**Integrated Data Review Assist (IDRA)**

# One Plan. Every Reviewer. Full Traceability.

Saama's Integrated Data Review Assist (IDRA) transforms Integrated Data Review planning from static documents to a governed, AI-assisted process. It is a centralized platform for planning, governing, and tracking Integrated Data Reviews across clinical studies.

Rather than managing review plans through disconnected documents and manual workflows, IDRA establishes a single source of truth for Integrated Data Review planning and governance. It enables sponsors and CROs to create review plans using AI-assisted recommendations, standardize review processes across studies, collaborate across teams, and maintain complete auditability and inspection readiness. Approved review plans seamlessly transition into SDQ for execution.

## Benefits

### Uncover Hidden Clinical Risks

Identify complex, cross-domain inconsistencies and physiological anomalies that evade traditional rule-based checks.

### Enhance Multi-Domain Accuracy

Systematically validate intricate relationships across Adverse Events, Labs, Medical History, Concomitant Medications, and Procedures.

### Eliminate Programming Overhead

Deploy highly advanced clinical pattern surveillance without requiring extensive manual rule configuration or custom coding.

### Accelerate Finding Triage

Receive a ranked, confidence-scored list of potential queries with integrated evidence files for immediate human review.

### Scale with Trial Complexity

Adapt automatically to large, evolving datasets without the need to continuously reprogram study-specific rules.



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## Features

### AI-Assisted Check Recommendations

Accelerate plan creation using global and therapeutic area-specific libraries, similar study recommendations, historical study patterns, and reusable check catalogs.

### Collaborative Review Workflows

Enable multi-user collaboration across clinical, medical, and data management teams with structured approvals, sign-offs, and plan-level visibility.

### Metadata Change Detection

Automatically detect study changes that may impact review plans, flag affected checks, and enable guided remediation and re-review workflows.

### Compliance Reporting and Governance

Provide continuous visibility into review execution through compliance summaries, query metrics, variance reports, and programming status tracking.

### Reusable Enterprise Library

Maintain global and therapeutic area-specific reusable check libraries with governance controls, versioning, and study-level reuse.

### Closed-Loop Platform Integration

Directs approved review specifications straight into Saama SDQ for execution, ensuring total traceability from the initial planning stage through operational data cleaning.

## The Saama Difference

Saama's IDRA acts as the strategic command center for Integrated Data Review governance. While conventional approaches rely on fragmented documents that introduce compliance gaps, IDRA enforces a unified, inspection-ready planning workflow. By binding metadata-driven automation with rigorous corporate standardization and native SDQ integration, IDRA ensures the correct reviews are defined, executed, and tracked consistently across every study in a clinical portfolio.

**Contact info@saama.com. to schedule a personalized demonstration.**