INSIDE PMB

November 2014

Inside

PMB Contact Information

Investigator Brochures for which CTEP holds IND:
ibcoordinator@mail.nih.gov

Investigator registration questions:
pmbregpend@ctep.nci.nih.gov

Questions about IAM account establishment process:
CTEPREGHelp@ctep.nci.nih.gov

Cancer Therapy Evaluation Program
Division of Cancer Treatment and Diagnosis

U.S. Department of Health and Human Services

National Institutes of Health
National Cancer Institute

Communication

Technology and social networking have clearly created a new platform and changed the way we communicate. Twitter and Facebook have revolutionized the social media network, and PMB chose YouTube as a communication platform to deliver our Investigational Drug Service (IDS) educational training. Additional information on the live training videos is below.

Other highlights in this issue are a list of new agents in the PMB agent portfolio, page 2; an update on the MATCH trial on page 4; and steps and guidelines for checking investigator registration status, page 3.

We want to hear from you. Send us suggestion and recommendation!

PMBafterhours@mail.nih.gov

PMB Video Launch Takes Off

The first set of PMB Investigational Drug Accountability Training Videos is now live at http://ctep.cancer.gov/branches/pmb/drug_training_videos.htm and is also accessible from the PMB main page.

1. DARF Basics (length 00:05:05)
2. DARF Header (length 00:04:33)
3. Oral DARF(length 00:06:12)
4. Agent Receipt (length 00:06:03)

We can't wait to see the number of views and we welcome your comments. Please direct comments to PMB by calling (240) 276-6575 Monday through Friday from 8:30am to 4:30pm Eastern Time or by emailing "PMBAfterHours@mail.nih.gov" at any time.

Thank you for watching and stay tuned for news about additional videos in the series!

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Stability Updates

Pazopanib tablet (NSC 737754)

Stability: An opened original container of tablets is stable for 3 months. If exact quantity must be dispensed, then extra tablets must be removed, documented and destroyed immediately. Alternatively, if exact quantity is dispensed in a pharmacy bottle, the supply should be assigned a 30-day expiration.

Blinatumomab (NSC 765986)

Stability: The stability of the prepared IV solution is 8 days when stored refrigerated at 2^0 to 8^0 C. The total storage and administration time must not exceed 8 days. Once at room temperature, discard the IV bag after 48 hours.

Eribulin (E7389; NSC 707389)

Stability: Original supplies are stored refrigerated (2˚-8˚C / 36˚-46˚F) and will continue to be stored refrigerated.

New supplies storage condition is at room temperature (25˚C / 77˚F); excursions permitted from 15˚C to 30˚C (59˚F to 86˚F).

Please check the agent label upon agent receipt for the recommend storage temperature.

New Agents

Agent	NSC	Class	Route	Availability	Protocols/Diseases
Ganitumab (AMG 479)	750008	IgG1 against IGF1R	IV	210 mg vial (70 mg/mL)	AEWS1221 trial (upcoming)
Nivolumab (BMS 936558; MDX106)	748726	Anti-PD-1 monoclonal antibody	IV	100 mg vial (10 mg/mL)	Various trials – melanoma, solid tumors, etc.
VX-970	780162	ATR inhibitor	IV	200 mg vial (20 mg/mL)	Combination with a DNA-damaging agent in refractory solid tumors

Stock Notification Letters
A Few Considerations…

The stock notification letter accomplishes two things:

1) Alerts sites as to when PMB-supplied agent is going to expire or is required to be returned for other reasons.

2) Instructs sites to return any material within 90 days of the expiration or other return reason.

We issue these stock notification letters with as much advanced notice as possible based on communication we receive from the manufacturer. However, when stock recovery is initiated for an expiration date, agent should only be returned once the product is expired, not in advance. PMB expects sites to use agents for patient therapy up until the expiration date. Before reordering agents, sites should consider factors such as if any patients are actively being treated, the number of patients actively being treated, length of protocol-defined treatment cycles and any site-specific dispensing procedures.

Please do not reorder just to “replace” agent sitting on the shelf.

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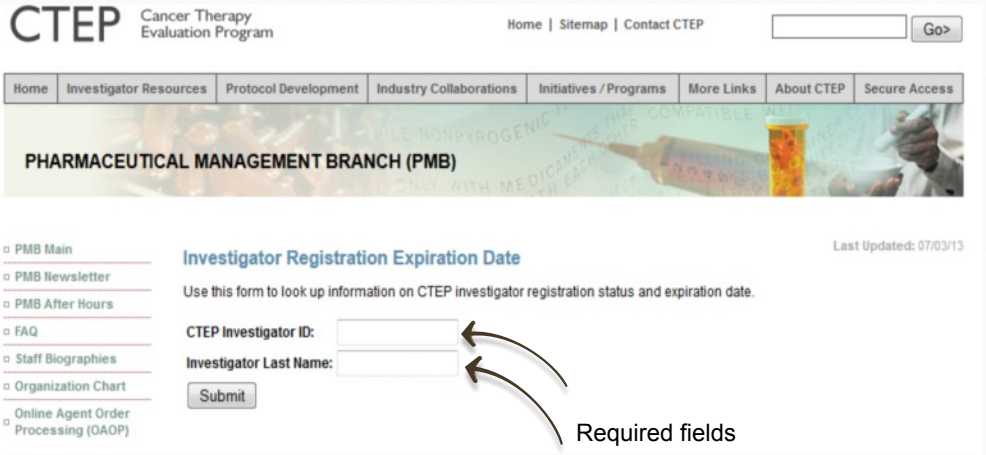
Investigator Registration and Expiration Date

CTEP investigator status can be queried by entering the investigator ID and his/her last name in the required fields. Both fields must be populated to receive the requested information. This query has been updated to provide a list of the active organization affiliations for the investigator.

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



A few suggestions if investigator ID is unknown:

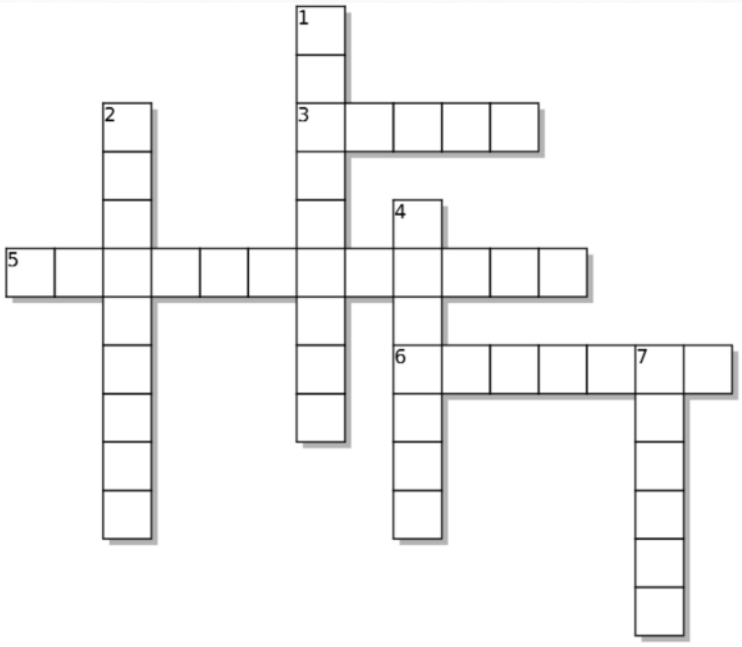
- Look up the investigator ID via OAOP - all investigators who are registered with CTEP with whom the OAOP user is associated can be accessed through OAOP; or
- Check with the institution's Research Coordinator

The CTSU website may be useful if you have access to it. The "Regulatory" tab can provide a list of all investigators at the site including the investigators' registration status, CTEP investigator ID number, and organizational affiliations.

Congratulations to **Kim Turner** from Genesis Cancer Care Institute in Davenport, Iowa and **Donald Winters** from Meridian Health Neptune, New Jersey for being the first ones to turn in the crossword puzzle of the August 2014 issue.

Answer keys to the August issue crossword puzzle are on page 4.

Crossword Puzzle



ACROSS

3 ATR inhibitor
5 Is administered by continuous IV infusion
6 Social media

DOWN

1 Anti-PD-1-monoclonal antibody
2 IgG1 against IGF1R
4 Location of IDS training videos
7 or MATCH trial

Answer key p. 4

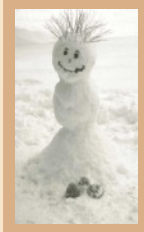
MATCH is Unparalleled

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

The Molecular Analysis for Therapy Choice (MATCH) study is the NCI's newest and largest precision medicine initiative to date. The "basket" trial design will feature multiple concurrently-accruing phase 2 arms, each with a different targeted agent(s)/mutation combination. Approximately 3000 patients with solid tumors and lymphomas who progress on standard care therapies will be screened for specific tumor abnormalities, with the goal of matching at least 1000 patients to one of the available agent/mutation combinations. When an arm reaches maximum accrual of 31 patients, it will close and another agent/mutation arm will be added. There is a potential for at least 40 arms over the course of the trial.

Patients will be asked to consent to molecular profiling first and then to the particular targeted arm if assigned. The large-scale screening effort is intended to find positive responses in multiple tumor histologies, some of which might not otherwise be prioritized in conventional trial designs. Since some agent/mutation combinations are already known to be effective in certain tumors, each arm will have specific eligibility criteria based on the current level of evidence. Certain tumor histologies/mutation combinations may be excluded. Positive findings will provide the basis for future investigation.

MATCH or EAY131, led by ECOG-ACRIN, is expected to activate in early 2015. It will be available through the National Clinical Trial Network (NCTN), which includes up to 2400 clinical sites. For more information visit http://dctd.cancer.gov/MajorInitiatives/NCI-sponsored_trials_in_precision_medicine.htm#h02.



Inclement Weather

The weather in the Washington Metropolitan areas is unpredictable. We have a plan in place should we close during the inclement weather and you need to know the followings:

- The PMB staff can be reached at pmbafterhours@mail.nih.gov.
- Do not leave a message on the voice mail.
- Drug shipments may be delayed and will resume as soon as possible.

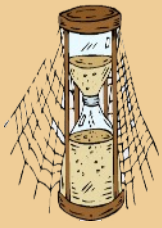
CTEP New Policy for International Participation in CTEP Trials

Due to shrinking resources, CTEP's capacity to support clinical trials has become increasingly limited. The Program has looked closely at all the studies we support. One area that has been evaluated is the support required for participation of international sites in CTEP trials. To address this issue CTEP established the International Site Coordinating Group to evaluate requests for international site participation in CTEP trials. The goal has been to develop policies and procedures to ensure that the Program identifies and supports those studies where international site participation is most valuable. CTEP continues to strongly support the National Cancer Institute initiative to expand the level of participation of international sites in our clinical trials, but is compelled to ensure that our resources are being utilized in the most efficient manner. CTEP will continue to evaluate this process and provide guidance as we develop these policies and procedures.

Augsut 2014 issue answer keys:

Across:
2. OAOP; 5. Oral; 8. IDF; 9. Medidata Rave; 10. NCTN

Down:
1. Umbrella; 3. Precision; 4. Basket; 6. Lot; 7. Five



Answer key:

Across:
3. VX 970; 5. Blinatumomab; 6. Twitter

Down:
1. Nivolumab; 2. Ganitumab; 4. YouTube; 7. EAY131

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