



“The TrialAssure system is flexible and scalable to meet new regulations quickly and seamlessly”

TrialAssure Software is Flexible & Scalable for Emerging Transparency Regulations: The “Final Rule”

CHALLENGE

In 2016, a “Final Rule” was announced by the US government that requires disclosure of additional information not previously required, including disclosure of trial results for investigational drugs. The timeframe allowed to report trial results and post updates has also shortened, requiring a quicker turn-around time, and additional data fields required for reporting have been introduced. The timeframe for implementation is also very short – the ruling was announced in September 2016, and it takes effect in January 2017.



TRIALASSURE SOLUTION

The TrialAssure system, a proprietary technology that manages transparency and disclosure reporting, is able to be adjusted to meet the new requirements. System settings can be modified to trigger system users to implement more frequent reporting.



The system can also be modified to allow for the reporting of additional data fields. The compliance metrics and reporting features of the system allow users to quickly adapt to managing compliance under a new regulation. With sponsor approval, expedited “Final Rule” updates can be pushed out, allowing for quicker implementation of new system specifications. As in the case with the “Final Rule”, TrialAssure is able to make adjustments in a very short time (3-4 months), which allows allow companies to remain in compliance when updated reporting requirements are released.

OUTCOME

Phase 2b Study Completed and Delivered Successfully

The TrialAssure system is flexible and scalable to meet new regulations quickly and seamlessly, and to ensure companies can get into and stay in compliance.

