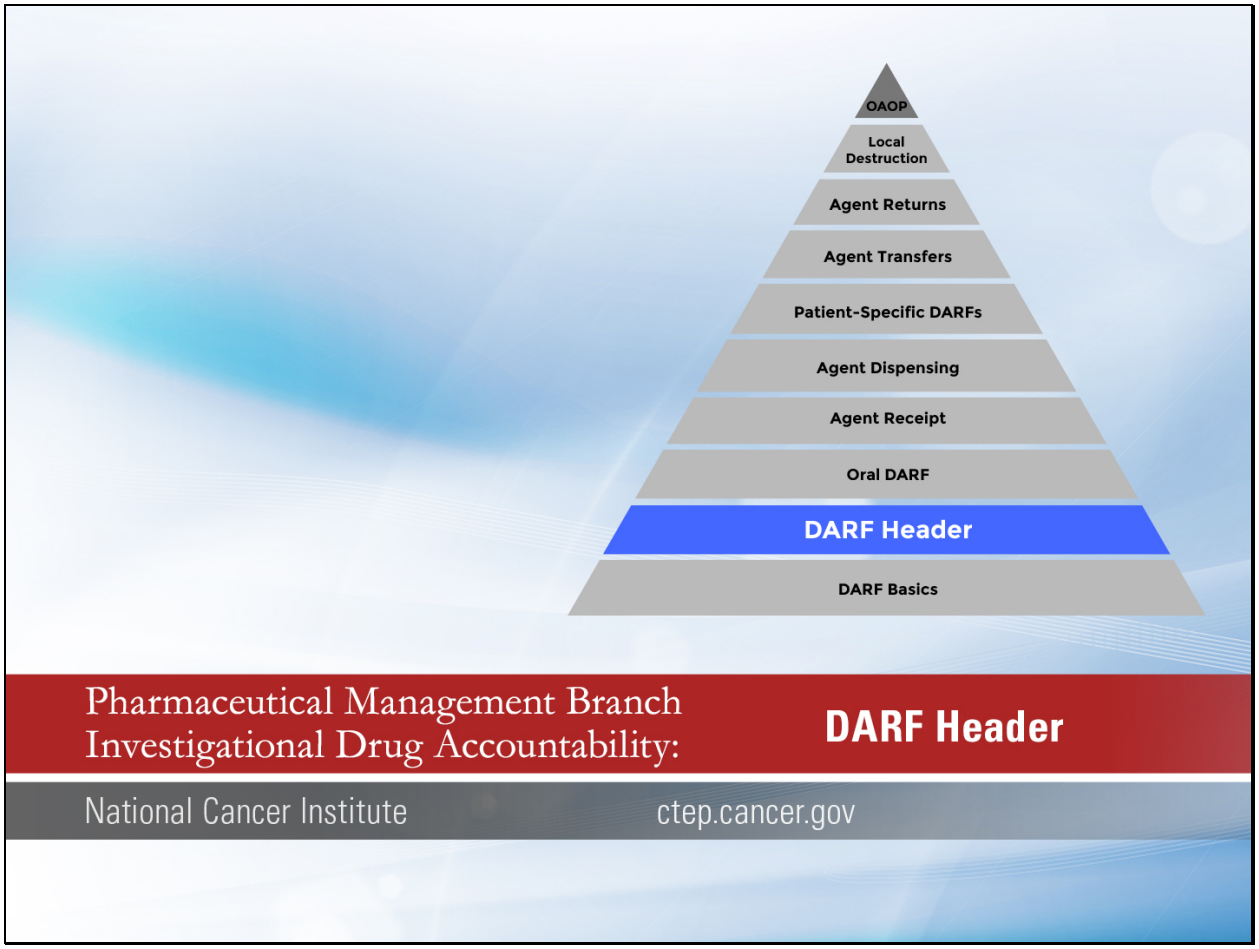
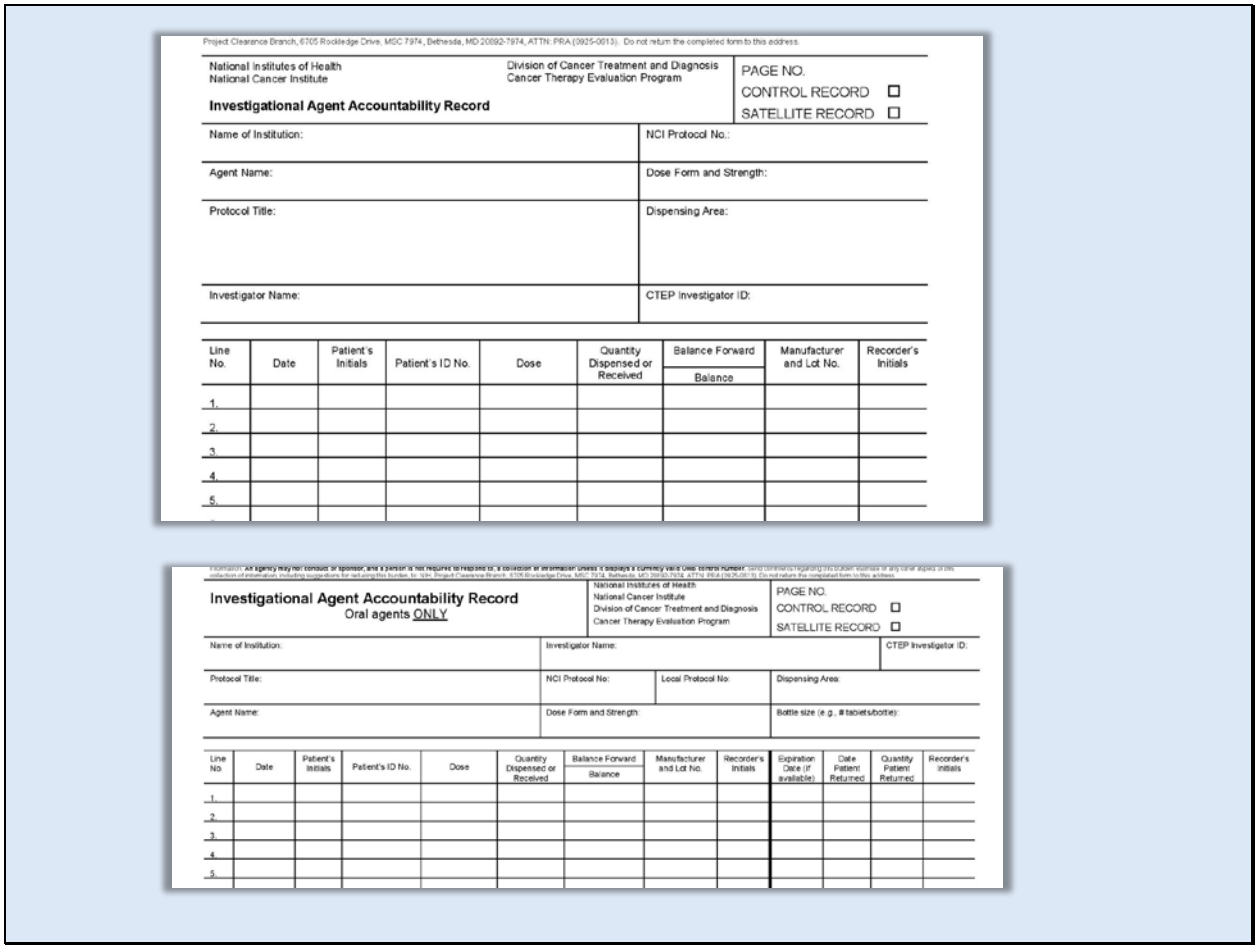
Slide 1



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

This video will review the process for completing the header of both the original and oral NCI DARF.

Slide 2



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.

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.								

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):

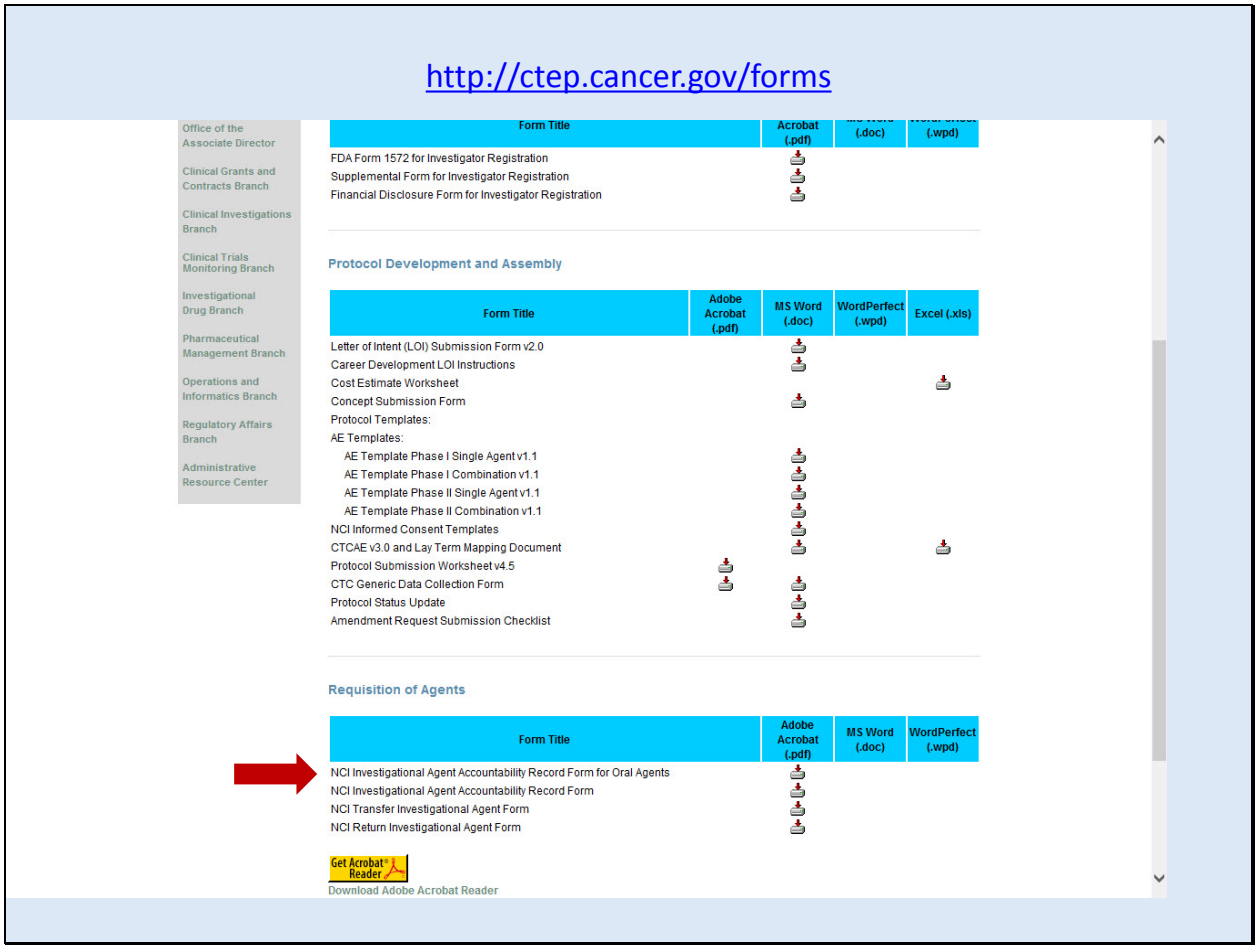
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
1.												
2.												
3.												
4.												
5.												

There are two Drug Accountability Record Forms: the original DARF and the Oral DARF.

You see the original DARF at the top of the screen and the Oral DARF underneath it.

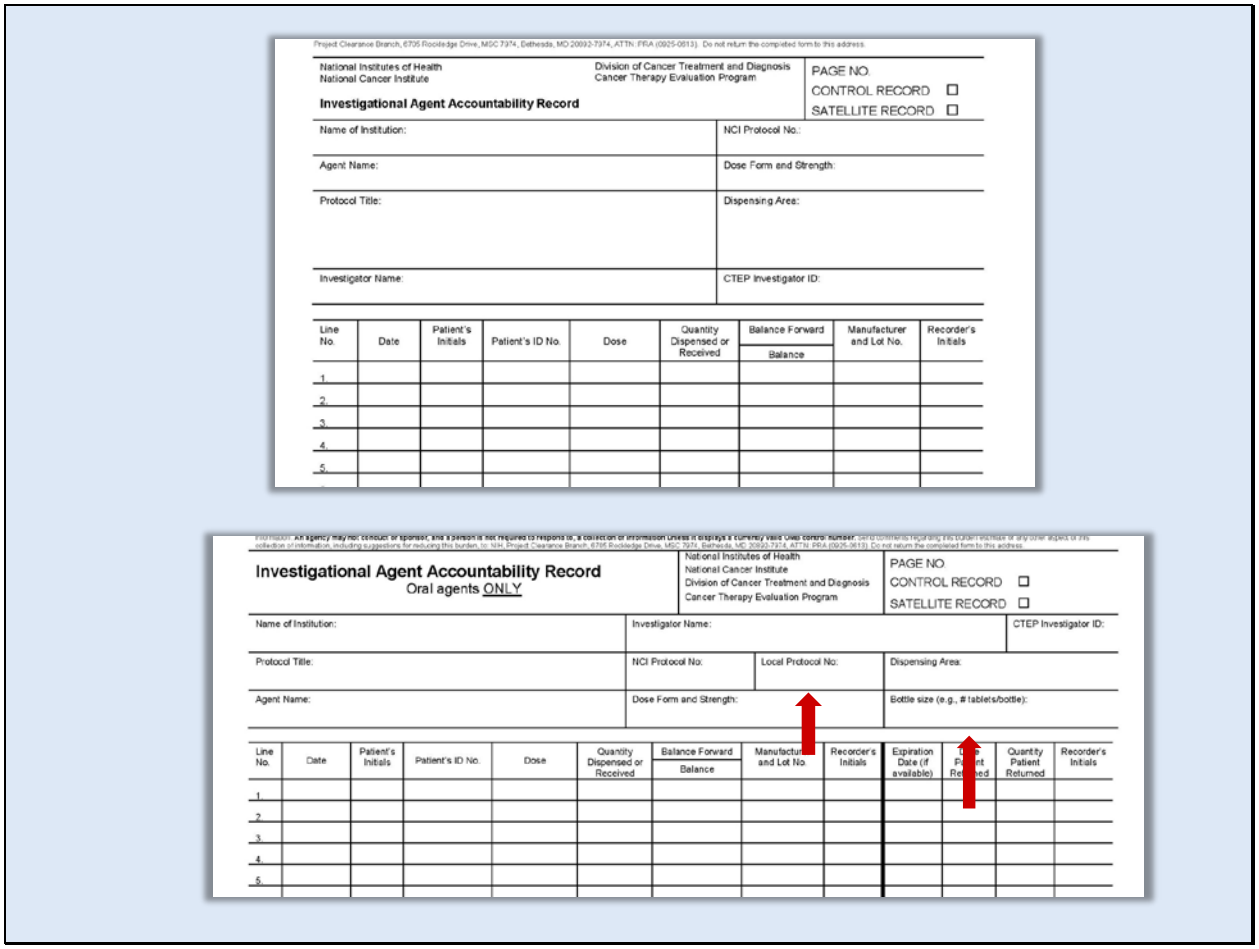
DARFs must be maintained to track the disposition of all study-supplied agents for NCI clinical trials.

Slide 3



Both DARFs are available on the CTEP website at http://ctep.cancer.gov/forms.

Slide 4



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Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

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.								

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):

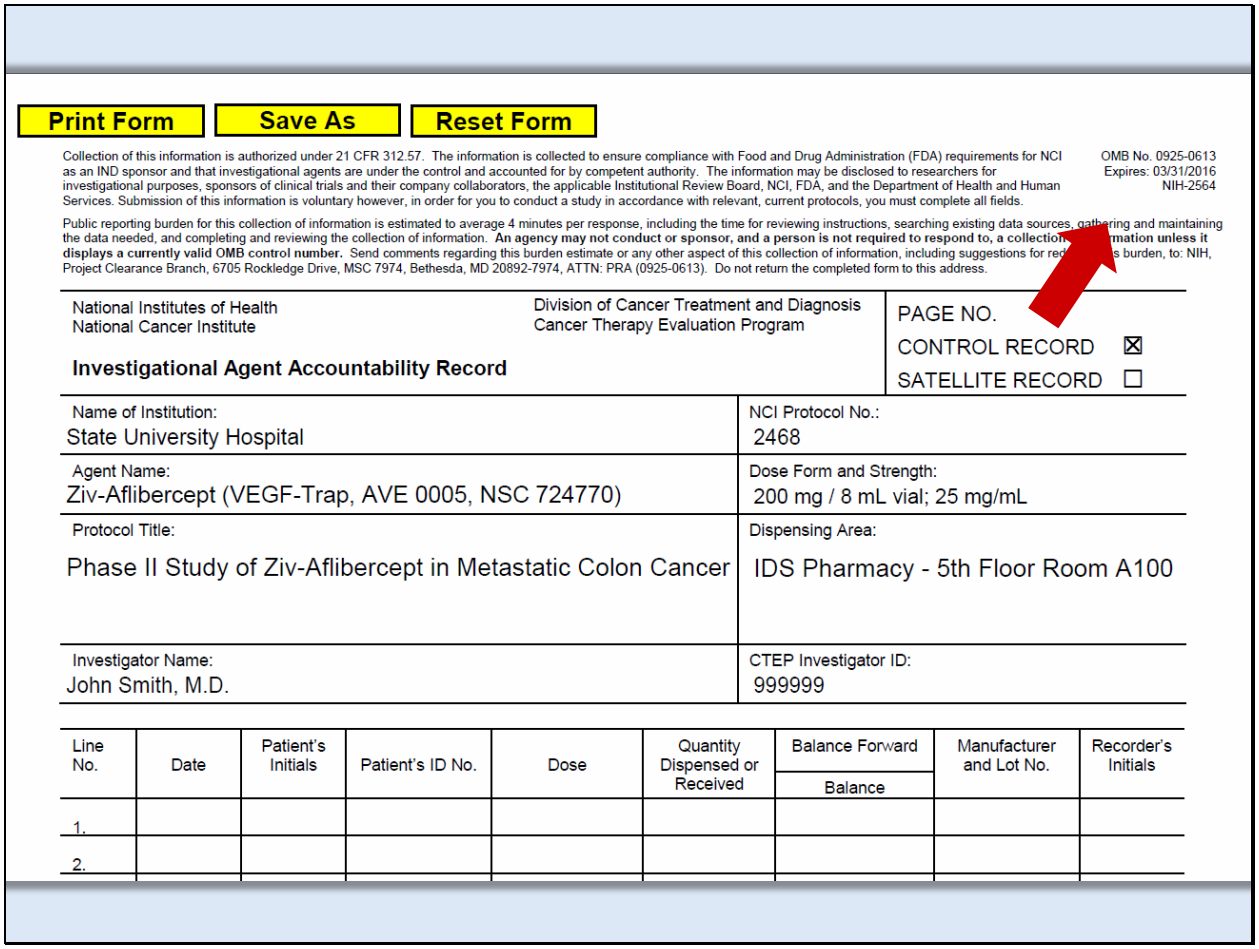
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
1.												
2.												
3.												
4.												
5.												

The header is the top section of the DARF above the agent transaction area. All fields must be completed on every page.

The headers of the original DARF and Oral DARF contain the same information with 2 exceptions: the Oral DARF contains areas to include the local protocol number and the bottle size.

Unless specifically stated, the information provided applies to both the original DARF and the Oral DARF.

Slide 5



Print Form Save As Reset Form

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

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National Cancer Institute

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Cancer Therapy Evaluation Program

PAGE NO.
CONTROL RECORD ☒
SATELLITE RECORD ☐

Investigational Agent Accountability Record

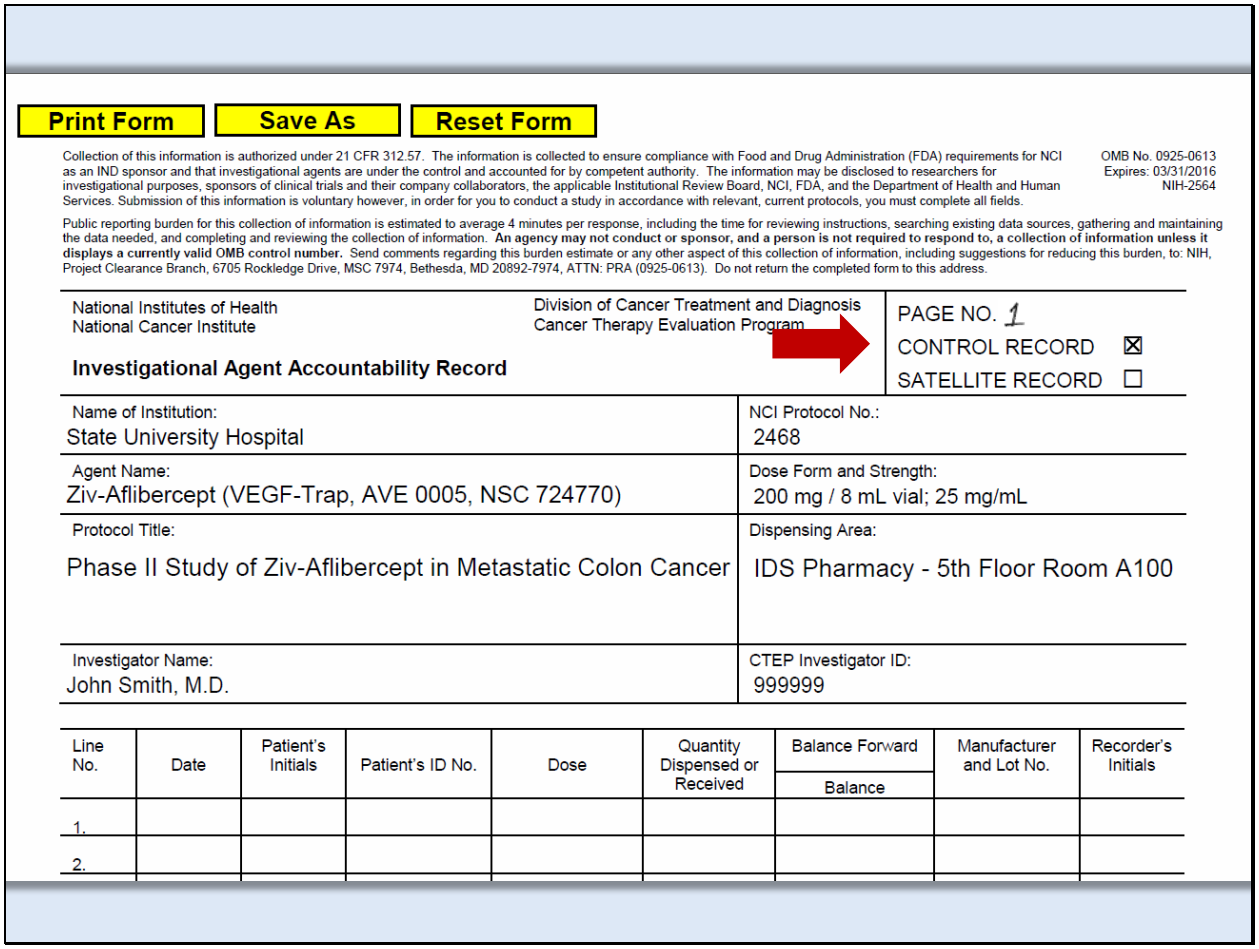
Name of Institution:	NCI Protocol No.:
State University Hospital	2468
Agent Name:	**Dose Form and Strength:**
Ziv-Aflibercept (VEGF-Trap, AVE 0005, NSC 724770)	200 mg / 8 mL vial; 25 mg/mL
Protocol Title:	**Dispensing Area:**
Phase II Study of Ziv-Aflibercept in Metastatic Colon Cancer	IDS Pharmacy - 5th Floor Room A100
Investigator Name:	**CTEP Investigator ID:**
John Smith, M.D.	999999

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.								

Note that the form has an expiration date located in the upper right corner. Once the expiration date has passed, do not start a new page without verifying it is the current form on the CTEP website.

In the event the current form on the website is expired, continue to use it until an updated form is posted.

Slide 6



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Investigational Agent Accountability Record

PAGE NO. 1
CONTROL RECORD ☒
SATELLITE RECORD ☐

Name of Institution:	NCI Protocol No.:
State University Hospital	2468
Agent Name:	**Dose Form and Strength:**
Ziv-Aflibercept (VEGF-Trap, AVE 0005, NSC 724770)	200 mg / 8 mL vial; 25 mg/mL
Protocol Title:	**Dispensing Area:**
Phase II Study of Ziv-Aflibercept in Metastatic Colon Cancer	IDS Pharmacy - 5th Floor Room A100
Investigator Name:	**CTEP Investigator ID:**
John Smith, M.D.	999999

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.								

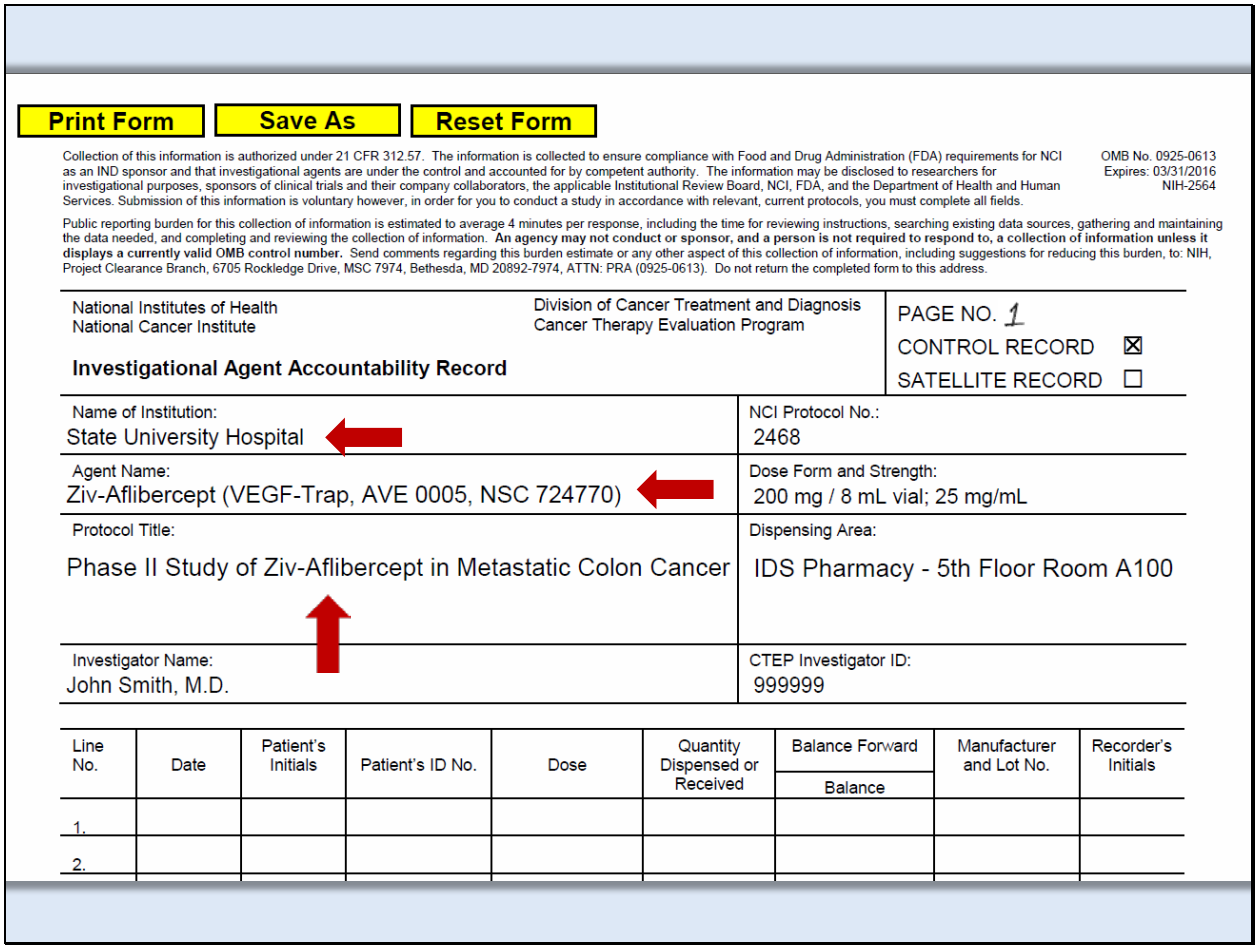
The header information can be typed before the DARF is printed or handwritten after printing. Please note the font size will automatically adjust based on the number of characters in the field. Anything handwritten must be legible.

Let's begin reviewing the header:

The first area to complete is the page number and record type. The DARF templates do not allow for the inclusion of a page number, it must be written in after printing.

Check the box indicating if this is a control or satellite record.

Slide 7



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PAGE NO. 1
CONTROL RECORD ☒
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Investigational Agent Accountability Record

Name of Institution: State University Hospital	NCI Protocol No.: 2468
Agent Name: Ziv-Aflibercept (VEGF-Trap, AVE 0005, NSC 724770)	Dose Form and Strength: 200 mg / 8 mL vial; 25 mg/mL
Protocol Title: Phase II Study of Ziv-Aflibercept in Metastatic Colon Cancer	Dispensing Area: IDS Pharmacy - 5th Floor Room A100
Investigator Name: John Smith, M.D.	CTEP Investigator ID: 999999

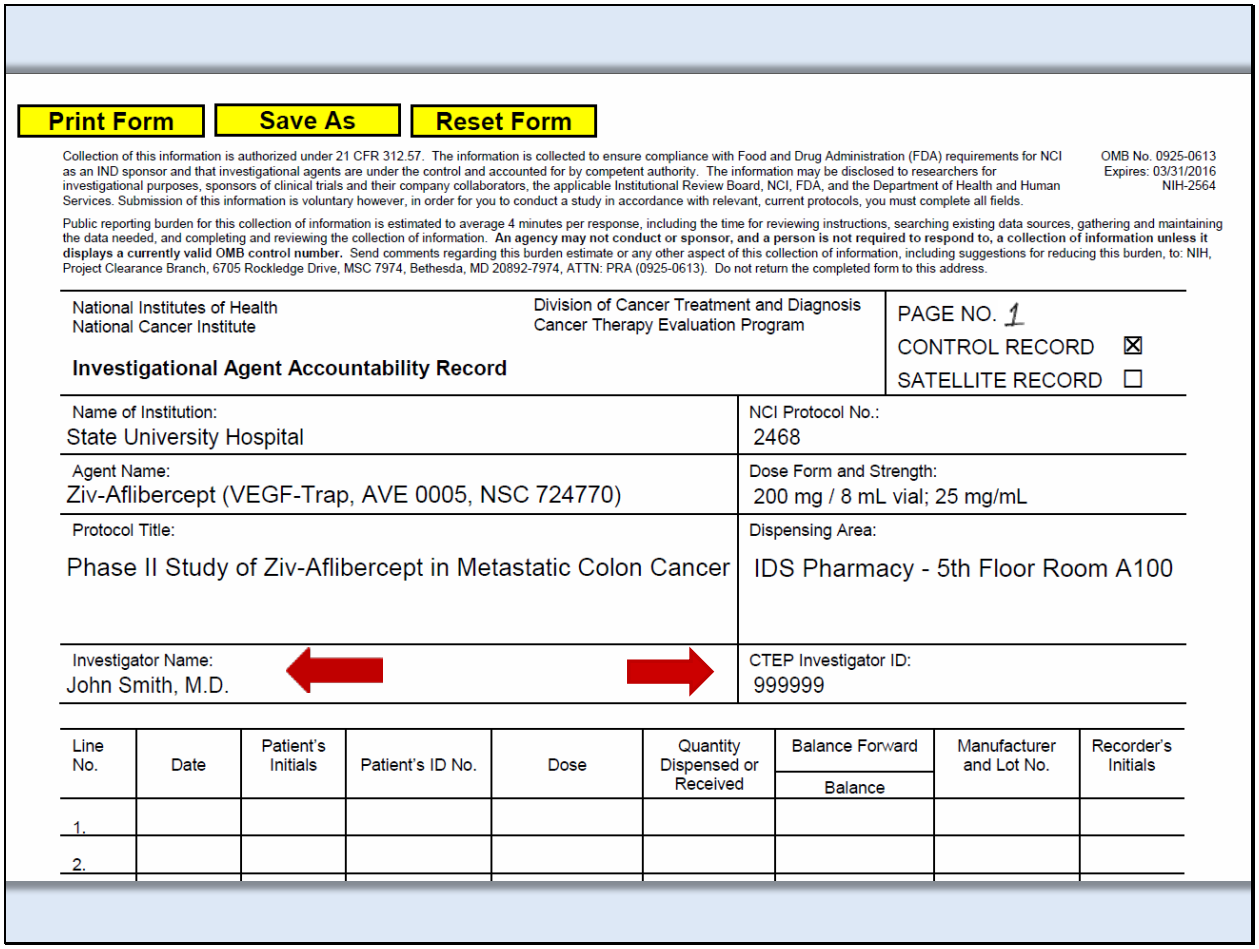
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials
1.								
2.								

Under the Name of Institution write out the name, avoiding abbreviations if possible.

For Agent Name include all names on the shipping receipt. While not required, add the NSC number.

Add the Protocol Title. Long titles can be abbreviated, but not to the point the protocol is unidentifiable or could be confused with another trial.

Slide 8



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Investigational Agent Accountability Record

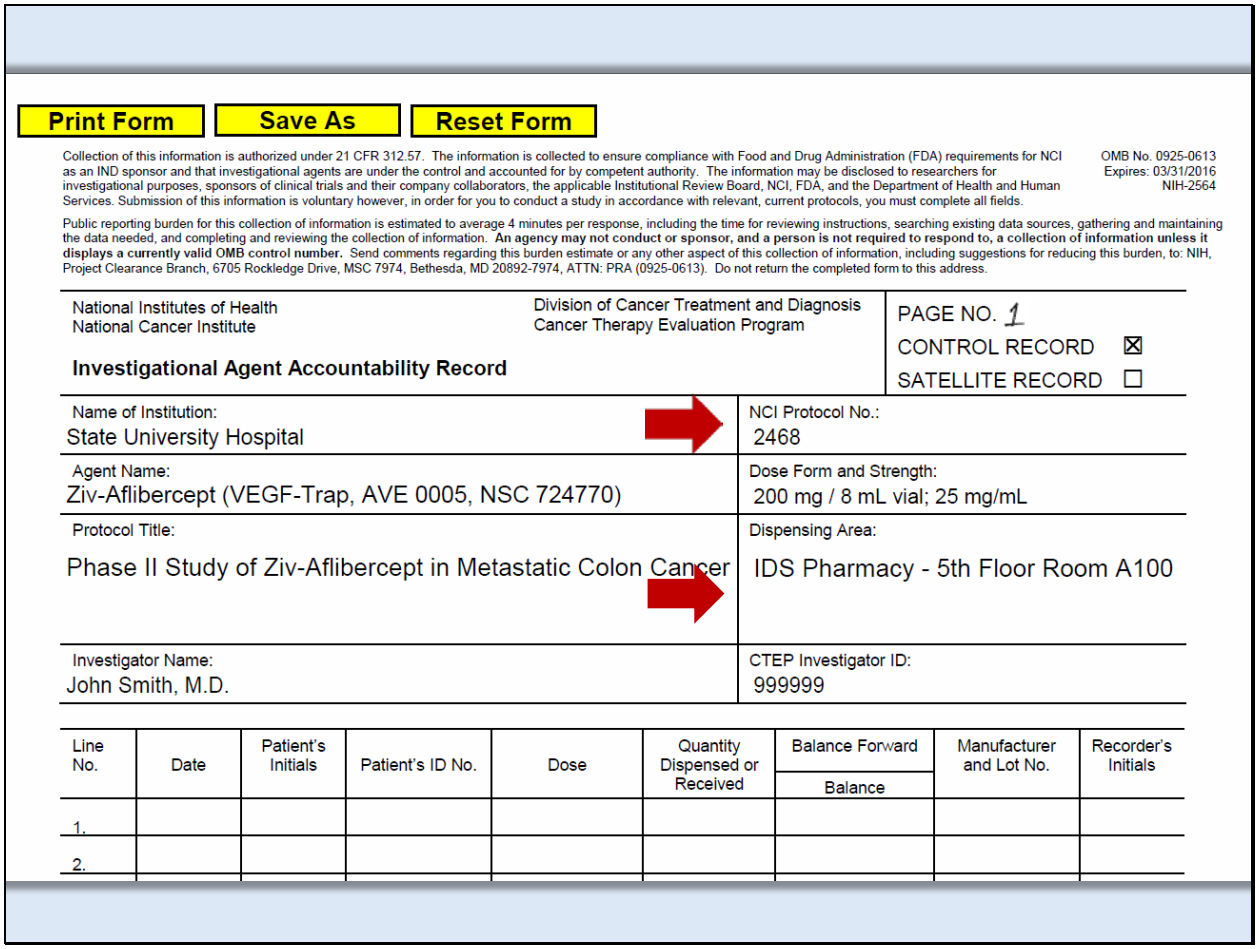
Name of Institution:	NCI Protocol No.:
State University Hospital	2468
Agent Name:	**Dose Form and Strength:**
Ziv-Aflibercept (VEGF-Trap, AVE 0005, NSC 724770)	200 mg / 8 mL vial; 25 mg/mL
Protocol Title:	**Dispensing Area:**
Phase II Study of Ziv-Aflibercept in Metastatic Colon Cancer	IDS Pharmacy - 5th Floor Room A100
Investigator Name:	**CTEP Investigator ID:**
John Smith, M.D.	999999

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.								

For the Investigator Name include the first and last name. This is especially important with common last names such as Smith.

Add the CTEP Investigator Number. Note that a separate DARF is required for each ordering investigator.

Slide 9



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PAGE NO. 1
CONTROL RECORD ☒
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Investigational Agent Accountability Record

Name of Institution: State University Hospital

NCI Protocol No.: 2468

Agent Name: Ziv-Aflibercept (VEGF-Trap, AVE 0005, NSC 724770)

Dose Form and Strength: 200 mg / 8 mL vial; 25 mg/mL

Protocol Title: Phase II Study of Ziv-Aflibercept in Metastatic Colon Cancer

Dispensing Area: IDS Pharmacy - 5th Floor Room A100

Investigator Name: John Smith, M.D.

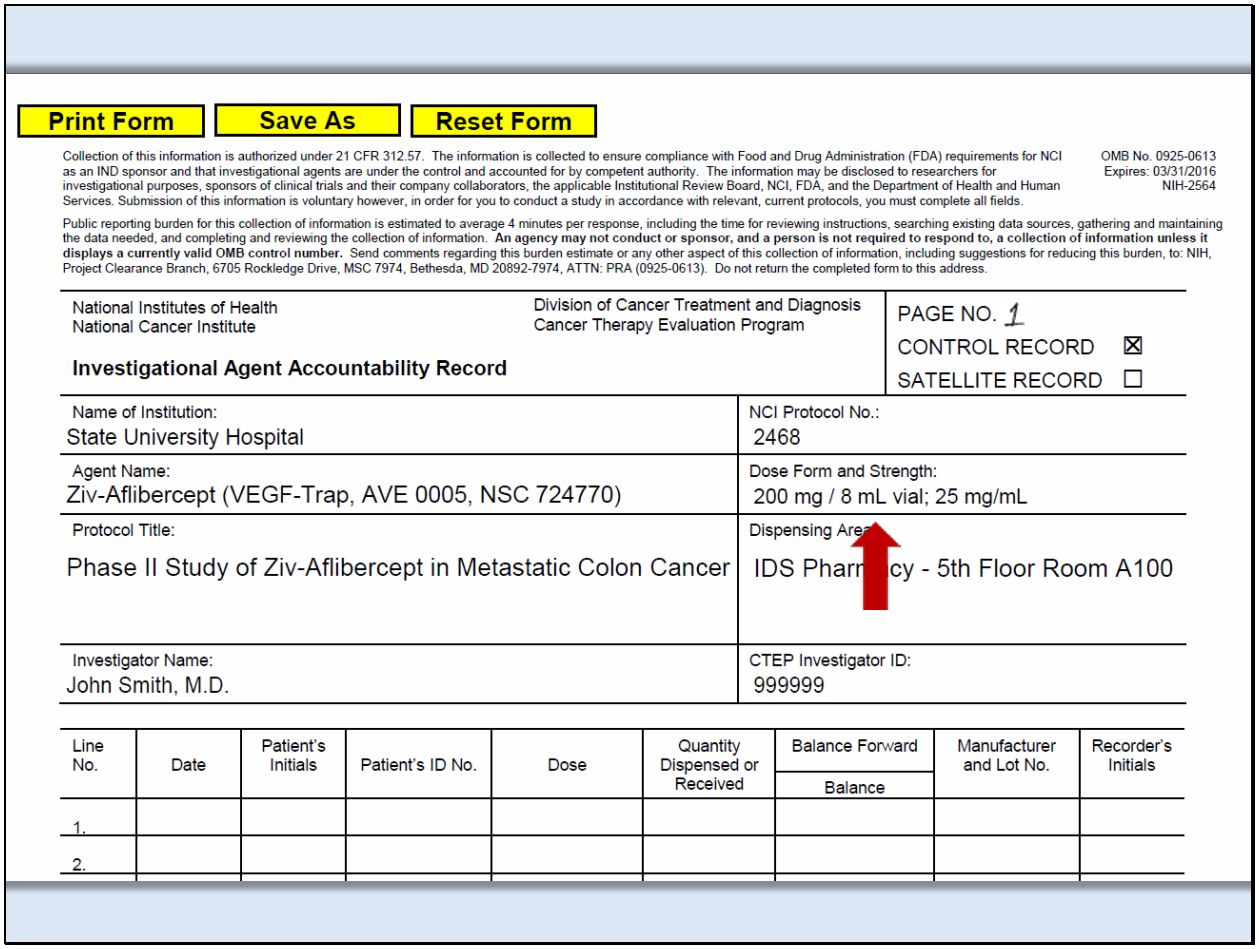
CTEP Investigator ID: 999999

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.								

Next is the NCI Protocol Number. The NCI protocol number is required. The local protocol number is optional on both the original and Oral DARF. If a local protocol number is assigned, it can be added to the original or Oral DARF.

Next, identify the Dispensing Area. This is the location where the agent is stored.

Slide 10



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PAGE NO. 1
CONTROL RECORD ☒
SATELLITE RECORD ☐

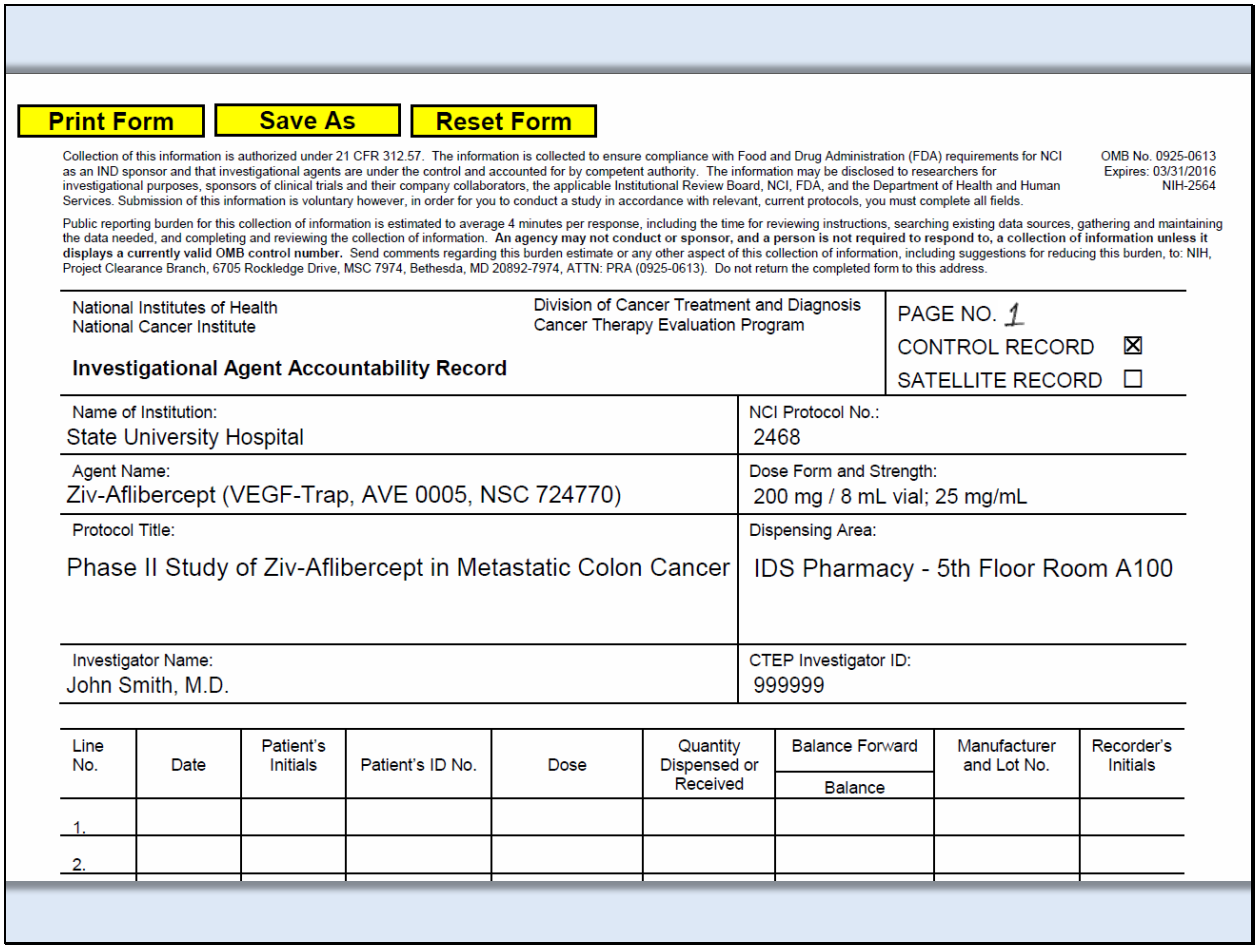
Investigational Agent Accountability Record

Name of Institution: State University Hospital	NCI Protocol No.: 2468
Agent Name: Ziv-Aflibercept (VEGF-Trap, AVE 0005, NSC 724770)	Dose Form and Strength: 200 mg / 8 mL vial; 25 mg/mL
Protocol Title: Phase II Study of Ziv-Aflibercept in Metastatic Colon Cancer	Dispensing Area: IDS Pharmacy - 5th Floor Room A100
Investigator Name: John Smith, M.D.	CTEP Investigator ID: 999999

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.								

Under Dose Form and Strength record the agent strength and formulation in this field. For injectable preparations include the concentration and volume per vial (for example 200 mg/8 mL vial, 25 mg/mL).

Slide 11



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Investigational Agent Accountability Record

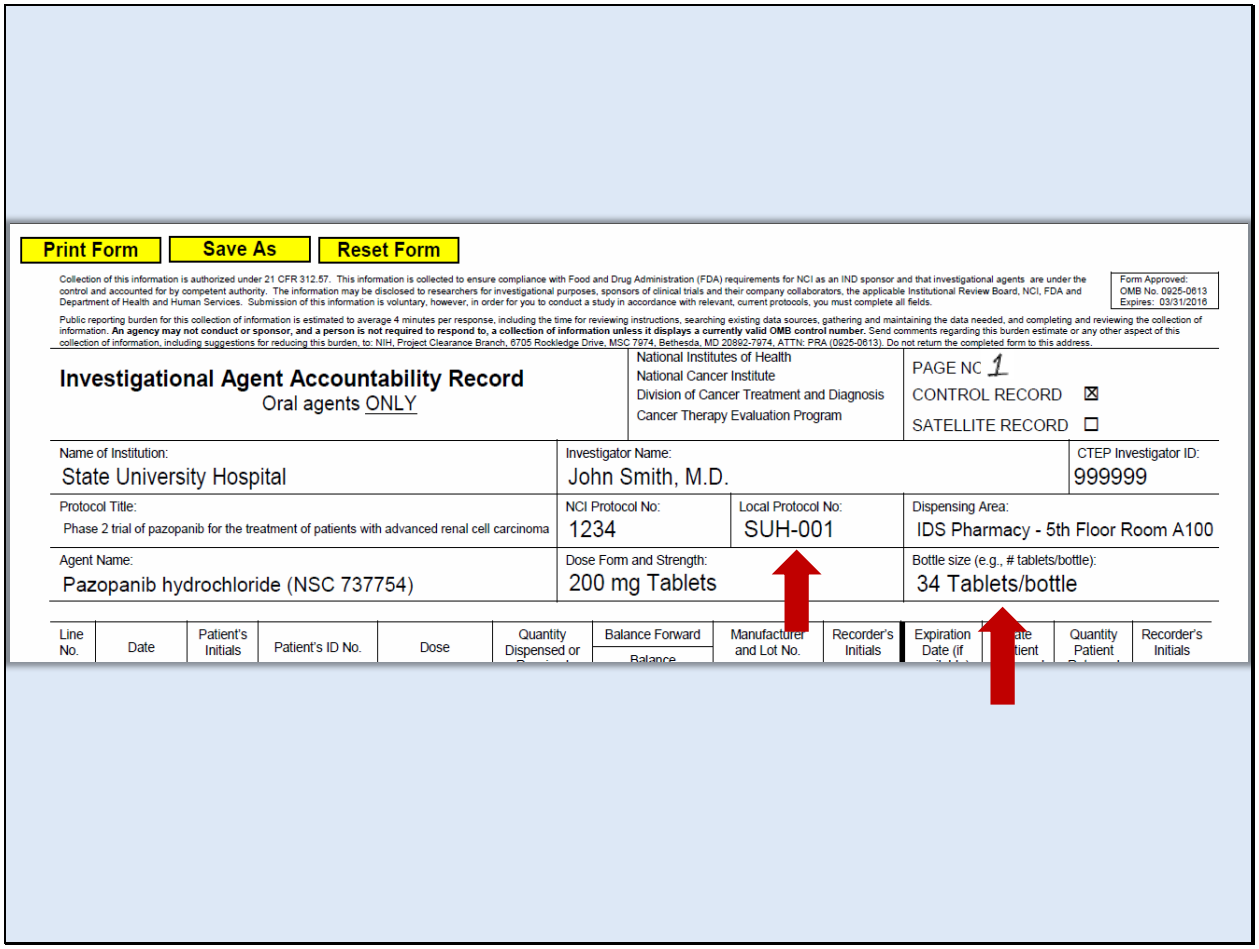
Name of Institution:	NCI Protocol No.:
State University Hospital	2468
Agent Name:	**Dose Form and Strength:**
Ziv-Aflibercept (VEGF-Trap, AVE 0005, NSC 724770)	200 mg / 8 mL vial; 25 mg/mL
Protocol Title:	**Dispensing Area:**
Phase II Study of Ziv-Aflibercept in Metastatic Colon Cancer	IDS Pharmacy - 5th Floor Room A100
Investigator Name:	**CTEP Investigator ID:**
John Smith, M.D.	999999

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.								

Here is an example of a completed original DARF header.

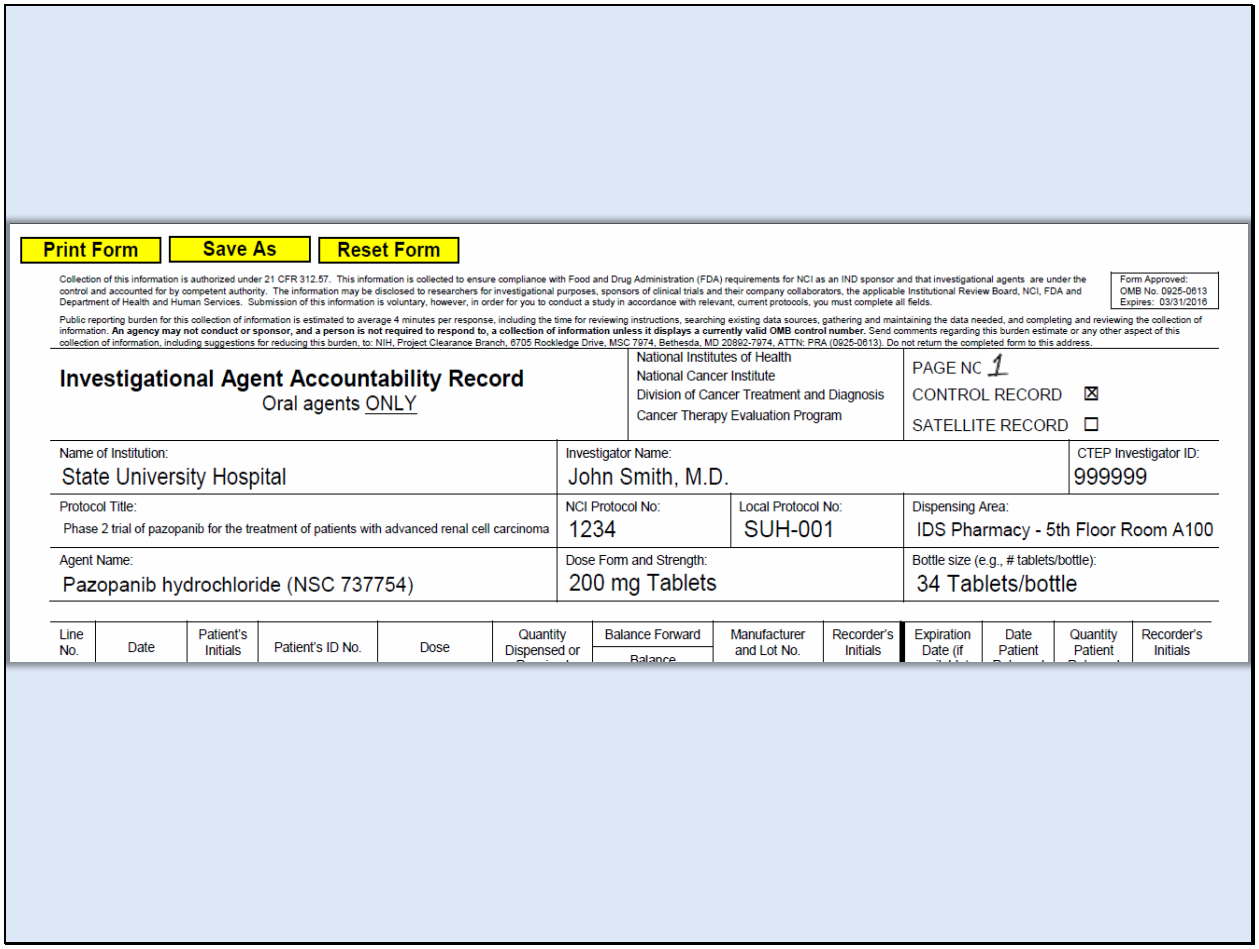
Next we will review the Oral DARF header.

Slide 12



There are two items specific to the Oral DARF. The Local Protocol Number, if there is no local number, leave the space blank or write in N/A and Bottle Size, add the number of tablets, capsules, etc. If this is a liquid preparation indicate the concentration and total volume per container.

Slide 13



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

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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 NC 1
CONTROL RECORD ☒
SATELLITE RECORD ☐

Name of Institution:	Investigator Name:	CTEP Investigator ID:
State University Hospital	John Smith, M.D.	999999

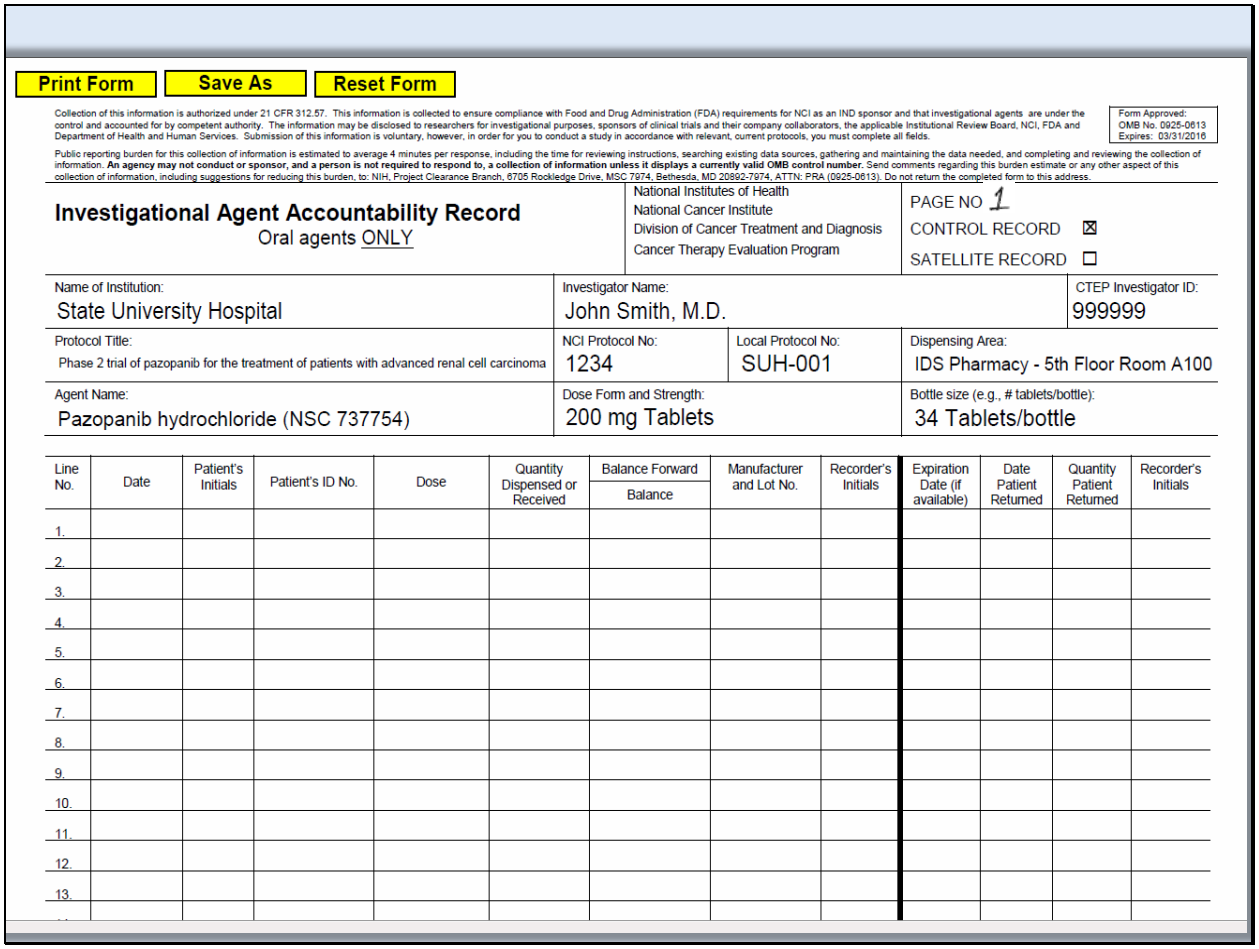
Protocol Title:	NCI Protocol No:	Local Protocol No:	Dispensing Area:
Phase 2 trial of pazopanib for the treatment of patients with advanced renal cell carcinoma	1234	SUH-001	IDS Pharmacy - 5th Floor Room A100

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	Balance Forward / Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if	Date Patient	Quantity Patient	Recorder's Initials

Here is an example of a completed Oral DARF header.

Slide 14



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.

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 1
CONTROL RECORD ☒
SATELLITE RECORD ☐

Name of Institution:	Investigator Name:	CTEP Investigator ID:
State University Hospital	John Smith, M.D.	999999

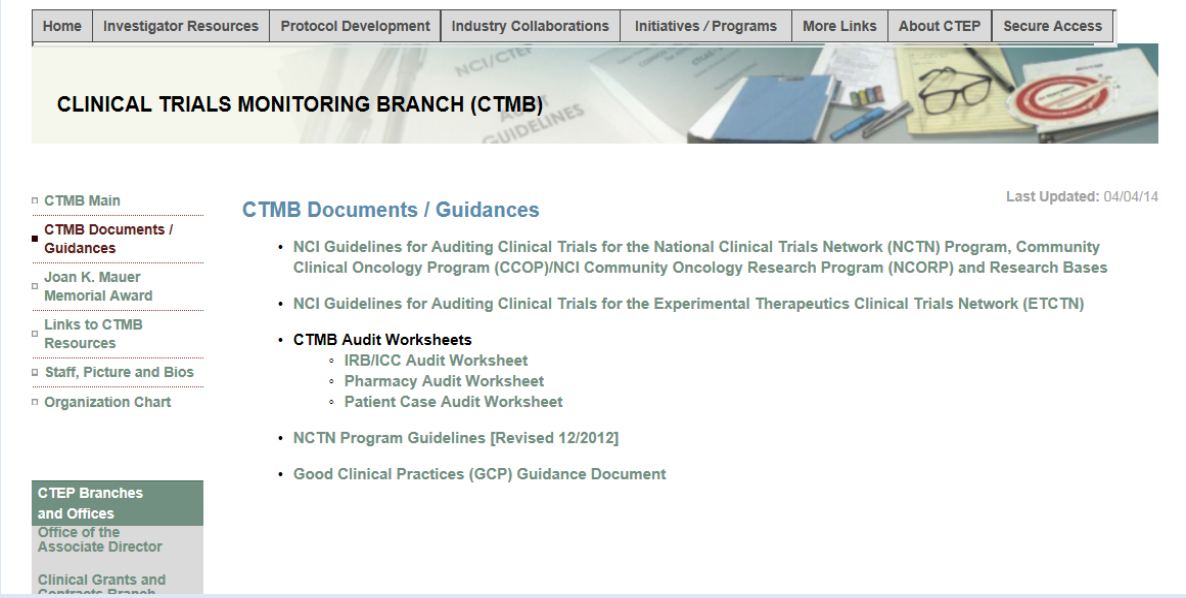
Protocol Title:	NCI Protocol No:	Local Protocol No:	Dispensing Area:
Phase 2 trial of pazopanib for the treatment of patients with advanced renal cell carcinoma	1234	SUH-001	IDS Pharmacy - 5th Floor Room A100

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.												
2.												
3.												
4.												
5.												
6.												
7.												
8.												
9.												
10.												
11.												
12.												
13.												

The DARF with a completed header may now be printed. If the appropriate software is available, the form may be saved for future use.

Slide 15



http://ctep.cancer.gov/branches/ctmb/clinicalTrials/docs/ctmb_audit_guidelines.pdf

To learn more about the difference between Control and Satellite Dispensing Areas, refer to Section 5.3 of the Audit Guidelines.

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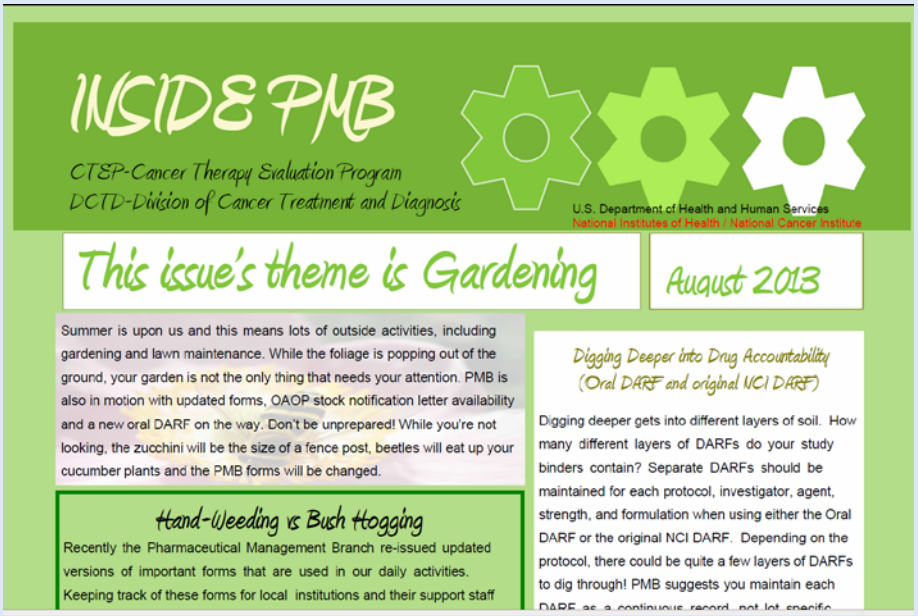

INSIDE PMB

CTEP-Cancer Therapy Evaluation Program
DCTD-Division of Cancer Treatment and Diagnosis

U.S. Department of Health and Human Services
National Institutes of Health / National Cancer Institute

This issue's theme is Gardening

August 2013

Summer is upon us and this means lots of outside activities, including gardening and lawn maintenance. While the foliage is popping out of the ground, your garden is not the only thing that needs your attention. PMB is also in motion with updated forms, OAOP stock notification letter availability and a new oral DARF on the way. Don't be unprepared! While you're not looking, the zucchini will be the size of a fence post, beetles will eat up your cucumber plants and the PMB forms will be changed.

Hand-Weeding vs Bush Hogging

Recently the Pharmaceutical Management Branch re-issued updated versions of important forms that are used in our daily activities. Keeping track of these forms for local institutions and their support staff

Digging Deeper into Drug Accountability
(Oral DARF and original NCI DARF)

Digging deeper gets into different layers of soil. How many different layers of DARFs do your study binders contain? Separate DARFs should be maintained for each protocol, investigator, agent, strength, and formulation when using either the Oral DARF or the original NCI DARF. Depending on the protocol, there could be quite a few layers of DARFs to dig through! PMB suggests you maintain each

http://ctep.cancer.gov/branches/pmb/inside_pmb/aug2013.pdf

Or the August 2013 issue of the PMB newsletter.

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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.

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http://ctep.cancer.gov/

1-800-4-CANCER

Produced September 2014