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The Hidden Implications of Clinical Trial Disclosure Noncompliance

by Thomas Wicks

Potential fallout from noncompliance goes well beyond regulatory penalties; adherence has improved but less so for smaller companies.

Over the past decade, industry sponsors of clinical trials have expanded their commitments to data transparency, and overall compliance with trial disclosure regulations is markedly better. However, most of these improvements have been made by the larger companies. Many smaller biopharmaceutical organizations are reluctant to share data more broadly and remain significantly noncompliant with clinical trial disclosure regulations.

With increasing attention to clinical data transparency practices and the growing likelihood of negative consequences for nondisclosure, industry sponsors of all sizes should ensure full compliance with regulations and consider more generous transparency policies. Those consequences are wide-ranging – not just possible financial penalties but also, for example, negative evaluations by potential investors and partners.

While industry sponsors with 100 or more trials listed on ClinicalTrials.gov average more than 97% of their trials compliant with current results disclosure regulations in the US, those with fewer than 100 studies on average fall below 50% compliance. (*See chart below*.)

A Closer Look At Trial Transparency

This is the first in a four-part series on clinical trial disclosure issues. Look for our additional coverage over the next few weeks, including one article focused specifically on challenges for smaller companies.

The real costs of inadequate trial disclosure are often underestimated by those that consider only the lack of enforcement actions to date. Although financial penalties have yet to be levied, the potential fines are significant. Additionally, focusing only on fines fails to recognize the other effects of

inadequate transparency.

One data source for analysts covering the biopharmaceutical industry is the public registries, especially ClinicalTrials.gov. This is by far the largest registry, with more than 370,000 trials listed as of March 2021.

> *"Improper disclosure can lead to miscalculated valuations and subsequent risks related to management transparency." – biotech analyst Marc Fogarty.*

Lain Anderson, managing director at LEK Consulting, indicated that any reduced availability of clinical data on public registries limits companies' inclusion in market analyses. "If you do not have your information up on ClinicalTrials.gov, you do not even come up for us to recommend, and you are reducing the level of competition for you as an asset," he said.

Additionally, disclosure noncompliance will raise regulatory risks and may negatively affect valuation. "Many biotech investors are not investing in these companies for their initial financial performance, but rather for their scientific developments. As a result, it is even more important to ensure that all financial and scientific advancements are complete and accurate. Improper disclosure can lead to miscalculated valuations and subsequent risks related to management transparency," said Marc Fogarty, national biotech sector leader at EisnerAmper.

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A key element of a merger or acquisition in the life sciences sector is the regulatory due diligence assessment. While the focus may be on marketing authorization and clinical documentation, applications, quality management and disclosure noncompliance will raise significant concerns and derail or delay a transaction. Publicly available compliance websites such as the FDAAA TrialsTracker, the EU TrialsTracker or the Good Pharma Scorecard can point to potential issues that may raise significant concerns during due diligence.

"We are often working on diligence in these transactions and have seen many stopped because of compliance or legal concern to avoid acquiring someone else's risk," said Anderson.

Regulatory Inspections

In the US, the Food and Drug Administration completed pilot inspections and issued *final*

guidance on penalties relating to disclosure noncompliance. A sponsor faces potential financial penalties of up to $12,316 per noncompliant trial for every day the issue remains unresolved (a figure adjusted annually for inflation since the original $10,000 set in the 2007 FDA Amendments Act). In addition, notification of noncompliance will be made public on ClinicalTrials.gov.

Reports from sponsors indicate that some health authorities in the European Union have started to review results disclosure compliance on EudraCT as part of pharmacovigilance inspections. With the implementation of the new EU Clinical Trial Information System (CTIS) expected at the end of 2021, the *clinical trial regulation* will be fully applied. (Also see "*How To Use The EU's New Clinical Trial Submission System*" - Pink Sheet, 5 Feb, 2021.) Article 94 of the regulation requires member states to establish and enforce penalties applicable to infringements and that these penalties should be effective, proportionate and dissuasive.

With increasing scrutiny from health authorities, transparency advocates and industry analysts — not to mention the negative impact nondisclosure has on brand reputation — sponsors are well advised to assess their current level of compliance with regulations in every country in which they have conducted trials. To ensure inspection-ready disclosure, organizations should review their transparency policy, and also update related standard operating procedures and processes for managing clinical trial disclosure.

Thomas Wicks is chief strategy officer at TrialScope. He has more than 20 years of experience with performance and content management approaches in the life sciences, with particular focus on clinical trial transparency.