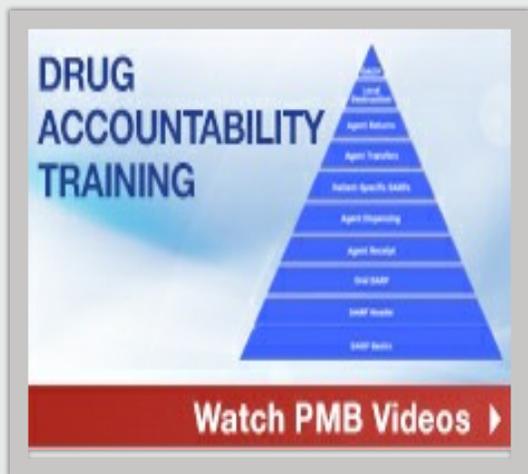


INSIDE PMB February 2016

Cancer Therapy Evaluation Program
Division of Cancer Treatment & Diagnosis

9609 Medical Center Drive, Rockville, MD 20850

Tel: (240) 276-6575; E-mail: PMBAfterhours@mail.nih.gov



http://ctep.cancer.gov/branches/pmb/drug_training_videos.htm

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FAQ webpage:

<http://ctep.cancer.gov/branches/pmb/faq.htm>

For questions:

Call 240-276-6575, Monday through Friday from 8:30am to 4:30pm Eastern Time or email PMBAfterhours@mail.nih.gov .

New Rules Coming for Shipping & Ordering Designees

PMB allows several types of persons to be linked to investigators as “designees” including:

- Primary Shipping Designee (PSD)
- Primary Ordering Designee (POD)
- Shipping Designee (SD)
- Ordering Designee (OD)
- Registration Coordinator (RC)

For several years, PMB has required all “Registration Coordinators” and all “Primary Shipping Designees” to register as an “Associate” via IAM (CTEP’s Identity and Access Management application) before being linked to an investigator as an RC or PSD. In addition, registration is required to access PMB’s OAOP (Online Agent Order Processing) application. **By the end of June 2016, PMB will require ALL persons linked to an investigator as a “designee” to be registered as an “Associate” or risk inactivation as a designee for all of their current investigators.**

The first round of automatic inactivations will occur at the end of February 2016 when the ordering designees who are linked to a “primary shipping designee (PSD)” package but are not registered as an Associate will be removed from the PSD package and inactivated as an ordering designee for all investigators to whom they are currently linked.

To avoid this “self-inflicted” headache, if you are named as a “designee” by any investigator on their “Supplemental Investigator Data Form”, please make certain that you are registered with CTEP as an “Associate” prior to February 29th, 2016 and that you maintain an “active” associate registration status by reviewing your personal information in IAM on an annual basis. If you can login to OAOP, you are “good to go”.

For additional information on registering as an Associate, check out CTEP’s Associate Registration web page:

< http://ctep.cancer.gov/branches/pmb/associate_registration.htm >

To register as an Associate or to check your current Associate registration status, access CTEP’s Identity and Access Management (IAM) application:

< <https://eapps-ctep.nci.nih.gov/iam/index.jsp> >

For questions, please contact the CTEP Registration Help Desk:

< ctepreghelp@ctep.nci.nih.gov >

Updates: Lung-Master Protocol (S1400)

Currently, Arm A (MEDI4736) is closed to accrual, and Arm I (nivolumab versus nivolumab + ipilimumab) is officially open to accrual. Those patients who are still on Arm A may continue treatment until off-protocol criteria are met. When you have no more patients on the treatment and/or the treatment arm is officially closed, return the clinical supply to the NCI Clinical Repository as follow:

- Package the returns to avoid breakage and contamination. Double-bagging is suggested. Return all agents at room temperature; i.e., there is no need to include blue-ice packs for agents that are stored refrigerated.
- Complete a return form (NIH-986) before shipping it to the NCI Clinical Repository. [Note: Do not send the drug to our Shady Grove Address.] The form is available at <http://ctep.cancer.gov> under "CTEP Forms."
- Information needed to complete all sections on the form can be found on the shipping receipt and DARF.

NCI Clinical Repository
627 Lofstrand Lane
Rockville, MD 20850
Attention: RETURNS



IND Withdrawal Notice in 2015

Last year, we issued a few IND withdrawal notices. In case you missed the announcement, the table shows the IND number, agent, affected protocol(s), and the letter date for your convenience.

If you don't have the letter, you can always retrieve a copy via OAOP. For those who need assistance, check out Inside PMB November 2015. It has guidance for querying the PMB notification letters in OAOP.

To return the remaining clinical supplies, use the same instruction for Drug Returns as described above.

IND #	Agent	Affected Protocol(s)	Letter Date
109290	RO4929097 (NSC 749225) and AZD2171 (cediranib) [NSC# 749225,732208]	8503	1/7/2015
111587	AZD6244 Hydrogen sulfate (selumetinib), and MK-2206 [NSC# 748727,749607]	8867, 8868, 9178, S1115	8/7/2015
9306	rV-CEA(6D)/TRICOM [Recombinant Vaccinia-CEA(6D)/TRICOM], and rF-CEA(6D)/TRICOM [Recombinant Fowlpox-CEA(6D)/TRICOM] [NSC# 710067,710068]	833, 5191, 5633, 5762, 6230, 6368, 6439	5/7/2015
117772	MK-8776 (SCH 900776) [NSC# 750505]	All trials using MK-8776	4/28/2015
46211	Alvocidib (flavopiridol) [NSC 649890]	All trials using alvocidib	3/23/2015
59073	EMD 121974 (Cilengitide) [NSC# 707544]	All trials using EMD 121974	3/20/2015
105994	RO4929097,GDC-0449 (Vismodegib) [NSC# 749225,747691]	8406, 8420	3/26/2015
61135	STI571 (imatinib, Gleevec) [NSC# 716051]	All trials using imatinib	1/7/2015
111671	PU-H71 [NSC# 750424]	All trials using PU-H71	1/5/2015

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New Look and Upgrades to PMB videos

The PMB Investigational Drug Accountability video series website design has a new look and exciting upgrades. Please visit http://ctep.cancer.gov/branches/pmb/drug_training_videos.htm to experience the following:

Enhanced navigation!	Each video has a topic index containing 3 to 4 of the main topics covered.
Enhanced viewing!	The videos now play in a new expanded window. The video handouts are reformatted with enlarged graphics.

Please continue to stay tuned in 2016. The series will be completed with the remaining 2 videos, Agent Returns and Local Destruction.

NCI-MATCH Updates

As some of our readers already know, EAY131 (NCI-MATCH) temporarily closed to accrual for screening (Step 0) as of November 4, 2015. The planned interim analysis was triggered when 500 patients were enrolled, but treatment assignment is still active (Step 1). Patients consented to screening before November 4, 2015 can still be assigned in Step 1. When you order agent for a new patient on EAY131, please indicate in the comment field of OAOP that you have a new patient enrolled to the specific arm you are ordering drug for. Starter supplies are not available for this study.

EAY131 originally opened for enrollment on August 12, 2015 with 10 treatment arms. By spring 2016, many more arms will open for assignment, therefore increasing the likelihood that patients will match to one of the targeted agents. NCI-MATCH updates can be found on the NCI's Precision Medicine website:

http://dctd.cancer.gov/MajorInitiatives/NCI-sponsored_trials_in_precision_medicine.htm

