Standardizing Monitoring Closure Decisions Within a Risk-Based Monitoring Framework

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BACKGROUND

Within Memorial Sloan Kettering Cancer Center's (MSK) implementation of risk-based monitoring (RBM), monitoring activities do not extend across the full study lifecycle, requiring clear criteria to determine when monitoring can conclude. In practice, closure decisions are often subjective and variable resulting in inconsistent oversight, inefficient resource utilization, and limited documentation of monitoring adequacy. These challenges highlight the need for standardized, objective criteria to support consistent monitoring closure decisions. A Monitoring Visit Progress and Closure Assessment framework, supported by a centralized dashboard, was developed to establish objective criteria for monitoring closure across investigator-initiated trials (IITs) and therapeutic trials, including therapeutic, therapeutic/quality of life (QOL), and diagnostic studies at MSK.

GOALS

- Standardize monitoring visit closure determinations using objective and reproducible criteria
- Reduce subjectivity and monitoring variability
- Improve monitoring efficiency within a risk-based monitoring model
- Enable real time visibility to support risk-based decision making
- Ensure predefined quality thresholds are met prior to closure

METHODS

The Monitoring Visit Progress and Closure Assessment dashboard was developed to support standardized monitoring oversight and closure decision making within MSK's RBM framework. The dashboard aggregates monitoring activity and tracks key performance indicators including visit frequency, data review coverage, monitoring ratings, and outstanding deficiencies. Rule-based logic applies predefined thresholds to assess closure readiness. 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 prior findings. Because monitoring intensity decreases over time in a RBM model, objective closure criteria are essential. These criteria are operationalized into consistent, rule-based logic within the dashboard to support objective closure determinations.

CLOSURE CRITERIA

DURATION

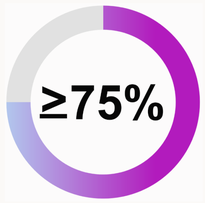
≥12 months

(exceptions: IRB closure, sponsorship transfer)

VISITS

≥4 monitoring visits

with participant data review



DATA COVERAGE

≥75% across key reviews

ICF, eligibility, treatment, outcomes, data quality, etc.

MILESTONE

Primary endpoints assessed

QUALITY

No monitoring visits rated 'Unacceptable'

DASHBOARD OVERVIEW

Study Number	Participants Monitored	Accruals	Planned Accrual	% Participant Monitored	Informed Consent	Informed Consent % Reviewed	Eligibility	Eligibility % Reviewed	Treatment	Treatment % Reviewed	Outcome	Outcome % Reviewed	Toxicity	Toxicity % Reviewed
24-001	100	100	100	100%	100	100%	100	100%	100	100%	100	100%	100	100%
24-002	90	100	100	90%	90	90%	90	90%	75	75%	75	75%	75	75%
25-001	60	100	100	60%	60	60%	60	60%	50	50%	50	50%	50	50%
25-002	55	75	100	73%	55	73%	55	73%	30	40%	30	40%	30	40%
26-001	20	50	100	40%	20	40%	20	40%	10	20%	10	20%	10	20%
26-002	10	50	100	20%	5	10%	5	10%	0	0%	0	0%	0	0%

RESULTS

Implementation of the Monitoring Visit Progress and Closure Assessment framework enabled standardized and transparent approach to evaluating monitoring readiness for closure.

The use of predefined thresholds:

- Reduced variability in closure decisions
- Strengthened documentation of monitoring adequacy
- Enabled earlier identification and resolution of deficiencies

The dashboard provides real time visibility at both protocol and portfolio levels, supporting efficient oversight and risk-informed decision making by Monitors and Managers.

CONCLUSION

A metrics driven, dashboard supported approach enables objective, consistent, and auditable monitoring closure decisions within RBM. This framework enhances operational efficiency, strengthens risk-based oversight, and improves the defensibility of monitoring practices within clinical research programs.