SDC
Statistics & Data Corporation

From Recovery to Resilience:

Using AI-Native Clinical Technology to Rescue At-Risk Trials and Prevent Repeat Setbacks

By Quan Doan, Vice President, Technology Solutions, SDC

Presented on April 28, 2026 | COG New England

Deep Dive Agenda

01

Why DM Failures Occur

Root causes & three real-world client scenarios

02

Executing a Successful Rescue

Discovery → Options → Transition planning

03

AI-Native Prevention

SDC Insights 2.0 + Sidekick AI in action

04

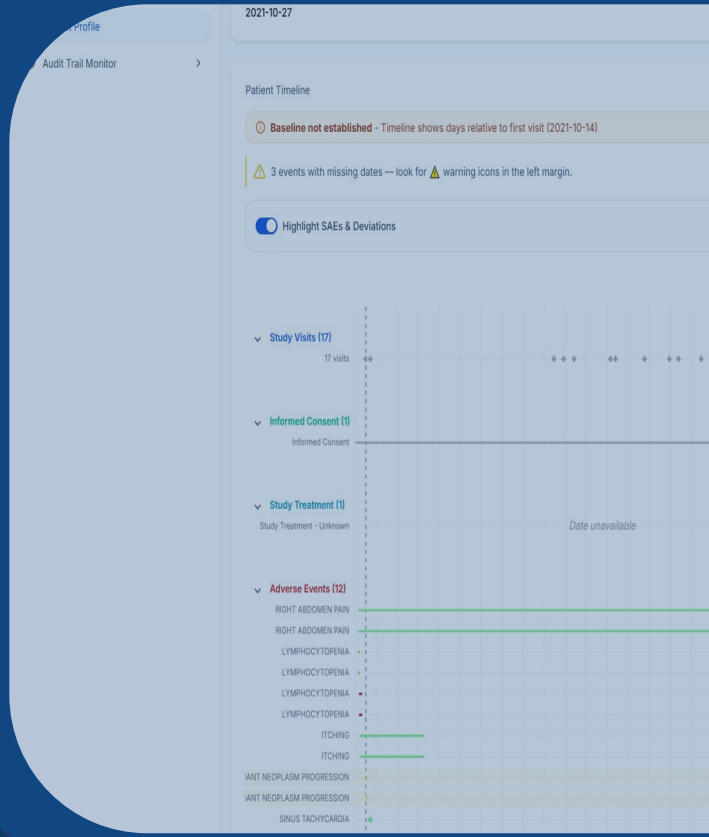
Key Takeaways + Q&A

Resilience, not just recovery

SDC
Statistics & Data Corporation

Why Data Management Failures Occur

Root causes, failure patterns, and three real sponsor scenarios



SDC
Statistics & Data Corporation

The Fundamental Problem: Reactive vs. Proactive Oversight

TRADITIONAL MODEL

Reactive

Remediation

- ✓ Fixing issues after they escalate
- ✓ Manual oversight — brute force reviews
- ✓ Siloed data, delayed insights
- ✓ Static risk thresholds — never dynamic
- ✓ DM team responds to crises, not patterns

AI-DRIVEN MODEL

Proactive

Prevention

- ✓ Predicting risks before they escalate
- ✓ Automated, real-time analytics
- ✓ Integrated data ecosystem — live view
- ✓ Dynamic, continuous risk scoring
- ✓ AI flags patterns humans miss at scale

SDC
Statistics & Data Corporation

Three Root Causes Behind Every Rescue

PEOPLE & PROCESS

- ✓ DMs unfamiliar with the protocol
- ✓ Poor sponsor communication & guidance
- ✓ No investment in study outcomes
- ✓ Lack of escalation pathways
- ✓ No proactive advisory relationship

TECHNOLOGY & BUILD

- ✓ DB doesn't reflect the protocol
- ✓ No lab normal ranges captured
- ✓ DB not updated for amendments
- ✓ Edit checks non-functional or absent
- ✓ Rudimentary build, no validation rigor

DATA QUALITY & CLEANLINESS

- ✓ No proactive data cleaning
- ✓ External data unreconciled (labs, ePRO)
- ✓ No Data Transfer Agreements in place
- ✓ Missing data left unaddressed
- ✓ Queries created without clinical purpose

SDC
Statistics & Data Corporation

Scenarios 1 & 2: Service & Build Failures

CLIENT SCENARIO 1

Disengaged DM Team, Poor Protocol Ownership

What Happened: A series of DMs who lacked protocol knowledge and were not invested in the study. Sponsor was not receiving the advisory support needed to keep the study robust.

What We Inherited: A database build needing major updates for numerous unapplied protocol amendments. Support quality was the primary failure — not the technology.

AI Prevention: Proactive study health dashboards and AI-driven amendment tracking would have flagged the growing protocol-to-database gap in real time.

CLIENT SCENARIO 2

Inexperienced CRO, Broken Build, No Data Hygiene

What Happened: A CRO with minimal EDC experience built a database that did not serve the protocol's data capture needs. No data cleaning, no lab normal ranges, no DTAs.

What We Inherited: Queries created purposelessly — many non-functional. Significant missing data. No external data reconciliation with labs, ePRO, or vendors.

AI Prevention: Live data validation and automated query logic would have surfaced broken edit checks and missing reconciliation within days of study start.

SDC
Statistics & Data Corporation

Scenario 3: Program-Wide Regulatory & Structural Crisis

6 CLINICAL STUDIES | ENTIRE PROGRAM AFFECTED | NON-COMPLIANT SYSTEM | FULL REBUILD REQUIRED

21 CFR PART 11 NON-COMPLIANCE

- ✓ System had no electronic signature capability
- ✓ No audit trail — data changes unattributable
- ✓ No access controls or user authentication logs
- ✓ System not validated to GxP/GAMP standards
- ✓ All data legally untrustworthy for FDA submission

INFRASTRUCTURE: DATABASE IN A BASEMENT

- ✓ System physically hosted on a private server
- ✓ No disaster recovery or backup infrastructure
- ✓ No data center security, SLAs, or uptime guarantees
- ✓ Single point of catastrophic failure for 6 studies
- ✓ No vendor qualification or SOC 2 certification

Enter Text

FREE-TEXT FIELDS: UNANALYSABLE DATA

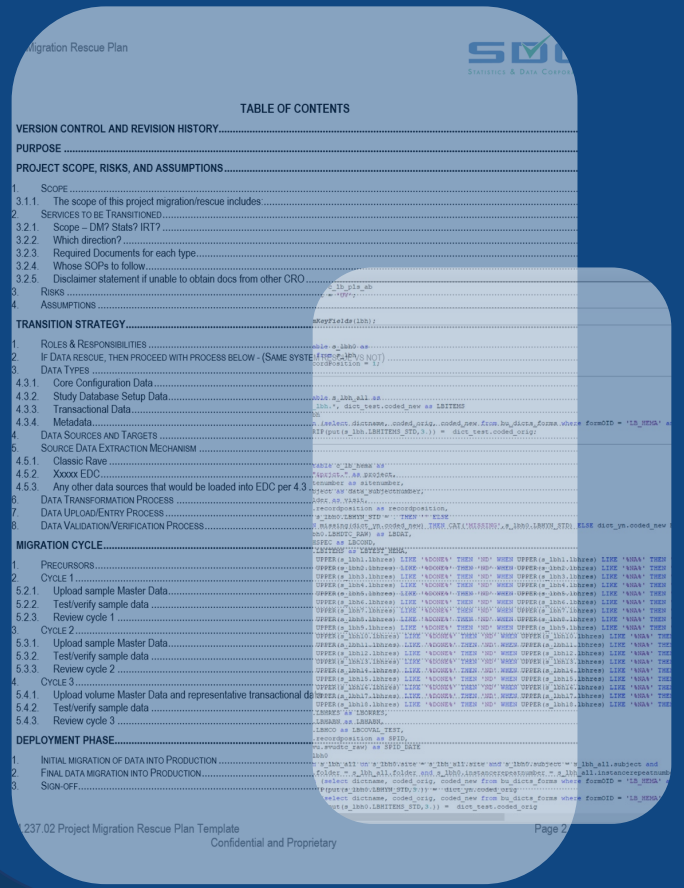
- ✓ Critical data points captured as unstructured text
- ✓ No controlled terminology or coded values
- ✓ Impossible to run standard statistical analysis
- ✓ TLFs / clinical summaries could not be generated
- ✓ Data required manual interpretation and re-entry

AI Prevention Insight: A validated, cloud-hosted AI-native EDC with structured data capture and built-in 21 CFR Part 11 compliance eliminates all three failure modes at the point of study build.

SDC
Statistics & Data Corporation

Executing a Successful Mid-Study Rescue

Without compromising data integrity, audit trail, or timelines



SDC
Statistics & Data Corporation

SDC's Proven Rescue Process: 25+ Successful Studies in 5 Years

Typical rescue timeline: 12–16 weeks per database | SDC has executed parallel-database rescues (offset by 1 week) for Phase 3 studies that proceeded to FDA NDA approval

SDC
Statistics & Data Corporation

Choosing the Right Rescue Approach

OPTION A

Maintain Existing EDC — Replace DM Services Only

Best when: technology is sound but the DM team was the failure point. New DM partner takes over within the current EDC. Minimal disruption to sites, audit trail, and data. SDC experts can also overlay an existing team to fill knowledge gaps without full transition.

OPTION B1

Full Migration to New EDC

Best when: the build is fundamentally broken. All subjects and historical data mapped and batch-loaded into new system.

Key consideration: Clean data prior to migration. Structural mismatches may require some manual re-entry.

OPTION B2

Split-Lock Strategy

Best when: study is mid-enrollment. Existing subjects locked in original validated DB; new subjects in new EDC.

Cross-study reconciliation via SAS. Two-part audit trail documented in DMP. Accepted by FDA.

SDC
Statistics & Data Corporation

Formalizing the Transition Plan: Critical Components

Risk Assessment

Categorize every data gap by severity. Not all missing data is equal — primary endpoints vs secondary. Quantify the remediation scope.

Database Gap Analysis

Map current DB build against the final protocol version. Identify every unapplied amendment, broken edit check, and missing field.

Data Migration Strategy

Define cut-over date. Plan admin access transfer. Minimise site burden — assess SDV and PI signature impact on workflow.

Document Handover (TMF)

Assess DMP, DTAs, all study DB documents. Retire former vendor documents. New DMP or addendum. Full TMF transfer documented.

Audit Trail Continuity

Every data touch must be attributable. Two-part audit trail for split-lock scenarios. Chain of custody for all data — FDA-inspection ready.

Realistic Timeline

12-16 weeks per database. Assess DB lock, statistical readout, and submission milestones. Build contingency — site re-training takes time.

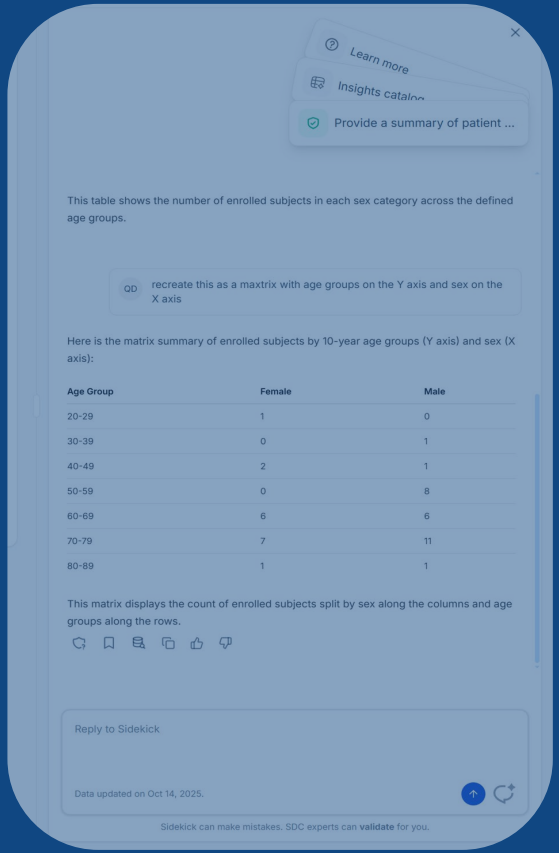
SDC
Statistics & Data Corporation

AI-Native Prevention:

SDC Insights 2.0 + SDC Sidekick AI

Traditional rescue is reactive — fixing what broke. AI-native DM is transformative — detecting issues before they become crises and preventing the same failures from ever recurring.

Technology + AI you Want with Services you Need



SDC
Statistics & Data Corporation

AI as Augmented Intelligence — Not a Replacement

AI IMPACT IN CLINICAL TRIALS

70% cost reduction in patient recruitment

40% faster trial completion

42% reduction in patient screening time

7-10 days earlier anomaly detection vs manual review

AUGMENTED ROLES WITH AI

Data Manager

Before: Manual query review, data cleaning backlog

After: AI flags discrepancies instantly; DM approves and escalates

CRA / Monitor

Before: Point-in-time site visits, delayed issue detection

After: Real-time site risk scores; targeted, risk-based monitoring

Medical Monitor

Before: Periodic manual safety review

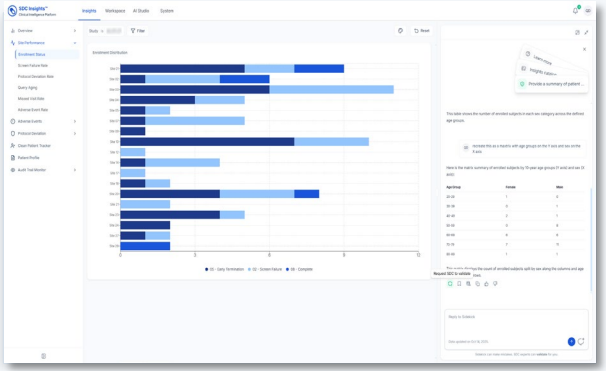
After: AI SAE clustering + narrative drafts for human review

SDC
Statistics & Data Corporation

SDC Sidekick AI: Live Platform Capabilities Today

Live Data Validation

Sidekick identifies range inconsistencies and cross-form discrepancies across EDC (Medidata, Mednet, Veeva, Oracle), Lab, and ePRO — in real time.

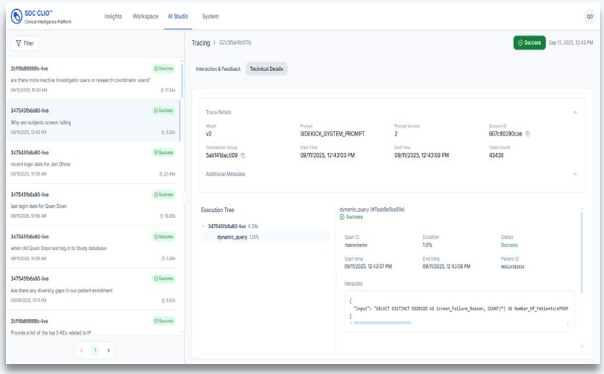


Explainable AI Traceability

Every flag is traceable to the raw data row. 100% audit readiness — every AI action is documented and explainable for regulatory inspection.

Data Summaries & Trend Analysis

Automated data summaries surface trends across sites, cohorts, and time points. Signals that would take days to spot manually appear within hours.



AI Studio & Model Monitoring

Advanced AI model monitoring with user-role–based personas. Track for Model drift and AI performance degradation

The Agentic Horizon: What's Coming Next

Unlike standard AI that suggests, Agentic AI can act, reason, and collaborate autonomously across workflows — with human oversight at every critical step.

Future Capability

Biometrics Agents

Coordinate cross-source reconciliations and automate SDTM mapping — the most time-consuming and error-prone manual task in data management.

Future Capability

Safety Agents

Identify SAE clusters across sites and patient populations, then draft initial patient narratives for medical monitor review — reducing narrative preparation from days to hours.

Future Capability

Monitoring Agents

Monitor site enrollment trends and trigger recruitment alerts autonomously — or suggest a pre-approved 'boost' campaign when a site falls behind threshold.

Governance principle: Even with autonomous agents, a human expert remains ultimately responsible. **Credibility assessment** must match AI model risk. **Human-in-the-loop** at every critical decision point.

SDC
Statistics & Data Corporation

SDC: Technology You Want with Services You Need

25+
Successful Rescue Studies (5 Years)

12
EDC Database Migrations

3
FDA NDA Approvals Post-Rescue

7-10
Days Earlier Anomaly Detection

> ***"There has been nothing but amazing feedback about SDC and their ability to jump in, rescue and get things going! Job exceptionally well done!"***
>
> **— Sponsor Representative (Board Member) | Following Phase 3 Parallel Study Rescue Leading to FDA NDA Approval**

Expert DM Services

- ✓ Protocol-invested DM team
- ✓ Proactive sponsor advisory relationship
- ✓ Rescue-tested, multi-system expertise

AI-Native Technology

- ✓ SDC Insights 2.0 — live study health dashboards
- ✓ SDC Sidekick AI — live validation, auto-query drafting
- ✓ Agentic AI roadmap — biometrics, safety, monitoring agents

SDC
Statistics & Data Corporation

Key Takeaways & Q&A

From recovery to resilience — the full journey

SDC
Statistics & Data Corporation

From Recovery to Resilience: 5 Strategic Principles

The goal isn't just to rescue a study — it's to emerge stronger, with better data, better systems, and a DM partnership built for long-term success.

Recognise the Warning Signs Early

Slow query resolution, unanswered protocol questions, and site dissatisfaction are early warnings — not isolated incidents. Earlier intervention = exponentially less damage to reverse.

Always Start with a Thorough Discovery

Don't guess at scope. Investigate the database, the DMP, the query reports. Data integrity gaps you don't find before the rescue surface at submission — far more costly to address then.

Match the Solution to the Study

Maintain-and-replace, full migration, and split-lock each serve different situations. Select based on data risk, timeline pressure, and study maturity — not cost alone.

Use AI to Accelerate and Prevent

AI-native platforms compress rescue timelines and catch problems 3–5 days earlier than manual review. Sidekick AI's live validation and auto-query drafting change the recovery equation.

Build Resilience, Not Just Recovery

The rescue is also your opportunity to establish the right DM infrastructure, AI tooling, and human expertise so this never happens again. Resilience, not just recovery.

SDC
Statistics & Data Corporation

THANK YOU

Let's Talk About Your Study

Whether you're in crisis, sensing early warning signs, or building a new study and want to start right — SDC's expert DM team and AI-native technology ecosystem is ready to help.

Visit us at Booth #6

sdcclinical.com

SDC Insights™ 2.0
with
SDC Sidekick™ AI

Book A Demo