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CMIC HOLDINGS Co., Ltd.

CMIC has started to manage a domestic pediatric clinical trial by using RBM（Risk Based Monitoring）

—Implementation of high quality trial operation by bulk administration of monitoring and establishing EDC and ePRO —

CMIC Co., Ltd., a consolidated subsidiary of CMIC HOLDINGS Co., Ltd., has announced that the company has started to promote its services of Risk Based Monitoring called "CMIC's RBM（Risk Based Monitoring）". CMIC has been encouraged minimization of risk and improving quality of clinical trials by determining the considerations in operation of medical institutions and taking approaches to maintain better quality control with medical experts and staff involved in the trials.

CMIC has started operating a clinical trial of pediatric sleep disorders with neurodevelopmental disability by Nobelpharma Co., Ltd. by using "CMIC's RBM", which provides high quality and effective operations for clinical trials. As a result of analyzing the characteristics of this clinical trial, CMIC has decided to manage the trial by using RBM based on aggregating clinical trial systems into an all-in-one platform and using a structure of collecting patient records as clinical data immediately.

In CMIC's RBM, the company analyzes the data acquisition process between corresponding medical institutions and CMIC, and then clarifies the problems. CMIC's monitors and Data Manager are proactively involved to establish the RBM model for risk management. The company also promotes to increase work productivity of cumbersome set-up process of clinical trials by using the characteristics of partner companies. Additionally, CMIC has simplified the procedures of clinical trials by using batch application services※1 including Medidata Clinical Cloud® provided by Medidata Solutions, Inc. CMIC is the first company to use the both application service in Japan.　CMIC has also adopted a mobile device "cPhone※2" for examinees manufactured by CROee Inc. "cPhone" carries ePRO (Medidata Patient Cloud) and an application which is a joint development of CROee Inc. and CMIC. The application enables support to take prescription drugs for pediatric examinees and expects to improve drug compliance for children.

※1 "Medidata Rave®""Medidata Patient Cloud®　(ePRO)" "Medidata Balance®（IWRS）" "Medidata Coder®"

※2 For more information of "cPhone", please visit: https://www.croee.com/services/technologies/cphone-2

CMIC has been encouraged operation of clinical trials using Electronic Data Capture（EDC）, which is a system of collecting clinical data via Internet or a dedicated line. The company will utilize ePRO to gain clinical data timely and accurately for confirming safe conditions of examinees.

CMIC has encouraged development and production of new medicines and provides efficient and improved quality services of clinical trials by using current technology, taking approaches to further the efficiency of tasks, and to enable smooth integration between systems.

【about CMIC's RBM】

"CMIC's RBM" is based on an idea that it is important to maintain a good balance between efficiency in tasks of medical experts and staff involved in clinical trials. CMIC has promoted the establishment of optimal "CMIC's RBM" and operates risk and quality management.

【CMIC Co., Ltd.】

CMIC Co., Ltd. has provided services to promote the efficiency and acceleration of clinical trials as the first CRO in Japan. CMIC Group today provides comprehensive support services for development, manufacturing, sales, and marketing of the pharmaceutical industry. CMIC Group has developed a unique business model that we call "Pharmaceutical Value Creator (PVC)" based on our abundant accumulated experience and knowledge as a CRO pioneer. CMIC utilizes PVC to create new value in the healthcare field.

For more information:

CMIC HOLDINGS Co., Ltd. : http://www.cmic-holdings.co.jp/e/index.shtml

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