Medidata Offers Breakthrough to De-Risk Clinical Trial Submissions

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Medidata Edge Trial Assurance uses AI to find data quality issues and helps resolve them before submission to the FDA

NEW YORK--(BUSINESS WIRE)--May 8, 2018-- To help organizations mitigate the risk of regulatory non-approval and delays, Medidata Solutions (NASDAQ:MDSO) is transforming how clinical trial data is validated prior to FDA submission with Edge Trial Assurance.

For over a decade, fewer than 10% of clinical trials that enter Phase I achieve FDA approval. Too many new drug submissions receive a rejection letter, request for further analysis, or label restriction, significantly delaying market entry, impacting patients and shareholder value.

Often, these issues are not about the efficacy of the treatments or devices but the quality of the clinical data. Medidata offers a new way to preempt submission of data errors, by using machine learning algorithms, put in the hands of Medidata's team of former FDA statisticians.

Medidata Edge Trial Assurance, already used in over 30 trials, has consistently detected 50-75 data anomalies per study by:

- Utilizing Artificial Intelligence (AI) to detect data entry errors, outliers, potential fraud or misconduct and misreported adverse events from sites
- Delivering a turn-key, comprehensive report of the results by a team of clinical analysts led by former FDA statistical reviewers
- Enabling the study team to proactively correct data issues before regulatory submission

Medidata's AI capabilities have received industry recognition. Recently, Medidata's risk-based monitoring solution Edge Strategic Monitoring earned a prestigious CARE Award for being the first and only end-to-end solution that combines the same advanced anomaly detection in Edge Trial Assurance with centralized issue management.

"The outcome of a regulatory submission has a profound impact, not only to the business but also for patients in need," said Glen de Vries, co-founder and president at Medidata. "Medidata's advanced machine learning capabilities and former FDA expertise empower organizations to confidently manage regulatory submissions and significantly reduce risk."

About Medidata

Medidata's unified platform, pioneering analytics, and unrivaled expertise power the development of new therapies for over 1,000 pharmaceutical companies, biotech, medical device firms, academic medical centers and contract research organizations around the world. The Medidata Clinical Cloud® connects patients, physicians and life sciences professionals. Companies on the Medidata platform are individually and collaboratively reinventing the way research is done to create smarter, more precise treatments. For more information: www.mdsol.com

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