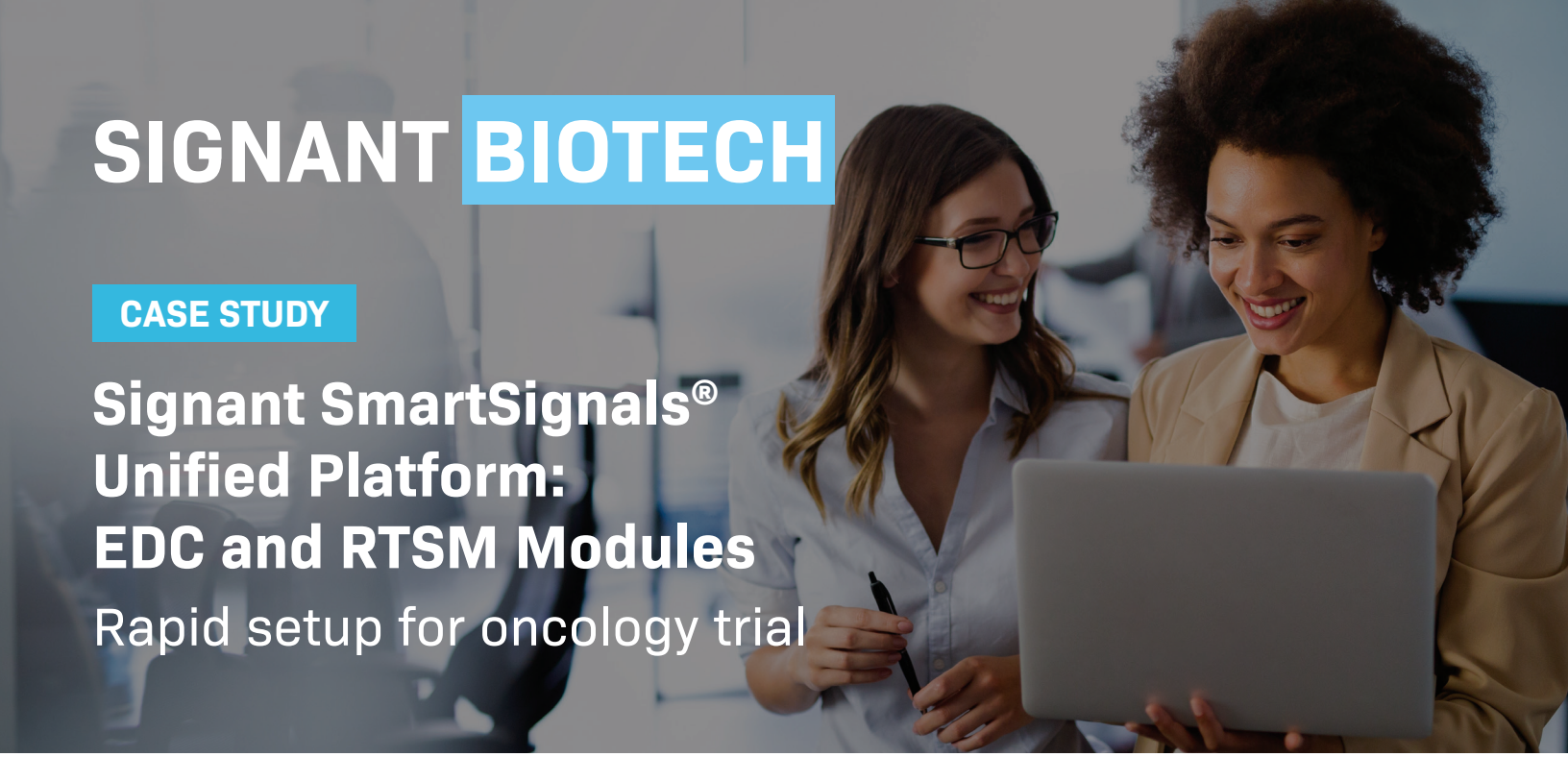

SIGNANT BIOTECH

CASE STUDY

Signant SmartSignals® Unified Platform: EDC and RTSM Modules

Rapid setup for oncology trial

Overview:

Signant Biotech helped an emerging biopharmaceutical company accelerate phase I of a new treatment for relapsed/refractory multiple myeloma, enabling successful application for breakthrough therapy designation.

Trial Summary:

Study Phase: Phase I

Therapeutic Area: Oncology

Participant Population: Adults

Number of Participants: 65+

Number of Sites: 10+

Number of Countries: 1 (USA)

Solutions: EDC, RTSM

Challenges:

01 ACCELERATE PHASE I START TO DRIVE EARLY APPLICATION FOR BREAKTHROUGH THERAPY

The sponsor expressed frustrations with the ability of existing vendors to meet study timelines, and different vendors' degree of expertise in translating protocol requirements into eCRFs and study-specific solution design. They sought a vendor that could deliver on time, and simplify their collaboration by applying disease indication experience to the interpretation of the protocol, and the development of the EDC solution and study database.

02 ENABLE COMPREHENSIVE PATIENT OVERSIGHT AND STUDY MANAGEMENT

The sponsor needed a vendor that could use their disease indication expertise to enable real-time access to insightful medical and statistical monitoring data throughout the study to enhance patient oversight and study management.

03 ACCELERATE DATABASE LOCK AND TIMELY STUDY ANALYSIS AND BREAKTHROUGH THERAPY APPLICATION

The sponsor intended that this Phase I study would form the basis of breakthrough therapy designation with the FDA, and PRIME eligibility application with the EMA. As such, the study and its findings were on the critical path for regulatory submission, and achieving rapid database lock was an important element.

Solutions:

01 COMBINE CONFIGURABLE MODULE DESIGNER WITH A CAR-T EXPERIENCED PROJECT TEAM TO DELIVER SOLUTION AHEAD OF TIME

Signant SmartSignals® Unified Platform is supported by a highly configurable designer that enables rapid study builds and efficient re-use without software coding. Signant's implementation specialists worked with a multi-disciplinary team of project managers, data managers and biostatisticians with CAR-T and multiple myeloma experience, to quickly design and implement the eCRF set, EDC and RTSM solutions, and study-specific workflows, to expertly meet the requirements of the study protocol.

02 ANALYTICS DASHBOARDS TO ENABLE ONGOING STUDY MONITORING

Our multidisciplinary project team, including clinicians with expertise in multiple myeloma, developed study-specific analytics dashboards to identify trends as well as facilitate ongoing medical and statistical monitoring of the study data.

03 DRIVE CLEAN DATA, QUICKLY

In-built data validations, reconciliations, and compliance checks enabled the project team to drive clean data and a timely database lock.

Outcome:

Signant Biotech was able to implement an EDC and RTSM system, built specifically for CAR-T treatment, two weeks faster than the proposed timeline, while taking into account all the study needs, including custom workflows and real time analytics.

Early submission led to breakthrough therapy designation from the FDA, and PRIME status from the EMA.

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

Signant Biotech is part of Signant Health, 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.