How Can We Improve Data Integrity in Risk-Based Monitoring? A Structured TSDV Strategy

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BACKGROUND

Targeted source data verification (TSDV) involves selectively reviewing Critical Datapoints (CDPs) within the electronic data capture (EDC) system. As a key component of risk-based monitoring (RBM), TSDV enhances monitoring efficiency while maintaining data integrity and patient safety. However, the absence of standardized methodology for selecting CDPs leads to variability in oversight.

Two common approaches to TSDV include:

1. **Study Participant-Based Selection** – A subset of participants undergo full monitoring for all CDPs. This approach may create oversight gaps if deficiencies are not present in the selected participants.
2. **Critical Data Point-Based Selection** – CDPs are categorized into tiers based on a risk assessment. Higher-risk CDPs are reviewed in a greater number of participants.

At Memorial Sloan Kettering Cancer Center (MSK), we have implemented a funnel approach to CDP-based selection, prioritizing the monitoring of informed consent and eligibility. In studies with numerous CDPs, those with similar risk levels are grouped into predefined tiers, ensuring a balanced and systematic review throughout the trial.

GOALS

To present preliminary data on the implementation of a structured TSDV strategy within a RBM framework, evaluating its feasibility and effectiveness in optimizing resources, focusing on CDPs, and maintaining patient safety and data integrity.

SOLUTIONS AND METHODS

At MSK, a funnel approach is applied in investigator-initiated trials (IIT) prioritizing informed consent and eligibility verification for the largest number of participants. For additional participant data review two different approaches are used depending on the overall number of CDPs:

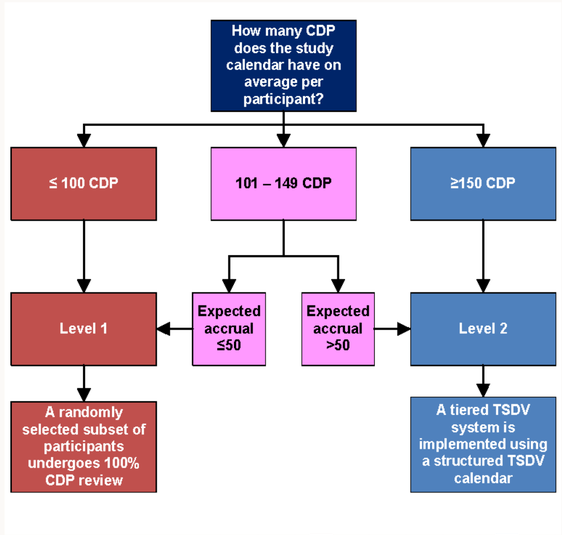
1. Level One (Fewer CDPs): A randomly selected subset of participants undergoes 100% CDP review.

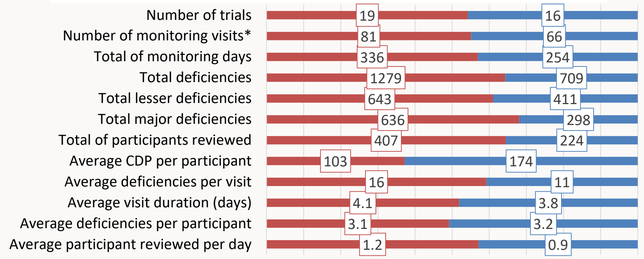
2. Level Two (More CDPs) A tiered TSDV system is implemented using a structured TSDV calendar, following these steps:

1. **Tier Definition & CDP assignment:** Tiers are organized based on CDP risk levels. High-risk CDPs (e.g., SAEs, screening assessments), are reviewed across all tiers, while lower-risk CDPs (e.g., routine vitals or blood tests during study) are proportionally distributed to balance monitoring activities.
2. **Random Participant Assignment:** Participants are randomly assigned to tiers based on predefined percentages, ensuring proportional distribution while maintaining CDP coverage.

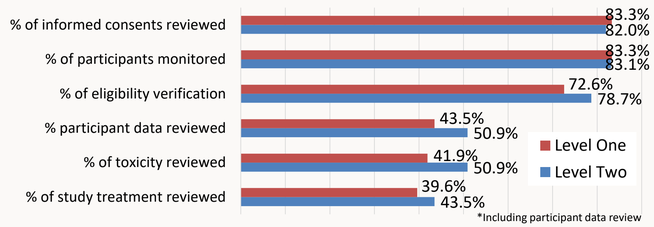
OUTCOMES

Between January 1, 2023, and December 31, 2024, the two-level TSDV strategy was implemented. The graphs on the right summarize participant data monitored during this period, including both closed trials and ongoing trials recently opened for monitoring.





LEVEL ONE VS LEVEL TWO APPROACH



Feature	Level 1 100 CDP Review of a subset	Level 2 Tiered TSDV Calendar
Purpose	Studies with ≤100 CDPs and ≤50 participants	Studies with >100 CDPs and >50 participants
Strategic Planning	Minimal; quick activation of all CDPs for monitoring	Higher; requires coordination with EDC team and calendar build
Participant Selection	Random subset undergoes full CDP monitoring	All participants are monitored in one of the tiers
Monitoring Scope	100% of CDPs for selected participants	High-risk CDPs across most or all participants. Low-risk CDPs reviewed proportionally
Efficiency	Faster set-up, less complex to manage	More efficient CDP coverage in high volume studies
Coverage Data Quality Management	May miss trends if random selection skips issues	Broader detection of trends and deficiencies across participants
Resource Management	Lower setup time, moderate monitoring effort	Higher setup time, optimized monitoring focus
Advantages	Simple to implement. Fast activation in EDC. Useful for low-CDP / low accrual studies.	Higher % coverage of high-risk CDP. Better trend selection. Balanced monitoring across tiers.
Limitations	Risk of oversight if issues are outside sample. Less efficient in large CDP-heavy studies.	More time consuming to build. Needs close coordination with EDC team.

LESSONS LEARNED AND FUTURE DIRECTIONS

The funnel strategy, paired with a tiered TSDV calendar, ensures broad CDP coverage while maintaining targeted verification. Level Two provided an effective solution for maintaining oversight across a higher percentage of CDPs. This highlights the benefits of structured TSDV in optimizing monitoring efforts.

Key Takeaways:

- Structured TSDV strategy streamlined monitoring, reduced workload, and improved accuracy.
- Tiered review (level two) improved early detection of data trends and deficiencies, allowing proactive corrective actions.

Future Enhancements:

- Expanding automation for CDP selection and monitoring workflows
- Refining risk-based tier assignments with real-time analytics for adaptative monitoring
- Exploring machine-learning for automated tiered TSDV calendar creation

By continuously refining this approach, we aim to improve efficiency, accuracy and oversight in clinical trial monitoring, ensuring high-quality data collection while optimizing resources.