



CASE STUDY:

SIGNANT SMARTSIGNALS eCOA – REMOTE SAMPLE COLLECTION

OVERVIEW:

A global pharmaceutical company implemented Signant's eCOA solution to enable the remote collection of stool specimens on an ad hoc basis from patients at home, reducing the need for unscheduled site visits.

TRIAL SUMMARY:

Study Phase: Phase III

Therapeutic Area: Infectious Disease

Participant Population: Adults and Senior Adults

Number of Patients: 15,000+

CHALLENGES:

01

ENSURE PATIENTS COULD PROVIDE SAMPLES AT HOME THAT COULD BE ANALYZED QUICKLY

When patients presented diarrhea symptoms, the sponsor wanted to give them the ability to provide stool samples from home for lab analysis. This method was convenient for patients and helped encourage compliance, though it was critical to ensure that the samples were provided to the laboratory in a timely manner to enable accurate analysis.

02

MAKE SURE EACH PATIENT HAS AVAILABLE STOOL SAMPLE COLLECTION KITS FOR USE

Diarrhea symptoms could occur unpredictably, and it was important for patients to provide a sample following each episode. Therefore, it was crucial to ensure that patients had a sample kit available for use at any time, and that these kits were replaced after use.

03

REMIND PATIENTS TO PROVIDE SAMPLES PROMPTLY IF AND WHEN SYMPTOMS PRESENTED

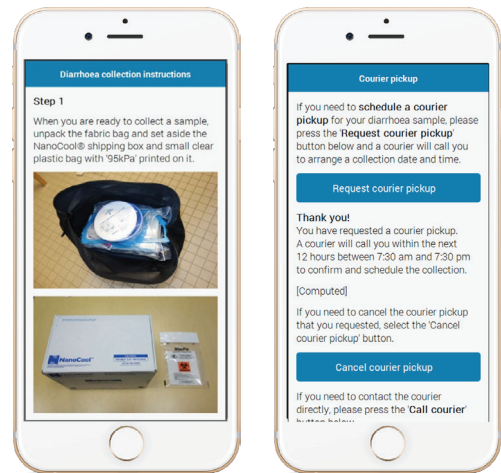
Since sample analysis was an important component of assessing disease recurrence, the sponsor had to ensure that patients would remember to take a sample once diarrhea symptoms presented.

SOLUTIONS:

01 EXTENSION OF SIGNANT'S eCOA APP INCLUDED SAMPLE KIT INSTRUCTIONS & COURIER INTEGRATIONS

The patient engagement component of Signant's eCOA app was used to provide comprehensive instructions on how to use the kit to secure samples.

When samples were ready, patients could flag this through their app interface. This triggered an integrated workflow with a specialist courier experienced in handling biological samples. The courier partner coordinated sample pickup from the patient then delivered it to the laboratory for analysis in a timely manner.



02 COURIER PROVIDED REPLACEMENT KITS AT THE SAME TIME AS THE SAMPLE COLLECTION

Courier activity was coordinated such that couriers could provide replacement kits while picking up new samples, or at any other time as requested through the eCOA app. By doing so, a free sample kit was always available to patients throughout the trial.

03 SAMPLE COLLECTION DIRECTION WAS INTEGRATED WITHIN PATIENT'S eCOA WORKFLOWS

Since Signant's eCOA solution was also used to collect symptoms through a patient diary which incorporated a Bristol Stool Chart, patients would be reminded to collect a sample when stool forms of appropriate types were recorded at the time of their patient diary submission. These reminders helped to ensure better compliance and adherence to protocol requirements.

ABOUT 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.