

Quality Assurance Program

Laura Gonzales, BSN, MA, RN, OCN Quality Assurance Manager Spring 2025

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Purpose of the audit program

- Verify study data that could affect the interpretation of primary study endpoints by checking compliance to protocol and regulatory requirements and accuracy of submitted data
- Assessment of trial related activities and documents for adherence to Good Clinical Practice (GCP)
- Provide educational support for data quality and data management practices

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Scheduling of Audits

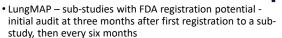


- patient registration
- New affiliates, components at next parent institution audit
- Institutions audited at least once every three years but remain at risk for more frequent audits
- FDA registration studies more frequent monitoring

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FDA Registration Study Site Visits



- LungMAP sub-studies that do not have FDA registration potential will be audited on the same schedule as treatment audits by the group to whom they are credited
- S2302 (Pragmatica) will be audited on same schedule as treatment audits

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On-Site Versus Off-Site Audits

On-site

- LAPS / Main Member / NCORP
- Component / affiliate with large accrual
- FDA registration study site visits for sites requesting onsite

Off-site

- · Most NCORP components and Main Member affiliates audited off site with parent institution
- Most FDA registration study site audits can be audited off site

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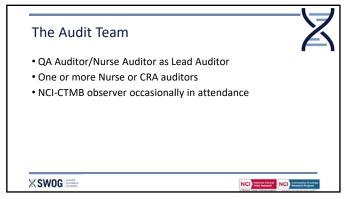
Notification Process



- Scheduled three to four months prior to the audit.
- Formal notification/case list by email four to six weeks prior to the audit.
- Includes detailed instructions on how to prepare for the audit and Site Questionnaire for audit planning.

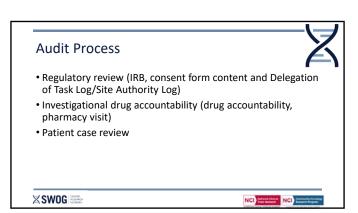
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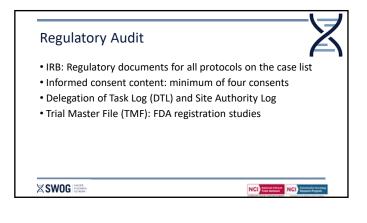


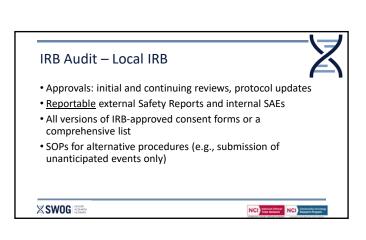




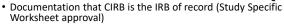








IRB Audit - CIRB



- · Approved boilerplate language for ICFs
- Date of local implementation of protocol updates and consent versions
- Submission of unanticipated events (e.g., reportable local
- NO COPIES OF CIRB APPROVAL DOCUMENTS REQUIRED

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Consent Form Content

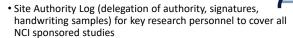


- Compared to model consent
- Contains all elements required by federal regulations
- Updated by protocol modifications
- Specimen banking/optional studies questions same as model
- CIRB sites: identical to approved boilerplate merged with model

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Delegation of Task Log



- Delegation of Task Log (CTSU website)
 - o All registration studies (\$1806, \$2302)
 - o LungMAP sub-studies
 - o All new studies that use investigational agents (since August 2020 for Ph III studies/since October 2020 for Ph I/II studies)

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Trial Master File

- Protocol
- Regulatory documents
- CLIA Certificates and list of normal lab values/range
- List of local SOPs
- Site training documents (GCP, protocol specific, etc.)
- Placeholder for centrally filed documents (e.g., CVs, 1572s)

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- Control and satellite records
- · Complete and timely entries
- Good documentation practices
- · Patient returns documented on Oral DARF

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agents



Investigational Drug Accountability



- Shipping receipts, transfer and return forms
 - Unused or expired drug returned or destroyed within 90 days of end of use
 - No substitution of commercial drug for investigational

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Investigational Drug Accountability



- Cross reference DARFs against patient records to verify dose and dates of dispensing
- SOP for authorized prescriptions (ordering investigator must have active CTEP account)
- On-site audits: Tour of pharmacy
 - Assess security and storage conditions
 - Verify physical inventory
- Off-site audits: Tour of pharmacy conducted via Teams, FaceTime, WebEx, etc.





Patient Case Review



- 10% of SWOG and CTSU accrual
- 10% of treatment and cancer control cases
- Minimum of one case for each non-SWOG FDA registration study
- Minimum of three cases
- One unannounced case for on-site audits

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Patient Case Review: Categories



- Informed consent
- Eligibility
- Treatment administration
- Disease / endpoint assessment
- Toxicity assessment
- General data quality

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Case Review: Categories



Chart preparation

- Shadow chart is acceptable
- Recommended chart organization: Consent and screening/eligibility, then chronological by cycle / reporting period - H&P, labs, disease assessments, etc.
- Color coded flagging
- Specimen submission documents flagged (print out of specimen tracking documents)
- If auditor will review records in EMR, EMR Source Documentation Locator Form must be completed prior to the audit

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Informed Consent



- Most current version signed prior to registration
- Contains all required signatures
- Informed of new findings in a timely manner
- Specimen banking/optional studies offered and intent reported correctly in OPEN at time of registration
- HIPAA authorization signed

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Eligibility



- Verify diagnosis by review of pathology or other diagnostic reports
- Review medical history for exclusion criteria
- Verify pre-study assessments meet protocol requirements and performed within specified time limits
- · Eligibility affirmation signed
- NO EXCEPTIONS GRANTED

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Treatment Administration



- BSA / dose calculations verified
- Verification of both drug orders and drug administration
- Appropriate dose modifications
- Patient diaries or other supporting documentation of compliance to oral medications
- Documentation to support delays or deviations in treatment





Endpoint Assessment



- Disease/endpoint assessments performed per protocol
- Review of radiology reports, pathology reports, lab reports, records of physical examinations, etc.
- Same method of measuring the disease at baseline and at each assessment
- Tumor measurements documented
- Off treatment follow-up conducted per protocol

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Adverse Event Assessment



- Required baseline and follow-up studies performed
- Grade and attribution of AEs documented, signed off by investigator/qualified practitioner
- Documentation of immune-related status, if applicable
- Adverse events reported appropriately.
- Serious Adverse Events (SAEs) reported in a timely manner

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General Data Quality



- Adequate source documentation
- Data accurately reported on the data collection forms
- Timely submission of data
- Specimens/images/questionnaires submitted per protocol
- Good documentation practices

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Exit Interview



- Meet with PI and staff
- Summarize findings
- Clear up any questions
- Preliminary Report indicating any major deficiencies submitted within one working day to the NCI

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Audit Ratings



- Acceptable
 - See you in three years
- Acceptable, Follow-up Needed
 - A written response including a corrective and preventive action plan must be submitted

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