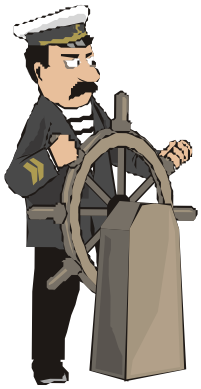
INSIDE PMB

May 2013

CTEP *Cancer Therapy Evaluation Program*
DCTD *Division of Cancer Treatment and Diagnosis*



THIS ISSUE'S THEME: "Ships at Sea"

The PMB experienced a high adventure of its own in March. We moved to a brand new ship in Rockville, commanded by Skip Hall. Hopefully our transition was smooth sailing for most of you, but choppy waters may be ahead as we set afloat initiatives such as the oral DARF, providing online access to stock recovery letters and shrinking the length of the informed consent document. We're hopeful the ship won't stall out in the middle of the ocean, but have your life vests ready just in case!

U.S. DEPARTMENT OF HEALTH AND HUMAN
National Institutes of Health / National Cancer Institute

Simplified NCI Consent Form Template Ready for Maiden Voyage

Informed consent documents can emulate the length and complexity of the Dead Sea Scrolls! With help from numerous shipmates including the FDA and OHRP, the NCI revised the consent form template to be shorter and more easily decipherable. Who wants potential study participants to feel seasick from waves of paper?! Remember the intent of the document is to assist passengers in making an informed decision about boarding the ship, whereas the consenting process supports passengers throughout their voyage at sea.

The NCI strongly recommends consent forms not exceed six to nine pages. By limiting the information to the research issues, a water-logged consent form becomes much more watertight. The new template also provides useful guidance to navigate the high seas such as:

- A "lay" title in addition to the official study title
- Brief description of "usual care" to place research in context
- Text examples of various trial types and phases
- Section limits
- Risks described from a study participant's perspective
- Potential side effects listed using a table format in the "Risks" section

For NCI-sponsored IND agents, risk profiles have been revamped into condensed risk lists to accommodate the new library of lay terms and new format. Please note this creates new CAEPR versions. The ship's crew is also creating risk lists for commonly used commercial drugs and regimens. The goal is to present risks for the entire regimen without repeating lay terms.

Full embarkation details for the maiden voyage of the revised consent template are available at http://ctep.cancer.gov/protocolDevelopment/default.htm (Informed Consent: Template,Tables of Side Effects, and more!). The final boarding call for new protocols to incorporate the consent template is May 15th. Use of the simplified NCI consent form template will help study participants to not feel lost at sea!

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Leave Hoarding to Pirates

A hoard is defined as a wealth deposit of valuable objects. Pirates plundered vessels on the high seas and then buried treasure for safe-keeping. It was retrieved at a later date if otherwise undiscovered. Archaeologists and treasure seekers have brought to light many buried hoards that were displaced or forgotten centuries ago.

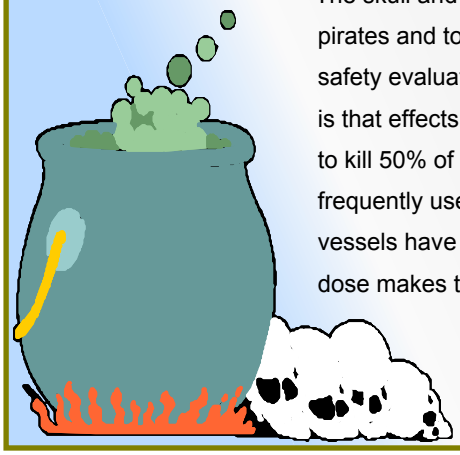
While we are trying to discover new therapies today for cancer patients, no archaeologist will be looking for your hoard of unused cancer drugs in 100 years. We know that a number of you order CTEP-supplied agents and never dispense them! Keep in mind that hoarded supplies on your shelf are supplies that are not available for patients at other sites. We do not allow starter supplies for most studies and limit orders to an 8-week supply per patient per order for this reason. If you are concerned about obtaining enough agent for your site, call us to discuss it. If an agent is in short supply, we will inform you of the shortage and try to get you what you need so study therapy is not delayed. Short supplies are harder to manage for sites that really need them when other sites have excessive supplies.

Tips to minimize hoarding supplies

Wait to order until a patient is being screened for the trial. Check the protocol for the maximum number of days allowed between patient registration and the first dose of therapy.

- Work with research staff to notify you when a patient is being screened for or coming off treatment.
- Dispense from the expiring supply IF the patient will complete the cycle / supply prior to the expiration date.
- Re-order supplies only IF you have patients currently enrolled on study and actively being treated and not just because supplies are expiring.
- Place orders closer to the anticipated dispense date.
- Forward PMB expiration and study closure notices to appropriate members of the team.
- Check OAOP for stock recovery letters if you suspect the expiration date is approaching.
- Request an agent transfer from one trial to another before the expiration date if possible.

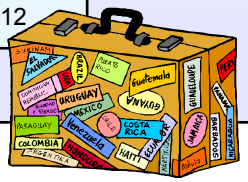
Pirates and Toxicology



The skull and crossbones symbol has a long history, but nowadays is commonly associated with pirates and toxicology. In preclinical research, toxicology studies are the necessary starting point of safety evaluations and are a required component of IND applications. A guiding principle of toxicology is that effects are dose-dependent. A measure of toxicity is the lethal dose (LD50), the dose required to kill 50% of a sample population of test animals within a specified time. Rodent species are frequently used for these evaluations; however, it is unknown if populations of ship rats on pirate vessels have ever been impacted. Toxic agents can kill but they can also cure cancer, hence “the dose makes the poison.”

"CTEP IND Status Changes"

Agent/s (Pirate/s)	NSC#	CTEP-IND status	Completed Date
E1M184V Peptide	732084	withdrawn	12/2/2011
Myeloma IG ID vaccine-KLH	678327	withdrawn	3/9/2012
Interleukin-12 and Interleukin-2 combination	672423 373364	withdrawn	3/9/2012
Bevacizumab and Cetuximab combination	704865 714692	withdrawn	3/12/2012
UCN-01	638850	withdrawn	6/5/2012
17-Allylaminogeldanamycin (17-AAG)	330507	withdrawn	6/21/2012
Pertuzumab	740102	withdrawn	6/28/2012
R)-(-)-Gossypol acetic acid (Ascenta's AT-101)	726190	withdrawn	8/17/2012
17-dimethylaminoethylamino-17-demethoxygeldanamycin (17-DMAG)	707545	withdrawn	8/23/2012



An Ounce of Prevention is Worth a Pound of Cure

Now that spring has arrived, many of us are putting the final touches on those summer vacation plans. Will your travels involve a dream trip across the sea? If so, check out the CDC web site for health information (http://wwwnc.cdc.gov/travel/page/cruise-ship-info-for-travelers.htm) about the CDC's Vessel Sanitation Program, specific health risks and preventative measures for cruise ship travelers (i.e., don't drink the water, or to avoid travel to this area).

Your planned activities will influence your risk. For instance, if your trek takes you to a place where coming into contact with mosquitoes is a possibility, insect repellent is a good idea. Going beach-combing on the Caribbean waters? Consider when you received your last tetanus booster.

Your current health status must be considered. The CDC website lists required versus recommended vaccinations, along with guidance for pregnant women, those who are nursing, as well as individuals with altered immune status (such as those with diabetes or HIV).

Did you know that there are only two required vaccinations for international travel? International Health Regulations require the Yellow Fever Vaccine for those travelling to sub-Sahara Africa and tropical South America. The government of Saudi Arabia requires the meningococcal vaccine annually during the Hajj.

Discuss travel plans with your physician at least 4-6 weeks before your departure. Be sure to check if your routine vaccinations are current. Many diseases virtually eliminated in the United States are still seen in other parts of the world. A little time planning now can save a lot of time and illness later.

Treasure Hunt Almost Over

Arghhh… Your quest for those missing stock recovery letters is coming to an end. No longer will these valuable notices be buried in the PMB treasure chest, but become **available through OAOP 24/7.** This includes access to **stock recovery** and **protocols status change letters** for open-label and blinded clinical supplies. Access is **now available!**

The Jolly Roger or pirate flag, thought to have originated with the Knights Templar in the middle ages, was adopted by pirate ships in the 17th century. After becoming synonymous with danger, the skull and crossbones symbol was used to label poisonous substances since 1850.

During the 1980s, safety advocates pushed for a different symbol (Mr. Yuk) because the skull and crossbones symbol was not a deterrent to children who frequently associate it with pirates.

NCI Clinical Repository Still At Anchor

The address for agent returns has **not** changed. All returns of NCI-supplied agents must go the NCI Clinical Repository (see below). The address is provided on the return investigational agent form found on the CTEP web site. **Do NOT return investigational agents to the NCI Shady Grove address.**

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

PMB Launches New Forms

Ahoy mates! The Office of Management and Budget (OMB) recently approved updates of the PMB's official forms. Note that these forms include **new contact information** that affects how we do business. Addresses for courier deliveries and regular mail delivery have changed in addition to our phone/fax numbers. Please destroy old copies of the forms and replace them with new ones found at http://ctep.cancer.gov/. The following forms have changed:

- FDA Form 1572
- Supplemental Investigator Data Form
- Financial Disclosure Form
- Investigational Agent Accountability Record (DARF)
- Transfer Investigational Agent Form

PMB is tracking uncharted waters with a new OMB-approved form, the DARF (oral). Many parties requested such a form over the last few years and we're excited that sites will be better able to track oral agents. The form looks different from the original DARF, but you'll have to wait to book your cruise because the crew is busy mapping the coordinates with the crew from the Clinical Trials Monitoring Branch. Be on the look-out for information in the next couple of months.