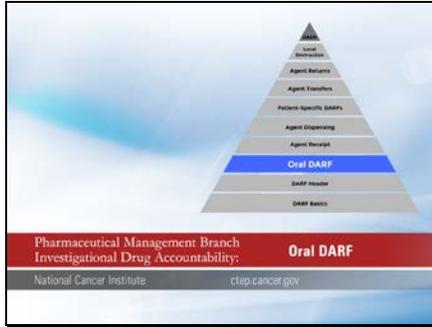


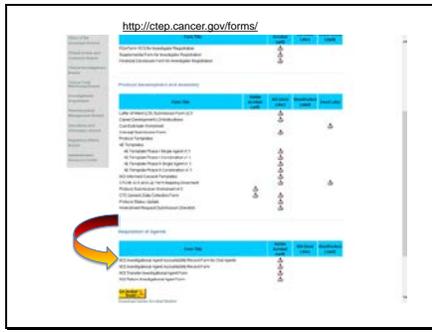
Slide 1



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

This video will review recording procedures when using the NCI Investigational Agent Accountability Record Form for Oral Agents, or Oral DARF.

Slide 2

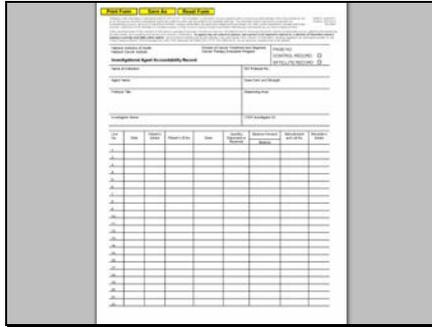


You can find the Oral DARF here on the CTEP website, Forms page.

Slide 3

The Oral DARF must be used for NCI studies using an oral agent, either open label, protocol specific, or blinded, patient specific.

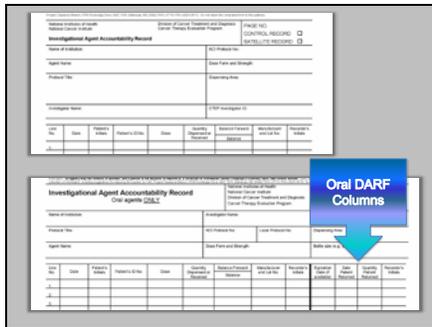
Slide 4



The image shows a standard NCI Investigational Agent Accountability Record (DARF) form. It includes a header with the NCI logo and title, followed by fields for Name of Institution, Agent Name, and Investigator Name. Below these is a table with columns for Date, Patient ID, Agent, and Amount. The table is mostly empty, with only a few rows filled in.

Please continue to use the original NCI DARF for all formulations not intended for oral administration.

Slide 5



The image shows the Oral DARF form, which is identical to the standard DARF but includes additional columns for Patient Returns. A blue callout box with a downward-pointing arrow is labeled "Oral DARF Columns" and points to the new columns: "Patient Returns", "Quantity", "Units", "Dose", "Route", and "Frequency".

The difference between the two DARFs is that the Oral DARF provides additional columns to document patient returns. These fields provide space for sites to record quantities of oral agents returned by patients.

Sites should not return dispensed oral agents to the NCI Clinical Repository. Patient returns should be destroyed on site in accordance with institutional policy.

Let's review the individual fields unique to the Oral DARF.

Slide 6

The image shows a form titled "Investigational Agent Accountability Record" for "One Agent". The form includes fields for "Name of Institution", "Investigator Name", "NCT Number", "Local Protocol", "Sponsor/Center", "Patient No.", "Study Site and Branch", and "Date dispensed". A red box highlights the "Bottle Size" field, which is currently empty. Below these fields is a table with columns: "Line", "Date", "Patient ID No.", "Agent's ID No.", "Site", "Quantity Dispensed", "Quantity Returned", "Expiration Date", "Lot No.", "Bottle Size", "Date Patient Returned", "Quantity Dispensed", "Quantity Returned", "Patient's Name", and "Patient's ID No.". The "Bottle Size" column is the 10th column in this table.

Bottle size is an additional field that appears in the Oral DARF header section. This information is useful as a link between the quantity dispensed and the quantity returned.

Slide 7

The image shows the same form as Slide 6. A blue box highlights the "Expiration Date" field in the table, which is the 8th column. The field is currently empty.

The first additional column is Expiration Date. In many cases this information will not be available. If the expiration date is not available at the time of agent receipt, it is not necessary to add it later to all prior line items where the lot was dispensed or returned. At the time the expiration date is known, it can be added for all lines items recorded for the lot from that point forward.

Slide 8

The image shows the same form as Slide 6. A blue box highlights the "Date Patient Returned" field in the table, which is the 11th column. The field is currently empty.

The next column is Date Patient Returned. Record the date received in the dispensing area, it may differ from the actual date received in the clinic.

Slide 9

The Quantity Patient Returned is located next to the right. If the quantity returned cannot be easily counted such as suspensions or solutions, you may record returned quantities as full or partial. Returns of sealed bottles do not need to be opened for physical count. Unsealed patient returns should be opened, counted, and recorded. Intact bottles should be recorded as quantity of bottles.

Slide 10

The Oral DARF is formatted for the dispensing and return information to appear in the same row. When rows of the Oral DARF are used to record activities other than dispensing, the return columns will not be used.

Slide 11

When a patient return is received, look at the label of the returned agent and find the correct Oral DARF by verifying information in the header section such as the protocol, investigator, agent, formulation, and strength.

Next, locate the correct dispensing row for the returned drug by matching the date dispensed, patient initials, patient ID number, and lot number to the row in which the dispensing was recorded.

Now let's go through some different examples of what steps to take when a

patient return is received.

Slide 12

Line	Date	Quantity Dispensed	Lot Number	Expiration Date	Quantity Returned	Lot Number	Expiration Date	Quantity Destroyed	Lot Number	Expiration Date
1	3/24/14	16	GLX12345678	03/2015	0	GLX12345678	03/2015	0	GLX12345678	03/2015
2	3/24/14	16	GLX12345678	03/2015	0	GLX12345678	03/2015	0	GLX12345678	03/2015
3	3/24/14	16	GLX12345678	03/2015	0	GLX12345678	03/2015	0	GLX12345678	03/2015

In the example on line 2, one bottle containing 16 tablets of pazopanib hydrochloride was returned to the dispensing area for patient AZ, 1234-001. The tablets were 200 mg of lot GLX12345678 used in NCI protocol 1234 and dispensed on March 24th, 2014.

Slide 13

Line	Date	Quantity Dispensed	Lot Number	Expiration Date	Quantity Returned	Lot Number	Expiration Date	Quantity Destroyed	Lot Number	Expiration Date
12	7/23/14	16	GLX12345678	03/2015	0	GLX12345678	03/2015	0	GLX12345678	03/2015
13	7/23/14	16	GLX12345679	03/2015	0	GLX12345679	03/2015	0	GLX12345679	03/2015

In the example on lines 12 and 13, two lots were dispensed to patient BT, 1234-002 on July 23rd, 2014. Each dispensing is recorded on a separate line and the return is recorded correctly on the corresponding line for each lot.

Multiple lots of agent dispensed on the same date must be recorded on separate lines of the DARF.

Slide 14

Investigational Agent Accountability Record
Oral Agent: **CELLE**

Investigator: **John Smith, M.D.**
Sponsor: **CELLE**
Protocol: **1234**
Site: **State University Hospital**

Drug Name: **Pazopanib hydrochloride (NSC 737756)**
Strength: **200 mg Tablets**
Supply: **34 Tablets/Bottle**

Line	Date	Quantity Dispensed	Quantity Returned	Quantity Destroyed	Quantity on Hand	Quantity in Inventory	Quantity in Storage	Quantity in Use	Quantity in Transit	Quantity in Other	Quantity in Total
1	5/16/14	24	0	0	24	24	0	0	0	0	24

What if a patient returns an empty bottle? In that case, there is nothing to record such as on line 6 or 7.

Keep in mind that the patient return columns are not intended to document destruction of oral agents or adherence to prescribed therapy. Patient adherence should be measured as described in the protocol.

Slide 15

Investigational Agent Accountability Record
Oral Agent: **CELLE**

Investigator: **John Smith, M.D.**
Sponsor: **CELLE**
Protocol: **1234**
Site: **State University Hospital**

Drug Name: **Pazopanib hydrochloride (NSC 737756)**
Strength: **200 mg Tablets**
Supply: **34 Tablets/Bottle**

Line	Date	Quantity Dispensed	Quantity Returned	Quantity Destroyed	Quantity on Hand	Quantity in Inventory	Quantity in Storage	Quantity in Use	Quantity in Transit	Quantity in Other	Quantity in Total
5	5/16/14	24	0	0	24	24	0	0	0	0	24

Let's look at another patient return on line 5. In this case, four partial bottles were returned from a single dispensing on May 16th, 2014. The bottles each contained six tablets. Count and add up the number of tablets from each bottle to record the total quantity returned, which is 24 in this example.

Slide 16

Investigational Agent Accountability Record
Oral Agent: **CELLE**

Investigator: **John Smith, M.D.**
Sponsor: **CELLE**
Protocol: **1234**
Site: **State University Hospital**

Drug Name: **Pazopanib hydrochloride (NSC 737756)**
Strength: **200 mg Tablets**
Supply: **34 Tablets/Bottle**

Line	Date	Quantity Dispensed	Quantity Returned	Quantity Destroyed	Quantity on Hand	Quantity in Inventory	Quantity in Storage	Quantity in Use	Quantity in Transit	Quantity in Other	Quantity in Total
3	5/16/14	24	0	0	24	24	0	0	0	0	24

For the final example let's review the steps to take when additional bottles are returned from a single dispensing but on different dates. The return fields in the dispensing row on line 3 were completed previously, so you'll need to go to a new line. Starting with the next blank row, line 9 in this example; reference the dispensing date, including Oral DARF page number and line number, then record in the return columns.

Slide 20

