



Enhancing Quality Oversight in Cancer Clinical Trials: Real-time Source Documentation Review

Quality & Regulatory Oversight Department

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Background

Quality control (QC) in oncology clinical trials is essential for safe, compliant and scientifically credible research. These complex trials often involve high-risk investigational products, intricate dosing algorithms, strict eligibility criteria, and medically vulnerable patients.

Embedding QC into daily operations ensures protocol compliance, accurate and complete source documentation, and protection of patients' safety and data integrity.

Goals

The Quality Control (QC) Program focused on source documentation at COH was established in March 2025 to ensure consistent quality oversight of clinical trials conducted at various COH locations.

The goal of this QC program is to establish a standardized process for reviewing clinical trial source documentation to ensure accuracy, completeness, and compliance with Good Clinical Practice (GCP), institutional policies, and sponsor requirements.

Solutions & Methods

QC monitors currently focus on **multi-state high-risk interventional clinical trials**. The QC monitor initiates source documentation review within **2-3 business days** (or sooner if the need arises) of the first subject's enrollment and after any subsequent study visit at each participating COH location. Additional reviews are conducted when deficiencies are identified.

Each QC monitor completes **20 to 25 QC reports monthly** encompassing detailed review of informed consent, progress notes, eligibility checklist, toxicities documentation, concomitant medications, study drug administration, diaries, questionnaires and other records.

Findings and observations are communicated to the study teams internally through QC reports. This helps to proactively identify and address compliance risks and documentation gaps prior to monitoring, audit or inspection.

QC Report Template

City of Hope.

QUALITY CONTROL VISIT – SUBJECT SPECIFIC REPORT

IRB Number: Site Co-Investigator: Location:
Lead PI: QC Monitor: Date of Report:

A. SCOPE

SUBJECT ID	TIME POINT(S) REVIEWED	SOURCE DOCUMENTATION TO BE REVIEWED
TREATING PHYSICIAN NAME		<input type="checkbox"/> EPIC Electronic Adverse Event Flowsheet <input type="checkbox"/> Paper Adverse Event Log <input type="checkbox"/> Concomitant medications <input type="checkbox"/> Study Drug Administration <input type="checkbox"/> IP Reconciliation <input type="checkbox"/> Diaries <input type="checkbox"/> Questionnaires, please list all applicable questionnaires: <input type="checkbox"/> Response Documentation/Disease Assessment Forms <input type="checkbox"/> Tumor Measurement Forms <input type="checkbox"/> Progress notes <input type="checkbox"/> Informed Consent Form <input type="checkbox"/> Consent Note Documentation <input type="checkbox"/> Eligibility checklist <input type="checkbox"/> Lab requisition forms <input type="checkbox"/> Other trial-specific documents, please list (ex.: GVHD assessment, stem cell lab documentation, registration forms, surgery documentation, etc.)

B. SOURCE DOCUMENT REVIEW
Please list all source documents that were included in this review and provide any comments on the appropriateness of source documentation:
Reviewed timepoint/s was/were within protocol window: Yes No, specify _____ NA, unscheduled visit

SOURCE DOCUMENT NAME	RESPONSIBLE RESEARCH STAFF	COMMENTS	ACTION ITEMS & OBSERVATIONS

C. DEVIATIONS
Did any deviations occur during this visit? YES NO
If YES, please complete the table below:

DEVIATION DESCRIPTION	DATE OF EVENT	CONFIRMATION OF REPORTING TO SPONSOR	DEVIATION RECORDED IN CORE

D. SERIOUS ADVERSE EVENT REVIEW
Were there any unreported Serious Adverse Events identified during this visit? YES NO
If YES, please complete the table below:

SERIOUS ADVERSE EVENT	DATE OF EVENT	CONFIRMATION OF REPORTING TO SPONSOR
SAE Term	Enter a date	<input type="checkbox"/> YES <input type="checkbox"/> NO

Quality Control vs. Quality Assurance



QUALITY CONTROL

Focuses on identifying documentation gaps
• Monitors source document accuracy



QUALITY ASSURANCE

Focuses on promoting protocol compliance
• Improves inspection readiness



Outcomes

400+ source reviews across **60+** research subjects

Key impacts:

- Identified and corrected consent documentation gaps
- Prevented eligibility deviations through early detection
- Flagged documentation deficiencies and potential deviations
- Identified protocol deviations requiring amendment
- Supported timely SAE submissions and reporting
- Helped mitigate AEs, concomitant medication errors, and documentation gaps
- Reinforced reporting of deviations and planned deviations.

Sample Monthly Trend Review

QC Trend Report

Timepoints: Consent, eligibility, screening, treatment, follow-up, end of study
Review period: March 1-31, 2025

*** Data shown are hypothetical and used for illustrative purposes*

Category	Site 1 (n=25)	Site 2 (n=4)	Site 3 (n=4)	Site 4 (n=3)	Site 5 (n=6)	Site 6 (n=1)	Site 7 (n=2)	Site 8 (n=1)
GCP Issues	4	1	0	--	1	--	--	0
EMR Notes	21	5	4	0	3	0	1	1
ICP Documentation	2	1	2	--	1	--	--	0
Protocol Deviations	26	8	7	0	2	1	1	1
Medical History/Baseline Event Documentation	8	1	2	--	4	--	--	1
AE Collection/Documentation	38	8	5	1	5	1	2	0
SAE Collection/Documentation	3	0	0	0	1	0	0	0
IP Documentation	18	3	4	0	3	1	1	1
Eligibility	4	3	2	--	2	--	--	1
Concomitant Medication	18	4	4	0	5	0	0	1
Missing/Unfiled Source	22	11	4	0	6	1	1	1
TMS/Disease Assessments	8	3	0	--	0	1	0	--

XX deviations noted across XX QC reviews performed in March*

Summary of Deviations in February:

- Missed labs and labs collected out of window
- Missed specimen collection and specimens collected out of window
- Missed assessment and assessments performed out of window
- IP compliance
- Study drug not administered per protocol requirements
- Visit out of window
- Pre-meds given out of window
- ECGs out of window
- Incorrect questionnaire administered
- Incorrect version of pill diary provided to subject
- Translated consent form errors in documentation and consent execution

Recommended Areas of Focus:

- AE collection and documentation
- Documentation of goeteds
- Real-time deviation entry in OnCore
- Uploading source in Florence in per SOP
- Consenting non-English speaking subjects

Context & Considerations:

- Trend Report provided to site medical directors and research leaders monthly with high-level summary of deviations and areas of focus
- Weekly cross-functional quality performance meetings held with research leaders to review aggregate data and prioritize areas for improvement and action plan development.

Lessons Learned & Future Directions

Implementation of a dedicated QC review program enables:

- Early issue identification
- Improved readiness for audits and inspections
- Standardized report language improves clarity and alignment with protocols and policies.

Ongoing collaboration with study teams enhances:

- Understanding of risk
- Consistency in issue resolution

Future focus:

- Expand risk-based oversight
- Integrate metrics to drive continuous improvement
- Strengthen proactive quality culture across research operations.