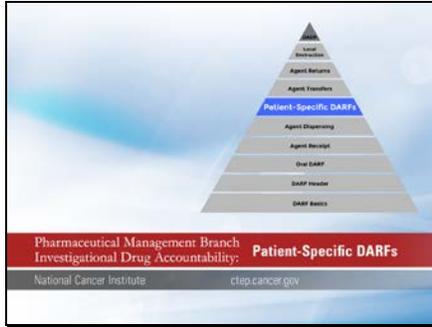


Slide 1



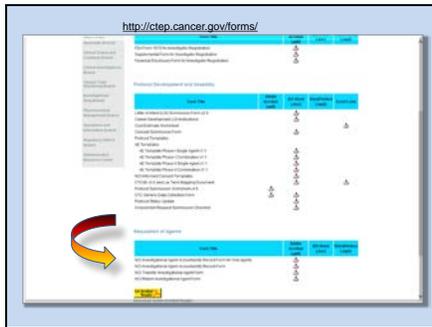
Welcome to this video tutorial on Patient-Specific DARFs in the PMB Investigational Drug Accountability series. This video will review how to manage your DARF when using it for a patient-specific or blinded study. For the purposes of this video, the term blinded and patient-specific will be used interchangeably. Any references to the Investigational Agent Accountability Record in this presentation apply exclusively to the NCI DARF.

Slide 2



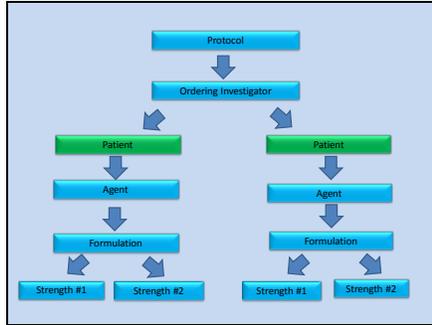
Much of the information in this presentation will build off of previously released videos in the Investigational Drug Accountability series. Please consider viewing the other videos in this series before viewing the patient-specific DARF video. From the earlier videos, you already know that DARFs must be maintained to track the disposition of all study-supplied agents for NCI clinical trials.

Slide 3



As a reminder, you can find the DARFs and other forms on the CTEP website listed here.

Slide 4



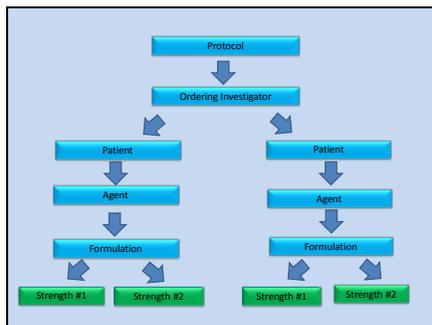
Before deciding whether a patient-specific DARF is required, you will need to determine whether the agent supplies are provided on a patient-specific basis. For agents that PMB distributes, most of these studies will be placebo-controlled blinded studies, which should be easily identifiable from the protocol title. This information is also clearly defined in the pharmaceutical section of the protocol under “Agent Ordering and Accountability.”

Slide 5

The image shows two screenshots of the 'Investigational Agent Accountability Record' form. The top screenshot shows the form with fields for 'Name of Institution', 'Agent Name', and 'Strength'. The bottom screenshot shows the form with fields for 'Name of Institution', 'Agent Name', and 'Strength'. Both screenshots include a 'Print Form' button, a 'Save As' button, and a 'Reset Form' button.

Once you have determined that the protocol provides patient-specific supplies you can create your DARFs. The agent’s route of administration will determine which DARF to use.

Slide 6



While protocol-specific DARFs allow you to record multiple patients on the same form, a patient-specific DARF is limited to a single patient. A separate DARF is required for each agent and each strength provided by PMB for the patient. In this example, you will receive 2 different strengths of the agent, which requires 2 unique DARFs for each patient. If you only receive a single strength with the initial shipment, you can start with a single DARF. If additional strengths are later required to accommodate a dose

adjustment, additional DARFs can be created at that time.

Slide 7

Here is an example of a completed patient-specific Oral DARF header. Please refer to the DARF headers video for instructions on how to complete the basic elements of the header for each form. To make the DARF patient-specific, you need to insert the patient identifier into the header. The identifier should include the patient ID assigned at randomization, along with the patient initials. The exact location is not important as long as the information is clear and does not obstruct the other fields in the header.

Slide 8

The investigator listed on the Shipping Receipt must be the investigator listed on the patient-specific DARF. Subsequent orders are submitted under this “responsible” investigator unless a patient transfer has been approved by the lead organization and a copy of the approval provided to PMB.

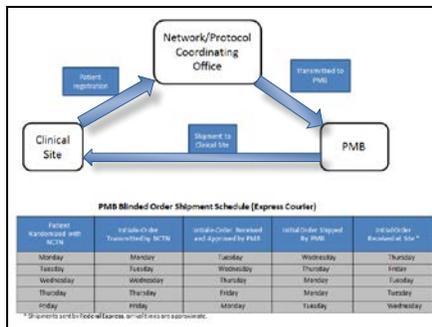
Slide 9

Original DARF patient-specific header

National Institutes of Health National Cancer Institute		Division of Cancer Treatment and Diagnosis Cancer Therapy Evaluation Program		PAGE NO. CONTROL RECORD <input checked="" type="checkbox"/> SATELLITE RECORD <input type="checkbox"/>	
Investigational Agent Accountability Record			IND Protocol No. 5679 PT ID 5679-003 / PB		
Name of Institution State University Hospital		Drug Form and Strength 400 mg / 0 mg per vial			
Agent Name bevacizumab / PLACEBO (NSC 704865)		Dispensing Area IDS Pharmacy - 5th Floor Room A100			
Protocol Title Phase II trial of bevacizumab or placebo in combination with oxaliplatin and fluorouracil in gastrointestinal malignancies			CTEP Investigator ID 99998		
Investigator Name Michael Jones		PT ID 5679-003 / PB			

You can see on this example of the completed Original DARF header, that the patient ID and initials have been included in a different spot than on the Oral DARF. Again, it is not important where the information is in the header as long as it is clearly noted.

Slide 10



Let's move onto documenting transactions such as receipt, dispensing and returns. For patient specific studies in which PMB distributes the agent, the first order is not entered in OAOP. When the patient is registered, the coordinating office transmits an electronic order notifying PMB that a patient was randomized and to which arm they were assigned. The PMB will prepare the shipment and send it to the site. Because patient-specific labeling is added to these supplies, the orders take a few extra days to arrive at your location. Keep in mind that next day delivery is not available for patient-specific orders. For the initial shipment, the Shipping Designee linked to the responsible investigator will receive an email notifying them of the impending shipment. This may be the first time you are notified of a new patient on the protocol. If that's the case, you should obtain and review a current copy of the protocol for details on the initial and subsequent orders for this patient.

Slide 12

Investigational Agent Accountability Record

Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

PAGE NO. CONTROL RECORD X
JULIAN DATE RECORD 23

Name of Institution: State University Hospital
Agent Name: bevacizumab / PLACEBO (NSC 704955)
Phase: Phase II trial of bevacizumab or placebo in combination with oxaliplatin and fluorouracil in gastrointestinal malignancies

Line No.	Date	Quantity	Balance Forward	Quantity	Balance Forward	Quantity	Balance Forward
1.	15/02/13	Received from NCI	12	12	15062013	12	15062013
2.	18/02/13	FR	8	8	15062013	8	15062013
3.	19/02/13	FR	8	8	15062013	8	15062013
4.	21/10/13	FR	8	8	15062013	8	15062013
5.	30/02/13	Received from NCI	12	12	15062013	12	15062013
6.	05/02/13	FR	8	8	15062013	8	15062013
7.	20/12/13	FR	8	8	15062013	8	15062013
8.	11/02/13	FR	8	8	15062013	8	15062013
9.	10/02/13	Received from NCI	12	12	15062013	12	15062013
10.	06/02/13	FR	8	8	15062013	8	15062013
11.	02/12/13	FR	8	8	15062013	8	15062013

The Julian Date and order number in the upper right hand corner of this label are used as the lot identifier. The Julian Date is a code for the exact day of the year and the order number is the sequence order number processed on that specific day. This is a unique identifier to this patient supply. Refer to the Agent Receipt video for more information.

Slide 13



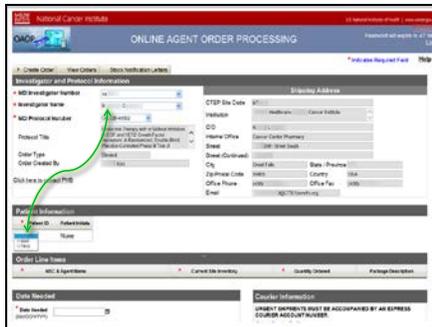
Once the supplies are checked in, make sure that the supplies are stored in a way that separates them from other studies and other patients on the same study. The supplies should not be removed from their original packaging (which contains the Julian Date) when stored at the site. For example, many of the vials that we distribute do not have space for a full label to be applied. In these cases, we package the supplies in a box with a full label on the outside of the box. The vials contained in the box only contain the patient ID number. Storing them in the original shipping box will ensure the supplies are connected to the appropriate Julian Date and shipment.

Slide 14



Now that you have stored your agents properly, it's time to dispense to the patient. This is the easy part. You document the dispensing the same way as on the open label record, but the DARF will only ever contain one patient ID.

Slide 15



When it is time to reorder supplies, please refer to the protocol for appropriate instruction. Specific instructions on the timing of reorders are stated in the Pharmaceutical Section of the protocol. Most reorders need to be entered by the site using OAOP. Because there is a unique link between the investigator listed on the Shipping Receipt and the patient ID, you need to order under the same investigator that is noted on the initial shipping receipt. Unless the patient has been transferred to a different investigator through direct discussion with the coordinating office and PMB is notified, the patient ID will only display under this investigator in OAOP. You will not be able to see the patient ID to order supplies under a different investigator or if you are not a designee of the investigator listed on the shipping receipt.

Slide 16

The image shows a Drug Accountability Record (DARF) form for a patient. The form is titled "Investigational Agent Accountability Record" and includes fields for "Phase ID", "Control Record", and "Satellite Record". A red prohibition sign is overlaid on the "Agent Supply" section, indicating that patient-specific supplies cannot be transferred to other patients.

Unlike open-label supplies, patient-specific supplies cannot be transferred to other patients.

Slide 17

The image shows a Drug Accountability Record (DARF) form for a patient. The form is titled "Investigational Agent Accountability Record" and includes fields for "Phase ID", "Control Record", and "Satellite Record". A yellow smiley face is overlaid on the "Agent Supply" section, indicating that patient-specific supplies can be transferred to a new investigator after the investigator transfer notification has been received and processed by PMB.

The only exception to transferring patient-specific supplies is if the patient changes responsible investigators. In certain situations, the agent supply may be transferred to the new investigator after the investigator transfer notification has been received and processed by PMB. If this happens, you need to submit the PMB agent transfer form found on the PMB website. Once the patient has been transferred to a new investigator, you also need to create a new DARF for that patient to reflect the updated investigator.

Slide 23

