

INSIDE PMB

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



U.S. Department of Health and Human Services
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This issue's theme is Gardening

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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 can be a daunting task. Just as you must regularly pull weeds from your garden to avoid having to bush hog it when it turns into a jungle, regular checks of each form's expiration date will save you more work later on. Changes in forms are usually mandated by a higher authority such as Mother Nature or by important new regulatory requirements.



While it is convenient to keep hard copies or electronic versions of these forms on file, keep in mind that we cannot accept outdated forms. Submitting outdated forms will delay action on your request, so stay ahead of the elements and save yourself a trip to the heavy equipment rental store. The current versions of the forms can always be found on the CTEP web site at <http://ctep.cancer.gov/forms/>. The new Oral DARF form is not released yet, but look for it soon at your local gardening center.

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 lot specific, to best manage the number of DARF layers.?



Quiz #1

OAOP Stock Notification Letter

Letters can be searched for using the following criteria: letter date range, NSC number, agent name and protocol number.

True or False?

Answer on page 4





DARFS Make Good Neighbors

You know the saying, “Fences make good neighbors.”

Just like a fence, the NCI Investigational Agent Accountability Form (formerly the Drug Accountability Record Form, or DARF), segregates all agent transactions between neighboring Control and Satellite areas. Documentation is required at both the Control and Satellite dispensing areas so the grass isn't always greener on one side than the other. To clarify what documentation is required where, we have a description of the two dispensing areas, along with a chart detailing who is responsible for recording the actions, such as pruning the adjoining trees, weed wacking between the posts and replacing the flower bed the dog dug up.

Control Dispensing Area

This is the primary storage area for an investigational agent. It is determined by the shipping address provided on the Supplemental Investigator Data Form submitted with the annual CTEP Investigator Registration packet, or by the site's Primary Shipping Designee Worksheet. The Control Dispensing Area is responsible for ensuring the Satellite Dispensing Area is compliant with agent accountability.

Satellite Dispensing Area

This is a local site away from the Control Dispensing Area. The Satellite Dispensing Area is under the direct responsibility of the Control Dispensing Area.

Control	Documentation	Satellite
X	Receipt of supply from PMB	
X	Transport to Satellite Dispensing Area	
	Receipt from Control Dispensing Area	X
X	Transfer to another study or investigator	
X	Return to NCI	
X	Dispense to patient	X
X	Authorized destruction of supplies	
	Return to Control Dispensing Area	X
X	Receive and destroy patient returns	X
X	Receive agent from Satellite Dispensing Area	
X	Create DARF if investigational agent is stored for more than 24 hours	X

Quiz #2

OAOP Stock Notification Letter

Answer-page 4



You search for an expiration letter for pazopanib lot# ABCD and don't get any results. What does this mean?

- a. The lot was supplied for a blinded study.
- b. There was no expiration letter generated for this lot.
- c. There is no PMB-distributed lot# ABCD for this agent.
- d. Your site didn't order this lot and therefore can't search for it in OAOP.
- e. Both b and c.

Drug Accountability for Patient Returns: Cultivating New Fields (Oral DARF)



PMB has been tilling the fields in preparation for using the new Oral DARF to record transactions with oral NCI-supplied study agents. In addition to the functions of the original NCI DARF, the Oral DARF will allow documentation of patient returns in fields titled "Date Patient Returned" and "Quantity Patient Returned". Prior to planting returns in these fields, we'd like to provide you with patient return seed packet instructions for optimal growing conditions.

GERMINATION



Please confirm the correct Oral DARF due to potentially lengthy germination periods between the date dispensed and the date returned.

- Protocol
- Investigator
- Agent
- Strength
- Formulation

Seed Packet
Instructions for
Patient Returns
on the Oral DARF



CROSS-POLLINATION



Please confirm the correct row due to risk of cross-pollination with returns from different dispensing dates, patients, or lot numbers.

- Date
- Patient Initials
- Patient ID number
- Lot number

Issues with germination and cross-pollination are easier to control if the agent is individually labeled during dispensing. Once the correct Oral DARF and correct row are ready for planting, please count and record the number of seeds remaining in returned packets, recording a "0" for empties. Keep in mind that the dispensed quantity may be recorded in whole seed packets but a new "Bottle Size" field included in the Oral DARF header will provide total seeds/packet. Patients are advised to always bring their medications to clinic, but if this does not occur, the return fields cannot be cultivated and should be left blank.

The Oral DARF also provides space for recording the expiration date if the date appears on the product label or if PMB issued notification of the date. This field may not always be cultivated either. PMB looks forward to growing with you to ensure that the new Oral DARF will establish roots and flourish.

Quiz #3 OAOP Stock Notification Letter

Stock notification letters are available:

- a. 24 hours 7 days a week
- b. 8:30 AM - 4:30 PM Monday thru Friday
- c. To shipping and ordering designees with an active IAM account
- d. Only for agents that are or were distributed by PMB
- e. All of the above

Quiz #4 OAOP Stock Notification Letter

OAOP is:

- a. An abbreviation for "Online Accountability Ordering Profile"
- b. The system PMB uses to manage investigational agent inventory
- c. A relatively new interface by which sites order and track investigational agent shipments
- d. A supplement to paper CDRs

Answers- page 4



Drug Accountability for Multi-Dose Vials: Digging for Ideas? (original NCI DARE)



There are numerous considerations to using multi-dose vials, such as appropriate storage and labeling with a new expiration date once opened or punctured. Even more challenges can arise with drug accountability. Trastuzumab (NSC 688097) is the only multi-dose vial distributed by PMB. There is no one definitive method, but PMB recommends tracking inventory either by milligram or by vial.

The preferred method will depend on factors relating to your site and staff. Tracking by milligram involves more calculations whereas the term "partial" can be used when tracking by vial. Record either the number of vials plus the word "partial" when using the vial method, or the number of vials plus the milligram amount remaining in the partial vial. Waste of partial vials must be recorded, but whether to discard the unused portion is up to your professional judgment depending on sterility and stability.

Miscellaneous-Agent News

Agent/ Strength	NSC #	Affected Protocol/s	Action/ comment
Docetaxel (Taxotere) 80 mg/ 2 mL or 40 mg/ mL	628503	CALGB- 90203	PMB is no longer supplying the 40 mg/mL dual vial. Docetaxel is now available as a 20 mg/mL or 80 mg/4 mL single vial size.
Navitoclax (ABT-263) 25 mg/tablet or 100 mg/tablet	750238	new CTEP trials	Must be dispensed in the original bottles.

Time to Plant Cover Crops!



Some important holidays are coming up in the next few months. Those important dates are:

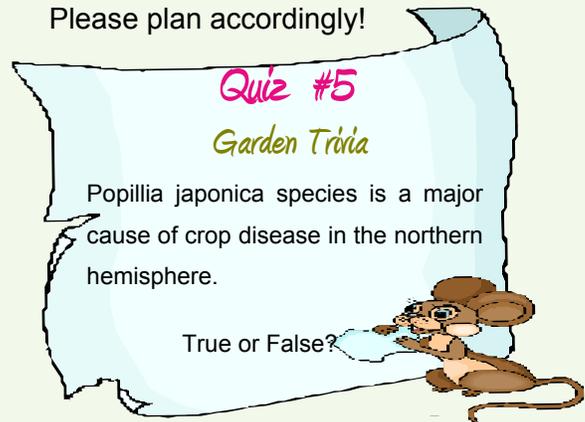
Labor Day (Sept 2), Columbus Day (Oct 14), and Veterans Day (Nov 11) - **all fall on a Monday**. The PMB will be closed and there will be no drug shipments going out on Monday.

For overnight shipments, please place a request by Thursday at 2:00 PM for drug shipment to arrive on Friday. Overnight orders entered on Friday or the holiday will be processed on Tuesday for delivery on Wednesday. Blinded supplies will require an extra day because of patient-specific labeling activities.

Thanksgiving is Thursday, November 28 and PMB is closed. We are open on Friday. However, Tuesday, November 26, is the last day of the week to place orders for next day delivery.

Christmas and New Year fall on Wednesday this year and we will be closed on those days.

Please plan accordingly!



Answers
1. True ; 2.e; 3.e; 4.c; 5. False

