



Welcome to this video tutorial on the DARG 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 DARG.

Slide 2

Project Clearance Branch, 6705 Rockledge Drive, MSC 7874, Bethesda, MD 20892-7874, ATTN: PRA (3925-0013). 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 <input type="checkbox"/> SATELLITE RECORD <input type="checkbox"/>	
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	Manufacturer and Lot No.	Recorder's Initials
						Balance		
1.								
2.								
3.								
4.								
5.								

FOIA(b)(7)(F) All 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. For information on obtaining copies of OMB control numbers, see 5 CFR 1720.33. Send comments regarding this information collection to the Project Clearance Branch, 6705 Rockledge Drive, MSC 7874, Bethesda, MD 20892-7874, ATTN: PRA (3925-0013). 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 <input type="checkbox"/> SATELLITE RECORD <input type="checkbox"/>	
Investigational Agent Accountability Record Oral agents <u>ONLY</u>					
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.												

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.

<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

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

Slide 4

Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: FDA (0205-0013). 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	Manufacturer and Lot No.	Recorder's Initials
						Balance		
1								
2								
3								
4								
5								

Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: FDA (0205-0013). 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
Oral agents ONLY

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)	Patient Returned	Quantity Patient Returned	Recorder's Initials
						Balance						
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.

Print Form

Save As

Reset Form

Collection of this information is authorized under 21 CFR 312.57. The 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.

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.

National Institutes of Health
National Cancer Institute

Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

Investigational Agent Accountability Record

PAGE NO. _____

CONTROL RECORD

SATELLITE 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	Manufacturer and Lot No.	Recorder's Initials
						Balance		
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.

<div style="display: flex; justify-content: space-around; align-items: center;"> Print Form Save As Reset Form </div>									
<p style="font-size: small; margin: 0;">Collection of this information is authorized under 21 CFR 312.57. The 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 style="font-size: x-small; margin: 0;">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.</p>									
National Institutes of Health National Cancer Institute				Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program			OMB No. 0925-0613 Expires: 03/31/2016 NIH-2564		
Investigational Agent Accountability Record						PAGE NO. <u>1</u> CONTROL RECORD <input checked="" type="checkbox"/> SATELLITE RECORD <input type="checkbox"/>			
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	Manufacturer and Lot No.	Recorder's Initials	
						Balance			
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.

<div style="display: flex; justify-content: space-around; margin-bottom: 10px;"> Print Form Save As Reset Form </div>								
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National Institutes of Health National Cancer Institute	Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program	PAGE NO. <u>1</u> CONTROL RECORD <input checked="" type="checkbox"/> SATELLITE RECORD <input type="checkbox"/>						
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	Manufacturer and Lot No.	Recorder's Initials
						Balance		
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.

<div style="display: flex; justify-content: space-around; align-items: center;"> Print Form Save As Reset Form </div>									
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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	Manufacturer and Lot No.	Recorder's Initials	
						Balance			
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.

<div style="display: flex; justify-content: space-around; margin-bottom: 10px;"> Print Form Save As Reset Form </div> <p style="font-size: small; margin: 0;">Collection of this information is authorized under 21 CFR 312.57. The 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 style="font-size: x-small; margin: 0;">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.</p> <div style="display: flex; justify-content: space-between; font-size: small; margin: 0;"> National Institutes of Health National Cancer Institute Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program OMB No. 0925-0613 Expires: 03/31/2016 NIH-2564 </div> <div style="display: flex; justify-content: space-between; margin: 10px 0;"> <div> <p>Investigational Agent Accountability Record</p> <p>Name of Institution: State University Hospital</p> <p>Agent Name: Ziv-Aflibercept (VEGF-Trap, AVE 0005, NSC 724770)</p> <p>Protocol Title: Phase II Study of Ziv-Aflibercept in Metastatic Colon Cancer</p> <p>Investigator Name: John Smith, M.D.</p> </div> <div style="border-left: 1px solid black; padding-left: 10px;"> <p>PAGE NO. <u>1</u></p> <p>CONTROL RECORD <input checked="" type="checkbox"/></p> <p>SATELLITE RECORD <input type="checkbox"/></p> <p>NCI Protocol No.: 2468</p> <p>Dose Form and Strength: 200 mg / 8 mL vial; 25 mg/mL</p> <p>Dispensing Area: IDS Pharmacy - 5th Floor Room A100</p> <p>CTEP Investigator ID: 999999</p> </div> </div> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th rowspan="2">Line No.</th> <th rowspan="2">Date</th> <th rowspan="2">Patient's Initials</th> <th rowspan="2">Patient's ID No.</th> <th rowspan="2">Dose</th> <th rowspan="2">Quantity Dispensed or Received</th> <th>Balance Forward</th> <th rowspan="2">Manufacturer and Lot No.</th> <th rowspan="2">Recorder's Initials</th> </tr> <tr> <th>Balance</th> </tr> </thead> <tbody> <tr> <td>1.</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>2.</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>										Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward	Manufacturer and Lot No.	Recorder's Initials	Balance	1.									2.								
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						Balance																															
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.

Print Form Save As Reset Form		OMB No. 0925-0613 Expires: 03/31/2016 NIH-2564						
<p style="font-size: x-small;">Collection of this information is authorized under 21 CFR 312.57. The 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 style="font-size: x-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 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0613). Do not return the completed form to this address.</p>								
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Investigational Agent Accountability Record		PAGE NO. <u>1</u> CONTROL RECORD <input checked="" type="checkbox"/> SATELLITE RECORD <input type="checkbox"/>						
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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	Manufacturer and Lot No.	Recorder's Initials
						Balance		
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).

<div style="display: flex; justify-content: space-around; align-items: center;"> Print Form Save As Reset Form </div>									
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						Balance			
1.									
2.									

Here is an example of a completed original DARF header.

Next we will review the Oral DARF header.

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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

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

PAGE NC 1

CONTROL RECORD

SATELLITE RECORD

Name of Institution: State University Hospital				Investigator Name: John Smith, M.D.				CTEP Investigator ID: 9999999	
Protocol Title: Phase 2 trial of pazopanib for the treatment of patients with advanced renal cell carcinoma				NCI Protocol No: 1234		Local Protocol No: SUH-001		Dispensing Area: IDS Pharmacy - 5th Floor Room A100	
Agent Name: Pazopanib hydrochloride (NSC 737754)				Dose Form and Strength: 200 mg Tablets				Bottle size (e.g., # tablets/bottle): 34 Tablets/bottle	

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or	Balance Forward	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if	Date Patient	Quantity Patient	Recorder's Initials
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There are two items specific to the Oral DARE. 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.

Print Form Save As Reset Form												
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Name of Institution: State University Hospital				Investigator Name: John Smith, M.D.				CTEP Investigator ID: 9999999				
Protocol Title: Phase 2 trial of pazopanib for the treatment of patients with advanced renal cell carcinoma				NCI Protocol No: 1234		Local Protocol No: SUH-001		Dispensing Area: IDS Pharmacy - 5th Floor Room A100				
Agent Name: Pazopanib hydrochloride (NSC 737754)				Dose Form and Strength: 200 mg Tablets				Bottle size (e.g., # tablets/bottle): 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.

Print Form
Save As
Reset Form

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

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.

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 7074, Bethesda, MD 20892-7074, ATTN: PRA (0925-0013). 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: State University Hospital	Investigator Name: John Smith, M.D.	CTEP Investigator ID: 999999
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Protocol Title: Phase 2 trial of pazopanib for the treatment of patients with advanced renal cell carcinoma	NCI Protocol No: 1234	Local Protocol No: SUH-001	Dispensing Area: IDS Pharmacy - 5th Floor Room A100
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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.												
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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.

Home | Investigator Resources | Protocol Development | Industry Collaborations | Initiatives / Programs | More Links | About CTEP | Secure Access

CLINICAL TRIALS MONITORING BRANCH (CTMB)

Last Updated: 04/04/14

CTMB Documents / Guidances

- 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/ICC Audit Worksheet
 - Pharmacy Audit Worksheet
 - Patient Case Audit Worksheet
- NCTN Program Guidelines [Revised 12/2012]
- Good Clinical Practices (GCP) Guidance Document

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.

The image shows the cover of the August 2013 issue of the PMB newsletter. The title 'INSIDE PMB' is written in a large, white, stylized font on a green background. Below it, the text 'CTEP-Cancer Therapy Evaluation Program' and 'DCTD-Division of Cancer Treatment and Diagnosis' is displayed. To the right of the title are three interlocking gears in shades of green and white. Further right, the text 'U.S. Department of Health and Human Services' and 'National Institutes of Health | National Cancer Institute' is visible. The main theme 'This issue's theme is Gardening' is written in a green, cursive font, with the date 'August 2013' in a white box to its right. The cover features three text boxes: a grey one on the left about summer activities and form updates, a green one at the bottom left about 'Hand-Weeding vs Bush Hogging', and a white one on the right about 'Digging Deeper into Drug Accountability'. A URL is printed at the bottom of the cover.

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, QAOP 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 DARF as a continuous record, not let specific

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

Or the August 2013 issue of the PMB newsletter.

Pharmaceutical Management Branch, CTEP, NCI



Email
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

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