SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

CASE STUDY:

SMARTSIGNALS eCOA

Signant Health helped a sponsor accelerate the delivery of a life-saving treatment to waiting patients

OVERVIEW:

Signant helped a top pharmaceutical company prove the efficacy and safety of a novel oncology treatment. The treatment was awarded FDA approval in spring 2021 and EMA approval in winter 2022.

TRIAL SUMMARY:

- **Study Phase:** Phase II
- **Therapeutic Area:** Oncology
- **Patient Population:** Adults
- **Number of Patients:** 550+
- **Number of Sites:** 150+
- **Patient-Reported Outcome Instruments:** 9
- **Countries:** 15+
- **Languages:** 25+

CHALLENGES:

Signant Health was asked to provide eCOA support for the sponsor's Phase II study of a compound that would help tens of thousands of cancer patients throughout the world. When interim results proved positive, the sponsor added a new cohort that more than doubled the patient population, included additional patient-reported outcome measures (PROMs), and required adding five additional countries. Signant was asked to quickly accommodate this design adaptation to enable rapid patient access to treatment and accelerated study timelines. This posed several challenges:

01 **SCALE MANAGEMENT**

Two new PROMs were added to the study for both the new and initial cohorts, after the first study period.

02 **LOCALIZATION**

An additional 10 languages were added, all requiring translation, linguistic validation, and license holder approvals.

03 **GLOBAL LOGISTICS**

350 patients and 50 sites in five new countries were added to the study and all required provisioned devices – tablet computers for sites, and smartphones for patients.

SOLUTIONS:

01 **SCALE MANAGEMENT**

Signant leveraged existing relationships with the license holders to ensure the correct versions of the new PROMs were acquired in a timely manner. Operational teams implemented the new scales in the system and provided screen reports for rapid sponsor, license holder, and IRB approvals.

02 **LOCALIZATION**

Signant worked with our preferred provider to expedite PROM translations and their associated certifications as well as obtain license holder approvals in the additional ten languages.

03 **GLOBAL LOGISTICS**

Signant provided the additional tablets and smartphones, effectively navigating country-specific customs. We also provided hands-on training to site staff that covered the provisioned devices and web portal.

RESULTS:

Faster implementation of mid-study protocol amendments

Oncology patient eDiary questionnaire adherence

Site questionnaire adherence

- The sponsor submitted its Phase II findings to the major regulatory agencies. The FDA granted approval for this first-of-its-kind treatment in spring 2021 and the EMA granted its approval in January 2022.
- The sponsor was very pleased with Signant's expertise, responsiveness, and data quality. Signant was awarded the follow-on Phase III study, along with other studies relating to the new compound.

ABOUT 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 20 years, over 400 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, eConsent, RTSM, supply chain management, and data quality analytics. For more information, please visit www.signanthealth.com.