The 9 Hidden Costs of Clinical Trial Disclosure

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 implementations can lead to long implementation periods and months of validation testing.

2. REGISTRY UPDATES
   Trial registries make as many as 15 changes to each registry each year, making updates challenging. Regular updates to the TrialScope Disclose system and disclosure engine can be included with your subscription at no charge.

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

4. SUPPORT
   Many vendors charge 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
   Regularity submissions require an extensive level of data validation requirements that are usually complex, time-consuming, and error-prone. TrialScope Disclose provides comprehensive validation support including the documents, evidence of automated regression testing and execution-ready test scripts.

7. REVIEW & APPROVAL
   To prevent releasing unreviewed information, draft disclosures undergo multiple reviews and are subject to several months of review and approval cycles. TrialScope Disclose optimizes and automates the 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. Regular updates to the TrialScope Disclose system and disclosure rules engine are included with your subscription at no charge.

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 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.