

Analysis of 381,000+ Clinical Trials Finds More Than Half Show Execution-Risk Exposure

SILVIA-Powered SASI Benchmark Published by TrialSite News Identifies Disclosure Risk as Greater Systemic Challenge Than Trial Failure

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/EINPresswire.com/ -- [Cognitive Code](#) today announced that findings from the SASI (Sponsor Analytics and Study Intelligence) initiative, powered by its deterministic AI platform SILVIA, have been published by [TrialSite News](#).

The analysis, covering 381,187 interventional clinical trials drawn from publicly available ClinicalTrials.gov, AACT, and FDA datasets, found that more than half of trials show some form of execution-risk exposure.

The publication marks an important milestone in the deployment of SILVIA-powered analytics in the life sciences sector, providing independent editorial validation of SASI's methodology and findings in one of the clinical research industry's leading media outlets.



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Key Findings



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*Brendan O'Shea, CEO,
Cognitive Code*

The SASI benchmark identified 53.2% of analyzed trials as exhibiting execution-risk exposure. Among those, the study distinguished between two categories of risk:

Hard-failure events: 43,757 studies were terminated, suspended, or withdrawn.

Disclosure-risk events: 159,215 completed studies did not post results within SASI's FDAAA-801-based reporting framework -- more than three times the rate of outright trial failure.

The benchmark also examined trial timing. Among 187,483 completed interventional studies, median time from submission to primary completion was 20 months. Among

65,022 commercial studies, 58% exceeded their own originally registered completion targets. Execution-risk exposure also varied significantly by therapeutic area. Cardiovascular studies

showed the highest exposure rates at 48.2%, followed by CNS and neurological disorders at 41.6% and oncology at 40.5%. Immunology and rare disease programs demonstrated comparatively lower exposure.

Deterministic AI at Scale

The benchmark was designed to be fully reproducible and auditable, with all metrics derived from source records. Unlike probabilistic AI systems, SILVIA's deterministic architecture produces consistent, traceable outputs -- a capability central to its application in regulated industries. "SILVIA was designed for environments where organizations need more than predictions -- they need accountability, traceability, and confidence in how conclusions are reached," said Brendan O'Shea, Chief Executive Officer of Cognitive Code. "The SASI benchmark demonstrates that deterministic AI can deliver explainable intelligence at scale in one of the most demanding sectors in the world."

Industry Context

Clinical trial execution risk carries substantial financial, regulatory, and patient consequences. Study delays increase development costs, extend site and CRO commitments, delay patient access, and erode the commercial value of patented therapies. The SASI findings suggest that reporting discipline and disclosure practices represent a systemic challenge that has received comparatively little structured attention.

"For too long, clinical research has focused almost exclusively on scientific outcomes while largely ignoring the operational realities that determine whether studies succeed, fail, or ever deliver their findings to patients. What SASI and AI-platform SILVIA have demonstrated is that execution itself can now be measured objectively, transparently, and at scale. If we can benchmark execution risk with the same rigor we apply to scientific endpoints, we have an opportunity to improve accountability, accelerate development, strengthen public trust, and ultimately help bring better therapies to patients faster."

-- Daniel O'Connor, Founder, TrialSite Inc.; Board Member, Site Accreditation and Standards Institute (SASI)

The full SASI benchmark analysis is available at TrialSite News:

<https://www.trialsitenews.com/a/more-than-half-of-clinical-trials-show-execution-risk-exposure-silvia-powered-sasi-analysis-finds-972d2c82>

About Cognitive Code

Cognitive Code is the developer of SILVIA(TM) (Symbolically Isolated Linguistically Variable Intelligence Algorithms), a deterministic artificial intelligence platform designed to provide explainable, auditable, and reproducible decision support. SILVIA combines symbolic reasoning, structured intelligence, and transparent inference capabilities to support mission-critical applications across healthcare, life sciences, enterprise, government, and defense environments.

About SASI

SASI (Sponsor Analytics and Study Intelligence) is a clinical research intelligence initiative focused on applying advanced analytics and explainable artificial intelligence to identify operational risk, execution challenges, and performance trends across the clinical trial ecosystem. SASI is designed to provide sponsors and stakeholders with actionable intelligence to improve trial planning, execution, and oversight.

About TrialSite Inc.

TrialSite Inc. is a clinical research, healthcare intelligence, and media company focused on increasing transparency, awareness, and engagement across the global clinical development ecosystem. Through TrialSite News, data-driven research initiatives, patient engagement programs, and strategic industry partnerships, the organization connects patients, investigators, sponsors, healthcare professionals, and policymakers with timely information and actionable insights on clinical research and healthcare innovation.

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