Audit Guidelines and Tips for Success

Cancer Trials Support Unit
Clinical Trials Monitoring Branch (NCI)
Pharmaceutical Management Branch (NCI)
Presentation Outline

• Introductions
• Basic CTMB Audit Guidelines
• Common Deficiencies
• Open Forum
• Obtaining Help
CTMB Audit Guidelines

• **Purpose**: To document the accuracy of data submitted to the Cooperative Groups and to verify investigator compliance with protocol and regulatory requirements, adherence to Group policies / procedures and to provide information to institution staff on good clinical practices (GCP) related to regulatory requirements, data collection and data management
CTMB Guidance

• CTMB staff serve:
  – as an educational resource to the cancer research community issues related to monitoring and regulatory requirements for conducting clinical trials.
  – are responsible for reviewing the scheduling of all audits, for reviewing audit reports and findings, and for assessing the adequacy and acceptability of any corrective actions.
Responsibility for Conduct of QA Programs

• The guidelines established by CTMB are the **minimum** set of guidelines that must be met.

• Groups, CCOP Research Bases and CTSU must meet the minimum standards of the CTMB audit guidelines, however **more stringent policies** and procedures may be established and enforced by the Groups, CCOP Research Bases and CTSU.
Audit Scheduling

- Sites will be audited at least once every 36 months, but may be selected for audit at any time.
- Any site accruing a high number of patients within a 36 month audit cycle will be at risk for audit prior to 36 months.
Audit Scheduling

- Special audits or *for cause audits (off cycle)* may be warranted when there are significant irregularities found through quality control procedures or when allegations of *possible* scientific misconduct are made.

- CTMB staff or NCI designee may be present during an audit and *must* have full access to all documents and materials present for the audit.
Audit Scheduling

- The CTSU may choose to perform the audit of multiple related institutions at one central location.
- For any set of audits scheduled centrally, all applicable source documentation from each location must be available for audit.
  - Complete medical records, scans, DARFs and IRB documentation and copies of the locally utilized IC must be available.
Preparations for Audit

• **Cases selected for audit:** CTMB recommends a sampling stratification for 10% of Group cases, plus 10% of endorsed/endorsement + cases (where applicable), plus 10% of non- endorsed cases (where applicable), and 10% of non-treatment cases (where applicable). This sampling will be taken from all patients accrued since the last audit.
  
  – The 10% of cases reviewed apply to each participating site being audited.
  
  – For selection purposes, the 10% of chosen cases will always be rounded up. For example if 12 cases are eligible for selection, at least two cases will be audited.
  
  – **Emphasis** will be given to IND, multimodality, intergroup, prevention trials, high accruing studies and potential licensing trials.
Site Notification & Preparation for Audit

• Notification to Site: institution being audited will receive case selection list **at least 2 but no more than 4 weeks** prior to audit

• Institution is responsible for ensuring **that all relevant materials** are available for review at time of audit
  – Including: xrays, scans, research notes, IRB documents, NCI DARFs, informed consent documents and any other relevant information
Source Documentation

• **Source documentation** may include but is not limited to:
  – Inpatient and outpatient medical records (progress notes, diagnostic reports, lab data, admission forms)
  – Study flow sheets and other research records that are signed and dated on a real time basis
  – Protocol or study roadmaps
  – Enrollment tracking sheets
  – Subject diaries/calendars
  – NCI Drug Accountability Forms (DARFs)
  – Informed consents and IRB documents
Audit Deficiencies

• The Cooperative Groups, CCOP Research Bases and the CTSU use a common set of terms or examples of **MAJOR** or **LESSER** deficiencies (reference list attached)

• A common system is used to assess each component of an audit and to report the audit findings via the CTMB Audit Information System
Audit Component Areas

- An audit consists of reviewing and evaluating the following:
  - **IRB**: documentation and conformance to IRB and approved consent requirements
  - **Pharmacy**: review of pharmacy and use of NCI DARFs or NCI approved drug logs
  - **Patient Case**: review of individual patient cases
Audit Assessment

• Each component will be assigned a assessment of one of the following:
  ▪ Acceptable
  ▪ Acceptable Needs Follow-Up
  ▪ Unacceptable
IRB Documentation

• For each protocol selected for audit, the following minimum items will be reviewed:
  – Documentation:
    • Full initial IRB approval of each protocol
    • Full IRB annual reapproval of each protocol
    • IRB approval for protocol amendments that affect more than minimal risk
    • IRB approval or reapproval prior to patient registration
IRB Compliance Areas

- **Reapprovals**
  - **Delayed**: reapproval by the IRB delayed up to one year
  - **Expired**: reapproval by the IRB delayed for > one year
  - **Missing**: missing documentation of reapproval (letter from IRB, IRB minutes, etc)
IRB Compliance Areas

• **Expedited review**: a review by the IRB chair or one or more IRB members which involves no more than minimal risk or involves minor changes in previously approved research.

• **Amendment Approvals**: must be approved by the IRB of record within 90 days of the Group’s notifications. Amendments that are editorial in nature are exempt from the 90 day requirement.
IRB Compliance- External Safety Reports

• External safety reports for adverse events that are unexpected and ≥ Grade 3 (attribution of possible, probable or definite) must be submitted to the local IRB within 90 days of the Group’s notification. A random sample of at least 10% of external safety reports should be reviewed.
  – Only deviation permitted: If the institution’s policy does not require such events to be reported, documentation of the institution’s policy on external safety report review must be provided at the time of the audit.
Sites Utilizing the NCI CIRB

• If the NCI Central Institutional Review Board (CIRB) is utilized by the local IRB through facilitated review, all documentation of CIRB approvals must be obtained by the local site.

• Since the local IRB has assumed responsibility through facilitated review, these documents (hard copy) must be present at the time of the audit.
IRB and Informed Consent Final Assessment

- **Acceptable:**
  - No deficiencies identified
  - Few lesser deficiencies identified
  - Major deficiencies identified during the audit that were addressed and/or corrected *prior to* the audit for which documentation exists *and* no further action is required by the cooperative group, institution or principal investigator
IRB and Informed Consent Final Assessment

• **Acceptable Needs Follow-Up**
  – Any major deficiency identified during the audit but not corrected and/or addressed prior to the audit
  – Multiple lesser deficiencies identified

• **Unacceptable**
  – Multiple major deficiencies identified
  – A single major flagrant deficiency found
  – Excessive number of lesser deficiencies identified
Pharmacy Non-Compliance- DARFs

- Inability to track the receipt, use and disposition of DCTD/DCP supplied IND agents
- DARF not maintained
- Incorrect agent, dose, route of administration, or dates documented on DARF
- Erasure or Whiteouts
- Corrections not lined and initialed
Pharmacy Non-Compliance-Protocol and Drug Specific

- Substitution with any non-DCTD supplied agents, including commercial agents
- Each agent not accounted for separately by protocol
- One DARF used for more than one protocol
- One DARF for a multi-agent protocol
- One DARF used for multiple strengths or dosage forms of an agent
Pharmacy Non-Compliance - Transaction Records

- Agent order receipts not retained or not available for review
- Lack of documentation of other agent transactions
- Agents have been borrowed
- Transfer IND Form (NIH-2564) not used when transferring agent
- Quantities not accounted for; shelf counts and inventories do not match
- No satellite NCI DARF
Pharmacy Non-Compliance-
Return of Drug to NCI

- DCTD/DCP agent not returned to NCI or transferred to an appropriate NCI protocol
- DCTD/DCP agents not returned for patients in follow-up when no DCTD/DCP agent is being administered
- Patient returns of IND supplied agents are recorded on the DARF for non-double blinded studies
Pharmacy Non-Compliance - Storage

- IND not stored separately by agent
- Agents used for more than one protocol combined in storage
- Agent not stored under proper conditions
- Agent stored in insecure dispensing area
- Unauthorized people having access to a secure area without supervision
Pharmacy Operations Final Assessment

- **Acceptable**
  - Compliance found for all categories
  - All non-compliant items identified during the audit that were addressed and/or corrected prior to audit for which documentation exists and no further action is required by the cooperative group, the institution or the principal investigator
Pharmacy Operations Final Assessment

• **Acceptable Needs Follow-Up**
  – Category found non-compliant during the audit which was not corrected and/or addressed prior to the audit

• **Unacceptable**
  – Inability to track the disposition of DCTD-supplied investigational agents
  – Multiple non-compliant categories
Patient Case Review

• CTMB (NCI) recommends a sampling stratification for 10% of Group cases, plus 10% of endorsed / endorsement + cases (where applicable), plus 10% of non-endorsed cases (where applicable) and 10% of non treatment cases (where applicable). This sampling will be taken from all patients accrued since the last audit.

• Each patient case will be reviewed for:
  – Properly signed and dated informed consent
  – Eligibility
  – Correct treatment and treatment sequence
  – Evaluation of disease outcome / tumor response
  – Adverse events related to treatment
  – General quality of the data collected
Patient Case Review

• Missing documentation:
  If identified as missing at the time of the audit and requested by the audit team- the documentation **must** be supplied within a **maximum of two weeks** following the audit to clarify patient case findings
Patient Case Review of Deficiencies

• **Major Deficiency**
  – Defined as a variance from protocol specific procedures that make the resulting data questionable

• **Lesser Deficiency**
  – Defined as a deficiency judged to not have a significant impact on the outcome or interpretation of the study
Patient Case Review Final Assessment

• **Acceptable**
  – No deficiencies identified
  – Few lesser deficiencies identified
  – Major deficiencies identified during the audit that were addressed and/or corrected prior to the audit for which documentation exists and no further action is required by the cooperative group, institution or principal investigator
Patient Case Review Final Assessment

• **Acceptable Needs Follow-Up**
  – Multiple lesser deficiencies identified
  – Any major deficiency identified during the audit **but not corrected** and/or addressed prior to the audit

• **Unacceptable**
  – Multiple major deficiencies identified
  – A single major flagrant deficiency found
  – Multiple lesser deficiencies of a recurring nature found in a majority of the patient cases reviewed
Patient Case Review- Data Management Quality

- The Groups, CCOP Research Bases and CTSU have established guidelines and acceptability of the timeliness, completeness and accuracy of submitted data.

- Disregarded or untimely data reporting per Group, CCOP or CTSU guidelines may be rated as a major deficiency.
Corrective Action Plans

- For each component rated as **Acceptable Needs Follow-Up or Unacceptable**, the institution is required to submit a written response or corrective action plan.

- A copy of the response / corrective action plan must be forwarded to CTMB within **45 days** of the date the final audit report is submitted in AIS.
Re-Audit Requirements

- For any component rated as Unacceptable, a **re-audit is mandatory** if the institution continues in Group, CCOP Research Base or CTSU studies.

- The reaudit will be performed no later than a year after an Unacceptable audit or when sufficient patients have been accrued (3-5 patients).
Suspension of Participating Institutions

• Site failure to provide a corrective action plan for one or more audit components rated as acceptable needs follow-up or unacceptable within the required 45 day time limit may result in the following actions:
  – The CTSU will provide written notice to the Principal Investigator at the institution that the response/corrective action plan is overdue and a five working day grace period will be granted for the submission of the response/corrective action plan.
  – If follow-up or a corrective action plan is not received by the Group during the five day grace period, the CTSU will immediately suspend patient registrations from that institution
Repeated Failure to Submit a Corrective Action Plan

- On subsequent audits the failure to submit a timely response/corrective action plan may result in permanent termination from participation in NCI sponsored clinical trials through the Cooperative Group, CCOP or CTSU mechanisms.
Probation of Participating Institutions

- If a participating institution is deemed unacceptable for the same audit component(s) on two consecutive audits, the institution will be placed on probation.

- During the probationary period, accrual will be closely monitored by the CTSU with increased utilization of quality control procedures at the time of patient registration and timely review of data submission.
Resources Available

Help!
Material Available on CTSU Website

**Protocol Card** assists with screening

**Time and Events** gives overview of protocol events

**PowerPoint Presentations** help train research staff

**Physician Fact Sheet** offers a summary of treatment plan and patient population with schema on the back, for each protocol
Audit Tools for Site Use

CTMB Audit Deficiency Examples (not an all inclusive list)
The Site’s Perspective

<table>
<thead>
<tr>
<th>IRB Major</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol never approved by IRB</td>
</tr>
<tr>
<td>Initial IRB approval documentation missing</td>
</tr>
<tr>
<td>Initial approval by expedited review</td>
</tr>
<tr>
<td>Expedited Reapproval for situations other than approved exceptions (Appendix 3 CTMB Guidelines)</td>
</tr>
<tr>
<td>Registration and/or treatment of patient prior to full IRB approval</td>
</tr>
<tr>
<td>Reapproval delayed more than 30 days but less than one year</td>
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<tr>
<td>Registration of patient on protocol during a period of delayed Reapproval</td>
</tr>
<tr>
<td>Missing Reapproval</td>
</tr>
<tr>
<td>Expired Reapproval</td>
</tr>
<tr>
<td>Internal Reportable adverse events reported late or not reported to the IRB</td>
</tr>
<tr>
<td>Lack of documentation of full IRB approval of a protocol amendment that affects more than minimal risk of IRB approval is greater than 90 days after Group’s notification</td>
</tr>
</tbody>
</table>

Audit reference sheets outlining examples of major and minor deficiencies
CTSU Audit Worksheets

• Worksheet created for every protocol on the CTSU menu
• Provided on the CTSU Member Website to sites for training and pre-auditing tool

**ECOG - E 2204 Site Audit Report**

<table>
<thead>
<tr>
<th>Site Visit Date:</th>
<th>Patient #</th>
<th>Institution/City/CTEP ID#</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Parent Institution (if applicable):</td>
</tr>
</tbody>
</table>

**CONSENT**
Is written, signed and dated informed consent available?
YES  NO
( ) ( )

Date Consent was signed:
______/__________/__________

Informed Consent Comments:
Resources

CTSU web site:  www.ctsu.org

CTMB web site:  http://ctep.cancer.gov/branches/ctmb/default.htm

PMB web site:  http://ctep.cancer.gov/branches/pmb
Instructions: Please provide a response for each question outlined below.

1. A site is eligible for audit
   a. 18 months after the first patient
   b. 36 months after the most recent audit
   c. If there are significant irregularities found through QC procedures
   d. Any of the above

2. Only those sites receiving an Unacceptable audit rating for any auditable component are required to submit a written response or corrective action plan
   a. True
   b. False

3. Any site utilizing the NCI CIRB as the IRB of record for a given protocol can expect that an auditor will review all CIRB documentation and approvals on-line (via the CIRB web site) while at the site
   a. True
   b. False

4. Which of the following is not true regarding external safety reports (ESRs)?
   a. The local IRB may draft a policy stating that local policy does not require the submission of ESRs and policy is made available for review at time of audit
   b. Typically, ESRs for adverse events that are unexpected with Grade ≥ 3 (attribution of possible, probable or definite) must be submitted to the IRB of record
   c. An ESR must be submitted to the IRB within 90 days of the date of the adverse event

5. Even if the patient case review reveals no deficiencies, a site may still receive a major or lesser deficiency for late data submission.
   a. True
   b. False

6. An audit component rating of Unacceptable will result in all of the following except?
   a. A requirement for a written response or correction action plan submission within 45 days of receipt of the final audit report

b. Automatic suspension restricting or prohibiting the site’s ability to enroll patients  
c. Reaudit of the site within one year  
d. Additional actions or sanctions as recommended by the Group or CTSU policies  

7. Which of the following will not result in a major IRB deficiency?  
   a. Initial IRB approval documentation missing  
   b. Internal reportable adverse events not reported to the IRB  
   c. Protocol reapproval delayed by 25 days  
   d. Expedited reapproval for situations other than approved exceptions  

8. Which of the following will result in a major Pharmacy deficiency? Mark all that apply.  
   a. Erasures or white-outs  
   b. Substitution with any non DCTD supplied agents, including commercial agents  
   c. One DARF used for multiple strengths or dosage forms of an agent  
   d. No faxed documentation from PMB of approval for transfer of agent  
   e. Agent(s) return to DCTD/DCP within 90 days of study closure  
   f. INDs not stored separately by protocol  

9. Which of the following will not result in a major deficiency for patient case review?  
   a. Additional agent or treatment utilized which is not permitted per protocol  
   b. Claimed response cannot be verified  
   c. Missing documentation to confirm eligibility  
   d. Dose deviation = 10%  
   e. Inaccurate reporting of adverse event grades, types or duration  

10. How long does the audit site have to submit missing documentation to the audit team after the audit?  
    a. 10 days  
    b. 2 weeks  
    c. 3 weeks  
    d. 5 days
Correct Answers in Blue.............

1. A site is eligible for audit
   a. 18 months after the first patient
   b. 36 months after the most recent audit
   c. If there are significant irregularities found through QC procedures
   d. Any of the above

   Reference: Slides 6, 7
CTMB Audit Guidelines:
   • Section 3- “All institutions (main members, affiliates, CCOPs and CCOP components) that accrue patients to a Cooperative Group, CCOP Research Base, or CTSU clinical trials during a three-year period are eligible for an audit at least once every thirty-six months but may be selected for audit at any time.”
   • Section 3.3- “Main member institutions will be audited within eighteen months after entry of the first patient. If an institution accrues rapidly the initial on-site audit should be done sooner than 18 months. Following the initial audit, main member institutions must be audited at least once every 36 months. For large accruing main member institutions, it may be appropriate for the Cooperative Group to audit these institutions on a more frequent interval given the large number of cases for review.”
   • Section 3.8- “Special audits or for cause audits (off cycle) may be warranted when there are significant irregularities found through quality control procedures or when allegations of possible scientific misconduct are made.”

2. Only those sites receiving an Unacceptable audit rating for any auditable component are required to submit a written response or corrective action plan
   a. True
   b. False

   Reference: Slide 35
CTMB Audit Guidelines (2006): Section 5.1- “For each component rated as Acceptable Needs Follow-up or Unacceptable, the institution will be required to submit a written response and/or corrective action plan to the Cooperative Group, CCOP Research Base or CTSU.”

3. Any site utilizing the NCI CIRB as the IRB of record for a given protocol can expect that an auditor will review all CIRB documentation and approvals on-line (via the CIRB web site) while at the site
   a. True
   b. False

   Reference: Slide 19
CTMB Audit Guidelines (2006): Section 5.2.1—“If the NCI Central Institutional Review Board (CIRB) is utilized by the local IRB through facilitated review, all documentation of CIRB approvals must be obtained by the local site. Since the local IRB has assumed responsibility through facilitated review, these documents (hard copy) must be present at the time of the audit.”

4. Which of the following is not true regarding external safety reports (ESRs)?
   a. The local IRB may draft a policy stating that local policy does not require the submission of ESRs and policy is made available for review at time of audit
   b. Typically, ESRs for adverse events that are unexpected with Grade ≥ 3 (attribution of possible, probable or definite) must be submitted to the IRB of record
   c. An ESR must be submitted to the IRB within 90 days of the date of the adverse event

Reference: Slide 18
CTMB Audit Guidelines (2006): Section 5.2.1—“External safety reports for adverse events that are unexpected and ≥ Grade 3 (attribution possible, probable, or definite) must be submitted to the local IRB within 90 days of the Group’s notification (unless the institution’s policy does not require such events to be reported and documentation of the institution’s policy on external safety report review can be provided at the time of the audit).”

5. Even if the patient case review reveals no deficiencies, a site may still receive a major or lesser deficiency for late data submission.
   a. True
   b. False

Reference: Slide 35
CTMB Audit Guidelines (2006): Section 5.4.1—“The Groups, CCOP Research Bases and CTSU have established guidelines and acceptability of the timeliness, completeness and accuracy of submitted data. Disregard or untimely data reporting per Group, CCOP or CTSU guidelines may be rated as a major deficiency.”

6. An audit component rating of Unacceptable will result in all of the following except?
   a. A requirement for a written response or correction action plan submission within 45 days of receipt of the final audit report
   b. Automatic suspension restricting or prohibiting the site’s ability to enroll patients
   c. Reaudit of the site within one year
   d. Additional actions or sanctions as recommended by the Group or CTSU policies

Reference: Slides 5, 35, 36, 39
• Section 5.1 - “For each component rated as Acceptable Needs Follow-up or Unacceptable, the institution will be required to submit a written response and/or corrective action plan to the Cooperative Group, CCOP Research Base or CTSU. A copy of the response/corrective action plan, along with an assessment of adequacy by the Cooperative Group, CCOP Research Base or CTSU of the response/corrective action plan, must be forwarded to CTMB within 45 days of the date the final audit report is submitted in the CTMB Audit Information System. Cooperative Group, CCOP Research Base or CTSU policies and procedures may recommend and/or require additional actions or sanctions. A re-audit is mandatory, if an institution continues to participate in the Group, CCOP Research Base or CTSU, for any of the three components rated as Unacceptable. A re-audit should be done no later than a year after the Unacceptable audit or when sufficient patients have been accrued (3-5 patients).

• Section 6.3.1 - “If an audited institution fails to provide a corrective action plan for one or more audit components rated as acceptable needs follow-up or unacceptable within the required 45 day time limit, the following actions will be taken: (1) The Group will provide written notice to the Principal Investigator at the institution that the response/corrective action plan is overdue and a five working day grace period will be granted for the submission of the response/corrective action plan, (2) If follow-up or a corrective action plan is not received by the Group during the five day grace period, the Group will immediately suspend patient registrations from that institution...”

7. Which of the following will not result in a major IRB deficiency?
   a. Initial IRB approval documentation missing
   b. Internal reportable adverse events not reported to the IRB
   c. Protocol reapproval delayed by 25 days
   d. Expedited reapproval for situations other than approved exceptions

Reference: Slides 16, 17, 18
CTMB Audit Guidelines (2006): Section 5.2.1- “Major IRB deficiencies may include but are not limited to: Protocol never approved by IRB, Initial IRB approval documentation missing, Initial approval by expedited review, Expedited reapproval for situations other than approved exceptions (see Appendix 3), Registration and or/treatment of patient prior to full IRB approval, Reapproval delayed more than 30 days but less than one year, Registration of patient on protocol during a period of delayed reapproval, Missing reapproval, Expired reapproval, Internal reportable adverse events reported late or not reported to the IRB...”

8. Which of the following will result in a major Pharmacy deficiency? Mark all that apply.
   a. Erasures or white-outs
   b. Substitution with any non DCTD supplied agents, including commercial agents
   c. One DARF used for multiple strengths or dosage forms of an agent
   d. No faxed documentation from PMB of approval for transfer of agent
   e. Agent(s) return to DCTD/DCP within 90 days of study closure
   f. INDs not stored separately by protocol
Reference: Slides 22, 23, 24, 25, 26

CTMB Audit Guidelines (2006): Section 5.3.1- “The following are guidelines for assessing compliance and noncompliance with drug accountability, use of NCI DARFs, and storage regulations for CTEP-sponsored trials using agents supplied by CTEP:

- NCI DARFs Completely and Correctly Filled out (Non-compliance)- There are erasures or ‘whiteouts’
- Protocol and Drug Specific (Non-compliance)- Substitution with any non-DCTD supplied agents, including commercial agents; One DARF used for more than one protocol, for a multi-agent protocol, or for multiple strengths or dosage forms of an agent
- NCI DARFs Kept as Primary Transaction Record (Non-compliance)- No faxed documentation from PMB of approval for transfer of agent
- Return of Drug to NCI (Compliance)- Return to DCTD/DCP agents within 90 days of study closure
- Storage (Non-compliance)- IND not stored separately by protocol”

9. Which of the following will not result in a major deficiency for patient case review?
   a. Additional agent or treatment utilized which is not permitted per protocol
   b. Claimed response cannot be verified
   c. Missing documentation to confirm eligibility
   d. Dose deviation = 10%
   e. Inaccurate reporting of adverse event grades, types or duration

Reference: Slides 29, 31

CTMB Audit Guidelines (2006): Section 5.4.1- “A major deficiency is defined as variance from protocol-specified procedures that makes the resulting data questionable. Following are examples of major deficiencies: Failure to document properly obtained informed consent (see section)…, review of documentation available at the time of audit confirms patient did not meet all eligibility criteria as specified by the protocol, documentation missing; unable to confirm eligibility… incorrect agent/treatment used, additional agent/treatment used which is not permitted by protocol, dose deviations, modifications, or calculations incorrect (error greater than +/- 10%)…Failure to evaluate response according to the protocol (i.e., inaccurate documentation of initial sites of involvement, protocol-directed response criteria not followed, claimed response (PR, CR, etc) cannot be verified)…Failure to assess and report adverse events according to protocol (i.e., grades, types, or dates/duration of serious adverse events inaccurately recorded, adverse events cannot be substantiated)….”

10. How long does the audit site have to submit missing documentation to the audit team after the audit?
   a. 10 days
   b. 2 weeks
   c. 3 weeks
   d. 5 days
Reference: Slide 30
CTMB Audit Guidelines (2006): Section 5.4- “Documentation identified as missing at the time of the audit and requested by the audit team must be supplied within a maximum of two weeks following the audit to clarify patient case findings.”