

ASKA and SUSMED Starts Specified Clinical Trial Using Digital Therapeutics App Designed for Patients with PMS/PMDD

ASKA Pharmaceutical Co., Ltd. (Head Office: Minato-ku, Tokyo/Representative Director: Sohta Yamaguchi, hereinafter "ASKA") and SUSMED, Inc. (Head Office: Chuo-ku, Tokyo/Representative Director: Taro Ueno, hereinafter "SUSMED") announced that two companies started a specified clinical trial (hereinafter referred to as the "Trial") using a digital therapeutics app (hereinafter the "App") designed for patients with Premenstrual Syndrome (hereinafter "PMS") or Premenstrual Dysphoric Disorder (hereinafter "PMDD"), in collaboration with Mariko Ogawa, Ph.D., a specially-appointed professor at Fukushima Medical Center for Children and Woman of Fukushima Medical University. The Trial will also utilize SUSMED's clinical trial system (SUSMED Source Data Sync®, hereinafter "SUSMED SDS"), which implements SUSMED's blockchain technology with the aim of improving the efficiency and quality of acquired data.

Background

In September 2023, ASKA and SUSMED signed an agreement¹ on joint research and development and sales of digital therapeutics apps in the field of obstetrics and gynecology. Based on this agreement, ASKA and SUSMED have been researching and developing this App by utilizing ASKA's knowledge and clinical development capabilities in the disease area, and SUSMED's digital therapeutics app development platform and digital therapeutics app research and development know-how. Through the research and development of this App, ASKA and SUSMED aim to provide new treatment options for PMS and PMDD and contribute to the development of medical care.

1: "Agreement concluded for joint research and development and marketing of digital therapeutics apps in the field of obstetrics and gynecology." (Japanese version only)

ASKA: <https://www.aska-pharma.co.jp/news/filedownload.php?name=2fce6c5392297fbb4da1231ca7eeee22.pdf>

SUSMED: <https://www.susmed.co.jp/news/post/4135/>

Summary of this Trial

This Trial is a specified clinical trial conducted in collaboration with Mariko Ogawa, Ph.D., a specially-appointed professor at Fukushima Medical Center for Children and Woman of Fukushima Medical University, with the aim of investigating the effectiveness and safety of this App for patients with PMS or PMDD.

PMS is defined as mental or physical symptoms that occur for 3 to 10 days before menstruation, and that lessen or disappear with the onset of menstruation. If the symptoms are mainly psychological and severe, they are classified as PMDD. Many women who are aware of PMS do not take appropriate measures, and it has been reported that it causes poor work performance before menstruation and has become a social issue as a health issue and labor loss specific to women.

Utilization of SUSMED's clinical trial system implementing blockchain technology

SUSMED SDS (see reference materials) provided by SUSMED will be used in this Trial. This Trial falls under the category of specified clinical trials under the Clinical Trials Act. Since the enactment of the Clinical Trials Act in 2017, monitoring operations to investigate whether clinical trials are conducted

properly are also required for specified clinical trials in order to ensure the quality and reliability of trials. The data reconciliation and other tasks that are part of the monitoring work have been covered by human resources, which have been pointed out to be inefficient in terms of financial and time-related resources. Thus, the efficient implementation of clinical trials has been an issue. It is expected that the use of SUSMED SDS in this Trial will contribute to reducing monitoring tasks and improving the quality and reliability of acquired data.

Reference materials

■ About ASKA Pharmaceutical Co., Ltd.

ASKA Pharmaceutical is engaged in business focusing on new drugs, specializing in the three key therapeutic areas of internal medicine, obstetrics and gynecology, and urology, under the corporate philosophy: "Contribute toward the improvement of people's health and progress in medicine through the development of innovative products." Under the Medium-Term Management Plan 2025, ASKA aims to become a "total healthcare company based on a specialty pharma company." As a leading company in the field of obstetrics and gynecology in particular, it is engaged in business activities to contribute to solving women's health issues.

Company name: ASKA Pharmaceutical Co., Ltd.

Location: 5-1 Shibaura 2-chome, Minato-ku, Tokyo

Representative: Sohta Yamaguchi, President and Representative Director

Founded: June 1920

URL: <https://www.aska-pharma.co.jp/english/>

■ About SUSMED, Inc.

SUSMED is a research and development company that promotes digital medicine, and working on the development of several digital therapeutics for insomnia and other disorders. In addition, the company have various patents such as medical applications of blockchain technology that leads to efficient clinical trials or mobile apps' technologies that makes digital therapeutics development more efficient and reliable.

Company name: SUSMED, Inc.

Location: 7-2 Nihonbashi Honcho 3-chome, Chuo-ku, Tokyo

Representative Director: Taro Ueno

Founded: February 2016

URL: <https://www.susmed.co.jp/en/>

■ About SUSMED SDS

SUSMED SDS, which implements SUSMED's patented blockchain technology, can reduce Source Data Verification (SDV) by using blockchain technology to ensure the authenticity of source documents and case report data obtained at medical institutions.

The results of the demonstration experiment on the functions of the blockchain technology introduced in the system, such as fault tolerance and data tamper resistance, have been published in several international medical journals (Ichikawa et al., 2017, JMIR mHealth uHealth, Motohashi et al., 2019, JMIR), and clinical research is being conducted with the National Cancer Center with approval by the Cabinet Office regulatory sandbox (A system that established to promote regulatory reform for accelerating business activities using new technologies and business models based on the Act on Special Measures for Productivity Improvement.). The result of the verification test under the regulatory sandbox was published in an international medical journal in June 2020 (Hirano et al., 2020, JMIR). Based on the result of the study, the Ministry of Health, Labour and Welfare (MHLW) issued a notice on December 4, 2020, stating that the SDV using blockchain technology is permitted as an alternative method under the Guideline for Good Clinical Practice (GCP Ministerial Ordinance).

Major examples of utilization

- SUSMED SDS is being used in two domestic Phase III clinical trials^{2,3} conducted by Aculy's Pharma, Inc. in 2022 and 2023. This is the world's first case⁴ of blockchain technology being used in a corporate clinical trial.
- SUSMED SDS is being used in a specified clinical trial on a digital therapeutics app for tinnitus patients researching and developing jointly by SUSMED, Inc. and KYORIN Pharmaceutical Co., Ltd. in 2023⁵.
- In 2024, SUSMED, in collaboration with Tohoku University Hospital, SUSMED established the "Integrated Venous Disease Registry System⁶." This system centralizes the use-results surveys of multiple medical devices and other products related to venous diseases, and can be used for post-marketing database surveillance, utilizing SUSMED SDS. This initiative is unprecedented worldwide, and it is expected that blockchain technology will sufficiently ensure the reliability of the data, enhance the value of the collected use-results surveys, and promote their utilization in applications for guidelines for proper use and for the expansion of indications.

2: "The domestic phase 3 clinical trial of Aculy's Pharma's Pitolisant, for which SUSMED provides a clinical trial system utilizing blockchain technology, starts." (Japanese version only)

<https://susmed.co.jp/wp-content/uploads/2022/11/aw5ser6xc7tv8y9uboni870.pdf>

3: "The domestic phase 3 clinical trial of Aculy's Pharma's Pitolisant treating patients with obstructive sleep apnea syndrome complaining excessive daytime sleepiness, for which SUSMED provides a clinical trial system utilizing blockchain technology, starts." (Japanese version only)

<https://susmed.co.jp/wp-content/uploads/2023/01/roeadxfgfuihoi34w5e6r8789tfyc.pdf>

4: "Aculy's Pharma and SUSMED have entered into a contract to conduct the world's first clinical trial utilizing blockchain technology - Introducing digital transformation (DX) for monitoring work and reducing new drug development costs - "

<https://susmed.co.jp/en/wp-content/uploads/2022/07/4e5r657tyuo7tu6ry5.pdf>

5: "Introduction of the clinical trial system utilizing blockchain technology in a specified clinical trial of the digital therapeutics app for tinnitus " (Japanese version only)

<https://susmed.co.jp/wp-content/uploads/2023/09/rtfgbnikwsxfqbnmyuhi.pdf>

6: "Establishment of an integrated venous disease registry system that promotes the utilization of data collected through the use-results surveys of medical devices - Ensuring labor savings and efficiency in the medical field and the reliability of medical information" (Japanese version only)

https://susmed.co.jp/wp-content/uploads/2024/12/susmed_press20241211.pdf

Notes

The information in this release regarding the App (medical device program) is intended to disclose management information of ASKA and SUSMED, and is not intended to promote or advertise the App.

Media Contacts

ASKA Pharmaceutical Co., Ltd.

E-mail: kouhou@aska-pharma.co.jp

SUSMED, Inc.

E-mail: support@susmed.co.jp