

# Shoot for The STARS!

## inside PMB

May 2009

### CYBERSPACE VOYAGE: TO BOLDY GO...

CTEP launched a new web site ([ctep.cancer.gov](http://ctep.cancer.gov)) into your space in autumn 2008, but it's still moving at the speed of light! Visit often: We've changed the PMB landing page (<http://ctep.cancer.gov/branches/pmb/default.htm>), and added resources to help you develop the pharmacy section in draft protocols. The latest version improves navigation through PMB's areas of responsibility. How? Hyperlinks! Many links are self-explanatory, but others penetrate the depths of our space to answer questions.

- Agent Management: A constellation of links to policies, forms and other web sites that address drug shortages.
  - Investigator Brochures (IB) List: Tells you which IBs we have, and the most recent version date in our possession.
  - Material Safety Data Sheets (MSDS) List: A convenient place to find the MSDS for many CTEP-supplied agents. (Be sure to scroll down on the page!)
  - Cytochrome P450 Drug Interaction Tables: Lists major substrates and effective inducers.
  - Investigator Registration: Contains forms and registration-specific information. See page 2 for more information about this section.
  - Investigator Registration Expiration Date: An interactive tool that lets you verify any investigator's registration expiration date from your own docking station. All you need is the last name and investigator registration number.
  - Treatment Referral Center and Non-Research Use of Investigational Agents: information, information, information!
  - Non-Protocol Access to Experimental Agents: Need an agent off-protocol? Look here.
  - Investigational Drug Handling Slide Show: When educated guesses aren't working, this is the equivalent of celestial navigation.
- CTEP Forms, Templates and Documents: What you need, at your fingertips!

You will also find additional tools under the Protocol Development Help link on the CTEP landing page.

Travel around this new tool; it will save you phone calls. As we explore additional improvements, let us know if you have suggestions.

### METEORIDS, METEORS

"Falling" or "shooting" stars are caused by tiny bits of dust and rock called meteoroids falling into the Earth's atmosphere and burning. They create a fleeting trail of light, or meteor. If any part of the meteoroid survives and actually hits the Earth, that remaining bit is then called a meteorite. So here are some examples of meteoroids (the route of potential problems), meteors (shedding light on the problem), and meteorites (the crash-and-burn information)

Meteoroid: NCI Sponsoring Agent

Meteor: Sponsoring an agent means holding the IND. CTEP sponsors many agents.

Meteorite: When this is the case, if you ship agent to the patient, or anywhere else for that matter, you violate CTEP's policy.

Meteoroid: NCI Distributing Agent

Meteor: In rare instances, PMB distributes agent for another sponsor, but doesn't hold the IND. (There's no easy way to know if this is the case; see page 4 for an example.)

Meteorite: Always refer to the protocol for information as to whether reshipping is allowed. If reshipping is allowed, it's probable that NCI is the distributor, but not the IND holder.

Meteoroid: Prescriptions for study agents are different than prescriptions for other drugs.

Meteor: Experimental means employing untried ideas, methods, or materials. So, DUH! We only give out a little at a time!

Meteorite: Never write or accept prescriptions for study agents that have refills.



## KEEP YOUR INVESTIGATOR "ACTIVE"

(1) To enroll patients on CTEP-sponsored clinical trials, order investigational agent from PMB, or obtain an Investigator Brochure, physicians must be NCI-registered investigators with "active" investigator statuses.

Registration packets include

- FDA Form 1572 (with original signature)
- Supplemental Investigator Data Form (IDF)
- Financial Disclosure Form (FDF; with original signature)
- Current CV

How can you help? Writable (meaning you can fill them in electronically) pdf versions of the 1572, IDF, and FDF are available on PMB's investigator registration page <http://tinyurl.com/djraw6> on the new CTEP web site.

(2) Investigators must re-register annually.

We mail re-registration packets (1572, IDF, FDF) to investigators 60 days before their registration expires. If we don't receive a complete packet 21 days before their registration expires, we automatically send a warning letter. And, finally, we send a suspension letter if we don't receive the complete packet before the expiration date.

How can you help? Become the registration coordinator for your investigators. We'll mail the initial re-registration packet directly to you, not to your investigator, alerting you that their re-registration is due and allowing you to coordinate the re-registration process. Send an email with the subject "Make Me a Registration Coordinator" to the CTEP Registration Help desk [ctepreghelp@ctep.nci.nih.gov](mailto:ctepreghelp@ctep.nci.nih.gov) for further details.

(3) Confirm your investigator's status.

If you know your investigator's NCI investigator number, you can check their investigator status at any time—and quickly. Go to [http://ctep.cancer.gov/branches/pmb/expiration\\_date.htm](http://ctep.cancer.gov/branches/pmb/expiration_date.htm) and enter your investigator's NCI investigator number and last name. If the number and name entered match an investigator in CTEP's investigator database exactly, the site will return the investigator's last name and current NCI investigator status.

As always, if you have questions, please contact PMB by phone Monday through Friday from 8:30am to 4:30pm Eastern Time at (301) 496-5725 or by email anytime 24/7 at [PMBAfterHours@mail.nih.gov](mailto:PMBAfterHours@mail.nih.gov).

*Big Black Hole*

## YOUR PMB HOROSCOPE

**TAURUS (4/20-5/20)** If you're working on acquiring or strengthening a skill, bear in mind that a whisper will get your message across more effectively than scream. Always gather your facts before you call PMB; know things like the investigator's name and NCI number, the agent's NSC, or the patient's ID number.

**GEMINI (5/21-6/21)** Be careful not to relax too much—you could fall into a pattern of bad behavior. Self discipline can be tough when you're on your own, so if you feel yourself blowing off your documentation, try the buddy system. Ask others to check your work.

**CANCER (6/22-7/22)** There's so much going on, you feel like you're being ripped in two. Save time by sending questions or concerns to [pmbafterhours@mail.nih.gov](mailto:pmbafterhours@mail.nih.gov). Or checking the web site's FAQ section.

**LEO (7/23-8/22)** Sometimes you need to seek out more direct communications. When PMB's FAQs (<http://ctep.cancer.gov/branches/pmb/faq.htm>) don't fit your situation exactly, skip the e-mail and call PMB at (301) 496-5725. Technology makes things easier, but it doesn't always help you convey what you're really trying to say.

**VIRGO (8/23-9/22)** You have to know when to stand your ground and not give in—not even an inch. Do not succumb to a request to "loan" NCI-supplied investigational agent to a sister organization.

**LIBRA (9/23-10/22)** Your unique style inspires quite a few followers from time to time, which is flattering. Avoid using this skill to create a new and "better" DARF! The NCI requires you to use the DARF without altering it. If you really need to get creative, do it on the back of the DARF.

**SCORPIO (10/23-11/21)** Despite your most fervent wishes, people do not do exactly what you want them to do, especially if your policies and procedures are hazy. Take a few minutes to reconcile your P&P manual with the P&Ps on PMB's web site (<http://tinyurl.com/d5vve5>).

**SAGITTARIUS (11/22-12/21)** The weather can affect your mood greatly, so keep an eye on the sky! As the weather gets warmer, also check your refrigerator temperature often. Too hot or too cold? The best way to determine if temperature excursions for multiple agents are acceptable is to e-mail the pertinent facts (highest or lowest temperature, length of excursion) and a list of the affected NCI-supplied agents to [pmbafterhours@mail.nih.gov](mailto:pmbafterhours@mail.nih.gov).

**CAPRICORN (12/22-1/19)** Little details overwhelm you this month, and you're getting a bit behind on certain tasks. Do not worry if you forget to order! If you fax your open label order by 2 PM, and include an express courier account number and a note that you need the agent the next business day, you'll have the agent when you need it. Don't be overwhelmed when it comes to blinded supplies, however! There's no next day delivery for blinded!

**AQUARIUS (1/20-2/18)** Don't bend to pressure today, when some coworkers may try some not-so-subtle tactics to sway your opinion. Do not even consider returning stuff to NCI that you didn't get from NCI. Doing so will ruin your karma.

**PISCES (2/19-3/20)** Secrets aren't safe with you today, but not because you're devious or manipulative! Sharing information among healthcare colleagues saves lives.

**ARIES (3/21-4/19)** If you experience friction with an auditor this month, hold your ground, especially if you have reviewed PMB's Investigational Agent Handling slide show. Politely, insistently defend your actions if they are compliant with the slide show's guidance.



**FAQ: What is a satellite? Or, is it OK for us to send drug that we have ordered from the PMB to one of our other offices/sites?**

**Answer:** It depends!

**And again:** IT DEPENDS!

A "Satellite Location" is a local site away from the control area or primary storage area (that is, the place to which PMB shipped the agent). Any transportation of PMB-supplied agents between the control location and satellite location must remain in the institution's immediate control. If delivery of an agent requires use of a secondary carrier (e.g. US postal service, Fed-EX, UPS), the other location is not a satellite.

When investigational agents are received at the control location, they may be transported to satellite locations (originally conceived as within walking distance, sharing staff, and covered by the same IRB). Any transportation must be in the receiving institution's direct control, and a third party shipper may not be used. Local satellite institutions or affiliates must be serviced by institution-employed couriers or central pharmacy staff. CTEP-supplied agents must not be repackaged or forwarded by mail or express courier. The NCI follows established policies that

- maintain validated shipping conditions (and therefore product integrity) for agents used for clinical research
- ensure that PMB can track all product immediately should there be a recall
- convey other important pharmaceutical information quickly when necessary, and
- assist in agent accountability.

Any transportation of investigational agents outside the direct control of the institution receiving the agent is considered secondary distribution. Secondary distribution violates NCI policy and procedures.

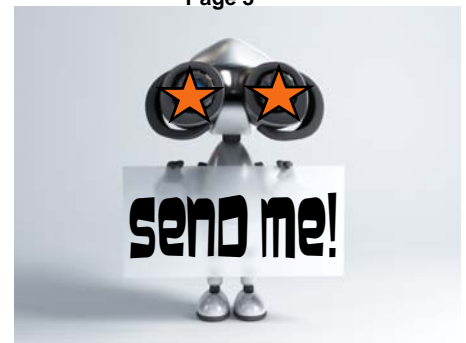
**And if my situation doesn't fit that description, what should we do?**

If your situation doesn't exactly fit this description, call PMB and ask to speak to a manager. She or he will ask some questions including the following:

- How far away is the satellite in both distance and travel time? How many patients will need this accommodation?
- Can we work together to develop a mechanism that works for you that will allow us to directly ship agent to your satellite?
- Does the staff member who will transport the agent know that it is considered a dangerous substance by the Department of Transportation if that is the case?
- How will you address the following?
  - agent stability issues both during transportation and for any storage at the local site.
  - safety issues (dangerous substance, how to handle a spill)
  - preparation of the patient's dose under appropriate conditions by appropriately trained staff
  - the need to have someone that can appropriately administer the medication at the site
  - a method for proper disposal of the waste, empty IV bags, etc.
  - a plan for returning unused medication to the central location
  - a back up plan for those instances where a replacement dose may be needed (product damaged, treatment had to be emergently interrupted, etc.) particularly if treatment has been started
  - confirmation that the medication was given (while not a PMB requirement, it is an investigational study requirement)
  - a plan for handling missed doses
  - a plan for multiple day therapies (are doses driven up each day)
  - agent accountability via a DARF

PMB always prefers to ship to the site where the patient is going to be treated. E-mail any questions to [ctepmbmngmt@mail.nih.gov](mailto:ctepmbmngmt@mail.nih.gov) (PMB Management), or call 301-496-5725

*another Black Hole*



It looks like astronauts and surgeons have something in common. Manned space exploration has been much in the news lately as the US looks at its space program. These programs are costly—and orbiting shuttle cost \$1.7 billion plus the cost of training astronauts—and risky—14 astronauts have died in shuttle disasters. Some scientists propose that unless a job or mission requires a human to do it, rockets and space shuttles can be manned with robots. They are less expensive, and they seem to like the work.

In cancer, an argument can also be made for greater use of robots. It turns out that robots can perform surgery! In robotic assisted surgery, the surgeon inserts tiny laparoscopic cameras into the patient's abdomen through small (1 cm) incisions. These transmit three dimensional pictures of the target organ to a surgeon-manned terminal. The surgeon manipulates robotic surgical instruments that can reach areas human fingers cannot via a control panel. The robot makes precise incisions that are smaller, bleed less and heal faster. Patients experience less pain, and hospitalization is shorter than that associated with open surgery. Patients are able to move to the next step in their treatment plan much more quickly, so the cancer can be treated more aggressively.

To date, this process is used most often with radical prostatectomy or kidney cancer. Outcomes of robotic assisted surgery, when performed by experienced surgeons at high volume centers, prove better than open surgery. Scientists are developing robot assisted surgical procedures for other malignancies, too.

Now, if astronauts were smart, they would get together with surgeons and figure out a way to have continuing education events held on Mars. Then, those highly trained astronauts could fly highly trained surgeons into space, preserving the manned space program and creating a new, exciting location for CE! Imagine the creative ways this could fund the space program...

## CONTEST:

### OUR FEBRUARY 2009 WINNER: Cyndi Rup, CPhT, Worcester MA

Match the situation in the orange column with the best term in the gray column. Fax answers and contact information to (301) 402-0429 or send them to PMBAfterhours@mail.nih.gov, and you'll be eligible for our drawing to win homemade cookies or dog biscuits!

1. The employee who floats off as soon as the order from NCI arrives and needs to be checked in.
2. The place where your faxes seem to go.
3. The clinician who wants you to drop everything every time he has a problem, question, concern, or complaint.
4. The drifty student who has no experience, interest or desire to work in oncology, but shadows you to fulfill a requirement.
5. The supervisor who seems to just know when you have made an error, and finds it effortlessly.

- A. Center of the universe
- B. Extraterrestrial intelligence
- C. The black hole
- D. Weightlessness
- E. Cosmic companion

**ALTERNATIVE OPTION:**  
Make up 5  
of your own definitions using  
space terms!

Pharmaceutical Management Branch/Cancer Therapy Evaluation Program/Division of Cancer Treatment and Diagnosis/National Cancer Institute  
6130 Executive Blvd \* Suite 7149 \* Rockville, Maryland 20852  
Phone: (301) 496-5725 \* Order fax: (301) 480-4612 \* Other fax: (301) 402-0429 \* E-mail: pmbafterhours@mail.nih.gov

## CANCER WALKS THE RED CARPET

Cancer doesn't discriminate or play favorites. It does not care how famous, rich, or poor we are. We are all mortal and fragile. We all share the same vulnerabilities, yet when we see an article about a famous celebrity's cancer, we often fixate and yearn for updates. We want to relate our stories to theirs because a relative, friend, or neighbor might have the same cancer.

Celebrities' testimonies about their cancers seem to empower us. Their powerful voices not only invite global awareness, but also promote clinical research, helping strengthen the scientific communities' quests for novel agents. Their fame often unites communities to fight for good causes. They make us feel important to the fight.



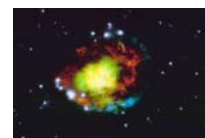
Lance Armstrong's story inspires us one way or another. This legendary bicyclist had a fifty percent chance of survival after his testicular cancer metastasized to his brain and lungs. Despite the odds, Lance's achievements gave us, and especially cancer patients, inspiration to never give up on life. "Livestrong" of Lance Armstrong foundation says it all.

Early detection leads to early prevention. Celebrities promote public education, cancer awareness, and especially cancer screening. A report on Celebrity Endorsement of Cancer Screening was published in the Journal of the National Cancer Institute of May 2005. That survey was conducted in more than 40% of adults in the US. About three-quarters (73%) of women over age 40 and older said that they had seen or heard celebrities campaigning for mammograms, and 25% of these women said that the campaign made them more likely to undergo screening mammography. Among men age 50 and older, two-thirds (63%) said that they had seen and heard celebrities campaign about PSA tests, and 31% said it made them more likely to undergo PSA testing. The study's authors concluded that celebrities should be judicious about advertising cancer screening. Such strong communication might benefit some people with early detection, but it might hurt others, leading to unnecessary testing and treatment. Therefore, they suggested celebrities concentrate on informing and not persuading on complex decision-making such as cancer screening.

The truth is we live in a complex world with complex diseases. Communities affected by health disparities are still among the most difficult population to screen for cancer. If a celebrity voice is the most effective means of communication to reach that population, the subtle difference between "informing" or "persuading" would not and should not matter. A worthy note: screening tests like mammograms are the front line defense for breast cancer. Some of the celebrities who have raised awareness of breast cancer are Christina Applegate, Sheryl Crow, Olivia-Newton-John, Kylie Minogue, and Kate Jackson.

## PMBAfterhours

Do you have a question and need an answer soon, but not necessarily right this minute?  
E-mail pmbafterhours@mail.nih.gov, any time day or night!  
Expect an answer on the next business day.



**NO  
NEBULAR  
FORMS!**



## WATCH FOR a NEW AGENT RETURN FORM

Very soon, PMB will post a new agent return form (NIH-986) on the web site. What's in it for you?

- The header will remind you to return only those agents that you received from us to us; some of you have been sending other "unidentified objects" and we can't handle it. (We suspect you wouldn't do this if you were shipping it to space. That would cost ~\$2,200 per ounce.)
- The "Reasons for Return" are more explanatory in nature. More choice, too! Nothing nebulous about it!
- You'll get feedback from our Repository if you make an error.



## OXALIPLATIN METEOROID:

On page 1, we discuss the "meteoroid" of PMB distributing agent for which we do not hold the IND. Such is the case for protocol E5202. We distribute commercial Eloxatin for this study, and only have the 100 mg vials. So although we have 50 mg and 100 mg investigationally labeled oxaliplatin for all other studies, no matter what you order for E5202 you're going to get 100 mg commercial supply.

**LOOK FOR INSIDE PMB QUARTERLY  
NEXT ISSUE: August 2009**