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INSIDE PMB

November 2016

New Investigational Drug Accountability Training Videos

New videos are now available at https://ctep.cancer.gov/branches/pmb/drug_training_videos.htm. These 2 videos complete the Investigational Drug Accountability series of 9 videos.

1. **Agent Returns** **Date produced:** 08/2016 **Length:** 07:35
   - Reasons for agent return
   - Agent return documentation
   - Strategies to reduce the need for returns
2. **Local Destruction** **Date produced:** 08/2016 **Length:** 05:57
   - Circumstances to request local destruction
   - Local destruction authorization and documentation
   - Reasons for rescission or denial

These videos build off previously released videos:

- DARF Basics (length 05:05)
- DARF Header (length 04:33)
- Oral DARF (length 06:12)
- Agent Receipt (length 06:03)
- Agent Dispensing (length 09:34)
- Patient-Specific DARFs (length 10:14)
- Agent Transfers (length 07:37)

Thank you for watching!

Inside:

New Agent Management Policy and Guidelines

The new Policy and Guidelines for Investigational Agent Local Destruction is now available at https://ctep.cancer.gov/branches/pmb/agent_management.htm.

- **Policy and Guidelines for Investigational Agent Local Destruction** (PDF) (09/16)

This is released in conjunction with the new Local Destruction Investigational Drug Accountability Training Video.

Updated Return Investigational Agent Form

An updated NCI Return Investigational Agent Form is now available at https://ctep.cancer.gov/forms/. The updated form replaces the request for a fax number with a request for an email address. Return receipts will only be emailed back to sites.

NCI Pediatric-MATCH Trial Update

The NCI-COG Pediatric MATCH Study is expected to activate sometime in the first half of 2017 with 8 arms. The proposed 8 arms include a TRK inhibitor, FGFR inhibitor, EZH2 inhibitor, PI3K/mTOR inhibitor, MEK inhibitor, ALK inhibitor, BRAF inhibitor, and PARP inhibitor. Some key points are:

- It is estimated that 300 patients will be screened per year.
- Each arm will enroll 20 evaluable patients and new arms could be added to the trial over time.
- All participating sites must use the pediatric CIRB.
- No starter supplies will be available: order study agents only after patients have enrolled on a specific arm.

The agent classes and estimated actionable mutations of interest (aMOI) frequencies are listed below:

Agent Class	aMOI Frequency
TRK Inhibitor	2-3%
FGFR Inhibitor	2-3%
EZH2 Inhibitor	2-3%
PI3K/mTOR Inhibitor	5-10%
MEK Inhibitor	10-20%
ALK Inhibitor	2-3%
BRAF Inhibitor	5%
PARP Inhibitor	2-3%

Drug Ordering Designee "Comments" Field

The designee "Comments" field in the OAOP can be used for additional clarification that will support your drug request that may not seem to be within the approved 8-week supply quantity.

Types of comments to provide:

- Patient weight when used to calculate doses
- Number of vials, bottles used per dose or per cycle
- Explain why a large supply is requested or there is an increased frequency of requests
- Replacing lost, damaged or expired product
- Add a note why blinatumomab order is not included when submitting an order for its IV Stabilizer Solution or vise-versa.
- Number of patients on study (screening vs. enrolled)
- Specific to Blinded Studies
    - Ordering non-standard quantities
    - Order placed ahead of schedule
    - Patient being dose reduced or crossed over to another arm

The additional information will help PMB to manage the drug order accordingly.

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