

SIGNANT SMARTSIGNALS® UNIFIED PLATFORM: EDC WITH RANDOMIZATION

Rapid setup for oncology trial



OVERVIEW

Signant 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: I

Therapeutic Area: Oncology

Participant Population: Adult

Geographic Scope: 1 country (USA)

Number of Sites: 10+

Number of Participants: 65+

Solutions: Our foundational EDC solution and its add-on module for Randomization

CHALLENGES

① 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.

② 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.

③ 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

① COMBINE CONFIGURABLE 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 Randomization module, and study-specific workflows, to expertly meet the requirements of the study protocol.

② 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.

③ 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.

RESULTS

- Signant was able to implement an EDC and Randomization 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.

WHO IS SIGNANT HEALTH?



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