Category: Quality Assurance – Work in Progress

Standardizing Monitoring Closure Decisions Within a Risk-Based Monitoring Framework

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1. Background

Within a risk-based monitoring (RBM) framework, clinical trials are not monitored across the full study lifecycle, requiring clear criteria to determine when monitoring activities may appropriately conclude. Closure decisions, however, often vary and may rely on subjective judgment.

2. Goals

The goals of this initiative were to improve consistency, transparency, efficiency, and to standardized monitoring visit closure determinations within an RBM model. The Monitoring Visit Progress and Closure Assessment framework, supported by a dashboard, was developed to establish objective criteria for monitoring visit close-out across investigator-initiated trials (IITs) and therapeutic clinical trials, including therapeutic, therapeutic/quality of life (QOL), and diagnostic studies at Memorial Sloan Kettering Cancer Center (MSK).

3. Solutions and Methods

The Monitoring Visit Progress and Closure Assessment dashboard was developed to provide a centralized view of institutional clinical trial monitoring activity and to support structured closure decision-making within a RBM model. The dashboard enables monitors to track performance metrics, identify monitoring gaps, highlight potential compliance risk, and assess whether a clinical trial has reached sufficient monitoring maturity to justify close-out. Monitoring visits are conducted every six to twelve weeks, typically lasting two to five days, with frequency and duration adjusted based on study complexity, accrual rate, visit ratings, and unresolved deficiencies. Because monitoring intensity decreases over time in a RBM model, objective closure criteria are essential. Closure eligibility is assessed using standardized criteria, including: (1) a minimum of twelve months of monitoring, with allowances for earlier closure due to IRB protocol closure or sponsorship transfer; (2) completion of at least four monitoring visits with participant data review, including critical data points; (3) achievement of a cumulative ≥75% data review threshold across informed consent, eligibility, treatment, outcomes, toxicity, and general data quality; (4) qualitative confirmation of primary endpoint achievement; and (5) absence of any monitoring visit rated as ‘Unacceptable’. These criteria are operationalized into consistent, rule-based logic within the dashboard to support objective closure determinations.

4. Outcomes

Implementation of the Monitoring Visit Progress and Closure Assessment framework enabled standardized and transparent evaluation of monitoring readiness for close-out within a RBM model. Defined thresholds reduced variability in closure decisions, strengthened documentation of monitoring adequacy, and facilitated timely identification of deficiencies requiring resolution prior to monitoring discontinuation. The dashboard allows monitors and managers to view monitoring activity at a glance,

either for a specific protocol or across a monitor's assigned portfolio, supporting efficient oversight and risk-informed decision making.

5. Lessons Learned and Future Directions

In a risk-based monitoring model where monitoring does not extend through the full study lifecycle, a metrics-driven, dashboard supported approach provides a defensible and reproducible method for determining when monitoring activities may appropriately conclude. This framework enhances consistency, supports risk-based oversight, and strengthens the integrity and accountability of monitoring close-out decisions within clinical research programs.