INSIDE PMB
May 2016

Cancer Therapy Evaluation Program
Division of Cancer Treatment & Diagnosis

INSIDE

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

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 .

Obtaining Investigator Brochures (IB) for DCTD/CTEP-Sponsored IND Agents

Near the end of April 2016, Investigator Brochures for DCTD/CTEP-sponsored IND agents will be accessible directly through the Pharmaceutical Management Branch Online Agent Order Processing (OAOP) website at <https://eapps-ctep.nci.nih.gov/OAOP/pages/login.jspx>. Further correspondence will be distributed when the documents become available in OAOP.

Access to this application is managed by credentialing the user in CTEP's Identity and Access Management system. An active account status and current password is required to access the site. Please refer to the FAQ: How do I access OAOP at <http://ctep.cancer.gov/branches/pmb/faq/docs/how_to_access_oaop.pdf>.

The IB documents will be accessible under the "Investigator Brochures" tab in OAOP. Instructions on how to access the documents and additional information will be available from the "Help" link within the "Investigator Brochures" tab.

All study PIs, site PIs, study grant PIs, investigators who received agent shipments or transfers for the affected trials, designated CTEP site coordinators for certain trials, and NCTN/ETCTN/Consortium/Network operations office-provided Org-to-PMB IB contacts as well as CIRB-provided Org-to-CIRB contacts will be notified via e-mail notification when new IB documents are posted in OAOP. These notifications will be sent from the "NCI PMB Investigator Brochure Notification" with the e-mail address of NCIPMBBrochure@mail.nih.gov . Please be sure to add this address to your "safe recipients" list in order to ensure receipt of the notifications. It is the site PI's responsibility to ensure all site-level research staff are provided with the documents for conduct of the research.

Additional site-level research staff cannot be added to these system-generated notifications. Other site-level research staff can be notified when new IB documents are available in OAOP by subscribing to the PMB Listserv. Individuals can subscribe to the PMB Listserv any time at the PMB Newsroom http://ctep.cancer.gov/branches/pmb/pmb_newsroom/default.htm. Site-level research staff with IAM credentials can access the documents in OAOP on behalf of their site PI for the trial.

Questions regarding obtaining an investigator brochure can be directed to the Pharmaceutical Management Branch (PMB), CTEP, NCI by calling (240) 276-6575 Monday through Friday from 8:30am to 4:30pm Eastern Time or by emailing ibcoordinator@mail.nih.gov at any time.

Tel: (240) 276-6575

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4 Things You Should Know About PMB-Supplied Dabrafenib and Trametinib

1. Previously active NCI studies using PMB-supplied dabrafenib and/or trametinib are now re-opened to accrual as of April 11, 2016. These studies were temporarily closed to accrual in February due to limited agent supplies. Patients who were already registered to studies were able to continue treatment with careful management of the remaining supplies.

2. CTEP has worked with the pharmaceutical collaborator over the last several weeks to reach a plan for re-supply so that studies could re-open accrual. Part of this plan involves switching future shipments to commercially-labeled supplies for investigational use. Be aware that the transition from investigationally-labeled to commercially-labeled supplies has started and will take months as the investigationally-labeled supplies are exhausted. Sites should continue to use the older supplies prior to transitioning to the newer supplies. Note that the bottle counts of the commercially-labeled supplies are different than their investigational counterparts.

3. Since no starter supplies are being provided, PMB will be able to ship study agents to sites only after new patients are officially enrolled to a treatment arm requiring one or both of these agents. When ordering in OAOP, please provide the patient ID numbers, doses and dosing schedule in the Comment field of each order so that the PMB pharmacist can verify the orders.

4. Until this transition is completed, protocol "How supplied" sections should include language about both supplies: investigationally-labeled and commercial-labeled supplies for investigational use. Study Principal Investigators are amending their protocols now to include these changes to the pharmaceutical sections. Depending on the time it takes for amendment activation, be cognizant of a potential delay before you see these changes. For any questions, call PMB at 240-276-6575 or email PMBAfterhours@mail.nih.gov.

Blinatumomab New Vial Strength

The NCI is replacing the current blinatumomab supply 30.3 mcg vials with new supply 38.5 mcg vials. This will also result in a different vial concentration following reconstitution of the drug, increasing from 9.87 mcg/mL to 12.5 mcg/mL. The following NCI protocols are affected by this change: E1910, AALL1331, and S1318.

For the transition, the PMB will issue a Stock Recovery Letter to the sites upon the Central IRB approval of the protocol amendment. The letter will instruct the sites to order the new 38.5 mcg vial strength and to return the remaining 30.3 mcg supply (intact vials) to the NCI. To avoid any treatment interruption, return the old vial strength only when the new supply has been received in the pharmacy.

Those sites that are still awaiting amendment approval from their local IRB may continue using the 30.3 mcg vials. Once the protocol amendment is approved, all new cycles must use the new vial strength.

The PMB has a limited supply of 30.3 mcg vials; therefore, we encourage sites to ask their local IRB to expedite the review and approve the protocol amendment no later than June 30, 2016.

Contact PMB at PMBafterhours@mail.nih.gov should you have questions.

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Pediatric MATCH

Pediatric MATCH is the pediatric counterpart of the NCI-MATCH ("Molecular Analysis for Therapy Choice") trial that activated in August 2015 for adults with solid tumors or lymphomas who have progressed on standard therapy. Pediatric MATCH will enroll children and adolescents with advanced cancers that have progressed on standard therapy and be led by the NCI-funded Children's Oncology Group (COG), a member of the NCI National Clinical Trial Network (NCTN).

Similar to the adult NCI-MATCH trial, DNA sequencing will be used to identify children and adolescents whose refractory/recurrent tumors have genetic abnormalities which may respond to existing approved or investigational targeted therapies. Pediatric MATCH will also have multiple arms which means agents cannot be ordered from PMB until a patient has been enrolled on a specific arm.

Pediatric MATCH is still under development and additional details will be provided at a future date. The goal is to start this trial in 2016 with at least 5 arms.

For more information on NCI-sponsored trials in precision medicine, please visit: http://dctd.cancer.gov/MajorInitiatives/NCI-sponsored_trials_in_precision_medicine.htm

Investigator Registration Forms & DARFs With a New Approved Date

The Office of Management and Budget (OMB) has re-approved the NCI Investigator Registration Forms (IR) and the NCI Drug Accountability Record Forms (DARFs) for another three years. The new expiration date is March 31, 2019 All forms are now available on the CTEP web site at http://ctep.cancer.gov/forms/.

We will continue to accept the old Investigator Registration forms for a period of 90 days; therefore, both "2016" and "2019" versions of the forms will be accepted through Friday, July 15th. Beginning Monday, July 18th, only the "2019" versions of the forms will be accepted.

The IR package consists of the following forms:

- FDA Form 1572
- Financial Disclosure Form
- Supplemental Investigator Data Form

If you have questions, contact PMB at pmbafterhours@mail.nih.gov.