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A2 Healthcare Corporation and Medidata Solutions, Inc.

collaborate for realizing Risk-Based Monitoring tailored for Japan

- *Accumulation of know-how toward ensuring reliability and streamlining in clinical studies*

Tokyo, Japan, 11 March, 2015 -- A2 Healthcare Corporation (Head office: Bunkyo-ku, Tokyo, President and CEO: Tadashi Katori, hereinafter referred to as “A2 Healthcare”) and Medidata Solutions, Inc. (Head office: Chiyoda-ku, Tokyo, Managing Director, Asia-Pacific Region: Takeru Yamamoto, hereinafter referred to as “Medidata”) today announces that the companies will further intensify the existing collaboration to introduce Risk-Based Monitoring (hereinafter referred to as “RBM”) tailored for the clinical study environment in Japan. RBM realizes efficiency and cost reduction in clinical trials, while ensuring study reliability required for drug and medical device development.

In recent years, there have been compelling demands for improvement of quality and speed in clinical studies along with fiercer competitions in pharmaceutical and medical device development. To achieve this, the regulatory authorities of Japan, the United States and Europe recommend an introduction of RBM. In the U.S., it is becoming widespread under the leadership of TransCelerate BioPharma Inc. (hereinafter referred to as “TransCelerate”), an NPO co-established by global major pharmaceutical companies striving for further efficiency in clinical studies. Likewise, the Japanese pharmaceutical and medical device industries have high expectations toward RBM; some leading pharma companies have already embarked on RBM application. Moreover, many Japanese pharma and medical device companies also have started to discuss RBM introduction at a practicable level.

Against this background, A2 Healthcare, a leading Japanese CRO with a strength in statistical analysis and in wielding IT in clinical studies, and Medidata, a leading global provider of cloud-based solutions for clinical research in life sciences, has agreed to provide mutual know-how and jointly expand the RBM solutions best suited to the clinical trial environment in Japan by aiming to start the first RBM trial with TSDV within this year.

- A2 Healthcare will strongly promote speed-up and quality improvement in pharmaceutical and medical device development through RBM application by offering the following comprehensive services:
  - Develop a protocol grounded in RBM and making excellent use of statistical analysis know-how

- Formulate a RBM execution plan by considering investigational product properties, a study protocol design and the Japanese clinical study surroundings
  - Identify and respond to potential quality risks in the early stages through the central monitoring activities that analyze various types of data comprehensively
  - Set-up and operate Medidata TSDV module
- Medidata provides the following tools to support RBM implementation in Medidata Clinical Cloud®.
- Medidata TSDV (Targeted Source Document Verification)  
A tool to support developing and carrying out a targeted SDV\* plan in the RBM method application  
\*Source Document Verification of critical trial data performed on targeted sites or patients
  - Medidata SQM (Site Quality Management)  
A data analysis tool to support the central monitoring, which is a key to the RBM method application, in light of quality of trial site activities
  - CSA (Central Statistical Analytics)  
A data analysis tool to support the central monitoring by visualization, trend analysis and automatic detection of outliers in Patient Profile

In addition, with a proven record in global business, Medidata will offer consulting services on formulating strategies and operating process for RBM introduction based on close collaboration with TransCelerate.

“There have been globally higher needs for realizing speedy and efficient clinical trials, and in delivering RBM, we place a significant emphasis on using tangible IT solutions to support Targeted SDV and the central monitoring as a key to successful implementation,” said Mr. Takeru Yamamoto, Medidata’s Managing Director, Asia-Pacific (APAC) Region. “On this occasion, we are delighted to team up with A2 Healthcare to familiarize RBM here in Japan as they are a major CRO well-versed in biostatistical analysis and with a number of CRAs who are knowledgeable about RBM. We are confident that the fusion of Medidata’s global RBM know-how and A2 Healthcare’s full service capabilities will deliver new value to our clients,”

“RBM is expected to be a strong and significant method ensuring patients’ safety and clinical trial’s reliability, and what is more, streamlining clinical studies,” said Mr. Tadashi Kartori, A2 Healthcare’s President and CEO. “A2 Healthcare has proactively attempted to absorb the RBM know-how; we started studying the guidance documents of Japan/US/EU when they were issued as a

draft as well as Position Paper of TransCelerate and RACT Tool. We are particularly glad to collaborate with Medidata, a global leader in cloud-based EDC solutions, to expand their RBM solution services including TSDV. We are certain that Medidata and A2 Healthcare will be able to deliver higher-quality services to clients at more budget-pleasing prices by building up a solid RBM track record here. Furthermore, we believe that the quality risk management methodology in the RBM central monitoring activities is also applicable to the post-marketing surveillance in Japan. We will therefore willingly develop the relevant business in that area.”

【A2 Healthcare Corporation (“A2 Healthcare”)】 <http://www.a2healthcare.com/>

A2 Healthcare is a CRO, with 860 employees in Tokyo and Osaka, providing full services for clinical development. A2 Healthcare was founded in November 2014 through the merger of former ACRONET Corporation and former A2 Healthcare Corporation established by splitting off the clinical development division from Asklep Inc. We are particularly experienced in the therapeutic areas such as oncology, CNS and respiratory as well as traditional lifestyle-related diseases. As another strong selling point, we have promoted cutting-edge IT solutions for accelerated clinical studies including RBM, eSource Data etc. Moreover, A2 Healthcare undertakes a number of global clinical studies through the exclusive alliance with PRA Health Sciences, ranked in the global Top 5 CROs.

【Medidata Solutions, Inc. (“Medidata”)】 <https://www.mdsol.com/jp>

Medidata is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud® brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

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