



Medidata Introduces New Edge Family of Products for Clinical Operations at SCOPE 2018

February 13, 2018

Life Science Buyers Identify Top Criteria to Support the New Generation of Trials

Edge Strategic Monitoring is Only RBM Solution to Address 95% of TransCelerate Technical Requirements and be Fully Compliant with ICH GCP E6 (R2) Requirements

NEW YORK--(BUSINESS WIRE)--Feb. 13, 2018-- As clinical trials become more complex, sponsors and contract research organizations (CROs) are looking for a unified platform to help them overcome challenges such as dealing with disparate systems, complying with new regulatory requirements and managing an increasing variety and volume of data.

This press release features multimedia. View the full release here: <http://www.businesswire.com/news/home/20180213005857/en/>

Medidata Clinical Cloud: One platform for Data Managers, Clinical Operations, Investigators, and Pat ...

Medidata Clinical Cloud: One platform for Data Managers, Clinical Operations, Investigators, and Patients to accelerate the science and business of research.

Today at SCOPE, [Medidata Solutions](#) (NASDAQ:MDSO) is introducing the [Edge](#) family of products, a holistic suite of intelligent trial planning and management solutions that seamlessly address today's operational and regulatory requirements. Edge enables clinical

operations teams to:

- Optimize study design, feasibility and site grants utilizing benchmarking from 14,000+ studies
- Eliminate site escrow accounts with automatic investigator payments triggered by EDC
- Comply with ICH GCP E6 (R2) requirements with an end-to-end RBM suite
- Utilize master data management for study management
- Automate the collection of up to 76% of a trial master file

Edge is supported by the [Rave](#) family of products, the most comprehensive data capture and management solution, and is powered by [Medidata Enterprise Data Store \(MEDS\) and AI](#). Rave allows sponsors to capture, manage and explore site, lab, imaging, genomic, app and sensor data, and real world data. Together, they comprise the Medidata Clinical Cloud®, which is the unified platform of choice for clinical operations and data management.

In a recent survey conducted by Medidata, life science decision makers and users identified the capabilities necessary to deliver the next generation of clinical trials, including EDC and risk based monitoring (RBM).

The top criteria for EDC are: price, (24%); integration (23%); robustness of features (18%); intuitiveness of software (18%); and database build speed (17%). Medidata's Rave EDC is ranked as the top solution across all criteria.

For RBM the top criteria are: risk identification & evaluation (26%); issue management & workflow (21%); reporting, analytics, visualization (21%); targeted SDV (17%); and site visit management (15%). Edge Strategic Monitoring is the only end-to-end comprehensive suite that combines risk assessment and anomaly detection with centralized issue management, enabling users to identify risks and document actions in real-time while complying with ICH GCP E6 (R2) requirements. Furthermore, Medidata addresses 95% of the 130 technical requirements suggested by [TransCelerate BioPharma Inc.](#)

Join Medidata (Booth #800) at SCOPE, Feb. 12-15, in Orlando, Florida. Additionally, Medidata experts will be speaking on the following topics:

- Nina Pruitt | **Speaker** "The Rx for your Clinical Financial Management" | Tuesday, Feb 13, 12:05 p.m.
- Anthony Costello | **Moderator** "What Is Holding Back The Adoption Of eConsent" | Tuesday, Feb. 13 at 4 p.m.
- Daniel O'Connell | **Speaker** "Think You're ICH E6 Compliant? Show Me The Quality Tolerance Limits" | Wednesday, Feb. 14 at 4:55 p.m.
- Hrishikesh (Rishi) Karvir | **Speaker** "Applying Machine Learning Frameworks to Improve Trial Outcomes" | Thursday, Feb. 15 at 9:55 a.m.

The double-blinded survey featured 100 life science respondents from the US, Canada, and Europe, and was conducted in July 2017.

About Medidata Solutions

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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