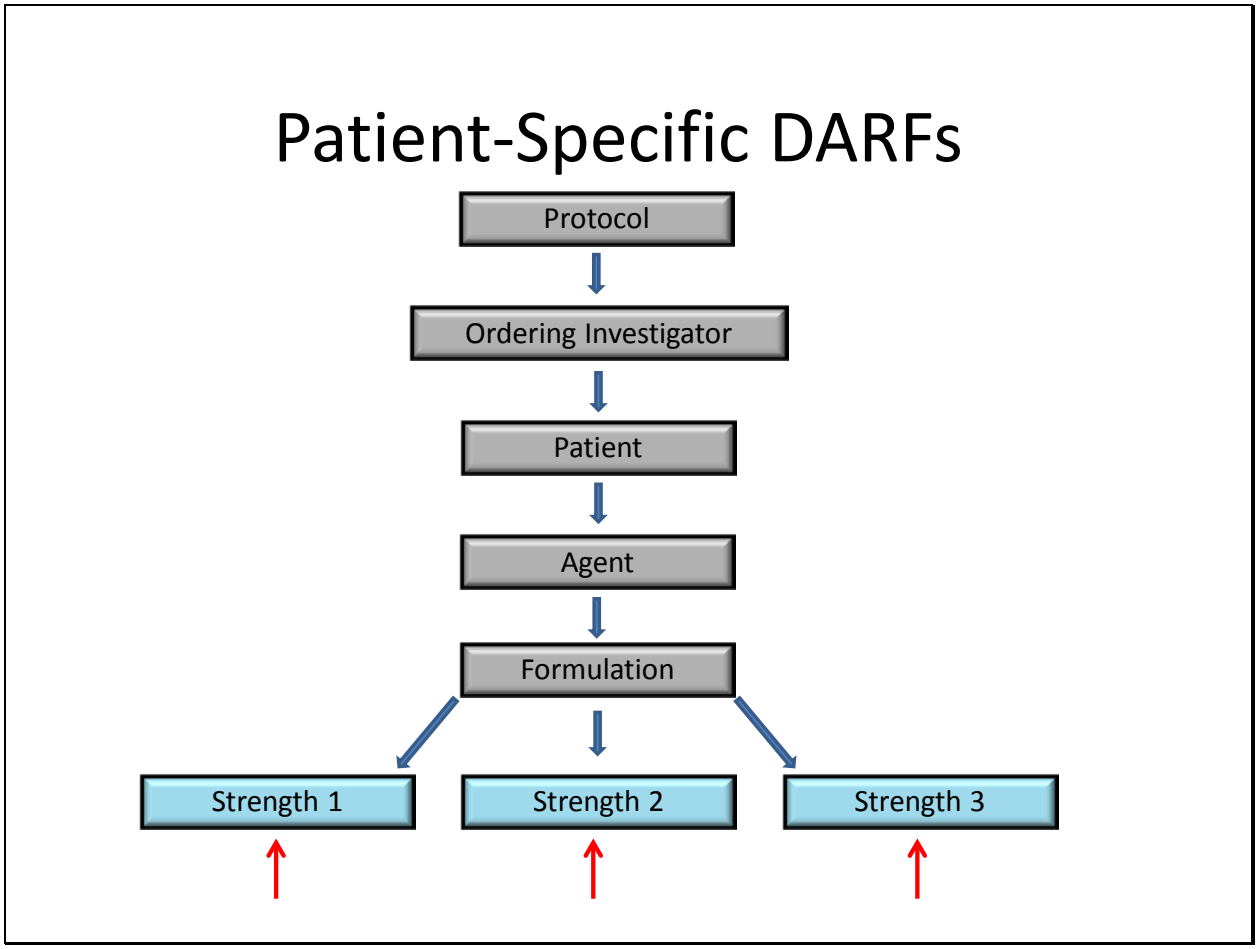
Slide 13



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.

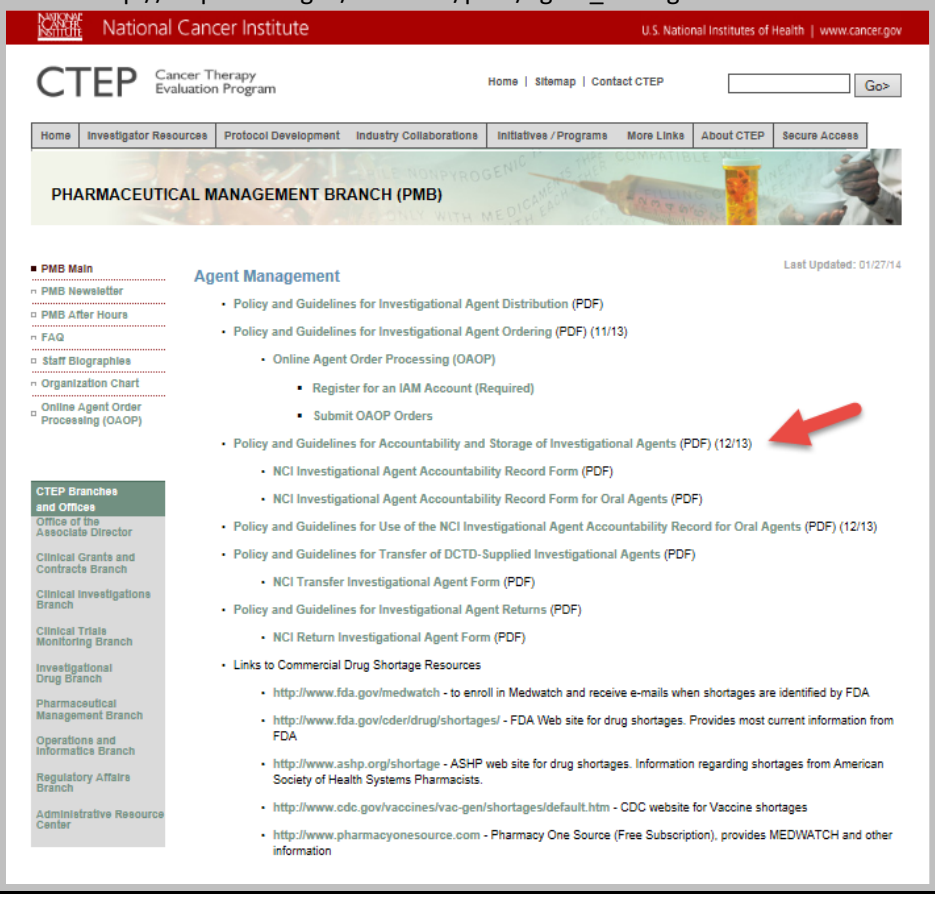
Slide 14



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.

Slide 15

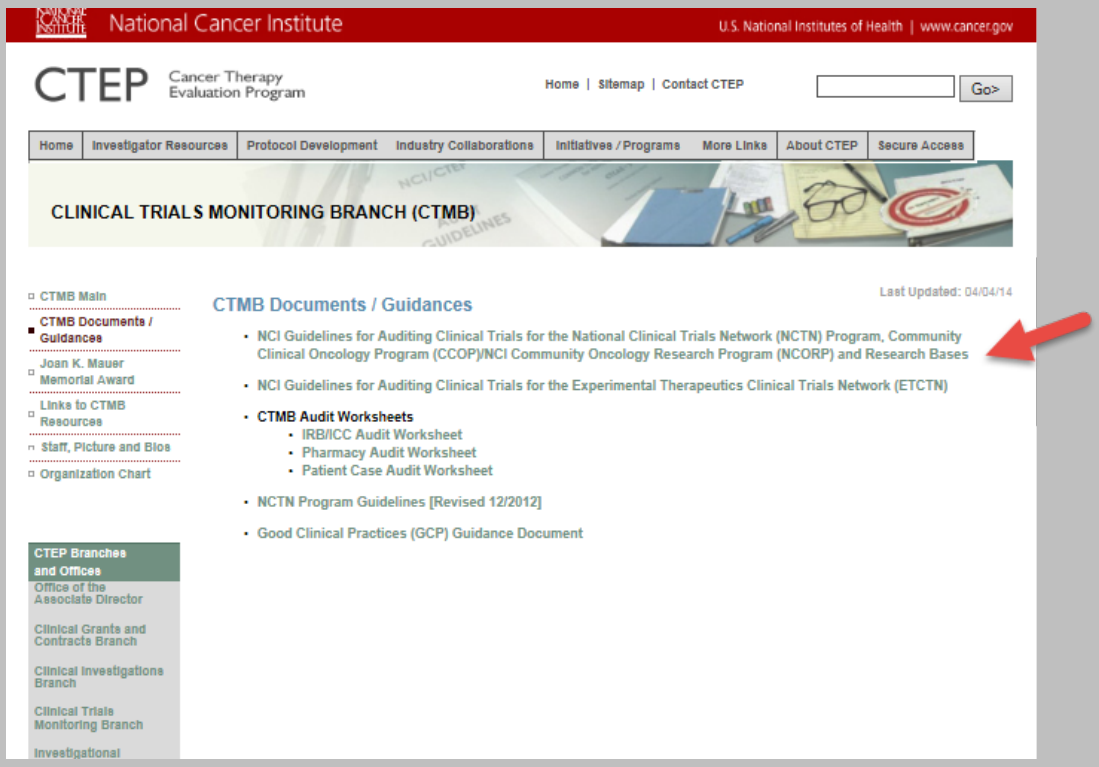
http://ctep.cancer.gov/branches/pmb/agent_management.htm



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.

Slide 16

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



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.

Slide 17

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.

Slide 18

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National Institutes of Health | National Cancer Institute

http://ctep.cancer.gov/

1-800-4-CANCER

Produced September 2014