

Title: **CP-CTNet DMASC Auditing Plan**

Version: 3.1

Version Date: November 03, 2025

REVISION HISTORY (most recent first)

Version	Effective Date	Summary of Changes
3.1	NOV-03-2025	Updated DMACC to DMASC throughout the document.
3.0	MAY-14-2025	Added Note to section 9, general clarifications and edits throughout.
2.0	AUG-13-2024	Updated section 9 <i>Participant Case Selection</i> to clarify the process for selecting participant cases to be audited for single arm or blinded studies vs. unblinded randomized studies.
1.0	MAY-24-2024	Original version of document.

1. INTRODUCTION AND PURPOSE

The National Cancer Institute (NCI) Division of Cancer Prevention (DCP) requires quality assurance (QA) audits of clinical trials data and processes at each Lead Academic Organization (LAO), accruing LAO, and Affiliated Organization (AO) participating in the Cancer Prevention Clinical Trials Network (CP-CTNet). Audits are conducted by the Data Management, Auditing, and Statistical Center (DMASC) Clinical Trials Auditing Unit. See CP-CTNet SOP 03-02 *Site Preparations for Quality Assurance Audits* for more information on preparing for LAO, accruing LAO, and AO audits.

This reference guide formalizes the procedures for planning audits at LAOs, accruing LAOs, and AOs. The CP-CTNet DMASC auditing plan applies to all studies conducted within CP-CTNet.

2. DEFINITIONS

Term	Definition
AO	Affiliated Organization
CNTs	Cross Network Trials
CP-CTNet	Cancer Prevention Clinical Trials Network
DCP	Division of Cancer Prevention
DMASC	Data Management, Auditing, and Statistical Center
INT	Inter-Network Trial; the DCP protocol numbering convention for CP-CTNet Cross Network Trials (e.g., INT21-05-01).
LAO	Lead Academic Organization
M-SOP	Manual of Standard Operating Procedures
PI	Principal Investigator
QA	Quality Assurance
SAE	Serious Adverse Event
SCNC	Serious or Continuous Noncompliance
SOP	Standard Operating Procedure
UP	Unanticipated Problem

3. AUDIT PLANNING

Site (LAO, accruing LAO, or AO) selection for a DMASC QA audit is performed monthly during the CP-CTNet DMASC-DCP Monthly Auditing meeting.

1. At least three to five business days prior to the meeting, the Audit Team provides the DCP Nurse Consultants with a current *Audit Overview* spreadsheet, which includes:
 - 1.1. A per protocol list (including protocol audit risk level) of all accruing LAOs and AOs and their current accrual.
 - 1.2. The accruing LAOs and AOs that meet the minimum accrual threshold (at least three participants) for an audit.
 - 1.3. LAO oversight audit plan.
 - 1.4. A listing of already scheduled audits, and a tentative projection of audits to be performed over the next six-month period.
2. Review of these files is a standing agenda item for each monthly meeting.

3. Unless the auditor is training a new auditor or otherwise determined necessary, audit visits are conducted by a single auditor.
 - 3.1. The Audit Team provides justification if more than one auditor is needed for a visit.
4. Due to the scope and intricacy of an audit and the burden placed on the study team at the site being audited, only one protocol is audited during a visit unless otherwise deemed necessary and appropriate. However, during the visit, an audit of a second protocol or an LAO Oversight Audit may be scheduled at the same time provided there is a separate auditor for each audit being conducted.

4. LAO OVERSIGHT AUDITS

1. Initially, each LAO has two annual, onsite QA audits.
 - 1.1. The timing (between 12 and 18 months from the last visit) and location (onsite or remote) of subsequent audits is decided by the Audit Team and DCP Nurse Consultants based on the following criteria:
 - Staff turnover (especially a change in PI or Lead Coordinator/Program Manager).
 - Number of safety/compliance concerns (e.g., SAEs, protocol deviations, or UPs/SCNC).
 - Compliance with CP-CTNet SOPs (especially SOP 03-03 *LAO Oversight Activities*).
 - Degree to which per protocol accrual goals are being met or addressed if there are barriers.
 - Monthly study team meetings are occurring and are addressing study concerns.
 - Number of data entry queries, data entry delinquencies, and query response delinquencies in the study database.
 - Findings during accruing LAO and AO audits.
 - CNTs and all studies funded under the LAO are being managed appropriately in terms of LAO monitoring, team engagement, etc.

Note: The DCP protocol numbering convention for CP-CTNet CNTs is INT, which stands for “inter-network trial” (e.g., INT21-05-01).
 - 1.2. This decision is documented on the *Audit Overview* spreadsheet.

5. ACCRUING LAO AND AO AUDITS

Selection of an accruing LAO or AO for audit is based on the following criteria:

1. **High-risk studies:**
 - 1.1. 100% of accruing LAOs and AOs meeting the accrual threshold (at least three participants) are audited. The timing of each audit visit is decided in conjunction with DCP.
 - 1.2. Follow-up accruing LAO and AO audits are conducted at least every three years, as appropriate and in consultation with the DCP study team and LAOs.
2. **Intermediate and Low-risk studies:**
 - 2.1. $\geq 50\%$ of accruing LAOs and AOs meeting the accrual threshold (≥ 3 participants) are audited.

- 2.2. Site selection is made in consultation with the DCP study team and the overseeing LAO.
 - Considerations for selecting or not selecting an accruing LAO or AO for audit may include, but are not limited to:
 - Compliance with the protocol.
 - Compliance with data entry requirements.
 - Familiarity with CP-CTNet (e.g., accruing LAO or AO is new to the network).
 - The LAO's assessment of the accruing LAO or AO's performance to date.
 - Responsiveness of the accruing LAO or AO to LAO concerns.
 - LAO monitoring raises no trends or concerns.
 - Rapid accrual to a protocol.
 - An "acceptable" performance rating on all visit components on a previous audit of another network protocol conducted by the same study team, provided there has been no turnover of key staff (e.g., PI, Lead Coordinator, or other member of the team that is highly involved in the overall conduct of the study) in the interim.
 - If an accruing LAO or AO only accrues one to two participants, then the site is not eligible for audit, unless an audit is determined to be warranted in consultation with DCP and the LAO.
 - As part of the SOP 03-03 *LAO Oversight Activities*, the LAO will perform 100% chart review/source documentation verification on the first two participants.
 - At the time of study closure, the Audit Team confirms that the LAO has done this review as part of their accruing LAO and AO closure procedures.

6. FOR-CAUSE AUDITS:

A for-cause audit is a repeat audit of the same network protocol at the same accruing LAO or AO. For-cause audits are not routinely performed and must be requested by the DCP study team, and/or recommended by the auditor or the LAO in response to a specific concern.

1. Reasons for a for-cause audit may include, but are not limited to:
 - 1.1. An Assessment of Performance rating of "Unacceptable" on an audit visit component if there are concerns or evidence that the accruing LAO or AO may be unable to create or execute an effective corrective action plan.
 - 1.2. Evidence of a significant decline in performance for any reason (e.g., staff turnover, major protocol change) such that participant safety may be at risk, regulatory requirements have been violated, or data or biospecimens required for study endpoint analysis are absent, lost, or at risk.
2. Unless otherwise requested, a follow-up for-cause audit is limited to the specific area(s) of concern identified in the request. The request, reason, and specifications for the scope of the audit are documented on the *Audit Overview* spreadsheet.
3. For-cause audits are added to the auditing schedule at the earliest possible opportunity.

7. CONSIDERATIONS FOR PRIORITIZATION:

1. Sites accruing rapidly to a protocol may be prioritized over sites that have met the accrual threshold but are accruing more slowly.
2. Protocol audit risk level is taken into consideration.
3. CNTs
 - 3.1. In consultation with the Lead LAO and DCP, the Audit Team may consider the number of open sites, total accrual to date, and rapid accrual to guide auditing.
 - 3.2. Consider the CNT and other studies in the same/similar population or done by the same team as the CNT to possibly audit more than one study at the accruing LAO or AO.
4. For-cause audits are added to the auditing schedule at the earliest possible opportunity and may be prioritized over planned routine audits.

8. AUDIT LOCATION (ONSITE VS REMOTE)

1. All for-cause audits are conducted onsite.
2. All attempts are made to conduct a first audit for a study-specific team at an accruing LAO or AO in person, unless otherwise prohibited by the accruing LAO or AO.
3. To the extent possible, remote audits follow the same format (duration and agenda) as an onsite audit to maintain consistency in our audit conduct and procedures.

9. PARTICIPANT CASE SELECTION

1. A minimum of three (3) participant charts per protocol/per site will be selected for participant chart review.
 - 1.1. For single arm or blinded studies, 100% source data verification is performed for the first two participants and the additional chart(s) to be audited during the visit are randomly selected by the DMASC statistician. In addition, all SAE reports will be reviewed.
 - 1.2. For unblinded randomized studies, 100% source data verification is performed for the first two participants randomized to an intervention arm. The additional case to be audited during the visit is randomly selected from either arm by the DMASC statistician. In addition, all SAE reports will be reviewed.

Note: If a site has accrued the minimum threshold of three participants but has not accrued at least two participants to the intervention arm, the site may still be selected for audit. This is done in consultation with the DMASC Audit Team, LAO, and DCP study team.
2. The audit report summary should list auditor recommendations for timing of the next audit based on audit findings.
 - 2.1. DCP gives its concurrence or rationale for disagreeing with timing.

10. ADDITIONAL INFORMATION

Please send questions and comments to the DMASC Audit Team at Audit_CP-CTNet@frontierscience.org.

11. REFERENCES

Note: All CP-CTNet SOPs are included in the [CP-CTNet M-SOP](#), which is available on the [CP-CTNet DMASC public website](#).

Resource	ID	Location
Lead Academic Organization Oversight Activities	SOP 03-03	Program Resources
Site Preparations for Quality Assurance Audits	SOP 03-02	Program Resources

12. APPENDICES

1. None