

Single Day Event

**Transforming Clinical Trials through Advanced
Data Integration and Risk-Based Monitoring**

Swaroop Kalla,
Bikash Swain
Eli Lilly

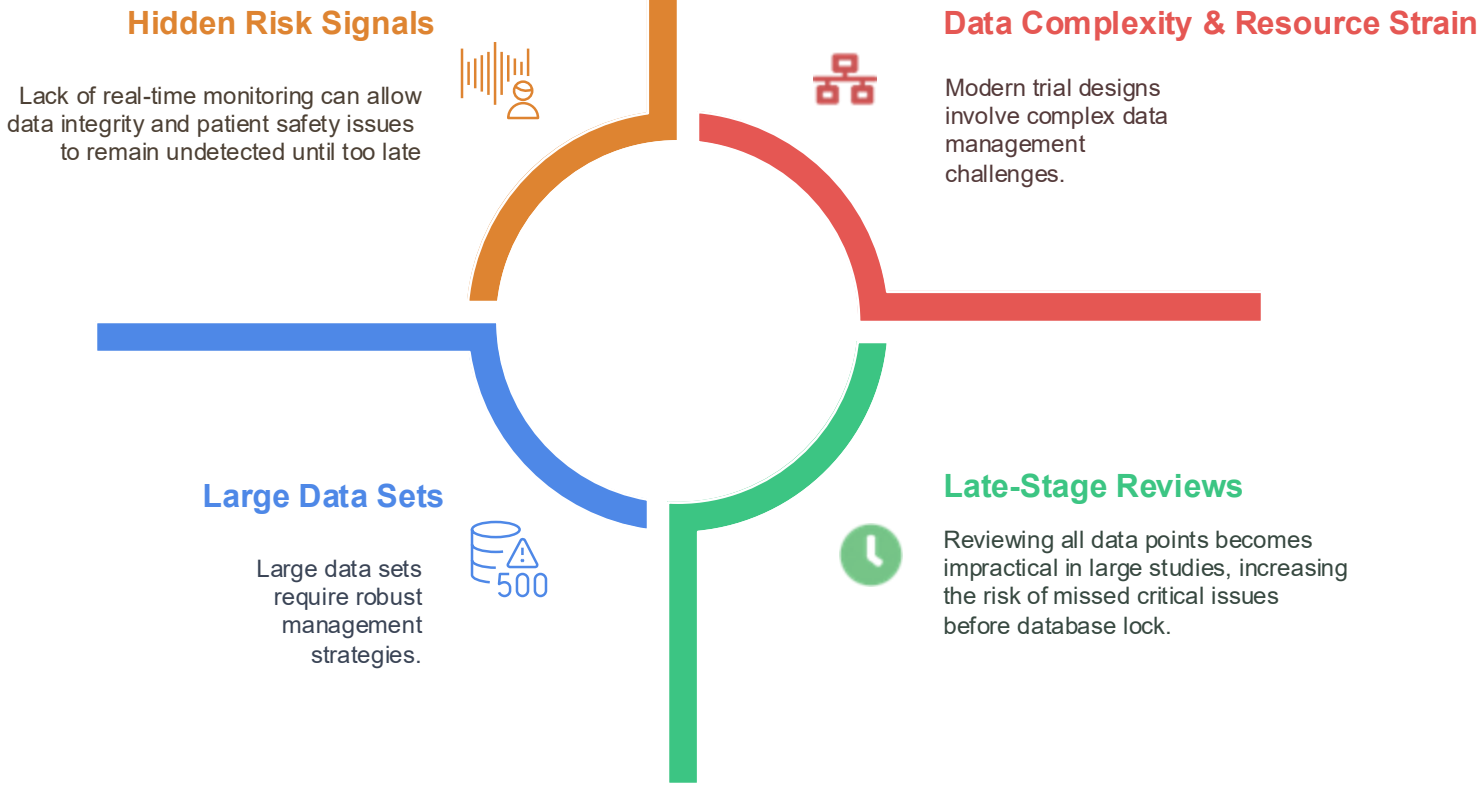


Agenda

- Overview of Traditional Clinical Monitoring Challenges
- Introduction to Risk-Based Monitoring Strategies
- Case Study 1: Threshold Metrics Implementation
- Case Study 2: Operational Synergy in Clinical Trials
- Results and Benefits of New Approaches
- Conclusion and Future Perspectives



Challenges in Traditional Clinical Monitoring





The Shift to Risk-Based Monitoring (RBM)



Real-Time Risk Detection

Identifies safety/data issues early using critical thresholds.



Endorsed by Regulators

Supports ICH E6(R3), FDA, and EMA guidelines.



Focuses on Critical Data & Processes

Identifies what truly impacts safety and outcomes.



Proactive Quality Assurance

Enables faster, cleaner database locks and fewer surprises.



Case Study 1: Threshold Metrics

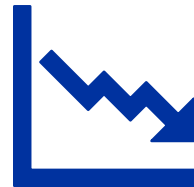


Problem Statement:

Traditional monitoring methods faced significant challenges in late identification of critical data issues, which hindered the efficiency and effectiveness of studies



Analytical Method: Descriptive analysis was used to flag safety issues early using critical data thresholds in real-time



Impact: Enables faster, cleaner database locks and fewer unexpected issues.



Case Study 1: Threshold Metrics

A traffic-light system for thresholds of critical datapoints to assess data quality and safety

Informed Consent 0.00% Total Subjects: 4610 0 Missing Consent	Ethnicity 0.00% Total Subjects: 2414 0 Missing ETHNIC	AE 0.02% Total AEs: 9486 2 AE Issues	Last Dose 19.26% Expected Doses: 758 146 Missing Last Dose	Medical History 0.01% Expected Events: 14733 1 Missing Medical History
Informed Consent Addendum 7 0.00 Expected Records: 1718 0 Missing Consent Addendum 7	Medical History Diabetes Duration 0.01% Expected Events: 14733 1 Missing MH Diab Dur	Disposition CRFs (Safety) 42.25% Expected DS: 14631 6,181 DS Issues	Thyroid Assessment 0.00% Expected Assessment : 235 0 Missing Thyroid	Hypoglycemic Events 3.33% Expected Events: 120 4 Missing Hypo Events
Cardiovascular Risk Assessment 0.02% Expected Events: 28032 6 Missing CVRISK	History of CVD 0.01% Expected Events: 14.73K 1 Missing CVD Events	Race 0.72% Total Subjects: 18267 131 Missing RACE	Vitals 0.09% Expected Events: 107.49K 95 Missing Vitals	Subject visit dates 0.55% Expected Visits: 499962 2759 Missing Visits in EDC



Case Study 2: Operational Synergy



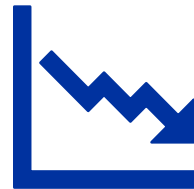
Problem Statement:

With multiple data sources, endpoints, decentralized models, and global sites, modern trials are increasingly complex.

This makes it harder to identify and manage critical data, increasing the risk of oversight.



Analytical Method: Statistical algorithms to detect risks, minimising the workload and optimising on-site monitoring by targeting at-risk sites



Impact: Minimizes risks through real-time monitoring with continuous email alerts. Early identification of riskier site. Enhances trial efficiency with increased data quality



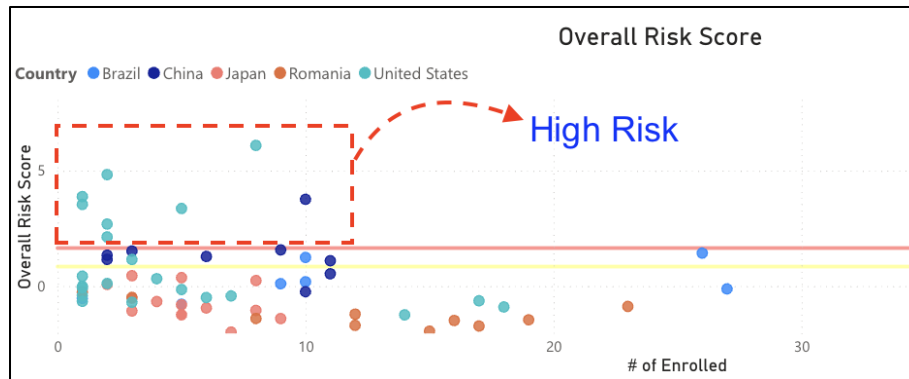
Case Study 2: Operational Synergy

A central Analytical tool that bring operational synergy to continuously track and proactively trigger risk sites.

Site	Country	Enrolled	Overall Risk Score	Enrollment (Weight=)	Study D/C (Weight=)	AE (Weight=)	IPD (Weight=)	Query Count (Weight=)	Follow Up Item (Weight=)	GCP (Weight=)	Query Response (Weight=)	CRF completion (Weight=)
2	United States	8	6.09	-0.36	5.99	0.05	8.19	2.72	0.38	0.96	4.65	-0.34
5	United States	2	4.83	-0.94	4.68	0.72	1.39	1.37	22.92	1.96	2.14	-0.12
5	United States	1	3.87	-0.94	10.04	-0.14	3.18	0.78	1.13	-0.07	1.01	-0.10
5	China	10	3.76	0.16	-0.46	1.31	-0.33	1.47	-0.31	4.74	3.95	1.89
7	United States	1	3.53	-0.79	-0.13	0.29	-0.20	3.18	0.95	4.92	1.34	-0.18
7	United States	5	3.36	-0.59	1.65	-0.64	3.95	1.98	-0.06	0.49	0.42	-0.26
4	United States	2	2.68	-0.74	2.46	-0.52	-0.29	1.27	0.28	2.07	1.62	-0.18
4	United States	2	2.12	-0.79	-0.13	-0.01	1.11	2.76	0.37	1.60	3.57	-0.13
5	China	9	1.56	-0.07	-0.44	1.73	0.11	3.65	-0.83	-0.06	1.45	2.05
5	China	3	1.52	-0.77	-0.28	0.06	-0.42	1.91	-0.48	-0.37	4.03	3.54
5	Brazil	26	1.43	2.34	-0.67	0.66	0.48	-0.22	3.31	2.13	-0.42	-0.65
6	China	2	1.34	-0.71	-0.21	-0.05	-0.31	-0.13	-0.31	1.87	-0.50	4.97
8	China	6	1.28	-0.39	-0.35	3.05	-0.53	1.83	-0.53	-0.47	0.59	2.70
6	Brazil	10	1.24	0.28	-0.42	-0.78	-0.23	0.96	3.54	1.59	1.81	-0.40
4	China	2	1.16	-0.80	-0.21	1.01	-0.31	0.99	0.22	-0.27	0.29	4.95
24	United States	3	1.15	-0.89	2.20	0.85	0.46	0.44	-0.33	-0.28	0.84	-0.21

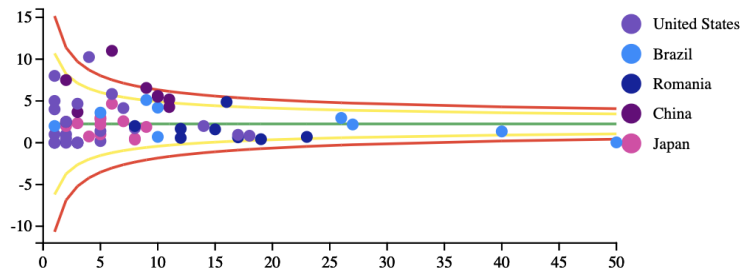


Case Study 2: Operational Synergy



Adverse event rate (ps) adjusted for site sample size

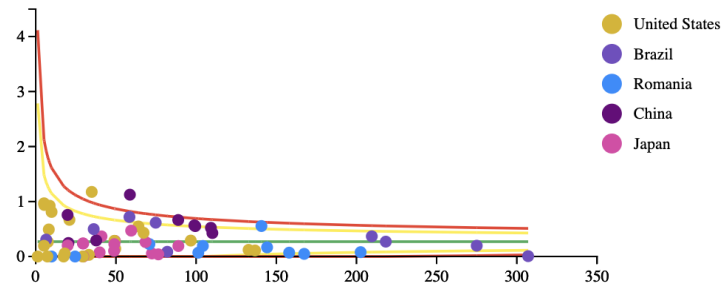
High Risk (95% CI)
Moderate Risk (80% CI)



of enrolled pts per site

Adverse event rate (pm) adjusted for observation time

High Risk (95% CI)
Moderate Risk (80% CI)



Observation time (months)



Results & Benefits



Proactive Risk Detection: Catches issues before lock through live alerts.



Improved Data Quality: Cleaner, audit-ready data with late-stage fixes.



Faster Trial Close-Out: Accelerates lock timelines by weeks.



Regulatory Readiness: Aligns with FDA, EMA, and ICH expectations.



Resource Efficiency: Focuses effort where it matters most.



Enhanced Patient Safety: Minimizes risks through ongoing monitoring.





Conclusion

In conclusion, the results of risk-based clinical data monitoring and operational synergies demonstrate its effectiveness in enhancing trial efficiency, data quality, regulatory compliance, and patient safety. This proactive approach is essential for modern clinical trials aiming for success in an increasingly complex regulatory landscape.



Disclaimer

The information included in this presentation represents the opinion of the speaker, and it is no way related to Eli Lilly and Company or its affiliates. No one can use the presentation contents as a base for any claim, demand or cause of action and, also no one is responsible for any loss incurred based upon



The Global Healthcare Data Science Community

Contact Channels

📞 UK +44 1843 609600
✉ office@phuse.global
🌐 phuse.global

Social Media

🐦 [@phusetwitta](https://twitter.com/phusetwitta)
📘 [/phusebook](https://facebook.com/phusebook)
▶ [/phusetube](https://youtube.com/phusetube)
🌐 [/company/phuse](https://company.phuse.com)