TrialAssure®
The ultimate transparency suite™

Support for Global Disclosure and Transparency Strategy Implementation

TrialAssure helps Sponsors develop a transparency and disclosure policy in line with global requirements

Challenge

A biopharmaceutical company needed support in creating a global disclosure and transparency policy complying with international regulations and integrating industry best practices.

The company's previous disclosure policy varied country by country. This approach is difficult, as only complying with US or local rules means diverting from other recommendations, such as ICMJE guidelines or other international regulations, and can potentially lead to manuscript rejection or rejection of a clinical trial application for a future study in Europe.

The challenge was to help the Sponsor develop a transparency and disclosure policy in line with their values and transparency requirements:

- Register all interventional studies
- Provide a results summary after the end of the trial
- Provide lay summaries to trial participants and the public
- Publish all phase 3 and pivotal studies in the scientific literature
- Develop a data-sharing plan to share clinical data with researchers upon request

TrialAssure Solution

TrialAssure performed a gap analysis to see what policy implementation was needed to fill the gap between the Sponsor's current policy and best practices. TrialAssure transparency experts educated senior management on the need for a global transparency policy and the consequences of only having a country-by-country process. TrialAssure recommended a shift in company policy to ensure compliance with international rules and proposed a roadmap to outline the implementation of the company's new transparency policy.

In addition, TrialAssure used TrialAssure REGISTRY as a compliance tool to ensure all compliance steps were taken, manage global clinical trial registries, keep track of trial site locations, and make clinical trial updates.

Outcome

Experts at TrialAssure were successful in implementing a full end-to-end global disclosure and transparency policy that aligned with transparency requirements and best industry practices on time. Data sharing principles were successfully adopted in company policy, and the Sponsor initiated a policy change to increase trust with medical communities. The data sharing principles were seamlessly integrated into company processes and became a part of their standard clinical trial activities. The Sponsor is in an excellent position for compliance implementation before the new EU Clinical Trials Regulation comes into effect in January of 2022.

TrialAssure | 6880 Commerce Boulevard | Canton, MI 48187 | www.trialassure.com