# INSIDE PMB

## August 2014

## Inside

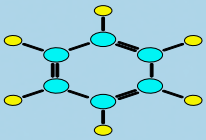


## PMB contact information

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

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

Questions about account establishment process (e.g., IAM account): CTEPREGHelp@ctep.cni.nih.gov



Cancer Therapy Evaluation Program
Division of Cancer Treatment & Diagnosis

U.S. Department of Health and Human Services

National Cancer Institute
National Institutes of Health



Does serendipity really play a role in science discovery? Although some believe that serendipity plays a role in science innovations such as the discovery of penicillin, it is fair to say that serendipity may be an important element in the revolutionary of science.

That said precision medicine needs a 'bit' more than a *good fortune* as it is a precise medicine that targets specific tumor cells in that patient cancer. The treatment is individualized. The NCI and the NCI collaborators are pleased to be part of this avant-garde medicine and to share it with the science community. For additional information on precision medicine, please read the article below.

We hope that you find this issue interesting. We try to bring relevant topics. To keep you involved, we have a crossword puzzle on page 3.

## Precision Medicine is Here!

Traditional cancer treatment targets the rapidly dividing cells at the tumor level. Yet, we observe that patients with the "same" cancer do not always respond to the same treatment. Today's innovative technologies target cancer at the molecular level, thus hitting the distinct biological factor that is driving the patient's tumor. This is called precision medicine or personalized medicine. Precision medicine drug development requires biomarker-driven trial designs such as "basket trials" and "umbrella trials". Both designs explore a variety of new drugs; however, basket designs test a predictive biomarker across multiple cancer types whereas umbrella designs test multiple predictive biomarkers within a single cancer type.

### Where are the trials now?

One umbrella trial is Lung Master Protocol (Lung-MAP) SWOG, S1400 launched June 26, 2014.

Lung-MAP is a phase II/III trial design in second line therapy for squamous cell lung cancer using a large scale approach in screening/ clinical registration. Genomic screening is used to identify specific molecular targets/biomarkers for which there is a targeted drug available, leading to selected drug treatments unique to the patient's tumor. This approach improves a patient's likelihood of receiving a drug that will work while allowing for new therapies to be added as the trial progresses. For more information please visit:

http://www.lung-map.org/

One basket trial is Molecular Analysis for Therapy Choice (MATCH) ECOG-ACRIN, EAY131. The NCI MATCH study will screen patients with multiple tumor histologies for specific mutations that are matched to a list of available targeted agents. It will consist of a number of phase II studies each addressing a single molecularly characterized cohort of patients. This trial is currently in review.

Stay tuned!

9609 Medical Center Drive, Rockville, MD 20850 . Tel: (240) 276-6575. Email:pmbafterhours@mail.nih.gov

# A Primer for Understanding NCTN

The NCI's National Clinical Trials Network (NCTN) officially launched March 1, 2014 consolidating the conventional cooperative group system into fewer groups of a network resulting in a more efficient and collaborative clinical trials system. Resources are shared throughout the network. A schematic below illustrates the new network structure.

What does this mean to the Inside PMB reader? You may notice some changes in the title page of existing protocols, new protocol language and other things. Some important points:

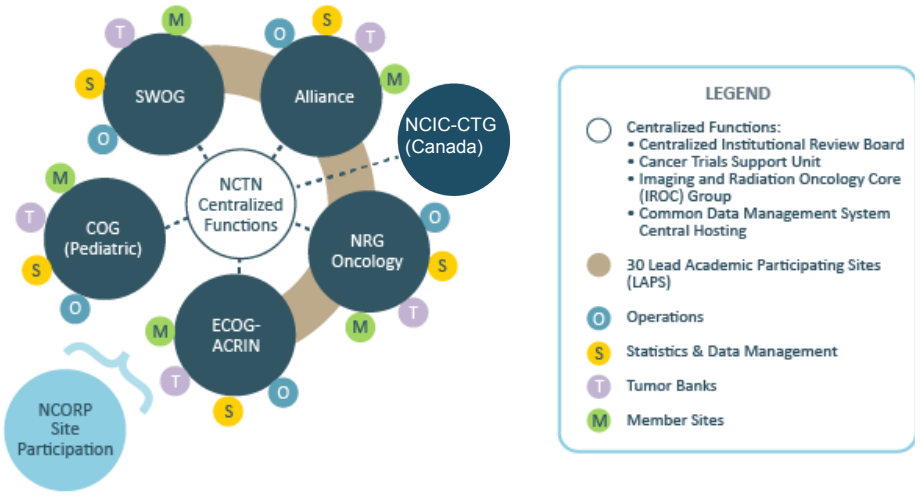
Protocol document

- All participating groups must be listed on the title page of every protocol; references to "participation through the CTSU" are not acceptable.
- Phase 3, phase 2/3 and most phase 2 trials will be open to the entire NCTN
- Patients are enrolled through OPEN (Oncology Patient Enrollment Network)
- Most protocols are reviewed by the NCI's Central IRB
- Data collection is through Medidata Rave

Investigator Status and Clinical Drug Requests

- Participating NCTN groups maintain current rosters of member sites and investigators
- Investigators must be listed on a participating NCTN group's roster in order to register patients through OPEN and order agents from PMB

**NCI National Clinical Trials Network Structure**




http://www.cancer.gov/clinicaltrials/nctn#trials

# Drug Shipment Status

A patient was registered to a trial at your site, you submitted a Clinical Drug Request to PMB through OAOP, and you would like to schedule the patient's clinic visit accordingly. You wonder if you will be notified when your agent order request is processed and when you should expect to receive the agent.

If you need information immediately, it's always best to speak to one of the PMB pharmacists directly to avoid any drug shipment delay or to avoid other issues that the PMB staff may encounter during the processing of the agent request. Sites can always query the order status in OAOP. When the agent order is shipped, the Ordering Designee for the request and the Shipping Designee for the investigator will receive an automated shipment notification e-mail, which contains the order details and the shipment tracking number.

As a reminder, PMB uses FedEx Ground Service for all non-expedited, room temperature shipments, which can take up to 5 business days to arrive at the shipping address after the order has shipped.

Please plan accordingly when placing requests through OAOP or provide an express courier account number to expedite receipt of the shipment.

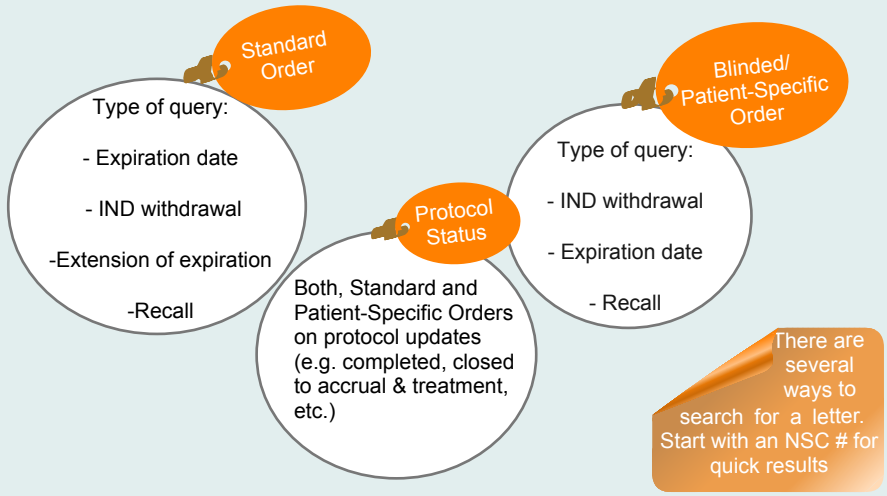
# Suggested tips

All PMB notification letters are accessible through OAOP to registered investigator Shipping Designees and/or Ordering Designees with an active CTEP IAM account. The answer is at the tip of your finger. Quick and simple process. HOW?

Log on to the OAOP website https://eapps-ctep.nci.nih.gov/OAOP/pages/login.jspx using your active IAM username and password.

Next, select the tab labeled “Stock Notification Letters”

Then, select one of the options: “Standard Orders,” Blinded/Patient-Specific Orders,” or “Protocol Status Change.”




## I don’t have an IAM account…

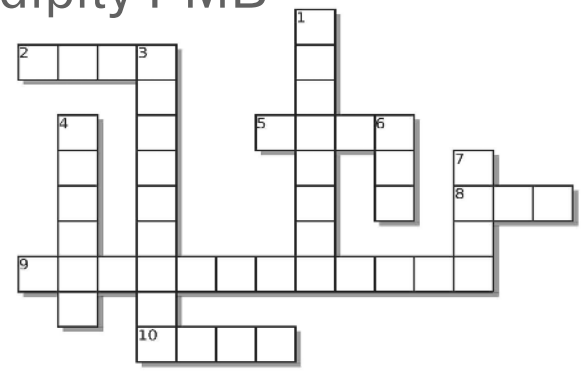
To obtain a CTEP IAM account, go to: https://eapps-ctep.nci.nih.gov/iam

Once you obtain an IAM account, you need to be listed on the Supplemental Investigator Data Form (IDF) as a Shipping Designee or an Ordering Designee to get access to OAOP.

IDF form can be found at:

http://ctep.cancer.gov/investigatorResources/docs/supplemental_investigator_data_form_final.pdf.

# Serendipity PMB



ACROSS

2 All notification letters are accessible through .....
5 New DARF is for ..... medicines.
8 All ordering designee should be listed on the Supplemental ..... (abbreviation).
9 Data collection is collected through .....
10 Officially launched March 1, 2014.

DOWN

1 The Lung-MAP trial is an ..... trial.
3 ..... medicine targets at the molecular level.
4 The NCI MATCH trial is a ..... trial.
6 The .... number must always be collected on the DARFs.
7 FedEx Ground Service takes up to ..... days for non-expedited drug shipment.

## Inside PMB: August 2014

Be the first to turn in a completed crossword puzzle.

Send in the completed crossword to pmbafterhours@mail.nih.gov. We will announce the winner in the November issue.



9609 Medical Center Drive, Rockville, MD 20850 . Tel: (240) 276-6575
Email:pmbafterhours@mail.nih.gov

"Our policy requires us to record an expiration date or a retest date," you said.

Please note that we issue a notification letter for an expiration date once the agent has reached its shelf-life. If the agent is still going under a stability testing, we cannot give you the retest date nor a notification letter. Questions?

Call:

240-275-6575

E-mail:

PMBAfterhours@mail.nih.gov

# Feature Column: Web and Video Updates

The following new and updated materials are available on the PMB webpage http://ctep.cancer.gov/branches/pmb:

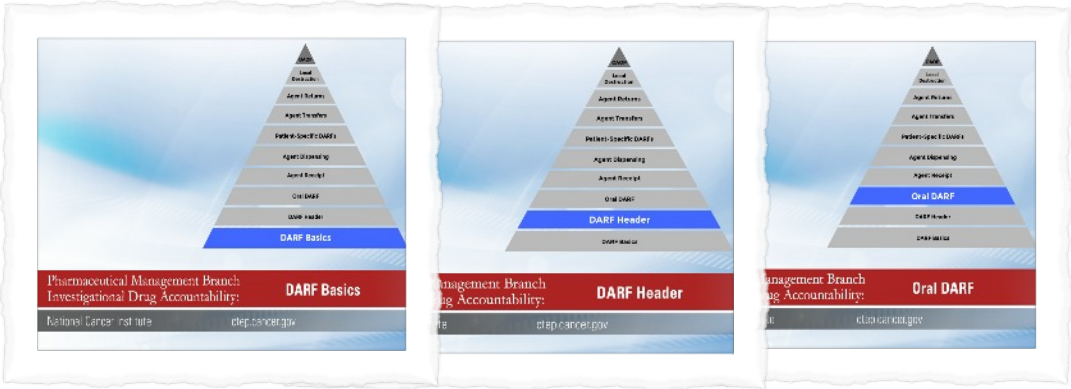
Agent Management

- Policy and Guidelines for Investigational Agent Distribution (UPDATED)
- Policy and Guidelines for Investigational Agent Transfers (UPDATED)
- Policy and Guidelines for Investigational Agent Returns (UPDATED)

· FAQ

- Returning agent to NCI Clinical Repository (UPDATED)

PMB is in the process of recording Investigational Drug Accountability training videos. The following videos will soon be available through PMB's website and linked to the NCI YouTube channel https://www.youtube.com/user/NCIgov/:




## Federal Holidays through January 2015

- Labor Day – Monday, September 1, 2014
- Columbus Day – Monday, October 13, 2014
- Veterans' Day – Tuesday, November 11, 2014
- Thanksgiving – Thursday, November 27, 2014
- Christmas – Thursday, December 25, 2014
- New Year's Day – Thursday, January 1, 2015
- Martin Luther King, Jr. Day – Monday, January 19, 2015

**Please plan accordingly**