

Press Release

June 29th, 2022
Aculys Pharma, Inc.
SUSMED, Inc.
CMIC Co., Ltd.

Aculys 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 -

Aculys Pharma, Inc. ("Aculys Pharma" Headquarters: Minato-ku, Tokyo, President and CEO: Kazunari Tsunaba), a company focused on the development and commercialization of new innovative drugs in the fields of neurology and psychiatry, has entered into a contract with SUSMED, Inc., a company that promotes digital medicine, ("SUSMED" Headquarters: Chuo-ku, Tokyo, CEO: Taro Ueno) to conduct the world's first¹ corporate-sponsored clinical trial using blockchain technology. The clinical trial utilizing this blockchain technology, provided by SUSMED, will be conducted in collaboration with CMIC Co., Ltd., ("CMIC" Headquarters: Minato-ku, Tokyo, President: Toru Fujieda), a pioneer in drug development support (CRO), with the cooperation of several medical institutions.

With the sophistication of research and development and the increasing cost of new drug development, improving the efficiency of clinical trials is one of the challenges in the pharmaceutical industry that requires addressing. In such an environment, efficient use of resources and pursuit of efficiency are required. And improving productivity and quality of new drug development is also extremely important for society as a whole. Under these circumstances, Aculys Pharma is working to improve productivity and quality of clinical trials by utilizing AI and digital technologies for the development and commercialization of new drugs.

The clinical trial system developed by SUSMED enables the reduction of data entry work and monitoring work² by medical institutions by using the SUSMED-patented technology that binds e-worksheets and eCRF using blockchain technology. In addition to publishing multiple medical papers³, the clinical research that SUSMED conducted with the National Cancer Center has been approved by the Cabinet Office regulatory sandbox⁴. The result of the verification test conducted by the regulatory sandbox was published in the International Medical Journal in June 2020⁵. With this outcome, The Ministry of Health, Labor and Welfare issued a notice on December 4, 2020 that source data verification (SDV: Source Data Verification) using blockchain technology is permitted as an alternative method under the GCP ministerial ordinance.

CMIC will promote these efforts for attaining an efficient clinical trial by 1) supporting the operation of the system at the medical institution, 2) cooperating with development of the e-worksheet and eCRF, and 3) complementing the functions outside the scope of the system.

This clinical trial which utilizes blockchain technology significantly reduces the number of processes around data entry at medical institutions and SDV compared to conventional methods, and also contributes to reducing the number of required CRA visits to the medical institutions. In addition, by taking advantage of blockchain technology, it is expected to have the effect of increasing the reliability of the clinical trial data itself. Through these methods, we aim to improve the efficiency of

the clinical trial-related work-streams necessary for new drug development, and to optimize new drug development costs without compromising reliability.

This clinical trial utilizing blockchain technology, which is a pioneering effort to solve medical problems in Japan, is joined by CMIC, Japan's first CRO company willing to adopt new technologies. By leveraging the strengths of each of the three companies, we will collaborate to achieve improvements in the quality and efficiency of clinical trials. These three companies will continue to contribute to Japanese society by identifying medical issues from a social point of view and by actively utilizing new technologies and external partnerships to resolve them.

1 PubMed (<https://pubmed.ncbi.nlm.nih.gov/>), a medical literature information Data Base, and ClinicalTrials.gov (<https://pubmed.ncbi.nlm.nih.gov/>), a clinical trial information Data Base managed by the National Library of Medicine of the National Institutes of Health. <https://www.clinicaltrials.gov/>), EU Clinical Trials Register (<https://www.clinicaltrialsregister.eu/ctr-search/search>), a clinical trial information Data Base of the European Medicines Agency, and SUSMED research based on other research tool.

2 Monitoring work: work to confirm that clinical trials are being conducted properly according to the protocol. Work also includes source data verification by checking clinical trial data by directly browsing the original medical records.

3 Ichikawa et al., 2017, JMIR mHealth uHealth, Motohashi et al., 2019, JMIR

4 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.

5 Hirano et al., 2020, JMIR

Kazunari Tsunaba, President and CEO of Aculy's Pharma, Inc., stated as follows.

"We are delighted to be able to conduct a clinical trial utilizing blockchain technology in collaboration with SUSMED and CMIC as Aculy's Pharma strives for providing new therapeutic modalities by making full use of the latest in digital technology. We expect this pioneering effort of three companies, which aim to improve the quality and efficiency of clinical trials, will realize digital transformation of clinical trial monitoring work and contribute to the optimization of new drug development costs. We will continue to actively introduce new technologies not bound by a conventional framework and aim to solve social issues surrounding Japanese healthcare by collaborating and partnering with external partners."

Taro Ueno, President and CEO of SUSMED, Inc., stated as follows.

"In the clinical trials conducted in the development of new medical technology, prevention of data tampering and cost efficiency have been issues. While developing therapeutic apps in the healthcare field, we have come to focus on the possibility of using blockchain technology in clinical development and continued research and development. This time, we are delighted to be able to collaborate with CMIC to conduct the world's first clinical trials using blockchain technology in a corporate-sponsored clinical trial of Aculy's Pharma, a company that focuses on the development and commercialization of new innovative drugs. We believe that utilization of blockchain technology enables us to realize efficient and reliable clinical development and we also can contribute for optimization and sustainability of future social security."

Toru Fujieda, President of CMIC Co., Ltd., stated as follows.

"CMIC was established in 1992 as Japan's first CRO and has supported a number of clinical trials of drug development. This time we are participating in the corporate-sponsored clinical trial of Aculy's Pharma with SUSMED. While digitalization will furthermore drive acceleration of process efficiency, we will continue to pursue further improvement of quality and efficiency of clinical trials in monitoring work by utilizing CMIC's know-how based on numerous clinical trial experiences over the past 30 years."

■ About Aculy's Pharma, Inc.

Aculy's Pharma is a biopharmaceutical company focused on the development and commercialization of innovations in the fields of neurology and psychiatry. Its corporate name was created from the philosophy of "Catalyst to Access." Aimed to act as a bridge for innovative medical care in the field of neuropsychiatry, Aculy's Pharma develops and commercializes novel pharmaceuticals and

provides innovations for better medical care to patients, their families, healthcare professionals, and society.

Company name: Aculy's Pharma, Inc.
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Representative: Kazunari Tsunaba
Established: Jan 2021
URL: <https://aculy.com>

■About SUSMED, Inc.

SUSMED, Inc. is an R&D-oriented company that promotes digital medicine. In addition to providing clinical development support systems that utilize blockchain technology, SUSMED, Inc. develops digital therapeutics for insomnia and other disorders. SUSMED, Inc. has acquired various patents for medical applications of blockchain technology and digital therapeutics.

Name: SUSMED, Inc.
Address: 3-7-2 Nihonbashi-Honcho, Chuo-ku, Tokyo
CEO: Taro UENO
Founding: February 2016
URL: <https://www.susmed.co.jp/en/>

■About CMIC Group

CMIC Group was founded in 1992 as the first Contract Research Organization (CRO) in Japan. Today CMIC Group is the largest clinical CRO in Japan with a global footprint, providing comprehensive services in drug development, clinical site management, manufacturing, regulatory consulting and contract sales & marketing solutions. CMIC Group helps pharmaceutical, biotech and medical device companies to enter the Japanese market, to conduct clinical trials in Asia, or to bridge drug development and manufacturing needs in the US, Europe, Japan and broader Asia. CMIC Group has over 7,000 employees and 24 sites globally. For more information about CMIC Group and services, please visit website below.
<https://en.cmicgroup.com/>

Company name: CMIC Co., Ltd.
Address: Hamamatsucho Bldg., 1-1-1 Shibaura, Minato-ku, Tokyo
Representative: Toru Fujieda
Established: Established in March 1985, opened in 1992
URL : <https://www.cmicgroup.com/>

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