



Rapid Launch of a Phase I COVID-19 Vaccine Trial

Achieving Database Launch and First
Patient In During the First Month



Background

In early March 2020, as the detection of coronavirus began to spread rapidly throughout the United States, Veristat™ was approached by a current client to quickly build and launch a database for a novel coronavirus vaccine (nCoV) Phase I trial in healthy volunteers.

SERVICES PROVIDED	
Project Management	DSMB/CEC Meetings
Data Management	Medical Writing
SDTM Implementation	Electronic Publishing and Submissions
Biostatistics & Programming	Team Meetings

Sites and Patients



1 Country
United States



2 Total Sites



30 Total Patients

THE CHALLENGE

The sponsor had already selected two sites with patients identified, and their gating factor for enrollment was getting the clinical trial database built. Veristat needed to design, build, test, and publish the clinical trial database live as quickly as possible. Since the sponsor had worked with Veristat previously, they knew that our integrated biometrics team could achieve a quick database launch.

SOLUTIONS

The Veristat project director and key data manager drove the project, which required collaboration, input, and approvals from many groups. Everyone had to work, review, and make decisions quickly. The sponsor needed to provide inputs and turnaround reviews. The Veristat team designed and built the database, performed quality control reviews, and completed user acceptance testing under immense timeline pressures.

We achieved the goal of getting the database live in two weeks by doing a split release of the database. All the screens were quickly released so that patients could get

screened and enrolled immediately. Then, we programmed and released the edit checks. While the more traditional and desired approach is to push everything live at once, the split-release approach allows quick database launch in shorter timelines.



The clinical trial database went live in 2 weeks, so that patient screening could begin immediately

The Rapid Timeline for the First Month of COVID-19 Vaccine Trial



It's been both personally and professionally rewarding to feel that we are contributing to the COVID-19 response."

Jan Adams, Project Director, Veristat

SUCCESS FACTORS

Lessons Learned from This Study So Far

The speed and urgency to get this database built, tested, and launched during the onset of the COVID-19 pandemic was a remarkable feat. All team members were working from home, coping with their own personal and professional stresses related to this outbreak as well as the complexity of the project. Ultimately this fueled the team's desire to get the vaccine trial up and running as quickly as humanly possible. In addition, our team delivered the first batch of DSMB outputs three days ahead of schedule, which allowed the second batch of 17 subjects to be enrolled quickly.

Below are the top three lessons learned from the team that spearheaded this achievement.

- 1. Collaboration is essential:** All parties need to work together collaboratively – including the sponsor, CRO(s), sites, labs, etc.
- 2. Decision-making must be swift:** The speed of decision-making can make or break the ability to achieve aggressive timelines. The sponsor made rapid decisions that allowed us to make immediate updates, which kept things moving forward.
- 3. Be flexible:** A traditional drug development approach won't work here. With such rapid timelines, be creative, stay flexible yet scientifically sound, and have a strategy that allows you to manage risks as the trial progresses.



The knowledge that our entire team gained working on this trial is paving the way for streamlining approaches on other COVID-19 trials we are working on.”

Katelyn LaBombard, *Manager, Data Management, Veristat*

Meet Veristat

We understand that the stakes are high no matter where you are in your development program. The changing regulations and rapid speed with which COVID-19 clinical programs are starting is overwhelming. We have the agility and scientific-minded experts to help you navigate these uncertain times.

Get introduced to Veristat today.

www.veristat.com

