NRG ONCOLOGY

Advancing Research. Improving Lives.™

Driving Quality Though Audit Best Practice

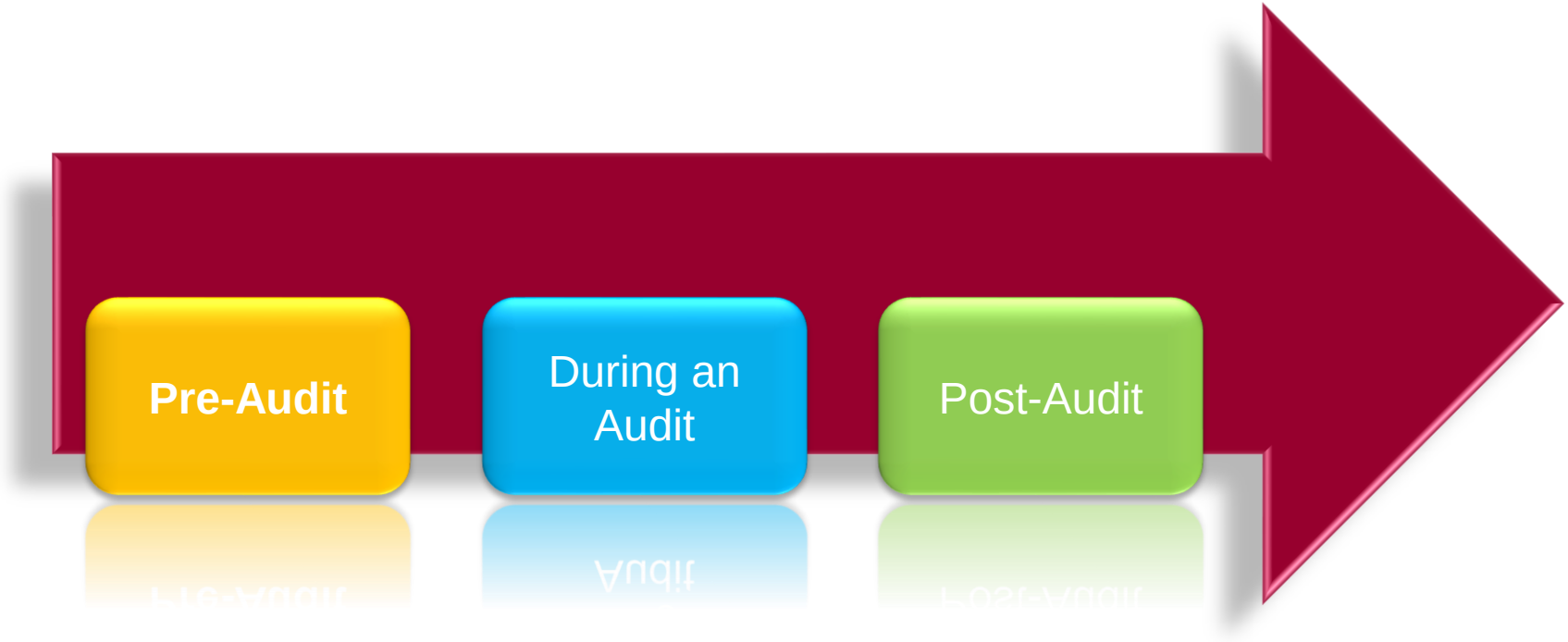
NRG CRA and CTN Protocol Committee & NRG Quality Assurance

September 2025

NCI National Clinical Trials Network
a National Cancer Institute program

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

Audit Plan and Process



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Continuous Quality Control Efforts

- **Establish Routine Review Schedule: Implement routine case reviews to identify and address potential compliance issues**
- **Utilize Data Reporting Tools: Monitor data entry completeness and timeliness using NRG Oncology Performance Reports**
- **Pre-Audit Mock Review: Conduct internal audits mimicking NCI audit criteria, focusing on areas such as informed consent, eligibility, treatment compliance, data reporting, and outcome measures**
- **Documentation Management: Organize and maintain source documents chronologically or by protocol timeline with consistent naming conventions.**
    - **Ensure consistency within sites/affiliates**

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Internal QA/QI Programs

QA/QI program example:

Staffed with dedicated experienced personnel who provide:

- **Individualized monthly reports to disease teams related to data timeliness and quality**
- **New staff quality checks at 6 months and 1 year post hire**
- **Process guides and checklists to standardize peer quality checks**
- **Single contact for audit/inspection teams**
- **Pre-audit/inspection support to disease teams**
- **Coordination of all staff (disease team, regulatory, pharmacy, etc) before and during an audit/inspection**

Real time peer reviews: ICF

- **Internal Informed Consent Form QA/QC at time of consent**
  - **Ensures quality and completeness**
  - **Addresses errors in timely fashion**
  - **Two CRCs involved**
    - **Submitter (CRC who performed consent and documents consent)**
    - **Assigned Reviewer (CRC is assigned to review ICF and documentation)**
  - **Reviewer checks to confirm:**
    - **correct version is used**
    - **signatures and dates are executed**
    - **all pages are included**
    - **sub-study selections are present**
    - **ICF note contains all appropriate elements**

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Real time peer reviews: Eligibility

- Internal Eligibility QA/QC
  - Ensures patients are truly eligible for the trial
    - Protects patient safety
    - helps ensure researchers achieve accurate results
  - 3 Reviewers sign off on eligibility criteria
    - CRC enrolling patient
      - Enters eligibility note in EMR
    - Treating Investigator
      - Reviews and attests to eligibility note in EMR
    - Second CRC
      - Uses standardized checklist
  - Our site uses Smartsheets to faciliate the QA/QC process

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NRG Quality Assurance Audit

QA Review List

- Outlines protocols selected for Regulatory/ICC/DTL/Pharmacy Review
- Contact person and submission due date
- Per NRG Standard Procedures IRB/ICC/DTL/Pharmacy documentation will be reviewed prior to the audit

Participant Announced Case List

- Selected cases for review
- NCTN Auditing Guidelines 15AUG2025
- Participant Case Review Consists of **7** Categories

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Internal audit when received

Process to assist site preparation:

- **Individual Case reviews**
  - Have a team member who is not the study coordinator (if available) review the case file
- **Regulatory reviews**
  - Review all related regulatory documents –remember regulatory and pharmacy documents will be reviewed prior to the onsite visit
- **Roadmap creation**
  - A "roadmap" or other outline of where auditors will verify source data points

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Case Review Example

Pre-Audit Tool – SUBJECT FILES

Study short title: _____

IRB#: _____

Subject initials: _____ **Subject #:** _____

Consent-

1) Correct version signed?
2) All parties signed and dated on same date, all questions within consent answered?
3) Documentation of ICF process, including patient given signed copy of ICF?
4) Reconsent(s) required?
    a. Correct version used for reconsents, all parties signed and dated
    b. Documentation of ICF process, including patient given signed copy of ICF

Eligibility-

1) Review protocol's eligibility checklist – correct version used?
2) All screening exams done on schedule of events table?
3) Locate documentation of each item on eligibility checklist & schedule of events:
    a. Progress notes
    b. Labs
    c. Chemo records
    d. Pathology
    e. Scans
    f. Height/weight/vitals
    g. Cardiac tests?
    h. Any other required documentation

Registration

1) Treatment assignment/Registration/Randomization page filed in chart

Each cycle/timepoint (tabbed)

1) Refer to time and events table
2) CRFs (if paper) should be filed in front of timepoint
3) Supporting source documents
    a. Progress notes: MD and chemo
    b. Labs filed
    c. Study labs drawn and documentation of send-out filed
    d. Correct chemo dose calculated
    e. Deviations reported?

Restaging

1) Reports printed
2) Measurements recorded on RECIST sheet and verified by MD if no measurements given in scan? (Solid tumor)

End of study

1) Documentation: completion of treatment/reason patient came off study including MD note and lab/scans as appropriate
2) Study procedures completed within correct window

Follow ups:

1.) All follow ups completed within time frame required by study?

SAEs

1) Initial documentation-when study staff found out
2) Supporting documents
3) Internal forms
4) Follow-up documentation
5) Supporting documents
6) Adeers-initial and follow-up completed
7) Verify IRB reporting

Logs

1) Concomitant Medications, if needed
2) Adverse Events, if needed
3) Medical History

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Roadmap Example

Patient: [redacted]
MRN: [redacted]

Study: GY026
Patient ID: [redacted]

Date of Consent: [redacted]

Date of Registration: [redacted]

Eligibility Criteria Version 12/06/2022	Type of Document	Date	Location (Epic or Florence) All EPIC locations are under "Chart Review Tab" except where noted
Criteria 3.1.1	MD Progress notes x 2 / pathology	11/07/22& 12/19/22 / 10/17/22 & 12/07/22	EPIC- "Notes" - "Progress Notes" /Epic-"Path"
Criteria 3.1.2	CT CAP	1/17/2023	EPIC-"Imaging"
Criteria 3.1.3	pathology	12/7/2022	EPIC-"Path"
Criteria 3.1.4	pathology	12/7/2022	EPIC-"Path"
Criteria 3.1.5	MD Progress note	1/10/2022	EPIC-"Notes"-"Progress Notes"
Criteria 3.1.6	Snapshot	9/9/1938	EPIC-Snapshot tab
Criteria 3.1.7	Labs	1/10/2023	EPIC-"Labs"
Criteria 3.1.8	Labs	1/10/2023	EPIC-"Labs"
Criteria 3.1.9	Labs	1/10/2023	EPIC-"Labs"
Criteria 3.1.10	MD Progress note	11/7/2022	EPIC- "Notes"-"Progress Notes"
Criteria 3.1.11	MD Progress note	11/7/2022	EPIC-"Notes"-"Progress Notes"
Criteria 3.1.12	MD Progress note	11/7/2022	EPIC-"Notes"-"Progress Notes"
Criteria 3.1.13	MD Progress note	11/7/2022	EPIC-"Notes"-"Progress Notes"
Criteria 3.1.14	MD Progress notes x 2	11/7/22 & 1/10/23	EPIC-"Notes"-"Progress Notes"
Criteria 3.1.15	Consent	1/10/2023	Florence- "Signed Copies of Informed Consents and Subject information Sheet
Criteria 3.2.1	MD Progress note	11/7/2022	EPIC- "Notes" - "Progress Notes"
Criteria 3.2.2	MD Progress note	1/10/2023	EPIC- "Notes"-"Progress Notes"
Criteria 3.2.3	MD Progress note	1/10/2023	EPIC- "Notes" - "Progress Notes"
Criteria 3.2.4	MD Progress note	11/7/2022	EPIC- "Notes" - "Progress Notes"
Criteria 3.2.5	MD Progress note	11/7/2022	EPIC- "Notes" - "Progress Notes" s
Criteria 3.2.6	MD Progress note	11/7/2022	EPIC- "Notes"-"Progress Notes"
Criteria 3.2.7	MD Progress note	12/7/22 & 1/18/23	EPIC- "Notes" - "Progress Notes"
Criteria 3.2.8	MD Progress note	11/7/2022	EPIC- "Notes" - "Progress Notes"

Baseline	Type of Document	Date	Location (Epic or Florence) All EPIC locations are under "Chart Review Tab" except where noted
Pathology report	Pathology	12/7/2022	EPIC-"Path"
HER-2 testing	Pathology	12/7/2022	EPIC-"Path"
H&P	MD Progress note	1/10/2023	EPIC- "Notes" - "Progress Notes"
Concomitant medications	MD Progress note	1/10/2023	EPIC- "Notes" - "Progress Notes"
Vitals (BP, HR, Temp, Pulse ox)	MD Progress note	1/10/2023	EPIC- "Notes" - "Progress Notes"
Performance Status (PS)	MD Progress note	1/10/2023	EPIC- "Notes"-"Progress Notes"

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Regulatory Review Worksheet

Pre-Audit Tool - REGULATORY/IRB

Study short title: _____

IRB#: _____

Date of Initial Approval: _____

Continuing reviews:

Date of Re-approval: _____
Date of Re-approval: _____
Date of Re-approval: _____
Date of Re-approval: _____
Date of Re-approval: _____
Date of Re-approval: _____

- ✓ Verify all approval letters are present and filed in Florence
- ✓ Verify DOA is completed in Florence
- ✓ Verify all protocol training is documented for all versions, all staff
- ✓ Verify SIV letter and all monitoring letters are filed.

Amendments:

AME Number	Title of Amendment/Summary	Date Received/Posted from Sponsor	IRB Approval Date	Patients re-consented?	Implementation Documentation (cIRB only)	Training completed for all staff members?

Reportable Events/UPIRSOs:

RE Number	Title of Reportable Event	Date Received from Sponsor	Date submitted to IRB

If no, list outstanding reports:

DOA Log Findings
Ensure DOA log is complete and accurate. Cross check with applicable Oncore staff.

Training Documentation Findings
Applicable to all initial training and amendments approved prior to 11/19/2019 (approval of required protocol training SOP).

CVs and Financial Disclosure Forms Findings
Required for PI and any sub-I's

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Logistics and Scheduling

- Identify staff who will support audit team
- If a remote audit, identify the primary method of communication (email, phone, video meetings)
- Organize site specific schedules with audit team
    - Important for offsite affiliates
- Determine if remote (video) pharmacy inspection is needed/possible and schedule in advance of the audit start date
- Provide audit team with clear directions to the site, parking considerations, and any other helpful information
- Be ready for auditors to arrive onsite at designated start time
- Ensure you have secured a quiet room with enough space to house the team for the duration of the audit

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Planning for EMR Access

- Know organizational requirements and time to establish external EMR access for all sites involved in the audit
- Provide confidentiality agreements in advance; some documents require additional NRG review
- Personal Identified Information (PII) should not be requested per the NCI CTMB Audit Guidelines, Section 4.4
- Establish access in advance to prevent audit start delays
- Guidance documents on where to find records in EMR system(s) is helpful for the audit team

Questions about pre-audit and preparation

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During An Audit

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Communication During the Audit

- Have one key contact identified to handle auditor queries
    - Queries should be responded to as quickly as possible – preferably same day or within no more than one business day
    - Key contact should check in with the team in person occasionally to address any complicated issues or obtain status updates
- If a remote audit, more frequent email monitoring is appropriate
- During the audit and at the conclusion of the audit address any missing documentation to resolve deficiencies. The site will have one week to provide the auditors with any source that would dispute a deficiency. Once the final audit report is submitted to NCI, updates to reports are not typically made

What is a Deviation?

Deviation or protocol violation

- **Any non-compliance with an approved protocol, procedure policy or facility**
- **A departure from the procedures and rules defined in a clinical trial's approved protocol**

Who can identify a deviation?

- **Clinic site staff**
- **Auditors and Monitors**

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Characteristics of a Deviation

- **Deviations can be intentional or unintentional**
- **They can potentially place participants at risk or undermine the scientific integrity of the study**

Examples:

- Failing to meet inclusion/exclusion criteria
- Missing a required lab test
- Dispensing the wrong dose of a study medication
- Conducting a study visit outside the required protocol-specified timeframe

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What is a Deficiency?

- A deficiency is a formal finding noted by an auditor during a quality assurance review of a clinical trial site
- These findings highlight variances or non-compliance issues

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Characteristics of a Deficiency

- Identified during an audit, which is an independent examination of trial activities to ensure they were conducted correctly
- A deficiency can be caused by various issues, including one-time deviations, or a pattern of deviations
- Deficiencies are graded according to their impact on the study
    - Lesser- Finding not expected to have a significant impact on study outcomes or interpretation
    - Major- Variance that makes data questionable or raises concerns for patient safety
    - Critical: Any practice that adversely affects the rights, safety, or well-being of a participant or compromises data integrity

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Answer

a) True

A deficiency is often the result of a deviation or a series of deviations. A formal finding noted by an auditor during a quality assurance review of a clinical trial site.

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Post Audit-Exit Interview

- How do you ensure the research team is aware and available to attend the exit interview?
- Findings will be reviewed
- Discuss any notable trends
- Troubleshoot and/or discuss preventing ongoing issues/trends
- The site is encouraged to ask questions as this is also a time for education

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Best Practice – Audit Follow-up Requirements

Corrective and Preventative Action Plan (CAPA)-*5 Questions*

1. What happened? Document the finding/issue
2. Why did it happen? Identify the root cause
3. Why else? Continue probing until the root cause is found
4. What was or will be done to correct it? Document corrective actions taken
5. What will be done to prevent it from happening again? Document preventative actions to prevent recurrence

Contact PI and Local PI (if applicable) signature(s) required by NRG

Table format preferred

Deadline for submission to NCI is set

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CAPA Plan Example Content

Finding	Root Cause	Corrective Action	Preventative Action
Describe the finding as captured in the audit report	Describe the root cause of the issue	Document actions taken to correct the issue	Describe what has been done or what will be done to prevent the issue from occurring in the future.
	The information in these areas should include the details of what was involved, who was involved, when steps were taken, what will be documented and frequency of any ongoing review.		

TIPS: Write a plan that will work for your site and is *achievable*.

Avoid incomplete sentences as explanations. CAPA Plan will most likely be returned for additional information and explanation.

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NRG Resources

Links to NRG resources

- NRG-PSC e-mail is the best way to contact us for more information about this presentation or other topics. NRG-PSC@nrgoncology.org
- PSC Newsletters written by the QC&C Subcommittees NRG > Home > News > Newsletters
- NRG is working really hard to make ourselves present on CLASS. We have about a dozen topics/modules in the works currently. The first round should be uploaded soon. YAY!!!! Catalog | CLASS (Compliance, Learning, and SOP Solutions)

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THANK YOU!

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