SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

CASE STUDY:

Signant's Rapid eConsent Implementation Contributes to the Advancement of DCTs in Japan

SUMMARY:

A major Japanese pharmaceutical company (sponsor) leveraged Signant's eConsent solution to support an observational study. The study was designed to demonstrate and validate how decentralized clinical trial (DCT) methods such as remote informed consent and central rating COA measurement can reduce trial participation burdens for sites and patients as well as support patient engagement.

Signant collaborated with the sponsor, Tokyo Center Clinic, and an independent consulting firm Inclusion Partner Inc., which supports operations related to clinical trial implementation.

TRIAL SUMMARY:

Study Phase: Validation

Therapeutic Area: CNS - Psychiatry

Indication: Major Depressive Disorder (MDD)

Participant Population: Adults above 18 and under 65

Number of Participants: 61
(31 MDD patients, 30 healthy subjects)

Number of Sites: 8
(1 leading site, 7 partner sites)

Countries: 1 (Japan)

Languages: 1

OVERVIEW:

Major Depressive Disorder studies often require consistent follow-up visits and in-person evaluations, which can be a barrier to trial participation for these patients. This can lead to low participation and retention rates, and unreliable endpoint data. Testing DCT approaches as solutions to these challenges, a major Japanese pharmaceutical company and Tokyo Center Clinic intended to validate remote HAM-D assessment and EEG measurement. The study teams also identified opportunities to apply eClinical technologies to support home-based trial participation activities.

Having had previous exposure to Signant's eClinical solutions, the study team selected Signant SmartSignals® eConsent to facilitate rapid enrollment of patients distributed across multiple sites throughout West and East Japan, reduce the burden of Informed Consent Form (ICF) management, and increase patient engagement.

CHALLENGES:

In clinical trials requiring visits to medical institutions from patients, there are physical and time barriers to study participation. Although patients residing in areas allowing them to visit sites have a chance to participate, patients residing in other areas do not. Moreover, trial participation is only possible during the hours at which sites are open for patients' visits. The main objective was to address these barriers.

Another priority was to resolve the common issues associated with the paper-based consenting process. Paper-based consent processes often result in ICFs with errors or ambiguous data, as well as problems related to version control and management.

Additional challenges for this study included:

- Rapid enrollment over a short period
- Adherence to IRB submission timelines
- Professional GPM service delivery in Japan time zone
- Translations of user interfaces as well as site and patient manuals
- Stakeholder communication and collaboration across languages and time zones

SOLUTIONS:

- Signant rapidly designed and implemented an eConsent solution customized to meet Tokyo Center Clinic's exact requirements, completing user acceptance testing (UAT) within three days.
- For seamless site communication and support, Signant dedicated staff to manage all support requests and coordinate activities between all stakeholders.
- The implementation also provided detailed tracking and analysis of participant interactions with the eConsent platform, including login activity.

RESULTS:

- Study participants were recruited electronically, consent explanations and acquisition were conducted remotely using eConsent. Examinations were conducted by the Tokyo Center Clinic and seven partner sites across Japan. Flexible eConsent solution and connection with partner sites removed both physical and time barriers, and increased patient engagement.
  - **36 (59%)** of all registered participants participated from other areas than the vicinity of the participating sites in Hokkaido (Sapporo), Aichi, Osaka and Fukuoka prefectures.
  - Patients received flexibly consent information, and consent could be obtained outside of sites' standard working hours: **31% of all logins occurred over the weekend; 18% of logins took place before 9 am and after 9 pm.**
- Signant's rapid eConsent solution design and implementation, along with quick customer validation, seamless support, and collaborative approach, contributed to a positive DCT experience for all stakeholders.
- Registration of all participants (61) was completed in a very short three-month period from September to December 2023.
- As a result of the study, the sponsor, site, consulting company, and Signant all solidified their roles as proven agents of more efficient clinical trials in the APAC region in Japan.

ABOUT SIGNANT HEALTH

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Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently capture, aggregate, and reveal quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 25 years, over 600 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, EDC, eConsent, RTSM, supply chain management, and data quality analytics. Learn more at www.signanthealth.com.