NRG Oncology Audits – Frequently Asked Questions

Q. Can the date of a scheduled audit be changed once the audit notification letter from NRG Oncology is received?

A. The NRG Oncology audit schedule is established months in advance, prior to site notification. Scheduling involves the coordination of audit due dates, the size of the audits, and the schedule of the audit team conducting the audits. NRG Oncology may be able to support a change request, but the schedules are relatively fixed, and the timing is per the NCI requirements based on the prior audit.

Q. Can the audit case list be provided more than 6 weeks in advance of my scheduled audit?

A. No, the audit window has been extended from 4 weeks to a maximum of 6 weeks by NCI. Additional extensions cannot be granted.

Q. When are unannounced cases part of my audit and what is the scope of review of an unannounced case?

A. Unannounced cases are only selected for on-site audits and are based on accrual per site CTEP ID. An on-site audit with 3 or more accruals selected for patient case review at one site (unique CTEP ID) has the possibility of an unannounced case. NRG Oncology caps the number of unannounced cases at 5 per network per audit. There are no unannounced cases for a remote audit. NRG reviews the entire case; all 6 patient case categories are reviewed. The review of the entire case is an NRG requirement and is within the scope of what is acceptable per the NCI CTMB Audit Guidelines. https://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring.htm

Q. Can audit deficiencies be changed after the final audit report is received?

A. There is an opportunity to work with the audit team during the scheduled audit. Deficiencies are also discussed at the time of the audit exit interview. An additional week is also allowed for audit follow-up to resolve any outstanding items that could not be addressed during the audit. Once the final audit report is submitted to NCI, all questions and issues are expected to be resolved.

Q. Does NRG Oncology request a Corrective and Preventative Action (CAPA) Plan for lesser deficiencies?

A. Yes, a CAPA Plan is likely to be requested for any regulatory audit component deficiency, regardless of severity and is requested for any pharmacy non-compliance, regardless of the nature of the issue. A CAPA Plan may be requested for lesser deficiencies noted in the patient case audit component. Repeated lesser deficiencies across cases are likely to require CAPA Plan follow-up. Additionally, repeated lesser deficiencies across cases may result in a major deficiency, depending on the nature and number of the deficiencies.

Q. If a patient is enrolled and/or randomized into a research study and then found to be ineligible does that mean they should be removed from the study?

A. No, the majority of NRG Oncology studies are designed as 'intent to treat', this means that when a subject is determined to be ineligible, they are still to participate per protocol. Patient safety and what is appropriate from a clinical perspective should determine subject treatment, but the subject should continue to be assessed per protocol.

Q. If there are no investigational agents required for review during a routine audit cycle, do the auditors still need to conduct a physical review of the research pharmacy?

A. It is possible that the audit team will request to review the physical pharmacy when there are no investigational agents to assess for pharmacy storage and security practices.

Q. What is the overall purpose of an NRG Oncology Quality Assurance Audit?

A. The overall purpose of an NRG Oncology Quality Assurance Audit is to 1) assure the quality of clinical trials execution; 2) verify the accuracy of submitted data; 3) document adherence to regulatory requirements; and 4) promote education. NRG stresses the educational component and strives to conduct the reviews in a way that is not punitive, but rather fosters learning for site research teams that will ultimately lead to improvement in the quality of research.

Q. How can I use the audit process as a learning experience and team building for research staff?

A. NRG Oncology audit teams have observed that sites (especially large networks) often bring their staff together during the patient case review portion of the audit to conduct internal training and team building. They utilize this direct and concentrated access to NRG audit staff to discuss deficiencies in detail, provide guidance, and answer questions. This learning/team building works best when on-site visits are utilized; sites often include geographically distant affiliate staff virtually. This strategy supports quality control educational functions aimed at addressing data collection, data management, and overall data quality. It also provides an opportunity for audit staff to obtain important feedback from site staff that can be brought back to NRG Leadership.

Q. What guidance document defines the requirements of an NRG Oncology Quality Assurance Audit?

A. NRG audits are conducted using the National Cancer Institute (NCI) National Clinical Trials Network (NCTN) Clinical Trials Monitoring Branch (CTMB) Guidelines which are located at https://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring.htm. The CTMB Audit Guidelines describe 1) background; 2) roles and responsibilities; 3) audit requirements/membership; 4) preparations for conducting the audit; 5) conducting the audit; and 6) reporting of audit findings and follow-up.

Q. Where can I find information on how the assessment of audit findings is conducted?

A. The NCI CTMB Audit Guidelines presents information on assessment of audit findings including listings of deficiency types with examples of Major versus Lesser deficiencies for each audit component (IRB, Pharmacy, Patient Case Review) https://ctep.cancer.gov/branches/ctmb/clinicalTrials/monitoring.htm.

Q. When is a Final Audit Report shared with the audited institution?

A. The Final Audit Report must be uploaded into the Clinical Trials Monitoring Branch (CTMB) Audit Information System (AIS) within 70 calendar days of day one of the audit. The institution Contact Principal Investigator and Lead Research Associate will receive the audit reports for their network immediately after NRG submission to NCI via AIS.

Q. Where do I find CAPA Plan/Follow-up requirements after the audit?

A. All Major deficiencies that required a CAPA will be discussed during the Exit Interview held at the close of the audit. The formal CAPA list will be presented in the Final Audit Report with directions and timelines for submission.

Q. Where can I find more information about the NRG Oncology audit process?

A. Audit resources are available on the NRG Oncology website: https://www.nrgoncology.org/About-Us/Statistics-and-Data-Management-Center-SDMC-/Quality-Assurance-QA-Resources

https://www.nrgoncology.org/Portals/0/Resources/Quality%20Assurance%20(QA)/NRG%20Audit%20Manual%20for%20Member%20Institutions%2025OCT2024.pdf?ver=ls_IvrjGxL3POw6_Rm7o9Q%3d%3d

Document Revision History

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