SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

CASE STUDY:

SIGNANT SMARTSIGNALS RTSM & DIRECT-TO-PATIENT CLINICAL SUPPLY MANAGEMENT

OVERVIEW:

A multinational pharmaceutical company implemented Signant Health's RTSM solution in a multiregional pediatric study to execute a mid-study switch to a central pharmacy direct-to-patient model, which replaced daily in-clinic dosing of the investigational product.

TRIAL SUMMARY:

Study Phase: Phase II

Therapeutic Area: Immunology

Participant Population: Pediatric

Number of Subjects:
30 patients

Number of Sites: 20 sites

Countries: 8 countries

CHALLENGES:

01

MAINTAINING FULL OVERSIGHT & INVESTIGATOR AUTHORITY

Study teams needed full visibility into treatments administered at home to ensure adherence to protocol, while limiting the visibility of secure patient information to home nurses.

02

IMPLEMENTING A MID-STUDY CHANGE THAT SIGNIFICANTLY ALTERED SUPPLY CHAIN MANAGEMENT

There needed to be a transition period to allow for the logistics of at-home delivery to occur while the patient was still actively visiting the clinic.

03

ENSURING AN INTEGRATED SOLUTION WITH HOME HEALTHCARE PROVIDERS

Due to the administration method of the supply, participants who opted out of in-clinic visits had to be visited daily by an at-home healthcare provider.

04

INCLUDING INDIVIDUAL FLEXIBILITY AND CHOICE FOR THE PATIENT/CAREGIVER/INVESTIGATOR

The direct-to-patient model needed to be configurable in nature to give patients or caregivers the choice to opt in or out of home delivery, and to allow investigators to determine whether an in-clinic visit was necessary.

SOLUTIONS:

01 SPECIALIZED REPORTING PROVIDED FULL VISIBILITY TO SITES

Signant enabled specialized reporting to ensure site and home healthcare providers gained visibility only to what they needed to fulfill their responsibilities. Sites had full visibility to all activity for their patients whether the visits were in clinic or at home, providing investigator oversight for at-home injections, while healthcare providers and nurses only had limited visibility to reports related to home visits.

02 FLEXIBLE RTSM ADAPTATION

Our RTSM solution was adapted to facilitate the transition to at-home visits while maintaining the ability to record in clinic. Site inventory levels were also adapted to accurately account for which upcoming visits were scheduled in clinic or at home, helping to ensure that sites had proper buffer levels and drugs on site for planned visits without the risk of overstocking the site for visits that were already set up for at-home dosing.

03 COORDINATION WITH HOME NURSES TO FOLLOW DRUG ACCOUNTABILITY PROCESSES

The sponsor partnered with home healthcare nurses who, upon arrival to the patient's home, were tasked with inspecting the shipment from the central pharmacy to ensure all contents were intact and stayed within the appropriate temperature range before handling returns or administering treatment. Following administration, standard drug accountability processes were followed in the RTSM system.

04 OPTIONAL TRANSACTION ADDED TO RTSM

An optional transaction was added to our RTSM system that allowed participants to transition to at-home visits after enrollment, relieving burdens associated with daily site visits. However, the frequency of at-home versus in-clinic visits remained at the discretion of the Investigator, in conjunction with participants' preferences.

ABOUT SIGNANT HEALTH

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

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.