SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

CASE STUDY:

ADVANCED BREAST CANCER RESEARCH SOLUTIONS

Signant Health's solutions helped a top pharmaceutical company to successfully evaluate the effects of treatment in Japanese women with advanced breast cancer.

OVERVIEW

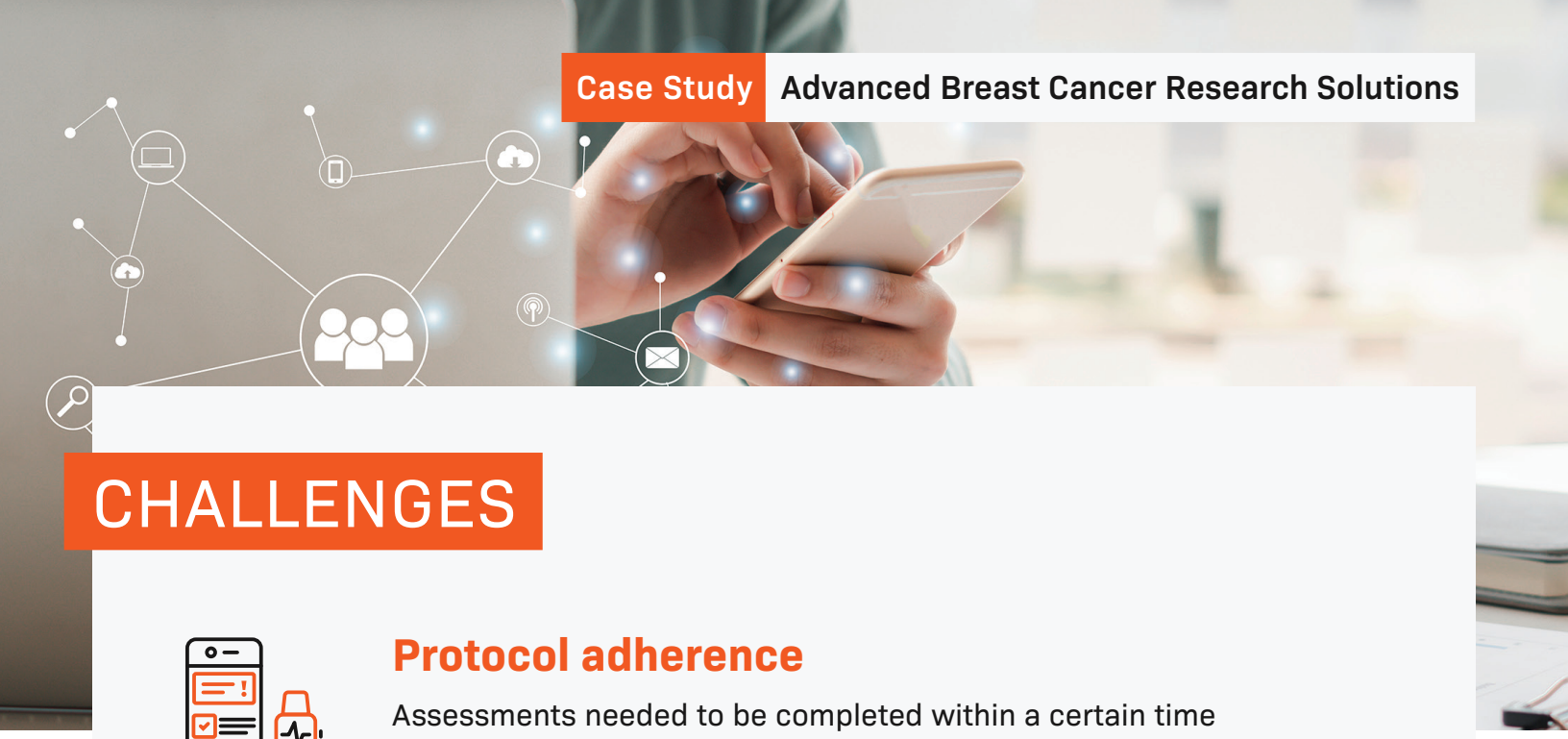
Traditionally, tumor response and survival data have taken precedent over quality-of-life data in breast cancer studies. This inspired Signant's customer to conduct a prospective, multi-site, observational study to better understand how their treatment and treatment-related adverse events (AEs) impact daily life.

The customer needed novel technologies that could remotely and accurately collect data from patients.

Signant's smartphone-based application for electronic patient-reported outcomes (ePROs) along with their Actigraph wearable sensors enabled the sponsor to conduct in-depth analyses on daily, weekly, and cycle-based assessments. Advanced technology also helped the researchers overcome many of the common oncology study challenges.

OBJECTIVES

1. Evaluate the change in patient-reported outcomes and physical activity in female, Japanese patients undergoing treatment for advanced breast cancer
2. Determine the association between the change in physical activity and quality of life as well as how the two correlate with:
   - investigator-reported adverse event(s)
   - patient-reported symptom(s)
   - disease progression
3. Assess wearable sensors as a tool to streamline data collection
4. Evaluate the concordance and discordance between investigator-assessed AEs and patient-reported symptoms
5. Understand factors associated with treatment satisfaction among patients



CHALLENGES

Protocol adherence

Assessments needed to be completed within a certain time window. Specifically, daily assessments needed to be submitted before midnight, weekly assessments within 72 hours, and cycle assessments before the end of the week. The protocol additionally required patients to wear a sensor for 24 consecutive weeks, only removing for bathing or sleeping.

Impact on quality of life

To collect physical, emotional, cognitive, and social function data, patients needed to complete diary entries. The time spent answering questionnaires could impede the patient's family time, social activities, and hobbies, so an easy-to-use diary was ideal to minimize time and effort. Since reporting their personal activity and sleep quality regularly could also be burdensome, non-obtrusive sensors were needed to capture accurate data on behalf of the patients.

Data quality

Gathering high-quality, reliable data is always the goal in clinical research. In order to have defendable data that passes regulatory inspection, the PROs need to be legible, logical, attribute, accurate, and timely.

THE SOLUTIONS

- For optimal **adherence**, the app's helpful notifications reminded patients to complete their daily diary entry at a scheduled time. Site staff were then notified if patients did not complete these tasks for four consecutive weeks, so they knew whom to follow up with.
- Signant's technologies digitalized the customer's disease-specific, multi-item questionnaires to facilitate accurate and real-time assessments. The EORTC-QLQ-C30 evaluated the impact of the treatment and disease on the patients' **quality of life**, while the PRO-CTCAE collected data on the severity and frequency of their symptoms. Actigraph's Centrepoint Insight Watch additionally collected metrics on physical activity.
- To ensure the highest **data quality**, investigators and study site staff were trained on the protocol as well as the unfamiliar technologies and study processes. All the collected data were reviewed by Signant Health's remote data managers for clarity and completeness.

THE APP'S SPECIAL FEATURES:

01 Upon downloading the app on their own device (BYOD), patients were guided through mandatory training.

02 Helpdesk assistance was available at the touch of a button.

03 Notifications reminded patients to complete questionnaires.

04 Reports were viewed and downloaded as often as the sites required.

CONCLUSION

The customer was pleased with Signant Health's contribution to the trial and plans to utilize our technology and expertise in future studies. Additionally, we received positive feedback from the sites who found our technology reliable and easy to use.

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WHO IS SIGNANT HEALTH?

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**
or email **hello@signanthealth.com**