November 30, 2021

EP-SOGO Co., Ltd.

Project to Promote the Use of DX in the Process of Clinical Trial of Pharmaceutical Product**s**

Announcement of a demonstration experiment of remote SDV systems and notice of commencing operation of "SPG-Remote Medical for SYNOV-R 2.0"

EP-SOGO Co., Ltd. (Head Office: Shinjuku-ku, Tokyo; Representative Director: Kenichi Yamamoto; hereinafter "EP-SOGO") and BitBrain Corporation (Headquarters: Fukui-shi, Fukui; Representative Director: Tomoyasu Saito; hereinafter "BitBrain") today announced the results of demonstration experiment conducted to analyze the effectiveness of SPG-Remote Medical for SYNOV-R, a remote SDV system jointly developed to promote DX in clinical trial process, based on the business alliance announced on June 16, 2021.

Based on the demonstration experiment results, EP-SOGO and BitBrain ensured the necessity of access control and user browsing control by connection reservations. In response to this, EP-SOGO and BitBrain will begin operating SPG-Remote Medical for SYNOV-R 2.0 (pronounced as *sainov*), which has improved its functions, starting as of today, and at the same time roll it out nationwide.

[Background of the demonstration experiment]

In multi-national clinical trials, which have become the mainstream of drug development, the participating regions, countries, and sites are selected based on the performance of the trial (quality, speed, and cost) as well as the size of the drug market.

Compared to other countries, Japan's position in terms of speed and costs is currently low, and if it remained unchanged, and if this situation continued, it might have a significant negative impact on the availability of new drugs in Japan. As a specific example, vaccines and treatment drugs for the new corona virus became available in Japan later than other countries, and their stable supply has not been achieved yet.

The reason for the low performance of clinical trials in Japan is that it requires much of cost and time per trial.*[1] In order to solve these problems by improving the efficiency of SDV operations, EP-SOGO and BitBrain developed a remote SDV system*[3], which enables SDVs to be implemented remotely, and evaluated its effectiveness through the demonstration experiment.

[Demonstration experiment]

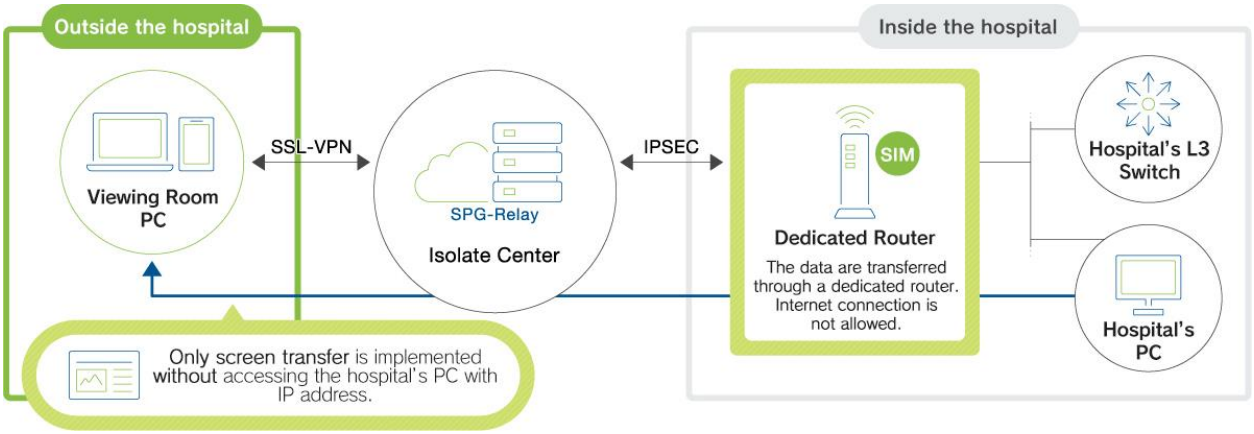
The demonstration experiment was conducted at five medical institutions undergoing trials in Hokkaido, Tohoku, Chugoku-Shikoku, and Kyushu areas starting in April 2021 to analyze the effectiveness of remote SDV. The experiment involved medical institutions representing each size: university hospital, general hospital, specialty hospital, and clinic. A satellite viewing room (dedicated room for verifying documents, including electronic medical records) in Tokyo was used.

SPG-Remote Medical for SYNOV-R was used for the experiment and its effectiveness was evaluated.

Areas of Medical Institutions	Types of Medical Institutions	Number of Medical Institutions	Sponsor	Viewing Room
Hokkaido, Tohoku, Chugoku-Shikoku, Kyushu	University hospital, general hospital, specialized hospital, clinic	5 sites	Large, medium, And small pharmaceutical companies	1 location in Tokyo (at EP-SOGO)

[Overview of SPG-Remote Medical for SYNOV-R]

This system enables screen sharing between the SDV terminal at the medical institution and a remote SDV terminal in a satellite viewing room outside of the medical institution, and remote operation of the remote SDV terminal.



This system enables screen sharing between the SDV terminal at the medical institution and a remote SDV terminal in a satellite viewing room outside of the medical institution, and remote operation of the remote SDV terminal.

[Results]

The experiment revealed the following five issues.

No.	Issue	Description
1	Decision-making on the introduction at medical institutions	The fact that not only the cost of introducing remote SDV but also the man-hour burden in terms of management was as same as that of on-site SDV contributed greatly to the decision to introduce remote SDV at medical institutions.
		The short lead time of introducing remote SDV (less than one month) and the fact that there is no need to change the settings of the system or network at the site and no construction work contributed greatly to the decision to introduce remote SDV.
		The fact that remote SDV can be used regardless of which electronic medical record system is used at the site contributed greatly to the decision to implement remote SDV.
2	Effectiveness when visits to medical institutions are restricted	In situations where external visits are restricted due to the new coronavirus pandemic, it was found that SDV without visits to the medical institutions ensures continuity of clinical trial operations (business continuity management of clinical trial operations).
3	Sponsor's efficiency	The experiment revealed it possible to increase the number of monitoring per site, while significantly reducing the cost of the site visits and the travel time. It was found that this improves the cost performance per trial (low cost, short time).
4	Needs for reservation functions	Needs for access control and user browsing control by connection reservations were revealed; this would only allow a clinical research monitor (CRA) to view the source documents of the subjects at an authorized site on the authorized time and date.
5	Viewing environment	The experiment results suggested that a viewing room (a dedicated room for verifying documents, including electronic medical records) near the sponsor's premises would further improve the effectiveness and efficiency.

The demonstration experiment revealed some critical factors affecting the decision-making for introducing remote SDV. The critical factors are: no cost burden on the sites, short lead time (less than one month), no construction work for the system or network in medical institutions, compatibility with all types of electronic medical record systems. These factors should be considered to popularize a remote SDV system.

In addition, the experiment suggested that remote SDV could realize the continuity of clinical trial operations (business continuity management for clinical trial operations) by enabling SDV without visiting the medical institutions.

On the other hand, access control and user browsing control through connection reservations were found to be needed for even more secure remote SDV.

In addition, the experiment suggested that it would further streamline the sponsors' tasks, who are the remote SDV users, to set-up viewing rooms (dedicated rooms for verifying the documents including the electronic medical records) near the sponsors' premises.

See the summary of the evaluation results attached at the end of this document.

[Additional functions and expansion of inspection rooms based on demonstration experiment results]

Through the demonstration experiment, it was found that there were needs for access control and user browsing control through connection reservation. It was also found to be important to establish a viewing room near the sponsors' premises.

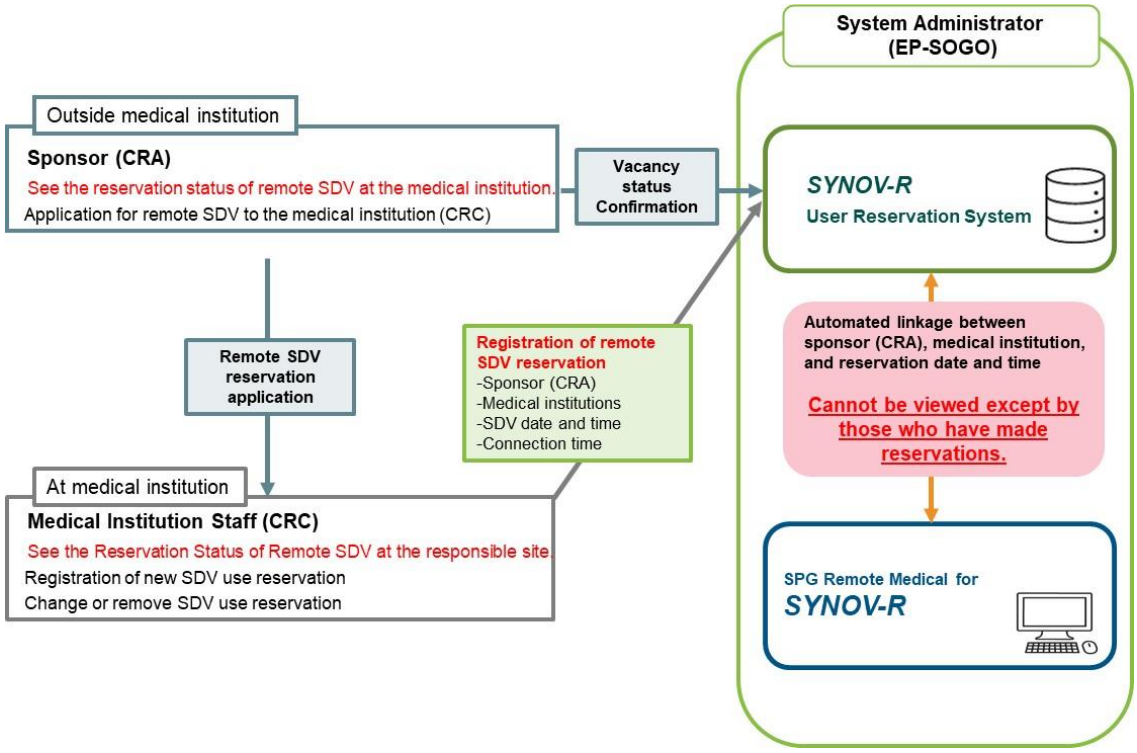
In response, EP-SOGO and BitBrain have developed SPG-Remote Medical for SYNOV-R 2.0, in which the access control and user browsing control functions by connection reservations are implemented. Furthermore, satellite viewing rooms were newly established in the Osaka area, which has the second largest number of sponsors and CRAs after Tokyo.

SPG-Remote Medical for SYNOV-R 2.0

The access control and user browsing control functions by connection reservations are implemented in SPG-Remote Medical for SYNOV-R.

With this reservation function enables a sponsor (CRA) applies for a remote SDV to a medical institution, and medical institution's staff (CRC) makes a reservation for specific time and date. Thereby connection from a remote SDV terminal of a viewing room to a SDV terminal of the medical institution is authorized.

With this function, remote SDV cannot be implemented for any trials, on any times and dates not authorized by the medical institution, so the system can be used more securely and conveniently avoiding mistakes in viewing targets.



Establishment of Satellite Viewing Rooms in Osaka

Two satellite viewing rooms are now available at Osaka Branch of EP-SOGO located in Osaka Area.

[Satellite Viewing Rooms in Osaka]

EP-SOGO Osaka Branch

3F Central Life Doshomachi Building, 1-5-18, Doshomachi, Chuo-ku, Osaka-shi, Osaka

TEL: +81-6-4706-3210 / FAX: +81-6-4706-3212

SPG-Remote Medical for SYNOV-R 2.0 was also developed ensuring security accommodating future use in locations other than the satellite viewing room of EP-SOGO.

In the future, it is assumed that sponsors (pharmaceutical companies) set up viewing rooms at their premises to use SPG-Remote Medical for SYNOV-R 2.0, which will enable dramatical improvement of clinical trial performances.

[Descriptions of Terms]

***1 Causes for poor clinical trial performance in Japan**

One of the duties of CRAs (clinical development monitor) is SDV*[2], which is a verification task, where they visit the medical institutions in order to verify the electronic medical records of subjects (patients participating in clinical trials) with the case report forms. In Japan, the number of the medical institutions per CRA is small, and the number of on-site monitoring (frequency of visits) is large. As a result, Japan's clinical trial performance is low in terms of speed and cost compared to that of other countries.

***2 SDV**

SDV (Source Document Verification) refers to direct inspection of source documents such as medical records and worksheets stored by medical institutions working on clinical trials of pharmaceutical companies, and verification of the submitted data (case report forms) against the records in the source documents. It is an important part of the monitoring process that is indispensable in establishing the reliability of a clinical trial.

***3 Remote SDV system**

A system with which the SDV is conducted remotely from a remote location.

[Contact information on this matter]
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[Attachment: Summary of Demonstration Experiment]

Efficiency Improvement Rate at Medical Institutions

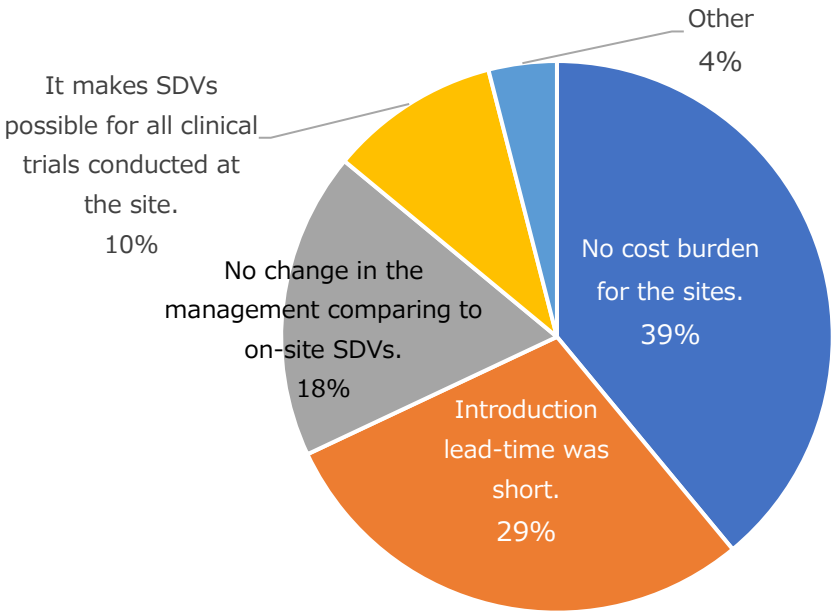
The efficiency improvement rates by introducing SPG-Remote Medical for SYNOV-R and the feedback from the sites are summarized below.

The system was highly evaluated for its high efficiency ratio, the installation costs and the installation lead time.

[Efficiency improvement rate]

	Conventional remote system	**SYNOV-R**	**Efficiency improvement rate by SYNOV-R**
Introduction costs	10 million JPY or more	Free	100%
Monthly expenses	1 million yen or more	Free	100%
lead time	6 to 9 months	1 month	83% to 89%
System construction at site	Yes	No	100%

[Feedback Comments]



Efficiency Improvement Rate of Sponsors (CRAs)

The efficiency improvement rate and feedback from the sponsors (CRAs) who had been conducting SDVs by on-site visits are summarized below.

The expenses, time, and working hours per day are shown in comparison with on-site SDVs involving travels from Tokyo to Hokkaido.

[Efficiency improvement rate]

	On-site SDV	**SYNOV-R**	**Efficiency improvement rate by SYNOV-R**
Transportation expenses	One-way 47,250 JPY (round-trip 94,500 JPY)	170 JPY / 1 way (340 JPY / 2 ways)	99.6%
Accommodation expenses	7,600 JPY per stay	0 JPY	100%
Travel time	5 hours / 1 way (10 hours / 2 ways)	10 minutes / 1 way (20 minutes / 2 ways)	96.7%
Working hours per day	4 hours	8 hours	200%
Time spent per site	2 days	1 day	50%

[Feedback Comments]