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Fujitsu launches SaaS solution tsClinical DDworks21/Trial Site

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Fujitsu has enhanced its clinical trial-supporting Fujitsu Life Science Solution tsClinical DDworks21 series with the launch of the SaaS solution tsClinical DDworks21/Trial Site. The new solution provides hospitals and other clinical trial sites in Japan with shared cloud-based control of documents conventionally exchanged in paper form between pharmaceutical companies developing new drugs and the sites conducting the clinical trials.

Clinical trial documents are records that prove a trial's reliability, so they are required by law to be stored long-term under strict control. Most clinical trial sites use paper records, and the exchange and storage of these documents remains labor intensive. After new drug approval, the documents must be managed properly for five years in Japan (in Europe, for a minimum of 25 years), a lengthy requirement that places a burden on hospital staff. The Trial Site solution reduces this operational burden and contributes to higher efficiency and lower costs. By adding this solution to the tsClinical DDworks21 series lineup, Fujitsu expands its business in the clinical trial field and contributes to the comprehensive optimization of clinical trials.

New drug development is generally said to take 10 years and cost between 20 to 30 billion yen in Japan. In total, pharmaceutical companies in Japan spend 1.4 trillion yen annually on drug development, and lowering the cost of clinical trials represents a significant challenge.

In recent years, various industries are increasingly going paperless by digitizing documents. In the medical field, while pharmaceutical companies, particularly in new drug development processes, are transitioning toward digitization, most clinical trial sites still operate by affixing seal impressions on paper documents in clinical trials. As a result, the printing of enormous quantities of documents generated during clinical trials, filing tasks, and securing storage space remain a significant issue. For pharmaceutical company staff (monitors) who repeatedly visit clinical trial sites to deliver and receive paper documents and check on storage conditions, reducing the workload associated with clinical trials is an urgent issue.

To overcome these challenges, Fujitsu drew on its know-how in operational support for clinical trials gained through the development of the tsClinical DDworks21 series to create a new solution for clinical trial sites. At hospitals and other clinical trial sites, documents are managed as electronic originals on the cloud, and processes related to this management are streamlined and the quality is improved.

Prior to launching this solution, Fujitsu conducted a field trial with National Cancer Center Hospital East and National Cancer Center Hospital. The trial verified higher efficiency and proper control of digitized exchange and storage of clinical trial documents as well as Institutional Review Board (IRB) operations.

Dr. Toshihiko Doi, Deputy Director of National Cancer Center Hospital East commented "In this field trial, we successfully identified how to reduce operational burdens and increase efficiency for trial administrators by utilizing document digitization and systemized operation of process management. I hope this solution will be widely used by clinical trial sites and eventually link to tsClinical DDworks 21, which is used by many pharmaceutical companies. I have high expectations that Fujitsu will play a leading role as pharmaceutical companies and clinical trial sites share information on their respective needs and create a new platform."