



The Patient Level Oversight Gap

Why Critical Safety Signals Are Missed in Spreadsheets

Subject-level risk appears long before it’s visible in aggregated metrics, and spreadsheets simply can’t keep pace.

If you’re still relying on them, you already know the impact: delayed insight, fragmented context, and decisions made without the full picture.

Modern trials demand more.

Where Oversight Fails in Excel

Patient-level data scattered across trackers



Updates delayed or inconsistent



Aggregated views blur real issues



No single story of each patient

The OPRA Advantage



Unified subject timeline with AEs, labs, vitals, dose & visits aligned



Change Detection highlights what’s new, updated or missing



Cross-subject comparison shows whether a finding is isolated or emerging



Structured tags & notes create a clear, traceable oversight record



Validated, audit-ready oversight aligned with E6(R3)

Excel vs OPRA Subject Monitoring

Spreadsheets	Subject Monitoring
Data fragmented across tabs and trackers	Unified subject profile on a single timeline
Reviewers reconstruct context manually	Context automatically aligned and clinically meaningful
No change detection leads to repeated full reviews	Automated Change Detection pinpoints what matters
Subtle trends buried in rows	Visual trend and risk detection across subjects
No audit trail or validation	Full audit trails, validated system, inspection-ready
High reviewer variability	Standardised oversight using Context, Change, Comparison
Signals often recognised late	Signals flagged early with clear drill-down context

OPRA in Action



Detect safety signals earlier, before they escalate into findings.

Strengthen inspection readiness with clear, defensible oversight.

Improve consistency across reviewers and studies, reducing variability.

Reduce manual rework, freeing teams to focus on clinical decisions.

Close the Oversight gap with OPRA

Get in touch with TRI to start simplifying your RBQM strategy today



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