



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](mailto:pmbafterhours@mail.nih.gov)

**FAQ: What if I use commercial drug for a study patient, or investigational drug for a commercial patient? Or in other words.....**

“I hate it when that happens!”.....For example, what do I do when the IV room pharmacist uses Velcade™ from the pharmacy’s stock for an NCI CTEP-sponsored trial participant instead of using NCI-supplied investigational PS-341?

Using commercial drug instead of investigational supply for a CTEP-sponsored trial is an audit compliance concern. What should you do?

■ On the drug accountability log, clearly document that commercial Velcade™ was dispensed in error.

What about the opposite “oops”? You used a CTEP-supplied investigational agent on a patient not enrolled on a CTEP-sponsored trial.

■ Clearly document on the drug accountability log, that an investigational agent was dispensed to a non-study patient.

■ Notify PMB of the error by E-mail or snail mail. Include the agent name, NSC number, amount used, a short explanation of the error, and corrective action implemented to prevent future occurrences in your narrative.

In both cases, certain actions are forbidden:

■ Do not replace the pharmacy’s supply of Velcade™ with the NCI-supplied, investigationally labeled PS-341 or vice versa.

■ Do not charge the patient.

As you can see, these compliance violations are costly for your pharmacy. The folks here at the PMB suggest these preventive measures:

■ Use pre-printed or computer generated, protocol-specific order sets.

■ Educate your oncologists and/or cancer center clinical trials office to alert you of newly enrolled protocol patients and to include the protocol number on all orders.

■ Generate a list of all patients enrolled in CTEP-sponsored trials using investigational agents and commit it to memory. 😊

September 7, 2008

*Prepared and distributed by the Pharmaceutical Management Branch, CTEP, NCI.  
Please do not re-distribute or post without permission.  
Information in this FAQ is subject to change without notice; check periodically for updates.  
Please contact PMB at (301) 496-5725 if you have questions.*