SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

Case Study Signant SmartSignals eCOA

SIGNANT'S EXPERIENCE & eCOA STUDY DESIGN CAPABILITIES HELP CNS TRIALS MEET KEY MILESTONES

Signant's rapid eCOA design and launch solutions, coupled with an expertise-driven, consultative approach, helped a sponsor get three Phase II studies back on schedule.

OVERVIEW:

When a global pharmaceutical organization's key clinical development programs became in danger of missing critical project milestones while working with a different vendor, Signant stepped in, applying **a consultative strategy, flexible eCOA design tools, and scientific expertise** to help the sponsor get back on schedule for three Phase II narcolepsy type 1 studies. However, to successfully rescue these studies, the project schedules and other complexities required more than just good, capable technology solutions.

TRIAL SUMMARY:

- **Study Phase:** II
- **Therapeutic Area:** CNS - Neurology
- **Patient Population:** Adults
- **Number of Patients:** 140+
- **Number of Sites:** 65
- **Instruments:** 13
- **Countries:** 12
- **Languages:** 16

CHALLENGES:

01 The studies required numerous assessments, including complex ClinRO and several PRO instruments, as well as many languages which had to be accounted for in the eCOA study design.

02 The sponsor's study team had already been working with an eCOA vendor, but system design specifications proved too complicated to be able to meet mission-critical milestones.

03 The study team needed experienced clinical, technical, and operational experts to guide the solution design and testing as well as support decision making.

SOLUTIONS:

01 Signant leveraged its flexible, modern eCOA study design tools and comprehensive technical capabilities to expedite the project build for the three studies.

02 With more than 20 years of experience as well as mature project delivery processes and resources, Signant's project team produced simplified, easy-to-understand specifications documentation to ensure comprehensibility and facilitate decision making.

03 By leveraging in-house clinical and eCOA science expertise, Signant advised the sponsor's study team on COA implementation, modality strategy, and other considerations for study build, enabling delivery of a complex solution through a simplified build methodology.

RESULTS:

The trial sponsor met its FPFV milestones with help from Signant's rapid study design and build capabilities, which ensured critical functions were built, tested, and launched in time. Relying on its expertise with complex, global eCOA projects, scientific know-how, and mature operational delivery models and resources, Signant helped the sponsor get back on schedule. Through this process, the study teams built a high-quality data capture solution, backed by experienced scientific and operational professionals, which served as a springboard for study success.