SUSMED
Sustainable Medicine

SUSMED Brings Greater Efficiencies in Clinical Trials by Using Blockchain Technology

Deregulations with Remarkable Results from a Regulatory Sandbox

TOKYO--(BUSINESS WIRE)-- SUSMED, Inc., has announced that it has received word from both the Ministers of Health, Labor, and Welfare, and of Economy, Trade, and Industry that the monitoring process, which is considered as necessary in clinical trials of pharmaceutical or medical equipment, can be replaced with the use of SUSMED's blockchain technology, and it does completely comply with the government directive. This government's conclusion comes from the remarkable achievements of the regulatory sandbox in 2019, in which SUSMED implemented its blockchain technology in the research with the National Cancer Research Center of Japan.

SUSMED will provide this blockchain technology system with pharmaceutical manufacturers, university hospitals, and other research institutions who are enthusiastically looking to increase efficiencies of clinical trials.

Since 1998 when the Good Clinical Practice (GCP) Ordinance was enacted, outsourcing costs to both contract research organizations (CROs) and site management organizations (SMOs) have been ballooning. Monitoring process (i.e. source data verification (SDV) with direct inspections), which is required by the GCP Ordinance in order to assure both the quality and reliability of clinical trials data, have also been a heavy burden for sponsors. In addition to that, the Clinical Research Act was implemented in FY2018 due to data falsification cases in clinical trials. It requires monitoring process even in specified clinical research, which also places a lot of loads on research facilities.

Monitoring is conducted by clinical research associates (CRAs) checking data in case report forms (CRFs) against source data during facility visits. It usually takes a lot of time, costs a lot of CRAs' wages and travel expenses. Although a variety of ways of monitoring, expected to reduce these burdens inherent in monitoring, have been proposed and attempted, none of them becomes a fundamental solution. Furthermore, with the spread of COVID-19 infections in the past year, CRAs have been refraining from visiting to medical facilities, which makes it difficult for them to confirm source data on site.

SUSMED has developed a clinical trial system which uses blockchain technology to thwart data falsification. Not only does this improve security levels in comparison to conventional methods, this system is much cost-efficient and enables to manage data in ways that ensure its accuracy.[1] Trial of the system received authorization in April of 2019 for a regulatory sandbox as part of a medical application of blockchain technology, and SUSMED together with the National Cancer Research Center of Japan carried out monitoring with the system in an actual clinical trial settings. During the trial, it has been verified that data reliability was maintained even without CRAs' visiting to medical facilities and the physical checking of between source data and CRFs.[2]

At the same time, there has been ongoing discussion about efforts to revitalize clinical trials within the Clinical Research Section of the Health and Welfare Science Council at the Japanese government. Moreover, the Headquarters for Healthcare Policy, a function of the Cabinet Secretariat directly reporting to the Prime Minister on pharmaceutical development topics, has also discussed a research system leveraging new technologies and new approaches as a top priority issue around research and development for pharmaceuticals. Under these circumstance in which the government are seriously considering productivity improvement with digital technologies, SUSMED's system has been recognized, due to the achievement in the regulatory sandbox, as practical countermeasure for clinical trial inefficiency in the growth strategy follow-up of Cabinet meetings in July, 2020.

Based on the outcome from the regulatory sandbox and the word in the growth strategy follow-up, SUSMED applied for the System to Eliminate Gray Zone established within the Industrial Competitiveness Enhancement Act so as to get confirmation that using SUSMED's blockchain technology in order to replace the SDV for the increase aforementioned monitoring efficiency would not violate the stipulations of the GCP Ordinance.

Today, SUSMED has received a response to its application from the Ministers of Health, Labor, and Welfare, and of Economy, Trade, and Industry, indicating that the use of blockchain technology eliminates the requirement for on-site SDV on clinical trials.[3] (See the attached reference materials.)

With this government interpretation in hand, SUSMED will provide the system for clinical trials and clinical research with pharmaceutical manufacturers, university hospitals, and other research organizations as a measure to increase clinical trial efficiencies.

SUSMED aims to contribute to maintaining and strengthening the international competitiveness of Japanese medical industries as well as sustaining social security in Japan via increasing clinical research development efficiency with fundamental reforms of labor-intensive monitoring process.

Footnotes:

1. https://mhealth.jmir.org/2017/7/e111/, https://www.jmir.org/2019/5/e13385/
2. https://www.jmir.org/2020/6/e18938/
3. https://www.meti.go.jp/policy/jigyou_saisei/kyousouryoku_kyouka/shinjigyo-kaitakuseidosuishin/result/gray_zone.html

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