

## CASE STUDY:

# SMARTSIGNALS™ eCOA



Our versatile eCOA solution provided interoperability with a reimbursement solution provider to drive engagement in the long-term follow-up period of a large global vaccine trial.

### OVERVIEW:

A top US pharmaceutical company asked Signant Health to partner with Greenphire, a leading clinical trial payments automation provider, to drive engagement and eCOA compliance for volunteers across sites participating in a high-profile vaccine trial.

The sponsor wanted to ensure that the solution would help retain participants and facilitate gathering of complete information on the emergence of disease-like symptoms for a period of up to two years after vaccination. In addition, the solution could not add additional workload to the sites in the high-volume trial, whose focus was needed on recruitment, dosing and other essential site conduct.

### TRIAL SUMMARY:

**Study Phase:** Phase II/III

**Therapeutic Area:** Vaccine

**Indication:** Infectious disease

**Participant Population:**  
Healthy volunteers

**Number of Subjects:** 44,000+

**Number of Sites:** 150+

**Countries:** 5+

**Languages:** 15+

### CHALLENGES:

This study presented a number of unique challenges:

01

#### KEEPING PARTICIPANTS ENGAGED AND COMPLIANT

It was imperative that healthy volunteers continued to provide disease symptoms data via their eCOA app or provisioned device at home for a period of up to two years from dosing.

02

#### OPERATION AT GREAT SPEED

This study required all stakeholders to operate at unprecedented speed. The apps, device and diary preparation for data gathering had to be flawless; the data exchanges to enable participant payments had to be complete and accurate each week, or the trial risked delays.

03

#### SCALE

This was the largest eCOA vaccine trial in history, involving over 44,000 subjects and over 150 sites.

### SOLUTIONS:

01

#### DATA INTEGRATION BETWEEN SIGNANT HEALTH AND GREENPHIRE

Leveraging our integration interfaces, Signant provided eCOA completion data and payment milestone summaries to Greenphire by secure data integration every day.

02

#### TIMELY PATIENT PAYMENTS

In the US, Greenphire made 30,000 micropayments a week to study participants. These were loaded onto each participant's ClinCard as a debit card credit, able to be used anywhere like cash.

03

#### SMARTSIGNALS eCOA APPS AND PROVISIONED DEVICES WERE DELIVERED ON TIME

Signant responded to the accelerated five-week timeline, preparing the full eCOA solution for participants worldwide and integration with Greenphire in the US. In addition to BYOD usage, over 8,000 provisioned devices were prepared and shipped globally.

## BENEFITS OF SIGNANT'S eCOA AND COLLABORATION WITH GREENPHIRE

### — Quality eCOA data

*The eCOA data collected in this trial formed part of regulatory submissions around the world. The vaccine received Emergency Use Authorization from the FDA and other regulatory agencies, and subsequently full FDA authorization.*

### — Excellent participant feedback

*Participants appreciated receiving regular micropayments to their debit card. According to one volunteer, "Having the money loaded in small increments made for a great reminder to fill out the diary every week."*

### — Reduced site burden

*Given the high number of patients recruited at each site, sites were initially fearful about "micropayments" being offered in case this led to additional work for their teams. However, when implemented they realized that the process was frictionless, requiring no work from them, allowing them to focus on recruitment, while the solutions aided participant retention.*

## 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](http://www.signanthealth.com).

## ABOUT GREENPHIRE



Greenphire is the leader in global clinical trial financial process automation. Greenphire's best-in-class solutions optimize clinical trial performance by streamlining payment and logistical workflows from sponsors and CROs to sites and patients. Greenphire's EnvisiX™, eClinicalGPS®, ClinCard® and ConneX® solutions easily handle any type of trial design and complexity, resulting in more accurate and compliant payments and simplified travel globally for both sites and patients. The choice of industry leaders worldwide, Greenphire provides better performance and better data, resulting in better trials. Learn more at [www.greenphire.com](http://www.greenphire.com).