

## CASE STUDY:

# SIGNANT SMARTSIGNALS eCOA

Signant SmartSignals eCOA, with its quick setup and data-collection features, played a vital role in Shionogi Pharmaceuticals' clinical trial of a COVID-19 oral antiviral drug by enabling the speedy enrollment of trial patients and retrieval of resulting data. Signant met Shionogi's needs by providing excellence in the Four S's of eCOA: Solution (with its technical capabilities), Science (generating reliable evidence), Scale (support for multinational studies), and Service (global project management).

### OVERVIEW:

In July 2021, amid the global COVID-19 pandemic, Shionogi Pharmaceuticals (hereinafter "Shionogi") prepared for Phase II/III clinical trials of a COVID-19 therapeutic drug with the intent of introducing the drug to society upon regulatory approval. Shionogi chose Signant Health's electronic Clinical Outcome Assessment (eCOA) system to support its goals of rapid trial implementation and high-quality data.

### TRIAL SUMMARY:

- **Study Phase:** II/III
- **Therapeutic Area:** Covid-19
- **Age of Patients:** 12+
- **Number of Patients:** 2,000+
- **Number of Sites:** 90+
- **Countries:** 4
- **Languages:** 5+

### CHALLENGES:

Shionogi's study required the following:

- 01 Real-time remote monitoring of patient-reported COVID-19 symptoms, blood oxygenation levels (SpO2), and body temperatures using the eCOA system.
- 02 Strong compliance, leading to reliable evaluation of drug efficacy and safety.
- 03 Quick system set-up, including scale acquisition, to facilitate early study start and patient enrollment in the midst of a global pandemic.

To overcome these challenges, Shionogi chose Signant SmartSignals eCOA, recognizing its industry-leading technical capabilities, global scale with local project management, and global logistics services were essential to the success of the study during the pandemic.

The trial was initially carried out in Japan only. However, enrolling trial patients became increasingly difficult with the decline of new COVID-19 cases in Japan shortly after enrollment began in September 2021. Shionogi decided to expand the trial to other countries, and Signant quickly supported the expansion process with its ability to respond quickly on a global scale.

### SOLUTIONS:

- 01 **REAL TIME ACCESS TO DATA**  
The system was configured to enable real-time monitoring of eCOA data, and performance indicators, such as ePRO completion rates and the status of site staff's access to the system, to ensure essential compliance monitoring.
- 02 **FLEXIBLE IMPLEMENTATION PLANNING**  
The user interface, reporting, and data export functions were designed and built in a phased process using three incremental steps to enable rapid study start timelines to be met. Project management was implemented globally.
- 03 **SUPPORT FOR TRIAL EXPANSION OUTSIDE JAPAN**  
Additional resources were allocated to the project management team to provide Shionogi with device logistics, which were becoming increasingly more complex under the pandemic, and 24/7 helpdesk support for site staff and trial patients in their respective local languages.

## BENEFITS OF SIGNANT SMARTSIGNALS eCOA:

- **HIGH DATA QUALITY THROUGH IMPROVED DATA ENTRY COMPLIANCE**

The eCOA system enabled site staff to access and monitor patient-reported data in real-time. In addition, patients were supported by Signant's global helpdesk services. These resulted in better patient eCOA completion compliance, and facilitated a reliable assessment of the drug's efficacy and safety.

- **SIGNANT'S RAPID PREPARATION LED TO PATIENT ENROLLMENT AHEAD OF SCHEDULE**

In Japan, enrollment was initiated within ten weeks following trial kick-off, and in South Korea, the time between trial expansion and patient enrollment was only six weeks, in both instances, exceeding Shionogi's expectations.

### ABOUT SIGNANT HEALTH



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 20 years, over 400 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, eConsent, RTSM, supply chain management, and data quality analytics. For more information, please visit [www.signanthealth.com](http://www.signanthealth.com).

### ABOUT SHIONOGI



Shionogi & Co., Ltd. is a pharmaceutical company that celebrated its 145th anniversary in 2022. Throughout its long history, Shionogi has always been striving to supply the best possible medicine to protect the health and wellbeing of the patients it serves. Shionogi has also been a leading company in the field of infectious diseases, engaging in the research and development of new drugs to treat infections such as HIV, influenza, and AMR (antimicrobial resistance that is emerging as a global health threat), as well as building a total care system to manage infections, including health promotion, prevention and exacerbations control. For more information, please visit the company's website: <https://www.shionogi.com/global/en/>