SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

CASE STUDY:

SIGNANT SMARTSIGNALS RTSM & CLINICAL DRUG DISPENSATION

OVERVIEW:

A pharmaceutical company implemented Signant Health's RTSM solution in a multiregional trial for schizophrenia patients to help properly dispense the investigational products around evolving visit schedules as well as maintain study balance across three subgroups over 26 weeks of treatment.

TRIAL SUMMARY:

Study Phase: Phase II

Therapeutic Area: CNS - Psychiatry

Indication: Schizophrenia

Participant Population: Adults with Schizophrenia

Number of Subjects: 150

Number of Sites: 35

CHALLENGES:

01

ENSURE SUFFICIENT DOSES UNTIL THE NEXT VISIT WHILE REDUCING WASTE

Due to the changing nature of the visit schedule because of the patient population, the key aim of the study was to ensure that each patient had access to enough of the investigational drug to allow for variable visit durations, which also posed expiry challenges.

02

MAINTAIN STUDY BALANCE ACROSS MULTIPLE STRATA AND SUBGROUPS

The patient population was stratified into three subgroups by the type of anti-psychotic medications the patients were currently taking. Each subgroup was then assigned a different dose of the investigational product or the placebo.

03

PREVENT INVESTIGATIONAL PRODUCT ALLOCATION TO DUPLICATE SUBJECTS

There were occasions where patients visited multiple sites to receive a larger dose of the investigational drug, impacting the endpoint reliability of efficacy data.

04

MANAGE RETURNS AND DESTRUCTION OF EXPENSIVE, CONTROLLED INVESTIGATIONAL PRODUCT

In all cases, including for early patient termination, unused investigational products had to be returned, accounted for, and properly destroyed. Destruction would then need to be verified and logged.

SOLUTIONS:

01 ENABLE USE AND RE-USE OF KITS ACROSS MULTIPLE VISITS

Signant's RTSM ensured that while new investigational products were dispensed for the current visit being allocated, there was also the ability to indicate an existing assigned kit as a backup (or to request a new backup). This ensured that no patient was ever without doses and even accounted for some visits being performed outside of the standard schedule. Our solution also helped to optimize supplies with sooner expiry and verify that all supplies were within a known stability range while in the patient's possession.

02 TRACK AND MANAGE DISPENSATION ACROSS SUBGROUPS

Our proprietary RTSM algorithms were flexible enough to adapt when visit schedules changed, and when lost or damaged doses needed to be replaced or when a patient required extra doses to carry them through to their next visit. Each dispensation was also recorded and tracked within the RTSM system.

03 RTSM NOTIFICATIONS FOR ALL TRANSACTIONS

Signant's RTSM provided reporting capabilities and contained a notification system that alerted appropriate stakeholders every time a transaction was conducted, including investigational product releases, patient visits, expiry date changes, and shipment requests or returns. Site personnel were warned about the possibility of duplicate patient registration during that process. The sponsor could also access a summary report that was sorted or filtered to identify duplicates.

04 RETURNS ACCOUNTABILITY SUMMARY WITHIN RTSM SYSTEM

The full tracking record for the reconciliation, return, and destruction of unused investigational products was conveniently logged within Signant's RTSM system, which provided all appropriate stakeholders with visibility to the returns accountability summary provided by the site monitor. Pill-level accountability that was handled at the destruction facility was also logged.

ABOUT SIGNANT HEALTH

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 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.