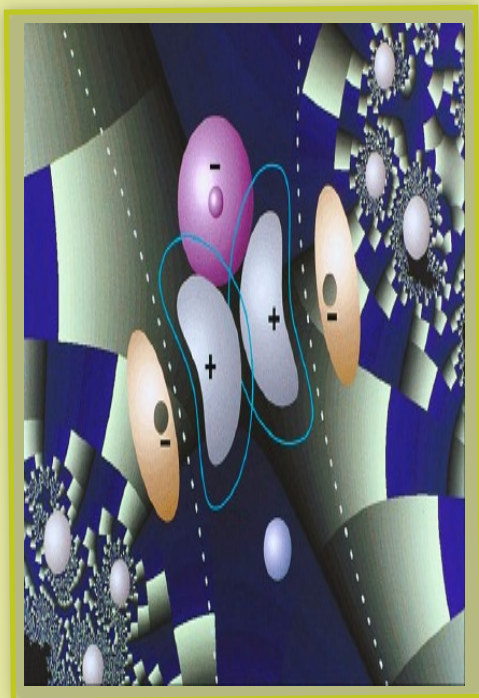


Inside PMB: May 2014

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](#)



Oral DARF, Video training updates, and more ...

We bring exciting and viable articles to keep you interested by providing you with the most up-to-date information and hope that you enjoy reading it.

This quarter issue is all about updates and clarification. As the result from the February article, we received many questions and requests about the Oral DARF. Pages 1 & 2 illustrate some of your concerns; however, our training videos will provide an in-depth education on the NCI DARFs for both oral and other formulations. The tutorial training videos will be available soon. Please refer to page 4 for additional information about the educational training videos.

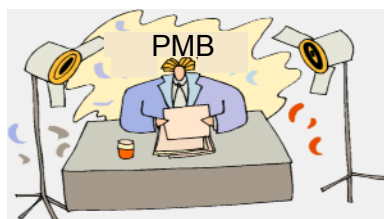
The revised NCI Guidelines for auditing clinical trials for the NCTN Program, CCOP/NCORP and Research Bases is available at CTEP website under CTMB or http://ctep.cancer.gov/branches/ctmb/clinicalTrials/docs/ctmb_audit_guidelines.pdf.

Enjoy your reading!

IN BOX

Please send your comments, suggestions, and inquiries to pmbafterhours@mail.nih.gov or call us at 240-276-6575.

Transition Timeline for the Oral DARF



PMB has received numerous queries about the transition to the new Oral DARF. In the Policy and Guidelines posted on the PMB website (http://ctep.cancer.gov/protocolDevelopment/requisition_agents/docs/oral_agent_accountability_policy.pdf) use of

the Oral DARF became effective March 1, 2014. For sites that had open studies using oral agents as of 3/1/14, transition to the Oral DARF could occur on or prior to March 1st or sites could start using the new Oral DARF when starting a new accountability record page for the trial. Realizing that some sites may be on the same DARF page for years, we do need some finality with respect to use of the original DARF for oral agents. If your site chose the option to continue to use the

existing DARF with the intention to use the Oral DARF when a new page was started for the trial, transition to the Oral DARF must be implemented by September 1, 2014 (even if you do not complete the entire page of the existing DARF).



Oral DARF continues next page

Oral DARF: <http://CTEP.cancer.gov/forms>

Our video IDS training has an amazing tutorial section on this topic. Its status is still in development. For the meantime, a few important points are highlighted here to keep you remained excited about the Oral DARF.

Print Form **Save As** **Reset Form**

Collection of this information is authorized under 21 CFR 312.57. This information is collected to ensure compliance with Food and Drug Administration (FDA) requirements for INDs as an IND sponsor and that investigators, agents, are under the control and accounted for by competent authority. The information may be disclosed to researchers for investigational purposes, sponsors of clinical trials and other company laboratories, the applicable hospital review boards, IRB, FDA and Department of Health and Human Services. Submission of this information is voluntary, however, in order for you to conduct a study in accordance with investigational, current products, you must complete all fields.

Form Approved: ONE No. 0225-0013 Expires: 03/31/2016

Investigational Agent Accountability Record
Oral agents ONLY

National Institutes of Health
National Cancer Institute
Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

PAGE NO.: CONTROL RECORD SATELLITE RECORD

Name of Institution: Investigator Name: CTEP Investigator ID:

Protocol Title: NCI Protocol No: Local Protocol No: Dispensing Area:

Agent Name: Dose Form and Strength: Bottle size (e.g., # tablets/bottle):

Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward Balance	Manufacturer and Lot No.	Recorder's Initials	Expiration Date (if available)	Date Patient Returned	Quantity Patient Returned	Recorder's Initials
1												
2												
3												
4												
5												
6												
7												
8												
9												
10												
11												
12												
13												
14												
15												
16												
17												

This upper portion must be fully completed except the "Local Protocol No." If have it, use it.

Abbreviate Title if it is too long

One line per each transaction and must be fully completed.

Can't remember Control or Satellite Record? Go to http://ctep.cancer.gov/protocolDevelopment/requisition_agents/docs/storage-03.pdf

Patients returns: If information is available, use it. It is NOT intended to document patient drug adherence

How should Oral DARF be used?

The upper portion of the form has to be fully completed with the exception of the "Local Protocol No." If you have it, complete it. The bottom portion of the form contains two parts separated by a dark line:

- The left fields of the dark line are designated for all transactions. Example, receiving the agent from PMB; transporting the agent to the dispensing satellites; or dispensing it to patients. One line for each transaction and must be fully completed.
- The right fields of the dark line are designated for patients returns. These fields allow you to record number of the returned tablets/capsules for destruction on site per institutional policy.

Do:

- Use it for open-label and blinded trials
- Use it for all oral formulations for NCI trials
- Record returned quantities in the return columns (right fields of dark line)

Don't:

- Maintain lot-specific DARFs
- Add returned quantities back into the inventory (left fields of dark line)

For additional clarification, please watch the training module or/and go to our FAQs <http://ctep.cancer.gov/branches/pmb/faq.Htm>.

New Agents in PMB Agent Portfolio



A few new agents have arrived at PMB. Some are already being used in the active NCI trials. Others are still in the working process. Nivolumab is still under the LOI mass solicitation.

Ganestespib (NSC 777169): HSP90 inhibitor targeting heat shock protein; testing in gastrointestinal cancer, NOS.

Rilotumumab (NSC 750009): anti-HGF/SF Mab targeting human hepatocyte growth factor/scatter factor; testing in squamous cell lung carcinoma

Blinatumomab (NSC 765986): Bispecific T cell engaging (BiTE) antibody targeting BiTE; testing in B-precursor ALL; ALL, NOS

Nivolumab (NSC 748726): Anti-PD-1Mab targeting programmed cell death-1 (PD-1) receptor; mass solicitation to test in many tumor diseases such as glioblastoma multiform, NSCLC, NOS, myeloma, Hodgkin lymphoma, nasopharyngeal carcinoma, solid tumor, ovarian epithelial cancer, AML, NHL, chondrosarcoma - just to name a few.

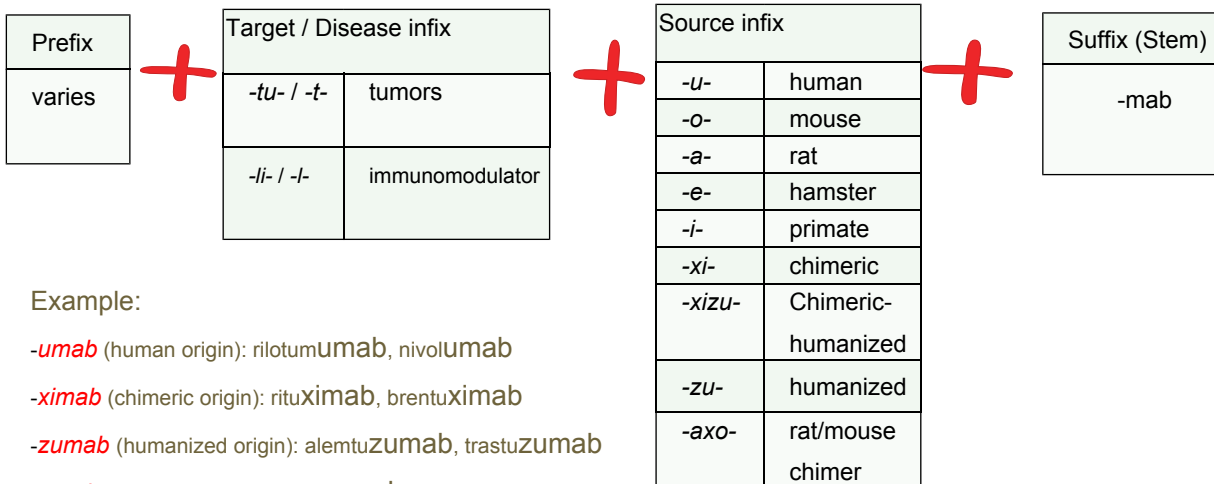
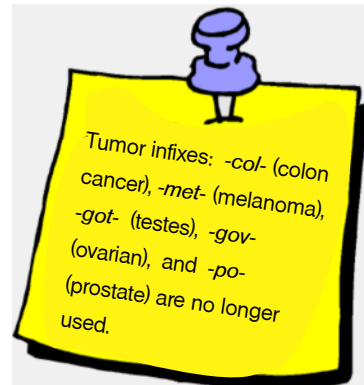
BMN 673 (NSC 771561): poly(AD-ribose) polymerase (PARP) inhibitor targeting PARP1 and PARP2; testing in solid tumor, NOS

MK-3475 (NSC 776864): anti-PD-1-Mab targeting programmed cell death-1 (PD-1) receptor; testing in Merkel cell tumor, cutaneous T-cell lymphoma, mycosis fungoides

Naming Monoclonal Antibodies (mAb)

The United States Adopted Names (USAN) Council serves as the expert to guide manufacturers in the nomenclature classifications of the nonproprietary names for drugs. They provide rules and regulations for the naming system of all generic drugs.

Most monoclonal antibodies' name ends with the suffix "-mab." The key elements to the naming system of the monoclonal antibodies are: (1) a prefix, (2) an infix representing the target or disease, (3) an infix indicating the source, and (4) the stem used as a suffix.





Returning NCI Agents to the NCI Clinical Repository

When ?

- The treatment plan is completed; i.e., no patients receiving the investigational agent at the site
- The clinical trial is closed
- The agent has been recalled
- You received the Lot Recovery Letter from PMB

How?

Package the returns to avoid breakage and contamination. Double-bagging is suggested. Return all agents at room temperature. Complete a **Return Drug List** (available under "CTEP Forms" at <http://ctep.cancer.gov>). Then, ship it to the NCI Clinical Repository at:



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

The return form must be **complete and accurate!**

1. Only agents supplied by CTEP, DCTD, National Cancer Institute are to be returned to the NCI Clinical Repository.
-Refer to the shipping invoice or protocol if uncertain of the source .
2. Fill in the address box, including the name of the institution.
3. Complete areas for Investigator Name and NCI Investigator No.
- Multiple agents and dosage forms on one page

is acceptable, provided they were all received under the name of the same investigator.

- This information is found both on the shipping receipt and DARF.

4. Complete one line for each lot.

-All sections must be completed.

-All necessary information is found on the shipping receipt and DARF.

5. Indicate the reason for the return.

6. Notification of Receipt

-To receive a completed copy of the Return Drug Form from the repository, check the box under the institution's address or place your fax number in the Return Receipt box (located at the bottom right corner)

7. Complete the signature area and save a copy for your records.

8. The Return Drug List form can be completed on line (preferred) or printed and completed by hand writing.

Note: Agents classified as Dangerous Goods (DG) require special shipping procedures. If your site is not qualified to ship DGs, contact the PMB to request permission for local destruction.

Feature Column: Training Videos



PMB is developing video tutorials intended to provide detailed step-by-step guidance on various aspects of drug accountability. The videos will be available through PMB's website and link to the NCI YouTube channel <https://www.youtube.com/user/NCIgov/>.

Each drug accountability video will be approximately 5 minutes in length and contain examples of completed DARFs. PMB is working diligently to bring you the following videos soon:

- Oral DARF
- DARF Basics
- DARF Header

PMB believes these videos will be the ideal media to communicate drug accountability procedures. Users will be able to easily locate a video of interest when learning for first time or looking for a refresher on the topic!

