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For General Release

Information Services International-Dentsu, Ltd.

ISID Provides Clinical Trial Document Management System ”Wingspan eTMF" to Chugai Pharmaceutical

Improvement of clinical trial quality and process efficiency

Information Services International-Dentsu, Ltd.(Head office: Minato-ku, Tokyo; President & CEO: Setsuo Kamai; “ISID”) implements SaaS-type cloud solution "Wingspan eTMF" as a clinical trial document management system of Chugai Pharmaceutical Co., Ltd. (Head offce: Chuo-ku, Tokyo, Chairman & CEO: Osamu Nagayama, “Chugai”), and its full-scale operation has started.

Due to intensified competition of drug development in recent years, pharmaceutical companies are required to further improve the quality of their clinical trials and shorten the period of their clinical trials. For that reason, electronic trial master file (eTMF) is becoming widespread. Especially in Europe, regulatory authorities may inspect the progress of ongoing clinical trials, so a document management system that can respond to inspections at any time is required. Therefore the eTMF become indispensable for pharmaceutical companies that expand their business globally.

Under these circumstances, Chugai has set the theme "Acquisition and implementation of competitiveness at a top global level" as the priority theme of the medium-term management plan "IBI 18" that began in 2016. And Chugai is developing global pharmaceutical products while emphasizing both quality and speed to market, centered on Japan, the US and Europe. As part of these efforts, "Wingspan eTMF" provided by ISID was adopted for the purpose of supporting clinical trials conducted at multiple locations and responding to inspections by national regulatory authorities.

“Wingspan eTMF”, the solution chosenby Chugai, is a SaaS type cloud solution that provides eTMF in compliance with the regulations of authorities in major countries including EMA※1 in Europe and MHRA※2 in the UK. It supports planning the required set of TMF documents according to the regulations of each country with simple operation. Users can immediately detect any quality deviations and perform root cause analysis. These functions improve the quality and efficiency of the trial.

Chugai introduced this system in the pharmaceutical development department including overseas bases this time. In the past, clinical document management was done on a paper basis at each site. Now, it is possible to do so globally and electronically. The new eTMF will contribute significantly to both the quality of trial documentation and to increased speed of drug development.
ISID will continue to contribute to strengthening the competitiveness of Japanese pharmaceutical companies by providing technology solutions

※1 EMA : European Medicines Agency

※2 MHRA : Medicines and Healthcare Products Regulatory Agency

Contact:

<For Service>
ISID Strategic Business Development Division
TEL:+81 3-6713-8068　E-mail：g-Lifescience-sales@group.isid.co.jp

<For Media>
ISID Corporate Communications Office
TEL:+81 3-6713-6100　E-mail：g-pr@isid.co.jp