April 25, 2022
EPS Corporation
EP-SOGO Co., Ltd.

News Release

Web Seminar Held to Consider Decentralized Clinical Trials (DCT) from the CRC Perspective

EPS Corporation (Head Office: Shinjuku-ku, Tokyo; President and Representative Director: Akira Sasa; hereinafter "EPS"), SP-SOGO Co., Ltd. (Head Office: Shinjuku-ku, Tokyo; Representative: Kenichi Yamamoto; hereinafter "EP-SOGO"), and Medidata Solutions K.K. (Head Office: Chiyoda-ku, Tokyo; Representative in Japan: Motohide Nishi; hereinafter "Medidata") held a two-day web seminar from March 30 to 31, 2022, entitled "DCT from the CRC[*1] Perspective" emphasizing eConsent[*2] and home visits as central topics.

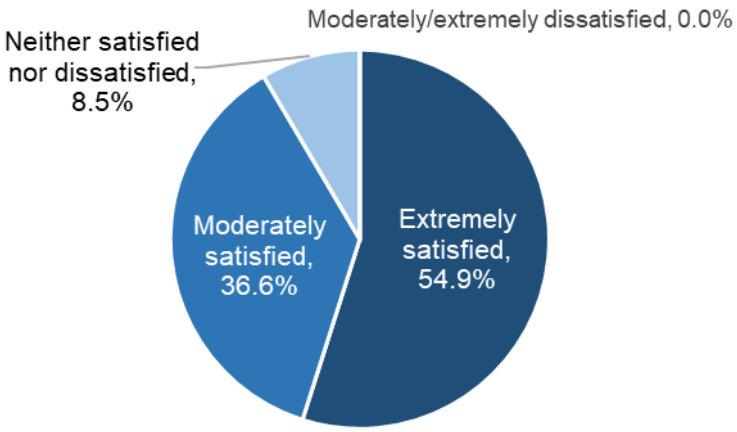
This seminar generated great interest in DCT with 552 people participating on March 30th and 548 people participating on March 31st.

This web seminar focused on "eConsent" and "home visits," which will be affected by regulatory amendments planned for fiscal 2022 and introduced ways to use and benefit from the "Rave eConsent" and "myMedidata" electronic consent and video conference tools provided by Medidata as the leader in state-of-the-art IT solutions. It also looked at the real challenges and solutions to adopting eConsent from the CRC perspective and described some examples of home-visit schemes and the essentials for promoting a digital transformation on medical sites.

A participant satisfaction survey after the web seminar showed a total of 91% were "Very Satisfied"

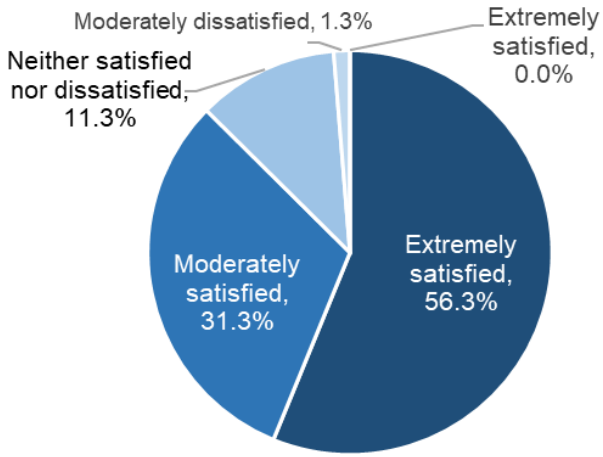
or “Satisfied” with the seminar on May 30th and a total of 87.6% on May 31st.
EPS launched *Virtual Go* as a framework to promote virtual/online clinical trials. In the future, it will hold regular web seminars as one effort to make virtual/online clinical trials commonplace.

Q：How satisfied were you with the web seminar today? (n=82)



Day 1

Q：How satisfied were you with the web seminar today? (n=80)



Day 2

EPS *Virtual Go* Framework

As a leading company supporting clinical study work, EPS is advancing the *Virtual Go* framework to promote virtual/online clinical trials using its wealth of expertise and experience in data science, which is backed by an extensive track record.

Virtual Go is a generic name for all EPS services used to promote virtual/online clinical trials. *Virtual*

Go always strives to satisfy two core ideas: "virtual/online clinical trials in which patients do not have to visit medical institutions" and "virtual/online clinical trials in which CRAs[*3] do not have to visit medical institutions." To do this, EPS handles everything from the proposal to operation and management of various schemes to advance virtual/online clinical trials right for the trial design and type of disease. This includes eConsent, online medical examinations, DDC[*4], eCOA[*5], the use of wearable devices, shipment of investigational product, home-visit nursing, and specimen collection.

EP-SOGO "At-Home Clinical Trials"

EP-SOGO has generated much interest in a new approach to clinical studies that does not require subjects to visit medical institutions in the development of pharmaceutical products by promoting patient centricity concepts and the use of digital technologies. This new approach to clinic studies is known as a decentralized clinical trial (DCT). This approach decentralizes the clinical study work typically done at medical institutions and encourages patients to take part in clinical studies by eliminating the need for regular hospital visits.

EP-SOGO enables patients to take part in clinical trials, even if it is difficult to visit the hospital, by working with the CRC and home-visit nurses who visit the homes or other living quarters of clinical subjects. This creates an at-home clinical trial program. With regulatory reforms in the future, EP-SOGO expects to handle both hospital and at-home visits through CRCs certified as nurses.

Medidata "Rave eConsent"

"Rave eConsent" is an innovative and patient-friendly electronic informed consent and patient enrollment system. This information onboards patients directly into Rave EDC so that institutions running clinical studies, CROs[*6], and sponsor companies can all verify the same enrollment information. This streamlines informational sharing and can reduce compliance risks to expediate useful analysis of clinical studies.

Medidata's *myMedidata*

myMedidata is a single-destination patient portal for all patient activity that allows patients to enroll and participate in remote clinical studies. Built on the industry's leading Rave EDC, *myMedidata* encompasses all of the capabilities of Medidata's patient-facing solutions. Electronic consent (eConsent), clinical outcomes assessment (eCOA), collection of important data from wearable and other biosensors (Sensor Cloud), tracking of COVID-19 infections, visits through live video conferences with the investigator, patient registries, and a web-based portal facilitate both hybrid and virtual/online clinical trials. Patients can use *myMedidata* from any device connected to the internet to fill out forms, have video conferences with staff at medial institutions, receive reminders and notifications about tasks for a clinical trial, and easily access results.

About EPS Corporation

EPS launched its business in 1991 as a CRO to comprehensively support clinical studies with the

focus on clinical trials and PMS[*7]. The company proposes new models to satisfy customers' needs by leveraging its data science expertise and digital technology cultivated through its extensive track record. These proposals are founded in its Trial GATE concept, which acts as the gateway for all promotion functions of clinical trials.

About EP-SOGO

As an SMO[*8], EP-SOGO supports pharmaceutical and medical device companies to implement GCP[*9]-compliant clinical trials utilizing its wide network of contracted trial sites (medical institutions). EP-SOGO works with investigators, research nurses and administration staff to reduce the total clinical trial work load and improve quality and speed.

About Medidata Solutions K.K.

Medidata Solutions promotes a digital transformation in the life science field to realize the hopes of an even greater number of patients. To maximize the value of new medical treatments, minimize risks, and optimize outcomes, Medidata Solutions supports the day-to-day research efforts of pharmaceutical companies, biotechnology companies, academic institutions, medical diagnostic and device manufactures, and other medical ventures to flush out evidence and gain new insights. More than 1,700 life science companies and organization have adopted the Clinical Cloud Platform provided by Medidata with over a million-certified users. The Clinical Cloud Platform is the largest platform in the world for clinical development, commercial, and even real-world use of data.
Medidata Solutions is a Dassault Systèmes Group company (Euronext Paris: #13065, DSY.PA) servicing clinical trial needs worldwide from its head office located in New York, USA and its other offices located around the globe. Please see its website (https://www.medidata.com/en/) or official Japanese social media accounts at LinkedIn and Facebook for more information.

*1: CRC (Clinical Research Coordinator)
*2: eConsent (Electronic Consent)
*3: CRA (Clinical Research Associate)
*4: DDC (Direct Data Capture)
*5: eCOA (Electronic Clinical Outcome Assessment)
*6: CRO (Contract Research Organization)
*7: PMS (Post Marketing Surveillance)
*8: SMO (Site Management Organization)
*9: GCP (Good Clinical Practice)

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