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EP-SOGO Co., Ltd
Fujitsu Limited

EP-SOGO Adopts Fujitsu's tsClinical DDWorks 21/Trial Sites, a clinical study solution for investigational medical sites

as the first site management organization aiming to accelerate digitalization and improve efficiency of clinical study documentations

EP-SOGO Co., Ltd [*1] (hereinafter, EP-SOGO), one of the affiliates of EPS Holdings, Inc., has decided to adopt "Fujitsu Life Science Solution tsClinical DDworks21/Trial Site" (Herein after, "Trial Site"), provided by Fujitsu Limited*2 (hereinafter, Fujitsu) and will start granting access to the system to pharmaceutical companies and its contract investigational medical sites starting clinical studies in February, 2021.

Trial Site is a SaaS (Software as a Service) solution which enables shared cloud-based control of clinical study documents by both the pharmaceutical companies and the investigational medical sites involved in new drug development. Even clinics conducting a limited number of clinical studies, which are therefore having difficulties to have systems with their own licenses, can use Trial Site with accounts granted by EP-SOGO. Thus, medical sites can prepare and share study-related documents electronically without system installation costs. Trial Site will enable the investigational medical sites to reduce the costs for document preparation, document exchange and travel, save the document storage spaces and improve the efficiency of document search.

In addition, this approach can also be a solution for the COVID-19-related challenges including reduction of physical contacts at document exchanges and printing issues in work-from-home situation. Digitalization by usage of Trial Site will reduce labor burdens at both pharmaceutical companies and medical sites, maximize efficiency, reduce costs and ensure safe implementation of clinical studies.

EP-SOGO will contribute to the holistic optimization of the clinical study environment by promoting digitalization of its study support services, including document archiving, while Fujitsu is supporting acceleration of the digital transformation in the healthcare sector by providing Trial Sites.

【 **Backgrounds** 】

In the process of new drug development, study-related documents have been prepared in paper forms. Efficiency improvement and cost reduction have been overriding issues as paper-based documents have been needed to be prepared, printed and filed, consuming archiving spaces. Moreover, visits or mailings were needed for the document exchange. Under these circumstances, both medical sites and pharmaceutical companies have started digitalization of documents; however, particularly at medical sites with a limited number of clinical studies, the high installation cost for dedicated software has been an obstacle.

EP-SOGO is a leading site management organization (hereinafter, SMO) in Japan, supporting the largest number of contracted medical sites with its strong clinical study experiences in a variety of therapeutic areas. By adopting *Trial Site*, Fujitsu's clinical study solutions for investigational medical sites, and by providing the access to the pharmaceutical companies and the contracted investigational medical sites, EP-SOGO will accelerate the digitalization of clinical study documents to further improve the efficiency at our contracted medical sites. At the same time, the enhanced digitalization at medical sites will lead to the cost reduction at pharmaceutical companies.

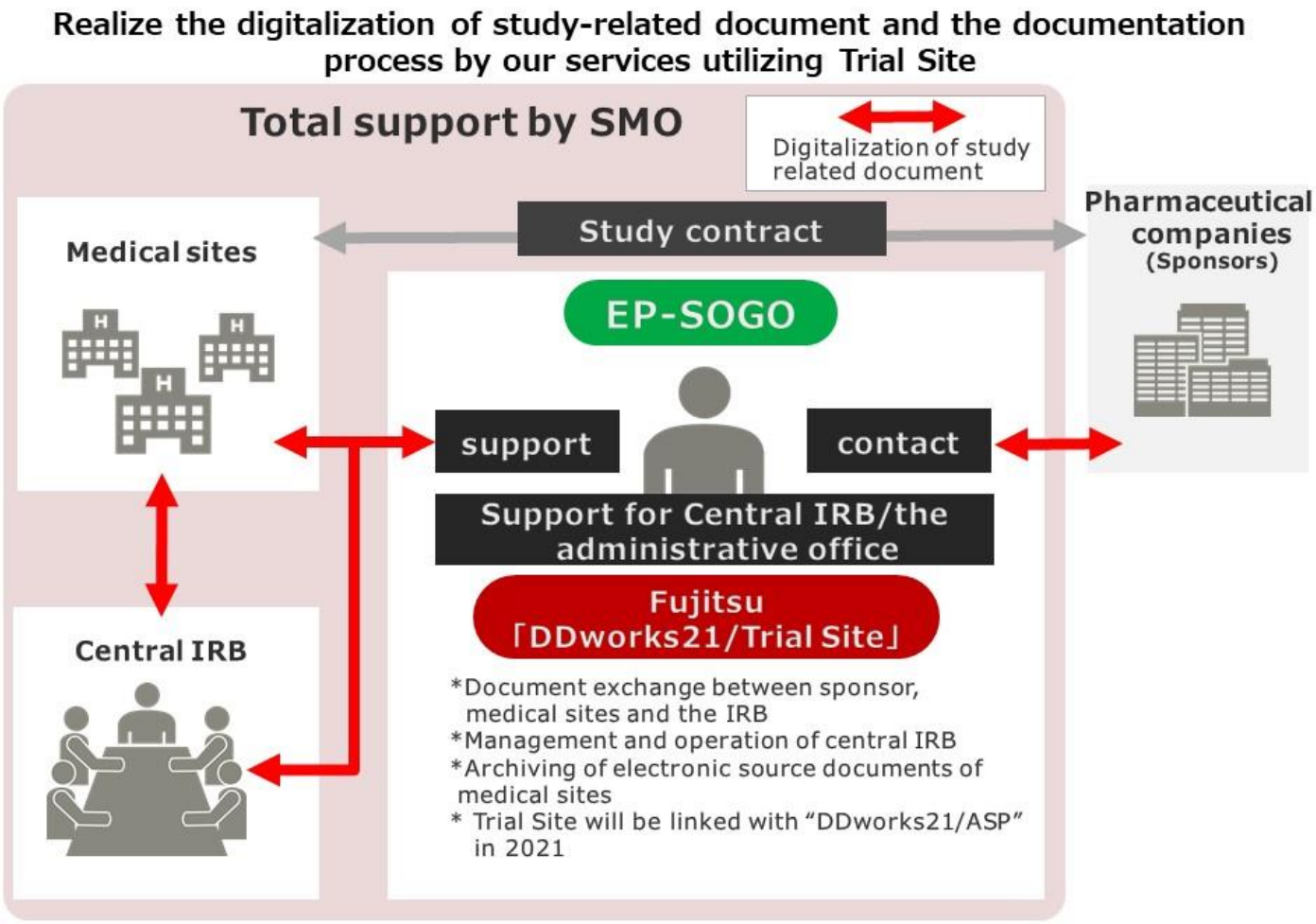
【 Outline of support services for medical sites in clinical studies utilizing Trial Site】

1. Electronic source document management at medical sites

   Documents issued at medical sites can be saved as an electronic source documents by using workflow function of Trial Site. In addition, when pharmaceutical companies deliver documents, the documents can be also delivered electronically via Trial Site and received as an electronic original document at medical sites. When the documents are saved, appropriate folders are automatically generated based on metadata such as date of document creation or study titles so that users can ensure the files and the versions are managed properly. Thus, users can easily access the latest data. Physical space for document storage will no longer be needed.

2. Efficient and secure operation of Central IRB[*3]

   Requests for IRB review have been requiring exchanging paper documents by post between the pharmaceutical companies, medical sites and the administrative office of IRB. In addition, the administrative office of IRB has undertaken heavy labor burdens with preparation of review materials, filling of the materials and preparation of approval letters as well as the above-mentioned document exchanges. Trial Site enables all requests for IRB reviews to be processed on the system. The administrative office of IRB can deliver review materials to board members and result notifications electronically based on the requests and materials integrated in the system. This can lead to quality improvement and speeding up in their operation. Also, pharmaceutical companies' workload will be reduced because documents can be shared online, and it's not necessary for the employees to come to the office for printing.



【 Future Scope 】

EP-SOGO will continue to strengthen our collaboration with Fujitsu, beginning with the system installation to the central IRBs, and will expand to individual medical sites with in-house IRB/IECs in future. To achieve a holistic optimization of the clinical study environment, EP-SOGO will reduce the workload and maximize the quality and speed.

Fujitsu will co-work with EP-SOGO to diffuse Trial Site to medical sites. In near future, Fujitsu will link Trial Site with "DDworks21/ASP*4", a clinical study management system for pharmaceutical companies, to enhance the digitalization of the entire clinical study process and to further improve the level of convenience of its services.

【 Relevant websites 】

・EP-SOGO's official website:
https://www.epsogo.co.jp/en/

【 Trademarks 】

Proper nouns such as product names mentioned here are trademarks or registered trademarks of each company.

【 Notes 】

*1 EP-SOGO CO., Ltd: the headquarters located in Shinjuku-ku, Tokyo. Kenichi Yamamoto, the representative Director (CEO), President

*2 Fujitsu Limited: the headquarters located in Minato-ku, Tokyo. Takahito Tokita, CEO & CDXO

*3 Central IRB: Central Institutional Review Board. For multicenter studies, central IRB is the IRB that conducts reviews on behalf of all study sites that agree to participate in the centralized review process.

*4 DDworks21/ASP: Study process management solution developed by Fujitsu, which was initially launched in 1997 and are currently used by 84 clients (as of Jul 2020).

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