




Quality Assurance Program

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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

- New LAPS, Members, NCORPs – within 18 months of first 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 with FDA registration potential - initial audit at three months after first registration to a sub-study, then every six months
- 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 audits

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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The Audit Team





- QA Auditor/Nurse Auditor as Lead Auditor
- One or more Nurse or CRA auditors
- NCI-CTMB observer occasionally in attendance

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Site Representatives

- ORPs
- Research Nurses
- Principal Investigator or designate
- Regulatory Representative
- Pharmacy staff

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Audit Process










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Audit Process





- Regulatory review (IRB, consent form content and Delegation of Task Log/Site Authority Log)
- Investigational drug accountability (drug accountability, pharmacy visit)
- Patient case review

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Regulatory Audit





- IRB: Regulatory documents for all protocols on the case list
- Informed consent content: minimum of four consents
- Delegation of Task Log (DTL) and Site Authority Log
- Trial Master File (TMF): FDA registration studies

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IRB Audit – Local IRB




- Approvals: initial and continuing reviews, protocol updates
- Reportable external Safety Reports and internal SAEs
- All versions of IRB-approved consent forms or a comprehensive list
- SOPs for alternative procedures (e.g., submission of unanticipated events only)

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IRB Audit – CIRB




- Documentation that CIRB is the IRB of record (Study Specific Worksheet approval)
- Approved boilerplate language for ICFs
- Date of local implementation of protocol updates and consent versions
- Submission of unanticipated events (e.g., reportable local SAEs)
- **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




- Site Authority Log (delegation of authority, signatures, handwriting samples) for key research personnel to cover all NCI sponsored studies
- Delegation of Task Log (CTSU website)
 - All registration studies
 - LungMAP sub-studies
 - 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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Investigational Drug Accountability




- Review of Drug Accountability Record Forms: NCI DARF or NCI Oral DARF (or equivalent) required for all studies using investigational agents
 - Control and satellite records
 - Complete and timely entries
 - Good documentation practices

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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 agent

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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.



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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 four 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
- Correlative studies, tests, and procedures
- 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



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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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Correlative Studies, Tests, and Procedures



- Section added when CTMB Audit Guidelines updated in August 2025
- Previously part of General Data Quality
- Specimens/images/questionnaires submitted per protocol



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General Data Quality



- Adequate source documentation
- Data accurately reported on the data collection forms
- Timely submission of data
- 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 in all 3 components
 - See you in three years
- Acceptable, Follow-up Needed in 1 or more components
 - A written response including a corrective and preventive action plan must be submitted








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Audit Ratings

Unacceptable in 1 or more components




- A written response including a corrective and preventive action plan must be submitted
- Repeat audit within 6 - 12 months
- If repeat offender: Site Improvement Plan required / possible suspension of registration privileges

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Some Helpful Hints




- Take lots of notes, sign and date them
- No white out
- Keep records on a real-time basis
- Document height and weight and performance status
- Keep logs for tracking adverse events, concomitant medications

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Some Helpful Hints

- Conduct secondary review of eligibility prior to registration
- Look at an audit as a “Positive Learning Experience”
- Include Affiliate/Component staff in the audit process
- Conduct internal audits, training
- Use reports on ORP (CRA) Workbench








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Additional Resources

SWOG website (<https://swog.org>: > Clinical Trials > Quality Assurance & Audits)




- Site Preparation for an Audit
- Best Practices guidance document
- SWOG regulatory guidance
- Patient chart review guidance
- Investigational drug videos / PMB policies

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Additional Resource on SWOG website

- Guidance on record retention
- Internal QA audits
- Site Authority Log
- Links to NCI and PMB
- TMF requirements for FDA registration trials

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Questions?
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