NCI National Clinical Trials Network
a National Cancer Institute program

# Clinical Trials Monitoring Branch (CTMB) Audit Guidelines

## Pharmacy Review

Transcript:

Clinical Trials Monitoring Branch (or CTMB) Audit Guidelines, Pharmacy Review. This module covers the pharmacy review component of a site audit. It provides expectations and reminders related to the Guidelines, as they pertain to your role as an auditor.

# Goal of the Pharmacy Review

The goal of the pharmacy review is to assess the institution's:

- Accountability of study-supplied agents
- Pharmacy operations

Transcript:

The goal of the pharmacy review is to assess the institution's accountability of study-supplied agents and pharmacy operations.

# Assessing Compliance

The pharmacy review is based on an assessment of compliance and non-compliance.

- Individual categories audited during the pharmacy review are each assessed as one of the following:
  - Critical Non-Compliant
  - Non-Compliant
  - Compliant
  - Not Reviewed

Transcript:

Assessing Compliance: The pharmacy review is a bit different from the regulatory and patient case review components in that it is based upon a system of compliance and non-compliance, not different levels of deficiencies.

When conducting a pharmacy audit, the auditor will review the different categories and assign each category one of the following ratings: Critical Non-Compliant, Non-Compliant, Compliant, or Not Reviewed. The next screen will provide more information on what critical non-compliance means.

# Critical Non-Compliance

A finding such as any condition, practice, process or pattern that adversely affects the rights, safety, or well-being of the patient/study participant and/or the quality and integrity of the data; this includes serious violation of safeguards in place to ensure safety of a patient/study participant and/or manipulation and intentional misrepresentation of data should be cited as a **Critical Non-Compliance** (as defined in Section 5.1 of the Audit Guidelines).

Transcript:

Critical Non-Compliance: A Critical Non-Compliance finding is one that potentially affects patient or study participant safety, rights, and/or well being, and/or the quality and integrity of the data, and/or a finding suggestive of intentional misrepresentation of data. It includes serious violation of safeguards in place to ensure a patient's safety.

# Audit Tool for Pharmacy Review

Location of the Pharmacy Review Worksheet, which lists items to review for compliance by category:

- On the CTEP/CTMB website, posted as Appendix 3 of the CTMB Audit Guidelines (under the link to the Guidelines themselves)
  - View the Pharmacy Review Worksheet
- From a tab in the CTMB Audit Information System (CTMB-AIS); under *Templates & Worksheets*

Transcript:

Audit Tool for Pharmacy Review: The CTMB provides a listing of items to review for compliance to assist you during the pharmacy review. The Pharmacy Review Worksheet is divided into nine sections, with the first page being the overall rating for each of the eight categories assessed. Subsequent pages list the individual items to be evaluated within each category and checked as compliant or not compliant, and whether they meet criteria for critical non-compliance.

You can find the Pharmacy Review Worksheet posted as Appendix 3 of the CTMB Audit Guidelines, along with the Audit Guidelines themselves, on the CTEP/ CTMB website, as well as directly by clicking on the direct link to the pharmacy audit worksheet shown on the screen. For those with access, this audit tool is also located under the Templates and Worksheets tab in the CTMB-AIS. It is helpful to keep a copy of this audit tool nearby, either in hardcopy or electronically, for reference during your pharmacy review.

## Pre-Audit Pharmacy Review

Your organization may conduct part of the pharmacy review in advance of the audit, by requesting and then reviewing National Cancer Institute (NCI) Drug Accountability Record Forms (DARFs) and other documentation.

- Even when documentation is reviewed in advance of an audit visit, the pharmacy (or pharmacies) must still be visited during the audit.

Transcript:

Your organization may conduct part of the pharmacy review in advance of the audit, by requesting and reviewing National Cancer Institute (NCI) Drug Accountability Record Forms (also known as DARFs) and other documentation. Even when documentation is reviewed in advance of an audit visit, the pharmacy (or pharmacies) must still be visited during the audit.

## Review of Accountability of Study-supplied Agents and Pharmacy Operations

While conducting a pharmacy review, assess the following:

- Drug accountability (documentation of receipt, dispensation, and transfer/return/destruction of study-supplied agents; transfer to/from satellite sites; and while on-site, comparison of balance on log to amount in stock).
- Proper maintenance and completion of NCI DARFs.

Transcript:

Review of Accountability of Study-Supplied Agents and Pharmacy Operations: While conducting a pharmacy review, you will need to assess the following: Drug accountability (which includes documentation of receipt, dispensation, and transfer, return, or destruction of study-supplied agents; transfer to and from satellite sites; and while on-site, comparison of balance on the log to the amount in stock). You will also need to assess the proper use of NCI DARFs.

## Review of Accountability of Study-Supplied Agents and Pharmacy Operations (cont.)

Also assess the following:

- Compliance with required procedures
- Appropriate storage and security of study-supplied agents
- Authorized prescriptions
  - Must be written by an investigator (IVR) or non-physician investigator (NPIVR) who is an authorized, study-eligible person with an active status in the CTEP Registration and Credential Repository (RCR), and is qualified to write orders per institutional policy, their local, state laws and regulations, or applicable international requirements.

Transcript:

You must also review the following: Compliance with required procedures; appropriate storage and security of study-supplied agents; and the use of authorized prescriptions. Of note, prescriptions must be written by an investigator (IVR) or non-physician investigator (NPIVR) who is an authorized, study-eligible person with an active status in the CTEP Registration and Credential Repository (RCR), and is qualified to write orders per institutional policy, their local, state laws and regulations, or applicable international requirements.

## Imaging, Radiopharmaceutical, and Cancer Control Studies

- Imaging and radiopharmaceutical agents may or may not be managed by the pharmacy, depending upon the protocol.
- These agents are usually delivered directly to the imaging, radiation oncology, nuclear medicine, or nuclear pharmacy or center.
- Cancer control/prevention and imaging study and radiopharmaceutical therapies are usually manufactured on-site or purchased from and distributed by commercial vendors.
- Even when not distributed by NCI, cancer control, imaging, and radiopharmaceutical therapy studies should abide by the same NCI/CTEP policies, e.g., the use of NCI DARFs is strongly suggested.

Transcript:

Some special notes about imaging, radiopharmaceutical, and cancer control studies: Imaging and radiopharmaceutical agents may or may not be managed by the pharmacy, depending upon the protocol. These agents are usually delivered directly to the imaging, radiation oncology, nuclear medicine, or nuclear pharmacy or center that will be conducting the study. Cancer control/prevention and imaging study and radiopharmaceutical therapies are usually manufactured on-site or purchased from and distributed by commercial vendors. That said, even when these agents are not distributed by NCI, cancer control, imaging, and radiopharmaceutical therapy studies should abide by the same NCI/CTEP policies, e.g., the use of NCI DARFs is strongly suggested.

# Types of Pharmacies – Control Pharmacy

- Identified as the shipping address receiving the study-supplied agent from the supplier.
- Directly receives study-supplied agent from the supplier.
- Appropriately stores and secures agents.
- Dispenses agents to study participants as prescribed by authorized providers (see screen 8).
- Performs overall inventory control.
- Handles final disposition of study-supplied agents.
- Performs physical destruction of patient-returned agents per applicable regulations, policies, and procedures.

Transcript:

Types of Pharmacies: A given site might utilize two levels of onsite pharmacy, and both need to be included in the pharmacy review component of an audit. [Please note that these are different from an affiliate pharmacy, which is covered in a later screen.]

The control pharmacy is the main or primary dispensing area or pharmacy at the site and is the one identified as the shipping address receiving the study-supplied agent from the supplier. The control pharmacy is responsible for direct receipt of study-supplied agents from the supplier, appropriate storage and security of agents, dispensing of agents to study participants as prescribed by authorized providers and dictated by each protocol, overall inventory control (including provision of agents to and oversight of satellite dispensing areas, and dissemination of agent stock recovery information), and final disposition of study-supplied agents (that is, returns, transfers, and authorized local destructions).

# Types of Pharmacies – Satellite Pharmacy

- Located at the same site but in a different location (infusion center, patient unit, etc.).
- Receives study-supplied agent from the control pharmacy.
- Appropriately stores, secures, and accounts for agents.
- Dispenses agents to study participants as prescribed by authorized providers (see screen 8).
- Returns agents to the control pharmacy for further or final disposition.
- May physically destroy patient-returned study-supplied agents, if permitted.
- DARF required if agent stored there >1 day.

Transcript:

Satellite Pharmacy: A satellite dispensing area or pharmacy is at a different location from the control pharmacy at the same site, for example, within an infusion center, or connected to a patient care unit. During an audit, the auditor must ensure that as with the control pharmacy, any satellite pharmacies are compliant with federal and NCI requirements, and also that study-supplied agent can be accurately tracked between the different locations.

A satellite pharmacy is under the direct responsibility of the control pharmacy and is responsible for receiving study-supplied agents from the control pharmacy via in-house personnel, appropriately storing, securing, and accounting for study agents, dispensing agents to study participants as prescribed by authorized providers and dictated by each protocol, and returning agents to the control pharmacy for further or final disposition. They may also physically destroy patient-returned study-supplied agents, if their policies and procedures allow for that. Do note that a DARF is required at the satellite pharmacy if study drug is stored there for more than one day.

# Types of Pharmacies – Affiliate Pharmacies

Pharmacies at affiliate institutions function administratively under a parent site but receive study-supplied agents directly from the supplier.

Review options per the CTMB Audit Guidelines:

- For routine pharmacy audits, auditing organizations can now use their own discretion to determine if/when an on-site audit should be conducted.
- If audited off-site, required documents can be sent to the audit location or to the auditing organization prior to the audit.

Is a re-audit needed for storage or security non-compliance? Conduct **on-site** within 12 months.

Transcript:

Affiliate Pharmacies: Pharmacies at affiliate institutions function administratively under a parent site and dispense study-supplied agent to study participants at their locations. These pharmacies do receive study-supplied agents directly from the supplier.

Review options per the CTMB Audit Guidelines: For routine pharmacy audits, the auditing organizations can now use their own discretion to determine if and when an on-site audit of an affiliate pharmacy should be conducted. If audited off-site, required documents can be sent to the audit location or to the auditing organization prior to the audit.

If a pharmacy (affiliate or main) requires a re-audit due to storage or security non-compliance, the re-audit must be conducted on-site, within 12 months.

# Reminders (1 of 3)

Details about these items can be found in the Pharmacy Review Worksheet as well as Section 5.3.4 of the Audit Guidelines.

1. Use of electronic drug accountability logs
   - Electronic logs must produce a paper printout that is identical to the NCI DARF.
2. Use of satellite drug accountability logs
   - Must be used if study-supplied agent stored in satellite pharmacy for > 1 day.
   - Cross-check with control pharmacy DARFs to confirm documentation of transfers.

Transcript:

Here are some reminders regarding the conduct of the pharmacy audit. You can find details about these items in the Pharmacy Review Worksheet as well as in Section 5.3.4 of the Audit Guidelines. 1) Any electronic drug accountability logs used must be able to produce a paper printout that is identical to the NCI DARF. 2) Satellite DARFs must be used if study-supplied agent is stored in a satellite pharmacy for more than one day. Cross-check these with the control pharmacy DARFs to confirm documentation of transfers between the pharmacies.

# Reminders (2 of 3)

3. Confirmation of dates/doses for patient cases selected
   - Cross-check DARFs with dates and doses on patient-specific CRFs.
4. Documents to review/cross-check
   - Review DARFs, shipping receipts, and return, transfer, or destruction forms.
   - Ensure that all agents coming into and going out of the applicable pharmacies are accounted for.

Transcript:

More reminders regarding the conduct of the pharmacy audit: 3) Cross-check DARFs with the dates and doses on the case report forms (CRFs) for patients selected for case review to ensure that they match. 4) Review all DARFs, shipping receipts, and return, transfer, or destruction forms to ensure that all agents coming into and going out of the applicable pharmacies are accounted for.

# Reminders (3 of 3)

5. Confirmation of physical quantities of study-supplied agents
   - Physical quantities in the pharmacies must match what is on the DARFs.
6. Adequacy of storage and security
   - Check temperature logs, ensure agents are stored properly.
   - Ensure physical security of the pharmacy itself.
7. Procedure for verifying prescriber's authority
   - Must be documented procedure to ensure prescriptions are written by an authorized, study-eligible person as described in screen 8.

Transcript:

5) Ensure that the physical quantities of study-supplied agents in all covered pharmacies match what is on the associated DARFs. 6) Check temperature logs to ensure that equipment is functioning properly and that agents are stored according to requirements and confirm that appropriate safeguards are in place to guarantee proper physical security of the agents within the pharmacy itself. 7) Make sure that the institution has a documented procedure for ensuring that prescriptions have been signed by an investigator (IVR) or non-physician investigator (NPIVR) who is an authorized, study-eligible person as initially described on screen 8.

# Assessing the Pharmacy Review (1 of 4)

The auditing organization will assess the pharmacy review based on the presence of non-compliant items identified during the visit.

- A rating of **Acceptable** may be assessed if the auditor identified:
  - Compliance in all categories and no follow-up being requested; or
  - Non-compliant items that were addressed **prior to notification of the audit** (with a written and dated Corrective and Preventative Action Plan [CAPA], and no further action required).

Transcript:

Assessing the Pharmacy review: The auditing organization will assess the pharmacy review based on the presence of non-compliant items identified during the visit.

To attain an Acceptable rating, the site must be compliant in all categories with no follow-up being requested or must have addressed and corrected any non-compliant items prior to notification of the audit (with a written and dated Corrective and Preventative Action Plan [CAPA], and no further action required).

# Assessing the Pharmacy Review (2 of 4)

- A rating of **Acceptable Needs Follow-up** must be assessed if the auditor identified:
  - Any non-compliant category during the audit.
- A rating of **Unacceptable** must be assessed if the auditor identified:
  - An inability to track the chain of custody of study-supplied agents;
  - A critical non-compliance; or
  - Multiple non-compliant categories.

Transcript:

If a category is found non-compliant during the audit, the rating must be Acceptable Needs Follow-up.

If an audit reveals that there is an inability to track the chain of custody of study-supplied agents, a critical non-compliance was identified, and/or there are multiple non-compliant categories, the rating must be Unacceptable.

Two additional assessment or rating options for the pharmacy review are covered on the next screens.

# Assessing the Pharmacy Review (3 of 4)

Two additional options are available for rating the pharmacy review component.

- **No Assessment Required:**
  - No study agent was in stock or in use during timeframe of review, and the only items reviewed consist of security, storage areas, and pharmacy procedures.
  - All reviewed categories were found to be compliant.

Transcript:

Two additional options are available for rating the pharmacy review component.

No Assessment Required is used when no study agent was in stock or in use during the timeframe being reviewed, and the only items reviewed consist of security, storage areas, and pharmacy procedures. The reviewed categories must be found to be compliant to receive this assessment.

# Assessing the Pharmacy Review (4 of 4)

- **Limited Review Needs Follow-up**
  - Non-compliance was identified during a limited review of security, storage areas, and pharmacy procedures.
  - CAPA or follow-up response is requested.

Transcript:

Limited Review Needs Follow-up is an additional rating option for the pharmacy component and applies only to onsite pharmacy audits. It is used when any non-compliance was identified during a limited review of security, storage areas, and pharmacy procedures, and a CAPA plan or follow-up response is requested.

## Resources to Review

- Pharmacy Review Worksheet (audit tool)
  - View the Pharmacy Review Worksheet
- Pharmaceutical Management Branch's (PMB) Investigational Drug Accountability Training Videos on the expectations for pharmacy operations and accountability
  - View the PMB training videos

Transcript:

Resources to Review: Please review the Pharmacy Review Worksheet, for a detailed listing of non-compliant items; you can find this by clicking on the direct link to the pharmacy audit worksheet shown on the screen.

Additionally, the Pharmaceutical Management Branch (PMB) has developed a series of investigational drug accountability training videos on the expectations for pharmacy operations and accountability. While these short videos are primarily intended for site staff, they provide valuable information for auditors as well. Please review all of the videos if you have not seen them before. They can be accessed by clicking on the direct link to the PMB training videos shown on the screen.

# Module Complete

- You have completed the Pharmacy Review module.
- Please exit and return to the course screen in CLASS.
- The module should now show as *Complete*.
- You can revisit completed modules in your My Courses screen.

This and the other training modules in this series were developed for the Clinical Trials Monitoring Branch of the Cancer Therapy Evaluation Program, Division of Cancer Treatment & Diagnosis, National Cancer Institute.
https://ctep.cancer.gov/branches/ctmb

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Transcript:

Module Complete: You have completed the Pharmacy Review module. Please exit the module using the X in the upper right corner of this window, and return to the course screen in CLASS, where the module should now show as completed. You can always revisit this and other completed modules in your My Courses screen.

Note, this and the other training modules in this series were developed for the Clinical Trials Monitoring Branch of the Cancer Therapy Evaluation Program, Division of Cancer Treatment & Diagnosis, National Cancer Institute. For more information on the CTMB, visit the URL for the CTMB home page shown on the screen. This version of this individual module was produced in March 2023.