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EP-SOGO Co., Ltd.

Next-Generation Remote Source Document Verification (R-SDV) System to Streamline and Accelerate Clinical Trial Operations

EP-SOGO Co., Ltd. (Head Office: Shinjuku-ku, Tokyo, CEO: Kenichi Yamamoto, hereinafter referred to as "EP-SOGO") and BitBrain Corporation (Head Office: Fukui City, Fukui Prefecture, CEO: Tomomi Saito, hereinafter referred to as "BitBrain") have jointly developed a Remote-SDV system to realize direct access to source documents (R-SDV) from outside of medical institutions for monitoring clinical trials. The system, named "**SPG-Remote Medical for SYNOV-R**" is based on the currently available, highly secure, remote access solution for medical institutions "SPG-Remote Medical".

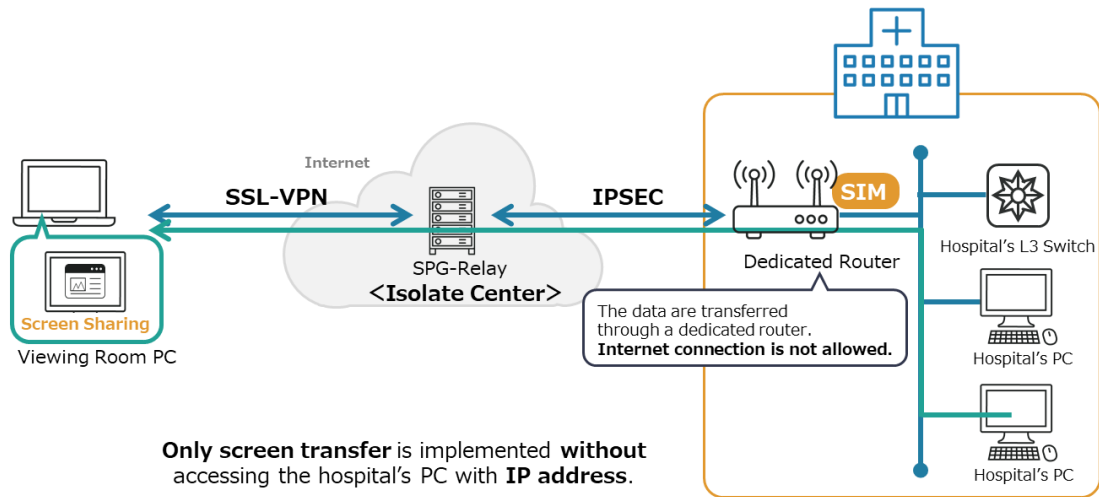
【 Backgrounds 】

SDV (Source Document Verification) refers to the direct inspection of source documents such as medical records and worksheets stored by medical institutions in clinical trials conducted by pharmaceutical companies to verify the submitted data (case report forms) against the records in the source documents. This is an important part of the monitoring process and is essential for establishing the reliability of a clinical trial.

On the other hand, due to the global spread of the new coronavirus pandemic since 2020, it has become difficult for Clinical Monitors to visit medical institutions to conduct SDV, making it harder to ensure the reliability of clinical trial data. It has been expected that safe and convenient R-SDV will be available to solve this problem.

Since the "Five-Year Plan for Revitalizing Clinical Research and Clinical Trials of 2012" (March 30, 2012, Ministry of Education, Culture, Sports, Science and Technology and Ministry of Health, Labour and Welfare) proposed the promotion of Remote Source Document Verification (R-SDV), various organizations and companies have been working on the development of such systems. However, introduction of R-SDV has been slow due to high hurdles such as cost and infrastructure.

【 Overview of SPG-Remote Medical for SYNOV-R 】



【 Features of SPG-Remote Medical for SYNOV-R 】

- SPG-Remote Medical for SYNOV-R allows you to view the medical records in the same way as you view them on site (with exactly the same information and appearance).
- SPG-Remote Medical for SYNOV-R works with all types of electronic medical record systems. Many of the other R-SDV systems currently on the market are limited to certain types of electronic medical records.
- There is no need to invest in special equipment and infrastructure for SPG-Remote Medical for SYNOV-R *Note: The operating PC (SDV terminal) needs to be provided by the medical institution.
- A satellite viewing room (R-SDV implementation room) is available at EP-SOGO (Shinjuku-ku, Tokyo).
- SPG-Remote Medical is the first remote-work product in Japan to include insurance for protection against personal information leakage (provided by Mitsui Sumitomo Insurance Co., Ltd.).

【 Overview of SPG-Remote Medical 】

SPG-Remote Medical, the basis of **SPG-Remote Medical for SYNOV-R**, is a system that enables the safe viewing and operation of hospitals' electronic medical record terminals on an isolated network from outside the hospital. Implementation of the system is as simple as installing a dedicated router in the isolated network and requires no construction work in the hospital. The networks of the electronic medical record networks of the hospital and the terminal outside the hospital are physically separated, and screen sharing-is done securely.

SPG-Remote Medical is a remote desktop solution for medical institutions that has been highly evaluated for its robust security, ease of installation and ease of operation.

【 Future developments 】

EP-SOGO has started pilot operation of **SPG-Remote Medical for SYNOV-R** at five sites in Hokkaido, Tohoku, Chushikoku, Kyushu. Based on the results of this verification, EP-SOGO will further improve the system, enhance its functions, and roll-out the system nationwide throughout Japan by the end of this year.

EP-SOGO plans to expand the satellite viewing rooms to its offices in the Osaka area as well, and to enable R-SDV at clinical trial sponsors' premises in order to meet the demands of even more customers.

[Comments from each company]

| Shunichi Takamatsu

Deputy General Manager, Business Planning & Promotion Department, Business Planning & Promotion Division, EP-SOGO Co., Ltd.

EP-SOGO is aggressively pursuing the streamlining of clinical trial operations by utilizing cutting-edge information technology, and has, since last year, been providing electronic central IRB and clinical trial progress management systems for medical institutions.

This **SPG-Remote Medical for SYNOV-R** system will be one of the products in this business lineup, and we believe that we will be contributing to the acceleration of clinical development in Japan by providing this service not only to EP-SOGO partner medical institutions, but also to other medical institutions conducting clinical trials nationwide.

Through this business alliance with Bitbrain, we will not only improve the SDV environment in response to the impact of the new coronavirus epidemic, but also aim to provide innovative solutions and services to further improve the clinical trial implementation environment of the future.

| Tomomi Saito

Representative Director, BitBrain Inc.

BitBrain is well versed in cutting-edge technologies for advanced networking and security. By creating products and services based on these technologies and distributing them in society, we aim to solve business and social issues and bring about better changes in society.

By delivering "**SPG-Remote Medical for SYNOV-R**", developed through the business alliance with EP-SOGO, as a remote access tool to medical institutions nationwide, we will contribute to society by providing a clinical trial implementation environment that reduces the burden on those involved in clinical trials in the future.

About EP-SOGO Co., Ltd. (<https://www.epsogo.co.jp/en/>)

EP-SOGO, which is responsible for the implementation and operation of this system, is the largest SMO company in Japan, covering many disease areas on a nationwide scale. 1,200+ CRCs (Clinical Research Coordinators) and SMAs (Study Management Assistants) are supporting more than 1,500 medical institutions from Hokkaido to Okinawa (more than 6,000 are partnered). In addition to oncology, which is the EPS Group's forte, our professionally trained staff provide comprehensive support for clinical trials at medical institutions in fields ranging from dermatology, orthopedics, and lifestyle-related diseases to medical devices and regenerative medicine.

About Bitbrain Corporation (<https://bit-brain.jp/>)

Bitbrain, which is responsible for the development and technical support of this system, is a company that specializes in cutting-edge network and security technologies. The SPG-Remote series, which we develop and market, is a remote desktop tool with various security features and network isolation functions. Due to its high level of security, it has been installed in financial institutions and hospitals, and has been featured in various media. It was awarded a special prize for its high security in the "Kansai Manufacturing Innovation 2021" sponsored by the Kinki Bureau of Economy, Trade and Industry of the Ministry of Economy, Trade, and Industry.

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