SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

CASE STUDY:

SMARTSIGNALS eCONSENT

OVERVIEW:

A global biopharmaceutical company implemented Signant Health's eConsent solution in a multinational breast cancer study.

TRIAL SUMMARY:

- **Study Phase:** Phase 3
- **Therapeutic Area:** Oncology
- **Indication:** Breast Cancer
- **Patient Population:** Women
- **Number of Patients:** 215+
- **Number of Sites:** 55+
- **Countries:** 6
- **Languages:** 8

CHALLENGES:

01

IMPROVE PATIENT UNDERSTANDING OF MULTIPLE, COMPLICATED INFORMED CONSENT FORMS (ICFS)

Two informed consent forms spanned a total of 60+ pages on paper, including the main ICF which is 42 pages long.

02

MANAGING IRB REVIEW ACROSS A HIGH NUMBER OF SITES

Final, site-, and country-specific ICF versions needed to be reviewed and approved by each IRB in a manner that was efficient and traceable.

03

MANAGE SCALE ACROSS MULTIPLE COUNTRIES AND LANGUAGES

There are 215+ patients enrolled in this study, spanning 6 countries, 8 languages, and 55+ sites, with country- and site-specific ICF versions and some sites using multiple languages.

SOLUTIONS:

01

INTERACTIVE MULTIMEDIA CONSENT EXPERIENCE

Our solution allowed patients to access and review the ICF remotely from home before their clinic visit and provided an engaging digital experience with videos and pictures to improve patient comprehension about the study and treatment. For patients consenting remotely and at-site, the solution captured content in the ICF that the patient wished to discuss, which was used to drive the pre-consent discussion with the investigator.

02

INTEGRATED IRB REVIEW

Our solution provided a full submission package to the IRB and Europe, including screenshots and PDF printouts of the ICF exactly how the patient views it, an administrative letter explaining the online system, a product description of our eConsent platform, and information on security and data custody. For IRBs willing to use the solution's in-built IRB review feature, SmartSignals eConsent also provided a package to the reviewer with a temporary link, username, and password to access country or site-specific ICFs.

03

REMOTE INSIGHTS AND REPORTING CAPABILITIES

Our solution's manager tool provided full visibility into 215+ patients and allowed the sponsor team to access real-time study progress metrics, including the number of consented patients, their access time spent on each page, and areas where Q&A flags by the patient were most common.

BENEFITS OF SIGNANT'S eCONSENT:

- **Improve overall patient comprehension**

  Signant's eConsent solution was designed to provide a fully interactive, multimedia experience that would ensure patient understanding of complex study information.

- **Simplify the IRB submission process for multiple and lengthy ICF**

  Signant is equipped to provide a full submission package to IRB to ensure that they are approving ICF exactly as the patient views it on our eConsent platform.

- **Manage scale across multiple countries, sites, and languages**

  Signant's teams and solutions can accommodate the need to manage scale and monitor the consent process for hundreds of global study participants.

ABOUT 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 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.