



Accelerating Clinical Development to Address the COVID-19 Public Health Crisis

The public health and research response to emerging infectious diseases such as COVID-19 (coronavirus) requires collaboration across the industry, including public and private partnerships.

Outbreaks present critical time issues—not only to protect patients, but also to ensure new product launch before a new strain emerges. Even after a vaccine or treatment is developed, clinical trials to test these during a pandemic demand extreme speed in start-up, a rapid operational tempo, and access to subjects in high-risk areas for the targeted disease.

The most important lesson that has emerged from pandemics of the past is that true collaboration among government agencies, academia, industry, international groups and local healthcare workers is essential.

Syneos Health is committed to improving global public health. As part of that mission and in partnership with our customers, we are poised to bring all of our therapeutic depth and expertise to bear on accelerating research to address the threat posed by COVID-19 and other emerging infectious diseases.

At Syneos Health, each and every one of us within our infectious disease business unit is devoted to advancing work in infectious disease (ID). From clinical research associate to project director, our ID study teams work only on ID clinical trials and under the direction of board-certified ID specialists and expert clinical scientists.

“ True therapeutic alignment gives us not only an unparalleled depth and breadth of expertise among our best-in-class ID study teams, but also deep partnerships with known and trusted sites and investigators across the globe—relationships that are mission-critical when time is of the essence during fast-moving outbreaks. ”

Industry-leading Experience Accelerating Clinical Development

Syneos Health has extensive organizational and individual experience in emerging infections, public health emergencies and biomedical countermeasures, including studies for Zika virus and Ebola virus vaccines and other emerging health threats.

Our extensive infectious disease experience includes:

Clinical trial acceleration

- Complete range of services covering Phase I-IV services at a global level, including full Phase I study capabilities for first-in-human and immunogenicity studies, in a wide range of subject populations
- Established, strong site relationships for rapid start-up and predictability, including sites in our Vaccine Catalyst Site Network, consisting of more than 30 high-performing sites focused on vaccine research

Regulatory engagement

- Agency interaction for planning and study start-up world-wide, supported by dedicated regulatory intelligence and country-specific regulatory specialists
- Parallel planning and execution of Phase II and III studies, expanded access programs, emergency IND programs, emergency use authorization enabling studies, and other programs

Special settings, patient populations and severe infections

- Serious hospital infection clinical trials, including in the intensive care setting for studies in the most seriously ill patients
- Wide range of subject populations including elderly, immunocompromised and hospitalized patients
- Clinical studies targeting a wide range of severe infections including influenza (flu) and respiratory syncytial virus (RSV)

Government and non-profit partnerships

- Experience in navigating the nuanced requirements and aggressive timelines set forth by governmental agencies
- Sub-contractor with studies funded by government bodies and non-profit groups including BARDA, National Institutes of Health, Department of Defense/US Army Medical Research Institute of Infectious Diseases, Innovate UK, World Health Organization and other private-public partnerships

Global reach, extensive technology capabilities and high capacity

- Capable of 24-hour operations in support of fast-moving trials, with contingent staffing for rapid mobilization
- Staff or capabilities in countries throughout Asia, Europe, Africa, Australia and the Americas for all elements of clinical research
- Several eTrial/technology alternatives such as electronic data capture, eDiary/ePro, eConsent, electronic trial master file, ePortals, eTraining, and remote central monitoring to reduce exposure and potential contamination, which will be critical during periods of containment and quarantine

An unparalleled set of capabilities for accelerating clinical research in COVID-19 and other emerging infectious diseases

For more information, please go to:
syneoshealth.com/infectious-diseases.

About Syneos Health

Syneos Health® (Nasdaq:SYNH) is the only fully integrated biopharmaceutical solutions organization. The Company, including a Contract Research Organization (CRO) and Contract Commercial Organization (CCO), is purpose-built to accelerate customer performance to address modern market realities. Learn more about how we are **shortening the distance from lab to life**® at syneoshealth.com.