Category: Quality Assurance – Work in Progress

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

H. Martirosyan, N. Cassim, A. Hammond

City of Hope Comprehensive Cancer Center

1. 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.

City of Hope (COH) Comprehensive Cancer Center provides advanced research through the national footprint of cancer centers and aims to continuously expand access to clinical trials.

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.

2. Goals

The goal of QC 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.

3. Solutions and Methods

QC monitors currently focus on high-risk interventional clinical trials activated at COH sites in two or more states and initiate source documentation review within two to three business days (or sooner if the need arises) of the first subject's enrollment and after any subsequent study visit at each participating site. 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.

4. Outcomes

Since the inception of the program in March 2025, the QC team has performed over 400 reviews for more than 60 research subjects, and noted the following achievements:

- Identified and advised addressing consent note documentation gaps
- Prevented eligibility deviations and improved eligibility documentation
- Alerted for potential deviations and documentation deficiencies
- Identified protocol deviation trends resulting in amendments to mitigate further deviations

- Alerted for timely serious adverse events (SAEs) submission and advised on complete SAE documentation
- Helped reconcile missing adverse events (AEs) and concomitant medication documentation and prevented monitoring findings
- Identified missing deviations and planned deviations and reminded the study teams to report as required

5. Lessons Learned and Future Directions

Implementation of a new quality control program focused on source documentation was initially challenging, particularly for staff not accustomed to the new process. Early responses to QC findings were largely reactive, prompting refinement of report language to ensure clarity and alignment with protocol requirements and institutional policies. Collaborative meetings with the study staff and their leaders improved understanding and consistency in addressing findings. In one instance, QC review resulted in no findings in the sponsor's monitoring letter. QC's meaningful impact increased teams' interests in additional QC reviews for more protocols.

Future efforts will focus on expanding risk-based quality oversight, leveraging dashboards and quality metrics for monitoring, and fostering a proactive culture of continuous improvement and inspection readiness through partnership with research operations and regulatory leadership.