

INSIDE PMB

Pharmaceutical Management Branch

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THIS ISSUE'S THEME:

CASINO



The House

Customer satisfaction and comfort are a priority inside the PMB house. We make sure our guests' needs and expectations are met. Here are the PMB players:

Managers:

- Skip Hall, Pit Manager
- Patricia Schettino, Pit Boss

Dealers:

- Matthew Boron
- Rodney Howells
- Cynthia Jiles
- Tali Johnson
- Ravie Kem
- Donna Shriner

House Staff:

- Melizza Ford
- Arie Gray
- Joseph Davis

Clinical Trials Cashiers:

- Joytrese George
- LaKita Haskins
- Reneisha Hill

Protocol Registration Bouncer:

- Beverly Bailey

Inventory Banker:

- Frank Scott

Technical Hostess:

- Ive Nascimento

Please note that Ive will always ask you what your call is about so she can direct you to the most appropriate help!

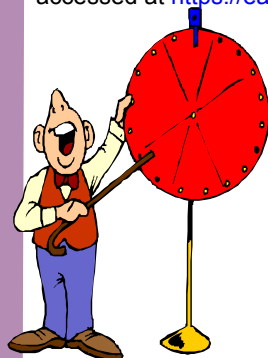
Whether you're a Slots-A-Fun kind of person or have a VIP pass for the Trump Taj Majal, you should enjoy our latest issue with a little nod to the gambler in all of us. We cover some drug development history, new protocol timelines and if you haven't tried your luck with OAOP, there's a series of must-read articles. All of our golden nuggets are intended to keep you in the game and maybe you'll even hit a winning streak, but you must participate to be a winner.



May 31 - Last Round of Play for Paper Orders

In the last edition of *Inside PMB*, we stated that we would announce the date when paper-based faxed copies of the Clinical Drug Request (CDR) would no longer be accepted. Well, here it is! **Beginning June 1, 2012, all sites must convert to order submission through OAOP for PMB-supplied agents.** The paper-based CDR, NIH Form 986, will no longer be accepted after this date.

Don't be a pigeon in a sawdust joint! Get yourself a most valued guest Online Agent Order Processing (OAOP) account and start playing with the high rollers. OAOP may be accessed at <https://eapps-ctep.nci.nih.gov/OAOP/pages/login.jspx>.



Two requirements before you use OAOP to order investigational agents from PMB:

- Create a CTEP IAM account and maintain an "active" account status and a "current" password
- Have the investigator associate you as either the shipping designee (box 11) or an ordering designee (box 12) on the most current Supplemental Investigator Data Form on file with PMB for each investigator for whom you want to order investigational agent

More specific instructions for accessing OAOP are provided in an FAQ available on the PMB website at http://ctep.cancer.gov/branches/pmb/faq/docs/how_to_access_oaop.pdf.

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

OEW..., OGW..., OEWG!

How much would you be willing to wager that your next Phase 2 protocol will be active within 540 days of the LOI being submitted to CTEP? (HINT: It's pretty much a sure thing.) How much would you wager that the same protocol will be active within 210 days?

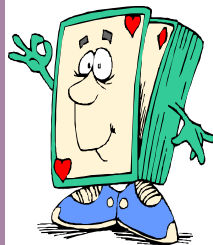
The Operational Efficiency Working Group (OEWG) advised the NCI to compress timelines for CTEP-Supported Cancer Treatment Trials. Our publically funded system should be more efficient so that we—and you—can better serve patients. It is in everyone's best interest to move good science along as expeditiously as possible. \$\$\$

The first phase of the implementation of the OEWG's advice was to carefully examine the time from submission to CTEP of an LOI or Concept (idea) to when the protocol is ready to enroll the first patient. The OEWG recommended two time points: a "drop-dead" (absolute) deadline after which a protocol is automatically disapproved; and a target deadline, which is an aggressive goal to shoot for. To help investigators and CTEP work together target timeframes were established for each of the major stages of protocol development; to not only provide guidelines for more rapid development, but to be able to pinpoint bottlenecks.

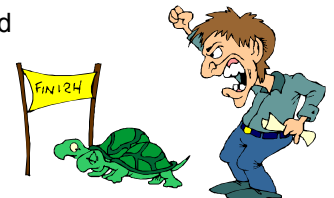


Catching Cards - Time to raise

Almost two years of data help us look at what works well and where we need to improve. The good news is that most protocols met the absolute deadline. This represents nearly a 50% improvement compared to historical data. The bad news is that most protocols didn't meet the target deadline. We all need to continue working on the problem areas to shorten protocol development times. For the majority of studies the time from protocol submission to activation is still the longest step in the process, with the time from CTEP document approval to trial activation being responsible for over one third of the total study development time. We need to work together to find creative solutions to shorten this step. Let's not leave protocol development to a roll of the dice: together we can motivate the key players to improve the system so cancer patients can have the deck stacked in their favor. They deserve it.



And to give you some insider information on the second phase of the OEWG recommendations—we are now focusing our attention on how to quickly enroll patients onto clinical trials so that the trials can be completed and provide useful results to help patients much faster. You can take that to the bank!

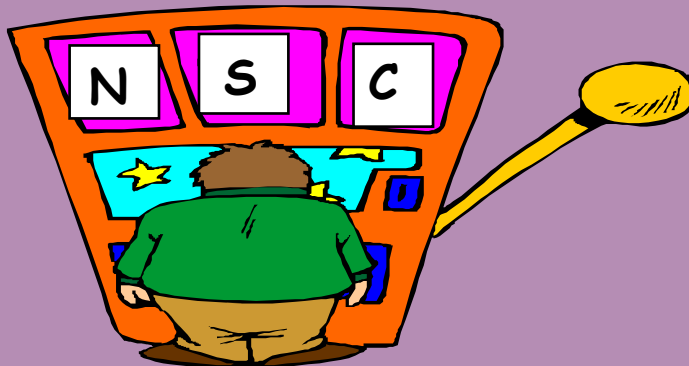


For more information visit <http://ctep.cancer.gov/SpotlightOn/OEWG.htm>

Odds Are Good for OAOP Communication Tool

One of the many advantages of OAOP is a built-in two-way communication tool. If we have a question regarding your order submission (e.g., quantity, courier account number, need by date, etc.) you will receive a query via e-mail from PMB and we'll wait for your response. Sites may also submit a question regarding a specific order through the OAOP order Notes function after the order has been submitted and has a status of In-Process. For tracking purposes, we ask that you please follow the instructions for responding as outlined in the e-mail i.e. log into OAOP to respond to the PMB query through the order Notes section.





What's Behind the NSC?

We're all familiar with the term NSC number. The NSC or National Service Center number is a unique identification number that stays with a compound throughout its life (the same as a social security number). The "NSC" refers to the former Cancer Chemotherapy National Service Center (CCNSC), created by Congress in 1955, primarily to provide grants for cancer research. A small part of its budget was set aside to acquire and evaluate compounds as possible anticancer agents. The CCNSC was incorporated into the Developmental Therapeutics Program (DTP) of NCI in 1976.

You'll need the NSC number to be a player in OAOP.

The NSC number is unique to the National Cancer Institute (NCI). Before the NCI gets involved in the development of a compound, regardless of its stage of development, an NSC number is assigned. CTEP uses the number as the primary agent identifier since the name of the compound can change many times over the course of its development.



There's no catch to MSDSs online

You don't need finely honed card-counting skills to find an investigational agent Material Safety Data Sheet (MSDS). PMB has electronic versions on the web at

<http://tinyurl.com/6tn5s7z>.

The true odds are high that the MSDS you're looking for is posted, but if not, give us a call at **301-496-5725** and we'll find the right person to grease and get you what you need—

ALL ABOVE BOARD OF COURSE!

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.



BUT Wait!

It doesn't stop there. Compounds go through the NCI-60 DTP Human Cell Line Screen. This screen utilizes 60 different human tumor cell lines, representing leukemia, melanoma and cancers of the lung, colon, brain, ovary, breast, prostate, and kidney. The goal of the screen is to determine activity and prioritize in which cancer(s) the compound should be studied. The owner of the compound then decides to work with the NCI to develop the compound or not. But regardless of who is involved in its development, the compound now has something that can never be taken away: its own NSC number.

Playing Roulette With Drug Shipment



We have experienced an increased number of requests to accommodate alternative methods of initiating expedited shipments using a site's express courier account. While we understand the reluctance of some to provide outside entities with the actual account number, PMB cannot process expedited shipments unless the account number is provided. The reason is that multiple regulatory, legal and shipping procedures prohibit use of a site-supplied courier label or a site-initiated pick-up of the package.

No Tipping Allowed

Good news...you have another resource available to answer many of your questions related to clinical trials research at CTEP. The revised Investigator's Handbook is now available on the CTEP website. Go to <http://ctep.cancer.gov> and check the drop-down tab under "Investigator Resources." We still don't mind if you call us, but we can't accept any gifts and certainly no tipping is allowed even for great customer service! Emails gushing with praise for PMB are free, however.



Considerations include:

- The shipping label contains a shipment date and weight of the package, which cannot be known by either you at the time of label creation or your bookie at the time of order placement.
- The shipping address is pulled from our investigator-registration database and cannot be altered by the site.
- Processing of the shipment within our database triggers a change in the order status, which is recorded on audit reports for the site.
- Agent stock recovery processes are generated based on orders shipped, which can only be identifiable if the shipment were created in our database.
- Shipments containing dry ice must indicate this on the courier label and must include the weight of the dry ice on the label, which cannot be known by the site at the time of label creation.
- Shipments of infectious substances and dangerous goods require additional items to be noted on the courier label and shipping manifests, which are triggered by and linked to the shipment processing function within our database. It's even more complicated than filling out a keno card.
- Our repository has many checks and balances that would be greatly impacted by not processing shipments within our database. Because of the thousands of shipments that are processed on a monthly basis, consistent processing is essential to ensure quality service. **And we're all about good customer service!**

Send Us Your Ideas and Other Things

A penny for your thoughts? A penny used to buy a lot, but is now considered by many to be a nuisance. We don't see it that way and would love to hear from you, our readers, about issues or questions related to PMB. Any topic is on the table from agent ordering, distribution, OAOP, IAM accounts, DARFs or whatever. If your topic is one that we think other readers are interested in, we'll put it in the next issue of *Inside PMB*. Don't send us any losing lottery tickets though, only winning ones.

JACKPOT!

Our Inside PMB puzzle winner from the November **P-M-BLEEKs** word search is Kristie Cavolo, CPhT from Washington University in St. Louis.

**CONGRATULATIONS
KRISTIE!**

