



Press Release, May 27, 2009

Notice of the Establishment of a Support Network for Clinical Trial Electronic Data Capturing Systems

Notice is given of the contract agreed for an operational alliance between CMIC Co., Ltd. (Head Office: Tokyo, Shinagawa-ku; hereafter “CMIC”) and PHT Corporation (MA USA; hereafter “PHT”) for CMIC to support PHT’s electronic patient reported outcome (ePRO) system, the LogPad® and SitePad™ providing a consolidated service network for Japanese pharmaceutical companies to use the above system in conducting clinical trials.

As Japan’s first CRO (contract research organisation), CMIC Group has been developing a business model which fully supports the medical business of pharmaceutical companies, encompassing development, production and marketing, and makes a contribution to value-added improvements. Among its core-operations as a CRO and health care-related business concern, CMIC supports trouble-free implementation of clinical trials for both sponsors and investigational sites by conducting operations including clinical trial monitoring, data management, subject recruitment, and trial coordination.

PHT is a global supplier of electronic data capture solutions for clinical trials focused on collecting and managing high quality clinical data directly from patients. PHT’s ePRO product suite is the leading IT service used directly by study patients to carry out real-time capturing and assessment of clinical symptoms, vital signs and drug administration conditions during trials via a hand-held PDA (Personal Digital Assistant).

In developing drugs, bringing safe and effective novel drugs to the market in a reduced time frame requires ever-larger volumes of clinical trial data to be collected in ever-shorter periods of time. In Japan, the numbers of “global clinical trials” are therefore increasing year on year, where mainly non-Japanese pharmaceutical companies conduct clinical trials simultaneously in a number of countries.

The IT-based service which is effective for three key elements required by such clinical trials; “quality”, “speed”, and “cost” is “ePRO”. Patient diary data should be collected in clinical trials, but in paper-based clinical trials, data can often be entered into the patient diary either retrospectively or illegibly, and proving data credibility to regulatory authorities

has been often an issue. In the case of “ePRO”, the system is designed to allow only clinical data capturing within restricted time-response windows, therefore latest subjective symptoms and vital signs could be captured, and reliability and accuracy as data could be obtained. “ePRO” is also designed to avoid omission of recording required items, reducing percentages of missing data to a large extent. Patient follow-up is possible by the real time online access to patients’ inputting status and contents.

In addition, offering savings of both time and cost of data acquisition, “ePRO” allows time-stamped data entry for highly dependable, accurate and speedy data collection. When using “ePRO” with EDC (electronic data capturing), the time required after a clinical trial for data manipulation is notably reduced compared to the case using a paper-based patient diary.

In comparison with using conventional paper-based patient diaries, electronic systems are superior in any of all three elements of “quality”, “speed”, and “cost”. However, such IT services are yet to become widespread in Japan, and when non-Japanese pharmaceutical companies conduct global clinical trials, patient diary data must be collected on a paper basis only in Japan.

Due to the consolidation of a support network for ePRO in Japan with PHT, CMIC looks forward to adding value to pharmaceutical companies conducting global clinical trials by improving both the overall quality of clinical data collected and reducing cost in the clinical development process.

[Any further enquiries]

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As Japan’s first CRO (contract research organisation), CMIC supports pharmaceutical and clinical industries from drug development through manufacture to marketing, by providing pharmaceutical consulting, monitoring, and data management services. CMIC also supports development activities for medical devices by carrying out pharmaceutical consulting, clinical trials and approval applications. CMIC maintains a global presence with extensive business practices in Japan, Asia (China, Korea, Singapore, Taiwan), and America among other territories. For further details please visit the website. <http://www.cmic.co.jp/>

[PHT Corporation]

PHT is the market-leading provider of electronic patient reported outcome (ePRO) solutions used in more than 390 clinical trials by 100 biopharmaceutical clients. The proven LogPad®

System and revolutionary SitePad™ Tablet deliver the voice of the patient, in 80 languages, from homes and sites in 60 countries around the world. By capturing high-quality and time-stamped assessments with minimal respondent burden, trial sponsors are able to run smaller and more conclusive clinical research programs resulting in significant R&D cost savings. Real-time study management through PHT StudyWorks™ features eClinical data integration, standard and custom data summaries for compliance and enrollment, SafetyPRO™ email alerts, and the industry's premier study archive. Patient experiences captured firsthand by PHT's ePRO Product Suite have been used successfully in at least 11 NDA submissions and seven approvals to date.

For more information, review interactive product demonstrations at the award-winning <http://www.phtcorp.com>

PHT, LogPad, eSense, StudyWorks, SafetyPRO and SitePad are among the registered trademarks and trademarks of PHT Corporation.

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