

# INSIDE PMB

## May 2015

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### Contact Information

Investigator Brochures for which CTEP holds IND:

[ibcoordinator@mail.nih.gov](mailto:ibcoordinator@mail.nih.gov)

Investigator registration questions:

[pmbregpend@ctep.nci.nih.gov](mailto:pmbregpend@ctep.nci.nih.gov)

Questions about IAM account establishment process:

[CTEPREGHelp@ctep.nci.nih.gov](mailto:CTEPREGHelp@ctep.nci.nih.gov)

### New Distribution Pool



At the end of April, PMB implemented an enhanced distribution process for stock recovery notices. The new process increases the pool of individuals at clinical trial sites that receive copies of the PMB-supplied agent stock recovery notices. In addition to the site investigator and shipping designee that originally received the agent shipment, **all current shipping designees and ordering designees at each site will also begin receiving these notices.** These notices will continue to be sent electronically. Please work with your Information Technology professionals to ensure these e-mails are received and not blocked by your e-mail servers. Notices will be sent from a mailbox named “**NCI PMB Investigator Notification Distribution**” with an e-mail address of [NCIPMBNotification@mail.nih.gov](mailto:NCIPMBNotification@mail.nih.gov). As with any communication, sites need to ensure these notices are acted upon. We are doing what we can to ensure these notices reach a larger audience at each site, but it is up to you to act upon these notices. All distributed notices remain accessible through the Stock Notification Letters tab in OAOP.

**Note:** If you want to be the shipping designee and/or ordering designee at your site, ask your investigator to add you as an authorized designee on the Supplemental Investigator Data Form or Primary Shipping Designee/Ordering Designee Form and submit it to PMB.

### Found Expired Agents

So you found an expired agent in your inventory a year later from the date of the formal Lot Stock Recovery Letter was issued. In that moment, your gut might say to destroy the agent per your institutional SOP; well, don't. All CTEP-supplied agents must be accounted for by us as the sponsor, which requires the agent to be returned to the NCI Clinical Repository or destroyed through the local destruction authorization process, if allowable, for the particular agent. Returns of agent supplies should be sent to the NCI Clinical Repository by completing the Return Drug List. The NCI Policy and Guideline for Investigation Agent Returns and the Return Dug List Form can be accessed at [http://ctep.cancer.gov/branches/pmb/agent\\_management.htm](http://ctep.cancer.gov/branches/pmb/agent_management.htm).

If you have questions, please contact PMB.

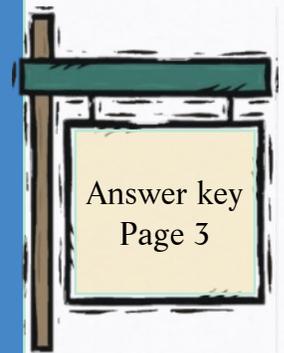


## Odd Issue ...

Occasionally, CTEP-IND agent may also be available as a marketed agent for different indications. For example, blinatumomab has just been approved by the FDA (also known as Blincyto™) for the treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor ALL. The investigational supply and the commercial supply may have the same formulation or may be different. As such, the supplies may be handled differently and may not be interchangeable between protocols. There are a few considerations to make to avoid dispensing errors. First, do not use study supplied investigational agents for non-study subjects and do not use commercial agent supplies in-place of study-supplied agent for study subjects. Second, always follow the preparation guidelines as specified in the protocols. And, always check to make sure you are using the correct agent supply for the study subject. CTEP-supplied study agents will always be labeled with the **IND Caution statement or with a “For Clinical Trial Use Only” label**. This helps sites to distinguish between study-supplied agents and commercial supplies. Please remember to always account for study-supplied agents using the NCI Drug Accountability Record Form.

Match the following chemical names with their generic names.

- |               |                          |
|---------------|--------------------------|
| 1. ABT-888    | a. Cixutumumab           |
| 2. PXD101     | b. Eribulin mesylate     |
| 3. IMC-A12    | c. Veliparib             |
| 4. CDX-011    | d. Ganitumab             |
| 5. E7389      | e. Ganetespib            |
| 6. BMS-936558 | f. Glembatumumab vedotin |
| 7. AMG 479    | g. Belinostat            |
| 8. GDC-0449   | k. Vismodegib            |
| 9. STA-9090   | l. Cediranib             |
| 10. AZD2171   | m. Nivolumab             |



## Discrepancy

in total quantity of the intact bottle

The count of capsules/tablets in the intact bottle is off. What should I do? Although this is an infrequent problem, here are steps to take:

1. Record the discrepancy in Oral DARF; particularly, if you are maintaining your accountability balance by capsule/tablet count versus by bottle.
2. Report it to PMB via [PMBAfterhours@mail.nih.gov](mailto:PMBAfterhours@mail.nih.gov) or by calling us. If this becomes a common problem with a particular agent, we can follow-up with the company collaborator.



## Handling and Disposal of MABs

Some of you have expressed some concerns regarding the handling and disposal of monoclonal antibodies in the CTEP-sponsored trials. This is a common question. Unfortunately there is no global answer to this.

The National Institute for Occupational Safety and Health (NIOSH) publication, "Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings" <http://www.cdc.gov/niosh/docs/2004-165/> is a good reference. Appendix A in the NIOSH Alert provides a list of the hazardous drugs. The most recent hazardous list can be found in "NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2014" <http://www.cdc.gov/niosh/docs/2014-138/>.

Note: If specific MAb is not listed on that list, use a more cautious and conservative handling and disposal approach.

## PMB Video Overview

Videos that are live:

- DARF Basics (length 00:05:05)
- DARF Header (length 00:04:33)
- Oral DARF (length 00:06:12)
- Agent Receipt (length 00:06:03)

available at [http://ctep.cancer.gov/branches/pmb/drug\\_training\\_videos.htm](http://ctep.cancer.gov/branches/pmb/drug_training_videos.htm)

Videos that are coming soon:

- Agent Dispensing
- Patient-Specific DARFs
- Agent Transfers

Thank you for watching!

