

Pharmaceutical Management Branch/Cancer Therapy Evaluation Program/Division of Cancer Treatment and Diagnosis/National Cancer Institute

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FAQ: What should I do when patients return clinical supplies of oral NCI-supplied investigational agents that were previously dispensed? Should I return them to the NCI Clinical Repository?

Answer: Patient returns of open-label and patient-specific supplies are to be recorded in the same manner on the NCI Investigational Agent Accountability Record for Oral Agents (Oral DARF). The purpose of documentation of patient returns on the Oral DARF is to <u>record quantities returned for destruction</u> on site in accordance with institutional policy (this is not the same as authorized local destruction of un-dispensed agent supplies). Do not record the physical destruction of patient returns on the Oral DARF. Patient returns of dispensed, unused agent should be provided to the dispensing area/pharmacy for proper destruction.

Do not return supplies dispensed to patients to the NCI Clinical Repository.

In summary, when a patient returns oral NCI-supplied investigational agent:

- Document the return on the correct Oral DARF (i.e., protocol, agent, strength, formulation, ordering investigator)
- Document the return on the correct dispensing row (i.e., date, patient initials, patient ID number, lot number)
- Record the date returned and the quantity returned (i.e., number of tablets/capsules counted)
- Record full or partial containers as the quantity returned for oral suspensions or solutions
- If multiple containers from a single dispensing are returned on the same date, record the total quantity returned (i.e., total number of tablets/capsules counted)
 - o If additional containers are returned on a different date, record the return on a new line and reference the dispensing row (i.e., page number, line number, date)
- If clinical supplies are not returned to the dispensing area/pharmacy, do not record in the return column on the Oral DARF.

Questions regarding return/destruction of clinical supplies can be directed to the Pharmaceutical Management Branch (PMB), CTEP, NCI by calling (240) 276-6575 Monday through Friday from 8:30am to 4:30pm Eastern Time or by emailing %MBAfterHours@mail.nih.gov+at any time.

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Information in this FAQ is subject to change without notice; check periodically for updates.

Please contact PMB at (240) 276-6575 if you have questions.

FAQ: Patient returns of oral clinical supplies . Page 1 of 1