SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

SIGNANT SMARTSIGNALS® UNIFIED PLATFORM SUPPORTS RAPID IMPLEMENTATION OF EDC RESCUE STUDY

OVERVIEW

Signant helped an emerging biopharmaceutical company get an ongoing phase III study back on track, following performance and service concerns with an existing vendor.

TRIAL SUMMARY

Study Phase: III

Therapeutic Area: CNS

Participant Population: Adult

Geographic Scope: 1 country (USA)

Number of Sites: 55+

Number of Participants: 350+

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

CHALLENGES

1 RAPID IMPLEMENTATION OF STUDY BUILD AND MIGRATION TO SMOOTH TRANSITION BETWEEN VENDORS

The sponsor sought a migration plan that would enable effective and rapid transition between vendor solutions, to minimize site user disruption, and reduce risk to the study.

2 FAST, SEAMLESS POST-GO-LIVE PROTOCOL AMENDMENT IMPLEMENTATION

A number of study amendments were planned which would require changes to the EDC solution and Randomization module. Based on poor previous experience with the current vendor, the sponsor sought an attentive provider that could implement changes quickly with minimal disruption to sites and patients.

3 RE-USE EFFICIENCY TO SPEED THE IMPLEMENTATION OF A SECOND, PIVOTAL TRIAL

A second, global phase III study was planned but had not started. The sponsor sought a provider that could implement the integrated EDC and Randomization solution for this study in a timely manner, and provide good re-use efficiency from the implementation of the first study.

SOLUTIONS

1 DEVELOP A MIGRATION PLAN AND LEVERAGE RAPID BUILD CAPABILITIES

Within four weeks of the contract agreement, Signant fully implemented a migration plan and executed the data migration to the exact format of the Sponsor's request. Our configurable designer and forms/templates library ensured that the EDC solution and Randomization module were configured rapidly, within a single build. Project and data management experts ensured that the data migration was done efficiently, effectively, and on time.

2 IMPLEMENT MID-STUDY CHANGES WITHOUT DOWNTIME

Signant supported five patient population and randomization schema changes requiring the randomization strata to increase to 32 from the original eight. Using the unified platform's simple designer ensured that mid-study amendments could be implemented seamlessly with no downtime interrupting site users. Signant's attentive project delivery team ensured changes were acted upon rapidly.

3 REUSE STUDY FORMS AND TEMPLATES TO SAVE TIME

A second phase III trial was implemented in a similar timeframe. The unified platform's designer generates a CDISC ODM database, and this standardization facilitated the re-use of existing study forms and templates, and other library elements, to enable efficient and expedient implementation of the second pivotal trial.

RESULTS

- Signant executed the study migration with minimal disruption to study sites by leveraging an improved and efficient database. In addition, expert, highly responsive project management services ensured ongoing study amendments were implemented rapidly. Further, Signant implemented an integrated EDC and Randomization solution for the second study on time, and to the required specification.

WHO IS 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 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**.