STATISTICS & DATA CORPORATION

It's like having a CDM, Biostatistician, Safety, and Programmer right by your side

SDC Insights™ 2.0

Now Enhanced with Sidekick™ AI

Smarter data. Faster and more accurate oversight. Stronger compliance.

Clinical research is moving faster and generating more data than ever—an average of 3.6 million data points per trial, up 300% in the last decade. Manual reviews and static dashboards can't keep up with this pace, nor with the requirements of ICH E6(R3). That's why we created SDC Insights™ 2.0, now powered by Sidekick™ AI. It's a platform that doesn't just show you what's happening—it tells you what to act on, why, and when in real time.

What's New in Version 2.0

Clinical teams need better ways to connect the dots across all their data without adding another disparate system. With Version 2.0, SDC Insights introduces capabilities designed to make oversight smarter, more predictive, and inspection-ready from day one.

- **Sidekick built in**: Streamlines data reporting process, surfaces cross-domain signals, and detects adverse events in near real time.
- **Real-time audit monitoring**: Centralizes oversight across multiple data sources with row-level traceability.
- **Enhanced analytics**: Custom dashboards highlight trends, anomalies, and compliance gaps instantly.
- **Workflow automation**: Role-based dashboards reduce manual prep time for CRAs, Safety, and Ops teams. Real time identification of data trends and issues.

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The Benefits in Action

Our enhancements aren't theoretical—they're proven across real studies. With Insights 2.0 and Sidekick, teams are already reducing workload, surfacing risks earlier, making timely decisions, and passing audits with confidence.

	Sidekick
Site-monitor visits	23% fewer visits within 90 days
Adverse event flagging	12 critical events flagged 24+ hours earlier
Deployment time	≤30-day deployment across sources
CRA time saving	4+ hours saved per CRA per week
Anomaly detection	Daily detection vs. monthly/quarterly reviews
Data visibility	See data issues and results in real-time

Top Use Cases

Modern oversight isn't just about looking at the past. It's about anticipating the future, avoiding costly delays, and meeting regulatory standards without adding headcount. Common use cases where SDC Insights + Sidekick shine include:

- Early signal detection & triage: Catch protocol deviations, emerging safety trends, and operational risks before they escalate.
- ICH E6(R3) compliance: Meet the 2026 mandate for real-time, explainable, and inspection audit-ready from day one.
- Stakeholder-specific dashboards: Tailored views for CRAs, Biostatisticians, Safety Monitors, and Clinical Ops leaders.
- Central monitoring & AI-augmented SDV: Reduce on-site monitoring costs while maintaining data quality and patient safety.

Built-In Compliance & Security

With ICH E6(R3) enforcement coming soon, explainability and traceability aren't "nice-to-haves." They're requirements. Insights 2.0 embeds compliance at the core, not as an afterthought.

- SOC 2 Type II and ISO 27001 certified
- 21 CFR Part 11 compliant
- Audit-ready with row-level traceability
- Hot-key validation for AI outputs (full explainability)

Who Benefits

Oversight is a team sport, and Sidekick AI adapts to every role in the trial ecosystem.

- Clinical Operations: Detect and manage risk 14 days earlier.
- Biometrics & Data Management: Focus resources with AI-powered triage.
- CRAs & CTMs: Cut meeting prep by 40% with auto-flagged dashboards.
- Safety Teams: Identify DLT clusters across labs, narratives, and EDC in hours, not weeks.
- Sponsors & Procurement: Achieve ROI in one study phase; predictable pricing, faster value.
- C-Suite/Board Level: real-time access to KPIs and Metrics to support strategic level decisions.

Ready to learn more?

Schedule a demo or talk to an expert by visiting

https://www.sdcclinical.com/contact