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The 9 Hidden Costs of Clinical Trial Disclosure

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From system implementation to protocol registration and process assessment, hidden costs lurk at every step of the clinical trial disclosure process. Not to mention that disclosure noncompliance can risk sponsors incurring substantial regulatory fines.

1 IMPLEMENTATION
Poorly executed system implementation can lead to delayed rollouts and months of validation testing.

TrialScope Disclose's proven implementation process has been perfected across 30+ customers and with a 100% track record of on-time/on-budget rollout.

2 REGISTRY UPDATES
Trial registries make an average of 75 technical and regulatory changes annually.

Regular updates to the TrialScope Disclose system and disclosure rules engine are included with your subscription at no charge.

3 TESTING
Validated software requires resources for user acceptance testing which can cost the sponsor many weeks of productivity each year.

TrialScope Disclose provides comprehensive validation support including the documents, evidence of automated regression testing and execution-ready test scripts.

4 SUPPORT
Many vendors charge additional fees for annual technical support services.

TrialScope Disclose's support organization has earned a 94% satisfaction rating the last year. Comprehensive help-desk services are included at no additional cost.

5 PROTOCOL MAINTENANCE
Once a protocol is registered, it requires repeated updates as any one of a dozen data elements change, often with a timed compliance deadline.

TrialScope Disclose's batch maintenance automates the data update process of multiple studies concurrently, including simultaneous submission to the PRS system.

6 VALIDATION
Registry submissions rejected for not meeting specific data validation requirements are usually rerouted for review and approval, adding time and risk.

Submission and field -level data validation are ingrained in TrialScope Disclose to ensure successful submission, complete compliance and avoid emergency rework.

7 REVIEW & APPROVAL
To prevent releasing confidential information, draft disclosures must undergo lengthy review and approval processes that involve multiple, usually senior-level stakeholders.

TrialScope Disclose optimizes and automates review and approval cycles to reduce stakeholder burden and accelerate timelines.

8 REGULATORY UPDATES
Global disclosure regulations are continuously evolving. There are 35+ registries representing more than 109 countries in which trials are conducted.

TrialScope Disclose's regulatory intelligence processes continuously track disclosure regulations and codify these into our disclosure application.

9 BENCHMARKING
Sponsors looking only at their data have no solid basis for assessing inefficiencies, which typically means no process improvements are made.

TrialScope Disclose's customers can access a range of exclusive benchmark reports that assess sponsor processes against benchmarks based on over 40% of all industry trials.

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TrialScope Disclose empowers clinical trial sponsors to do more with their trial information, from ensuring disclosure compliance and maximizing tria transparency to improving patient education, engagement and trust.

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