Global Medical Devices Company, MEL MEDICAL Enterprises, Modernizes Clinical Research with Multi-Year Medidata eTMF Agreement

November 20, 2017

Company Accelerates Bladder Cancer Research by Unifying Content, Data, and Workflows

NEW YORK & PETAH-TIKVA, Israel--(BUSINESS WIRE)--Nov. 20, 2017-- Medidata (NASDAQ: MDSO), the leading global provider of cloud-based solutions and data analytics for clinical research, today announced that MEL MEDICAL Enterprises, has selected Medidata eTMF to carefully and effectively manage regulated content involved in the development of new therapies for patients with non-muscle invasive bladder cancer.

MEL MEDICAL Enterprises is a global medical devices company specializing in developing minimally invasive therapeutic technologies for bladder cancer patients. By using Medidata eTMF, the company will achieve greater efficiency and transparency from study planning to study close. MEL will be able to better streamline communication and secure management of its Trial Master File (TMF) across 20 global sites and 2 labs while maintaining complete compliance and an audit trail that is inspection ready.

“As clinical trial complexities and regulatory pressures continue to increase in scope, efficiently maintaining and extracting both data and content in a compliant manner are paramount to successful trial outcomes,” says Igal Ruvinsky, vice-president clinical affairs, at MEL MEDICAL Enterprises. “To power our next cycle of clinical research, we need an easy to use, unified solution with a long-standing reputation as a stable system that streamlines data in the cloud. We look forward to collaborating with Medidata to bring life-saving therapies to cancer patients with greater ease and compliance.”

As part of the Medidata Clinical Cloud®, Medidata eTMF regulated content management solution accelerates study startup by efficiently standardizing and automating trial master file documentation. It allows users to create, store, view, edit and collaborate on an entire TMF lifecycle in a single application with cutting-edge UX capabilities fully integrated with Box. Powered with the first-of-its-kind Live Content Verification technology, it further supports higher compliance standard and inspection readiness throughout the study lifecycle.

“The adoption of eTMF solutions is significantly accelerating in the life sciences sector, and we’re proud to deliver the industry’s most comprehensive end-to-end platform that allows our customers to make better decisions during the clinical development process,” said Kevin Barrett, vice president document management solutions at Medidata. “We’re proud to partner with MEL MEDICAL Enterprises to improve the collaboration between clinical teams and trial stakeholders as they focus on new treatments for one of the most common malignancy among men and women.”

About MEL MEDICAL Enterprises

Medical Enterprises Group is a growing and dynamic medical device company. It has its headquarters in Amsterdam, The Netherlands, where sales and marketing activities are managed. Research and Development, technical support and clinical activities are managed from the facility in Israel. MEL MEDICAL’s R&D staff is a multifunctional team composed of physicists, electrical and mechanical engineers, software and QA experts. The clinical department is led by PhD level scientists who provide medical support to Urology Departments around the world, and handle clinical trials and publications. The company is focused on developing minimally invasive therapeutic technologies which provide benefits for both patient and healthcare system. The company's leading product, Synergo®, offers an advanced treatment modality for patients suffering from non-muscle invasive bladder cancer.

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 950 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 18 of the top 25 medical device developers—from study design and planning through execution, management and reporting.

View source version on businesswire.com: http://www.businesswire.com/news/home/20171120005567/en/

Source: Medidata

Medidata
Investor:
Medidata Solutions
Anthony D’Amico, +1 732-767-4331
adamico@mdsol.com
or
Media:
Medidata Solutions
Erik Snider, +1 646-362-2997
esnider@mdsol.com