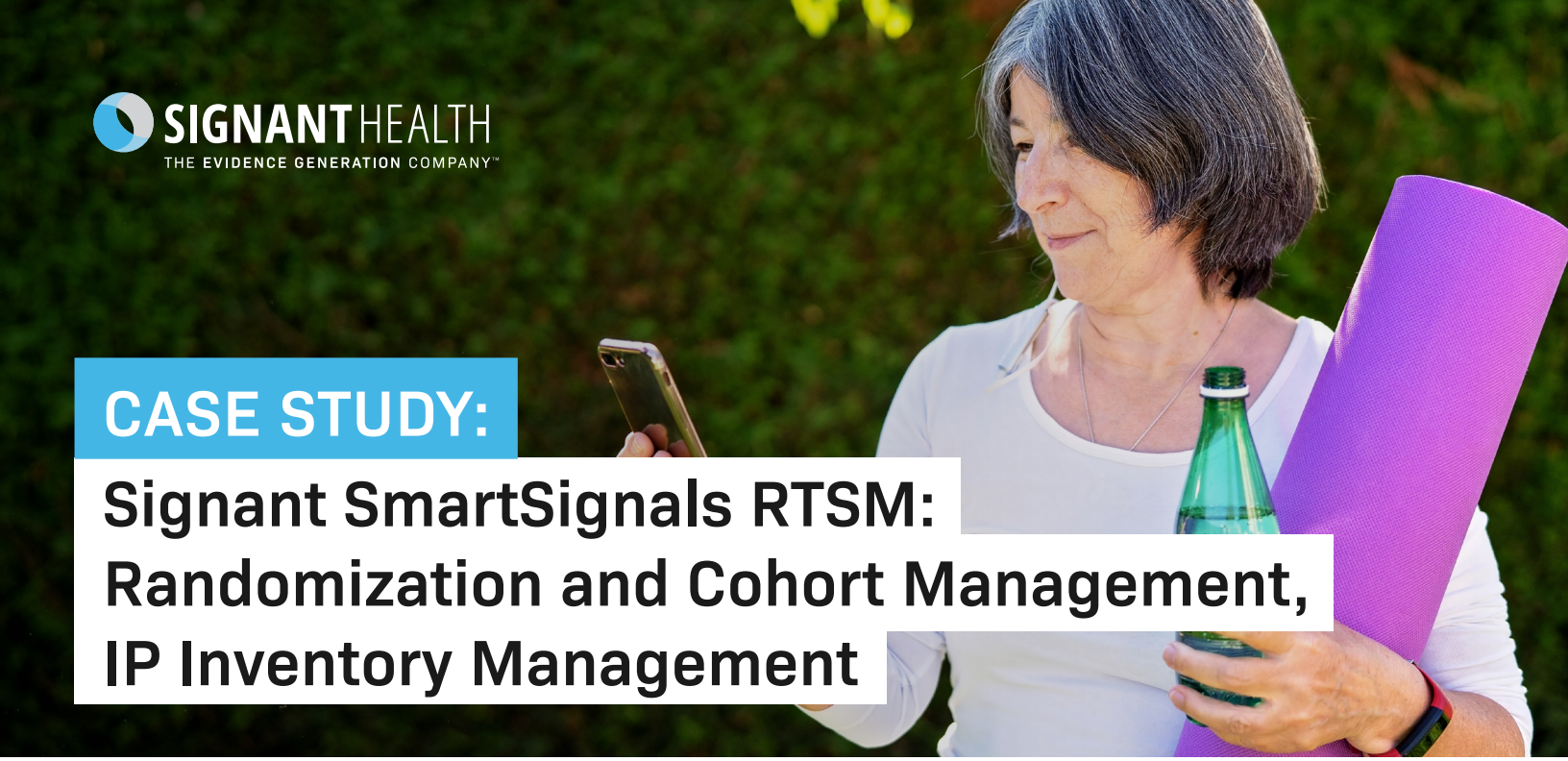
SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™



CASE STUDY:

Signant SmartSignals RTSM: Randomization and Cohort Management, IP Inventory Management

OVERVIEW:

Signant's SmartSignals RTSM solution helped an innovative biopharmaceutical company secure an FDA Orphan Drug designation for its cardiomyopathy drug.

TRIAL SUMMARY:

Study Phase: Phase II

Therapeutic Area: Cardiovascular

Participant Population: Adults

Number of Participants: 90+

Number of sites: 30

Countries: 4

CHALLENGES:

01

INTRICATE RANDOMIZATION AND COHORT MANAGEMENT

The protocol required an RTSM system that could accommodate numerous cohorts, each with varying drug combinations and visit schedules. Highly complex logic was needed to ensure the proper IP formulations were provided to each patient at each visit.

02

SEAMLESS TRANSITION OF ELIGIBLE PATIENTS FROM PHASE II TO PHASE III

The protocol allowed appropriate patients to migrate from the Phase II to the larger Phase III study, requiring a rigorous tracking process to ensure only approved patients could participate.

03

COMPLEX IP INVENTORY REQUIREMENTS

The protocol allowed for Principal Investigators to modify the IP dosage and visit schedules as patients responded to the treatment, so the RTSM system needed to adapt and respond in near real time to varying levels of IP required at each site.

SOLUTIONS:

01

COMPREHENSIVE, VERSATILE MEDICATION MANAGEMENT SOLUTION & OPERATIONAL SUPPORT

The set-up team studied the protocol, developed the complex on-site titration, dispensation, and scheduling logic, then articulated its design to the customer.

02

PATIENT COHORT & RANDOMIZATION MANAGEMENT SCHEME

The RTSM system design enabled seamless transition of eligible patients from Phase II to Phase III. Signant's project managers conducted regular meetings with the sponsor to ensure only appropriate patients rolled over to the next phase. Signant's expert set-up and implementation teams were a major reason why the customer chose to switch from another RTSM provider.

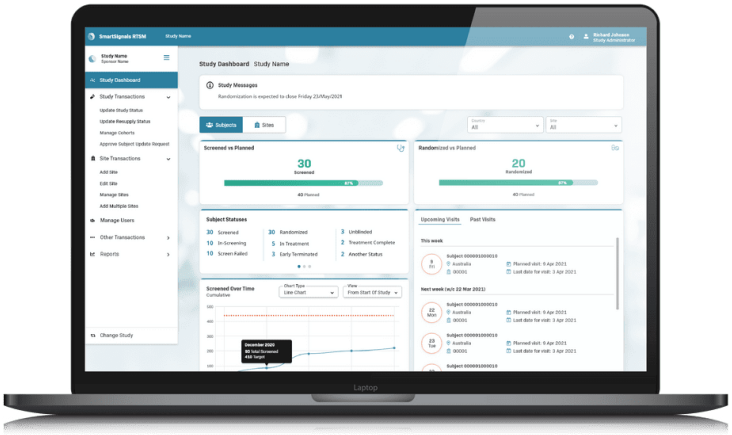
03

ROBUST REPORTING & REAL-TIME DATA

Dynamic and detailed reports from the SmartSignals RTSM solution provided the client with timely information about patient dosing and inventory levels, even with the adaptive nature of the study's IP use and scheduling. Signant's project team, which included a technical solution architect, biostatistician, clinician, and project manager, implemented changes quickly and provided supplementary training as needed. The system's agile-based design capabilities along with responsive project delivery ensured sites were well-supplied with the test compound.

RESULTS:

- The client was pleased with the performance of Signant's RTSM solution during Phase II and successfully extended its use into Phase III.
- The compound under study was granted Orphan Drug designation by the FDA in early 2021.



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 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.