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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.

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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.

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

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

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

Investigational Agent Accountability Record

NAME NO. 2468-001
CONTROL RECORD
SATELLITE RECORD

Name of Institution: State University Hospital
Agent Name: Ziv-Aflibercept (VEGF-Trap, AVE 0005, NSC 724770)
Protocol Title: Phase II Study of Ziv-Aflibercept in Metastatic Colon Cancer

Investigator Name: John Smith, M.D.

Line No.	Date	Patient's Initials	Patient's CI No.	Dose	Quantity Disposed or Received	Balance Forward or Balance	Manufacturer and Lot No.	Receiver'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.

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Investigational Agent Accountability Record

NAME NO. 2468-001
CONTROL RECORD
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Name of Institution: State University Hospital
Agent Name: Ziv-Aflibercept (VEGF-Trap, AVE 0005, NSC 724770)
Protocol Title: Phase II Study of Ziv-Aflibercept in Metastatic Colon Cancer

Investigator Name: John Smith, M.D.

Line No.	Date	Patient's Initials	Patient's CI No.	Dose	Quantity Disposed or Received	Balance Forward or Balance	Manufacturer and Lot No.	Receiver'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.

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Print Form Save As Reset Form

Investigational Agent Accountability Record

Investigator Name: John Smith, M.D. CTEP Investigator ID: 999999

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Disposed or Received	Balance Forward Balance	Manufacturer and Lot No.	Receiver'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.

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Investigational Agent Accountability Record

NCI Protocol No.: 2468

Dispensing Area: IDS Pharmacy - 5th Floor Room A100

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Disposed or Received	Balance Forward Balance	Manufacturer and Lot No.	Receiver'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.

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Print Form Save As Reset Form

Investigational Agent Accountability Record

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

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Disposed or Received	Balance Forward Balance	Manufacturer and Lot No.	Receiver'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).

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

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Investigational Agent Accountability Record

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

NAME: [X] CONTROL RECORD [X]
 [] SATELLITE RECORD []

Name of Institution: State University Hospital
 NCI Protocol No.: 2468

Agent Name: Ziv-Aflibercept (VEGF-Trap, AVE 0005, NSC 724770)
 Date Form and Strength: 200 mg (8.5mL, val: 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	Patent's Name	Patent's ID No.	Dose	Quantity	Department of Pharmacy	Balance For and Purpose	Manufacturer and Lot No.	Receiver's Name
1									
2									

Here is an example of a completed original DARF header.

Next we will review the Oral DARF header.

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

Investigational Agent Accountability Record

Oral Agent ONLY

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

Agent Name: Paliperidone hydrochloride (NSC 737754)
 Date Form and Strength: 200 mg Tablets
 Dispensing Area: IDS Pharmacy - 5th Floor Room A100

Quantity: 34 Tablets/bottle

Red arrows point to "200 mg Tablets" and "34 Tablets/bottle".

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.

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

Investigational Agent Accountability Record

Oral Agent ONLY

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

Agent Name: Paliperidone hydrochloride (NSC 737754)
 Date Form and Strength: 200 mg Tablets
 Dispensing Area: IDS Pharmacy - 5th Floor Room A100

Quantity: 34 Tablets/bottle

Here is an example of a completed Oral DARF header.

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The image shows a completed Investigational Agent Accountability Record (IAR) form. At the top, there are buttons for 'Print Form', 'Save As...', and 'Reset Form'. The form is titled 'Investigational Agent Accountability Record' and 'Drug Agent ONLY'. It includes fields for 'Name of institution' (State University Hospital), 'Investigator Name' (John Smith, M.D.), 'NCT ID Number' (NCT01234), 'Sponsor Name' (XYZ Pharma), 'Drug Name' (Pazopanib hydrochloride (NDC 737734)), 'Drug Form and Strength' (200 mg Tablets), and 'Dispensing Area' (34 Tablets/Bottle). Below these fields is a table with columns for 'Date', 'Amount', 'Balance', 'Status', 'Comments', and 'Signature'. The table contains several rows of data, with the first row showing a date of 11/11/11 and an amount of 100 tablets.

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

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The image is a screenshot of the Clinical Trials Monitoring Branch (CTMB) website. The header includes navigation tabs for 'Home', 'Investigational Resources', 'Product Development', 'Industry Collaborations', 'Business Programs', 'News Links', 'About CTMB', and 'Contact Us'. The main content area is titled 'CLINICAL TRIALS MONITORING BRANCH (CTMB)' and features a 'CTMB Documents & Guidance' section. This section lists various documents and guidance materials, including 'NCT Guidelines for Auditing Clinical Trials for the National Clinical Trials Network (NCTN) Program', 'CTMB Audit Worksheets', and 'NCTN Program Subsites (Revised 10/10/11)'. At the bottom of the page, there is a URL: 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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The image is the cover of the August 2013 issue of the PMB newsletter. The title is 'INSIDE PMB' and the subtitle is 'CTEP Clinical Trials Initiative Program'. The main theme is 'This issue's theme is Gardening'. The cover features a green background with a gear icon and the text 'August 2013'. Below the title, there is a short article titled 'Digging Deeper into Drug Availability' and another titled 'Mind-blowing & Buh-bugging'. At the bottom of the page, there is a URL: http://ctep.cancer.gov/branches/pmb/inside_pmb/aug2013.pdf.

Or the August 2013 issue of the PMB newsletter.

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Pharmaceutical Management Branch, CTEP, NCI



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(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.

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