SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

Case Study | COVID-19 Vaccine Research Solutions

# COVID-19 Vaccine Studies Succeed with Support from Signant Health

**Signant helped a leading sponsor meet accelerated timelines while generating high-quality COVID-19 vaccine safety and efficacy endpoint data.**

# OVERVIEW

**When the World Health Organization declared a novel coronavirus outbreak to be a Public Health Emergency of International Concern in January 2020, clinical development sponsors immediately began researching potential vaccine candidates.**

The unprecedented scale and urgency of the pandemic meant that a development process that historically required years would need to be condensed down to months to have any hope of mitigating the spread of COVID-19. To meet such a difficult schedule while observing new safety restrictions and precautions that would impact clinical research conduct, a leading pharmaceutical manufacturer sought a partner with the solutions, expertise, and global reach to help accelerate a series of multi-phase clinical trials.

Signant Health's clinical research technology solutions and expertise, coupled with previous experience delivering vaccine studies with the sponsor, proved to be a useful springboard to meet the challenges of the protocol and the pandemic.

# THE CHALLENGE

To combat a viral disease where previously no licensed vaccines or treatments existed, the sponsor began investigating vaccine candidates using new messenger RNA technology. The protocol presented additional challenges:


### OVERLAPPING PHASES

A safety-only phase I study would identify the preferred vaccine candidate followed by a seamless transition to a much larger and more complex combined phase II/III safety, tolerability, immunogenicity, and efficacy study.

### LARGE, GLOBALLY DISPERSED PARTICIPANT POOL

The protocol required at least 44,000 participants to self report occurrences of local reactions and systemic events through a reactogenicity eDiary, an application installed either on a provisioned device or on the participant's own personal device (BYOD).

### REGULATORY CONSIDERATIONS

Licensing and regulatory approvals needed to be coordinated and obtained for the import and export of tens of thousands of mobile devices into and out of seven countries.

### DATA MANAGEMENT

The sponsor required instant access to all clinical data for review and analysis, as well as regular planned interim analyses requiring coordinated data change resolution, database lock, and data transfer.

> Signant has partnered with this sponsor over the course of several years to conduct their vaccine studies, so when the team requested our services for a Phase I and a combined phase II/III COVID-19 vaccine study, we were prepared. However, the scope and speed of these studies was unprecedented. The protocol required that we design and launch an eCOA solution with the sponsor's reactogenicity diary built in, as well as provision and ship nearly 40,000 mobile devices to 100+ sites around the world, in five weeks. Normally, this process requires at least 10-12 weeks. To meet the schedule, Signant assembled a flexible, globally dispersed internal project team of multidisciplinary experts who worked in tandem with the sponsor's study team at all hours of the day. Because we had the right resources and an outstanding collaborative partnership with their team, we were able to meet the launch deadline, ultimately helping the sponsor achieve Emergency Use Authorization for the one of the world's first COVID-19 vaccines in record time.

**Nicholas Gambino**

Director, Project Management, Signant Health

# THE SOLUTION

**Signant Health, drawing on decades of experience and its in-house clinical science, medicine, and operations expertise, helped the sponsor "go live" on phase I/II in just five weeks and seamlessly transition into phase II/III as soon as candidate and dosing decisions were confirmed.**

Leveraging its flagship SmartSignalsTM eCOA solution, Signant implemented electronic versions of the sponsor's reactogenicity and COVID-19 illness diaries to collect patient-reported outcomes (PRO) data through its eDiary. The scale of the participant pool required that Signant provision, secure import/export licensing for, and distribute 38,000 mobile devices to seven countries in unprecedented time frames while navigating additional logistical and regulatory challenges caused by the pandemic.

To meet data management requirements, Signant maintained a secure, validated database to allow the sponsor's study team to review, analyze, and transfer clinical data, facilitating rapid interim analyses and decisions on design adaptations between phases. With 24/7 project management and help desk availability, Signant was able to respond immediately to all requests, changes, and amendments using its globally distributed staff resources.

# OUR SOLUTIONS ARE BETTER TOGETHER

**UNLOCK THE FULL VALUE OF VACCINE RESEARCH SOLUTIONS**

**eCOA**

**RTSM**

**Blinded Data Analytics**

# THE RESULTS

> We knew from past experience with Signant on several vaccine studies over the years that their eCOA platform and global team could handle large, complex protocols. What we didn't know is whether they would be able to meet our highly compressed schedule and aggressive milestone deadlines. Our study team was beyond impressed by the level of commitment, responsiveness, collaboration, and above-and-beyond efforts from the entire team throughout the course of our first COVID-19 vaccine studies. They responded to change requests, amendments, and all of our emails, phone calls, and texts immediately even in the middle of the night. We trust Signant as our reliable partner for global, complex studies and programs.

**Senior Scientist**
Sponsor

With the help of Signant's solutions and resources, as well as a collaborative team approach across both organizations, the sponsor successfully developed a first-of-its-kind COVID-19 vaccine with a 95% efficacy rate and achieved Emergency Use Authorization in a previously unattainable timeframe of just eleven months.

With subsequent investigational studies currently underway, the model established in these studies proved that new approaches and innovations in the drug development process can advance life-saving treatments faster.

## WHO IS SIGNANT HEALTH?

SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

As the evidence generation company, Signant Health equips clinical researchers with innovative technology solutions and clinical expertise to optimize the drug development process while improving the accuracy and reliability of endpoint data.