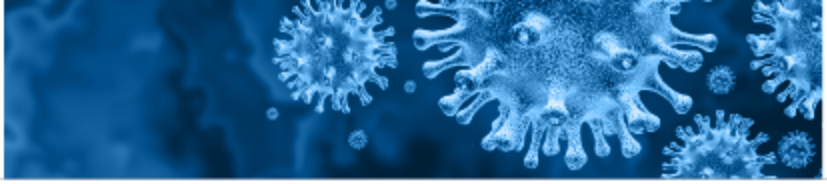
Sanguine

CASE STUDY



CONTRIBUTING TO MEDICAL RESEARCH FOR A BETTER UNDERSTANDING OF COVID-19

Sanguine Bioscience, a California-based biotechnology company focused on patient recruitment, sample collection engagement and digital health, has partnered with multiple biotech and pharmaceutical companies, such as Vir Biotechnology and EpiVax, Inc, to facilitate the patient recruitment for over 23 research studies, studies aimed at gaining a better understanding of COVID-19. Although the overarching goal of this research is to develop treatments and vaccines, valuable information can be obtained about the virus, its patterns of infection, and the effectiveness of community response to the epidemic.

KEY FACTS

- **Sanguine facilitated the patient recruitment for over 23 research studies aimed at gaining a better understanding of COVID-19**
- **48% of study sites miss their enrollment targets, and 11% fail to enroll a single patient.**
- **Sanguine can assist in both translational and clinical research, as well as clinical trials.**
- **Trial adherence rates can average 43%-78% in patients with chronic conditions.**

RECRUITMENT AND STUDY CHALLENGES

Recruitment and study challenges existed prior to COVID-19. According to a Tufts Center for the Study of Drug Development report, 48% of study sites miss their enrollment targets, and 11% fail to enroll a single patient. This results in the need for study sponsors to nearly double study timelines to meet recruitment criteria. In addition, one third of studies do not receive recruitment support, leaving individual study sites to allocate valuable time and resources to participant recruitment. All told, 80% of studies are delayed due to patient recruitment issues. Aside from patient recruitment challenges, clinical trials have increasing drop-out and lost-to-follow-up rates. The industry expectation is to plan for approximately a 30% drop-out rate; however, trial adherence rates can average 43%-78% in patients with chronic conditions.

Under the traditional model, clinical and translational research requires in-person visits to a medical center or study site for sample collection, patient evaluation, and patient-reported outcome assessments. However, during a global pandemic and home-isolation, a myriad of issues arises. In essence, study participants are unable to travel for the traditional in-person study visits, the facilities used for study visits may not be open/-accessible, and study staff may not be available as they are reallocated to other duties. Not to mention, study visits to a facility expose both the study participant and study staff to more people increasing the risk for COVID-19 infection.

The severity and duration of the pandemic are yet unknown; however, medical research difficulties are anticipated to intensify for on-going clinical trials, long-term safety monitoring initiatives, and for new research. Thus far, patients have not had hesitancy to participate in medical research, although they are concerned about appearing at medical facilities with the need to practice social distancing. Some patients have already stopped coming to clinics for their study visits

REFERENCES

1. Centers for Disease Control and Prevention. Symptoms of Coronavirus. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html. Accessed July 22, 2020

SANGUINE SERVICES APPLIED

CONSENTING & INTERVIEWS | HOME VISITS | SPECIMEN COLLECTION | LAB SERVICES

due to local travel restrictions and fear of exposing themselves to COVID-19. But looking past COVID-19, will patients be more cautious and hesitant to participle in the future?

Methods to protect the patient's safety, welfare, and rights while maintaining research integrity is made on a case-by-case and trial-by-trial basis – however, the FDA recognizes that sometimes the best decision for the well-being of the patient is to continue medical research with modified study conduct and protocols while maintaining compliance with good clinical practice (GCP) guidelines. One possible avenue to advance medical research during these unprecedented times is to implement at-home study visits to existing protocols and future research. The COVID-19 pandemic is devastating, and home-isolation is a life-disrupting, social responsibility. However, it does not necessarily mean medical research needs to cease to progress forward. Safeguarding the health and well-being of study participants, minimizing risks to trial integrity, while maintaining study continuity and GCP compliance is possible during these unprecedented times.

SANGUINE AND COVID RESEARCH

Sanguine's unique, medical research services model enables us to gather recovered, COVID-19 patient information and biospecimens quickly by bringing clinical trials and biospecimen research directly to patients' homes. Patients are recruited nationwide via partnerships with advocacy agencies and social media outreach and then screened and their criteria matched to research studies. Our medical research personnel cross-check and verify patient information with their medical records, obtain informed consent, and set up an at-home visit or multiple visits depending on the needs of the study. During the at-home visit, patients' identities are verified, study procedures are conducted, and biospecimen collection occurs. Our trained mobile medical professionals strictly adhere to study protocols and use universal precautions and infection control measures including personal protective equipment.

During a recent recruitment period for COVID-19 studies (March, April, and May 2020), we noticed interesting trends in our research participant data. During this time period, 481 individuals who experienced COVID-19 symptoms were screened and only 194 (40%) of them had received verbal confirmation or written documentation of their COVID-19 diagnosis. The other 60% of individuals felt they had symptoms but were not tested. (In a separate screening survey, 33/100 (30%) reported not being able to provide a positive COVID-19 test due to limited testing, lack of available testing, or testing availability after symptom resolution.)

Of those with a positive diagnosis, 81/194 (42%) reported they had been in contact with someone known or suspected to have had COVID-19 with the other 113 (58%) most likely contracting the virus through community spread. Of those with COVID-19 confirmation, 73 (38%) reported ageusia or anosmia (loss of smell or taste), 58 (30%) did not experience a fever, and 58 (30%) also experienced gastrointestinal symptoms. These symptoms are consistent with those reported to the Centers for Disease Control and Prevention.

The COVID-19 pandemic continues to control our world, how we function within it, and how we interact with each other. We at Sanguine are excited to provide our expertise in conducting efficient clinical research through our established infrastructure in the fight against this global pandemic. The more we study and learn about the virus and its patterns of infection, the more we can control its spread, protect those most vulnerable, and develop treatments and vaccines to combat this pandemic.