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Medidata Introduces Regulated Content and Document Management Capabilities to Its Industry-Leading Cloud Platform

Medidata's Regulated Content Management Solution Leverages Box Platform to Create the Only Content Integrity and Collaboration Platform for Both Regulated and Nonregulated Content

NEW YORK--(BUSINESS WIRE)-- On the heels of its recent acquisition of CHITA, Medidata (NASDAQ:MDSO), the leading global provider of cloud-based technology and data analytics for clinical research, today announced the availability of its regulated content management (RCM) platform, Medidata RCM.

In collaborating with Box, the leader in cloud content management, Medidata has expanded the Medidata Clinical Cloud® to include breakthrough products for standard operating procedure (SOP) management and electronic trial master file (eTMF) archive. These unified solutions provide customers the ability to manage all content, data and workflows in a single, integrated platform that meets the most rigorous usability, scalability, performance, compliance and security requirements.

The life sciences industry has historically viewed regulated content management systems as a "painful necessity" rather than a valued tool. Such perceptions have persisted due to outdated technology infrastructures, disparate solutions and clunky, pre-cloud UX designs. Yet, these systems are needed to ensure adherence to SOPs and regulatory requirements for FDA and other regulatory body inspections.

Medidata has taken a different approach with its RCM platform. The collaborative solution is designed to focus on the most important aspect of advancing clinical innovation, the user, by empowering key R&D players—sponsors, sites and contract research organizations (CROs)—to seamlessly manage regulated content in a single, unified platform.

"Medidata RCM improves the most crucial elements of working with regulated content in the clinical development space," said Medidata's chief operating officer, Mike Capone. "Built with incredibly intuitive workflows and accessible from anywhere at any time, Medidata RCM supports our customers in complying with their legal and regulatory requirements, while making content management and version control easier. This streamlined environment is a major milestone for our industry, as we provide the holistic technology infrastructure for sponsors, sites and CROs to extract and share data in real time, and ultimately advance scientific discovery for patients in need."

Medidata RCM is the only tool that allows users to create, store, view, edit and jointly work on both regulated and nonregulated content in a single application via Box's cloud content management platform. The fully-validated 21 CFR, Part 11 and Part 820-compliant system delivers first-of-its-kind, patent-pending live content integrity technology that actively ensures inspection readiness for life sciences companies everywhere.

"Since implementing Medidata RCM, our users have experienced a reduction in search and review time," said Hayley Lewis, VP of Regulatory Affairs and Quality at Zosano Pharma. "This has allowed us to increase our compliance. The platform is so easy to use, especially given its integration with Box, which creates a unified search across regulated and nonregulated content."

With one search box that is highly secure, compliant and accessible anywhere, sponsors and CROs can find the information they need, when they need it. With implementation timelines reduced to weeks instead of months, Medidata RCM is as simple to set up as it is to use. And, because Medidata RCM is pre-validated and pre-built on top of Box's cloud-based system, the platform is only a fraction of the cost of standard regulated content solutions.

"We are delighted that Medidata is leveraging our cloud content management platform to break new ground in offering the life sciences industry the ability to manage regulated and nonregulated content in one single solution," said Jeetu Patel, CSO and SVP of Box. "This approach gives the industry the ability to improve collaboration and efficiency by consolidating all documents and workflows into one place."

In the future, the Medidata RCM platform will also include eTMF, Corrective and Preventive Actions (CAPA) and other regulated document capabilities.

To learn more about the challenges of managing regulated content and Medidata RCM's unique approach, join us for an online forum on Tuesday, May 23, 2017 from 11:00 a.m. to 1:00 p.m. ET.

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About Medidata

Medidata is reinventing global drug and medical device development by creating the industry's leading cloud-based solutions for clinical research. Through our advanced applications and intelligent data analytics, Medidata helps advance the scientific goals of life sciences customers worldwide, including over 850 global pharmaceutical companies, biotech, diagnostic and device firms, leading academic medical centers, and contract research organizations.

The Medidata Clinical Cloud® brings a new level of quality and efficiency to clinical trials that empower our customers to make more informed decisions earlier and faster. Our unparalleled clinical trial data assets provide deep insights that pave the way for future growth. The Medidata Clinical Cloud is the primary technology solution powering clinical trials for 18 of the world's top 25 global pharmaceutical companies and is used by 16 of the top 20 medical device developers—from study design and planning through execution, management and reporting.

Cautionary Statement

Certain statements made in this press release are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that involve significant risks and uncertainties about Medidata Solutions, Inc. ("Medidata"), including but not limited to statements about the expected closing of the acquisition and the effect of the acquisition. Such statements are based on management's current expectations and are subject to a number of uncertainties and risks, which could cause actual results to differ materially from those described in the forward-looking statements. For additional disclosure regarding these and other risks faced by the Company, see disclosures contained in Medidata's public filings with the Securities and Exchange Commission, including the "Risk Factors" section of Medidata's Annual Report on Form 10-K for the year ended December 31, 2015. You should consider these factors in evaluating the forward-looking statements included in this press release and not place undue reliance on such statements. The forward-looking statements are made as of the date hereof, and Medidata undertakes no obligation to update such statements as a result of new information.

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