

# Full-Service Global Support for COVID-19 Studies

FHI Clinical addresses emerging pandemics, epidemics and outbreaks with expertise that supports health and research efforts globally. We are experienced in addressing the complex aspects of infectious diseases — from infection prevention and control to clinical research on diagnostics, vaccines and treatment.

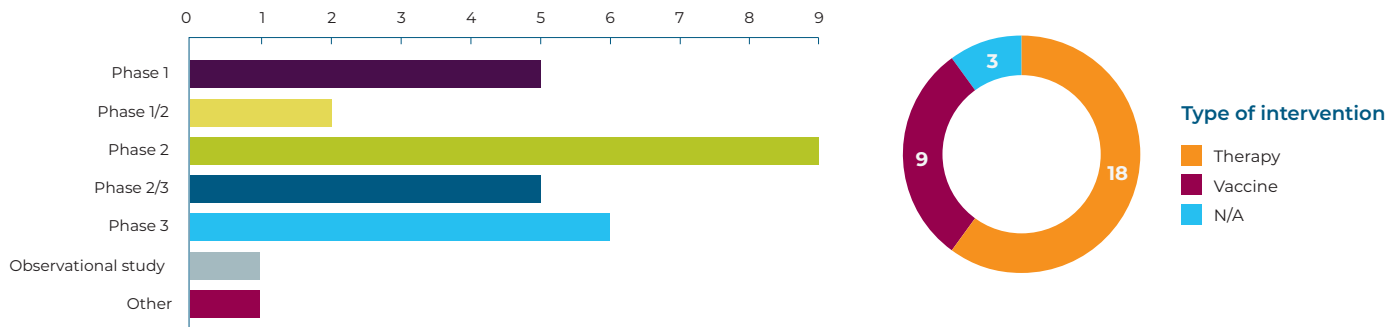
To ensure that we can start projects rapidly and accelerate recruitment in difficult-to-treat populations, we remain prepared to launch studies in response to the most challenging of situations. Because it is not *if*, but *when*, an emergency response will be required, the standard operating procedures (SOPs) and processes that we have developed and refined during our years of outbreak experience are up-to-date and ready to deploy when needed.

**We excel at challenging trials of  
infectious disease vaccines and therapies  
that require thorough planning and  
contingency planning.**



## OUR COVID-19 EXPERIENCE

Our involvement with COVID-19 includes Phase 1 to Phase 4 clinical trials for vaccines and therapeutics and an observational study to collect data about the characteristics and course of infection.



Data current as of April 1, 2023. The boundaries and names on this map do not imply official endorsement or acceptance by FHI Clinical.

## RAPID STUDY START-UP

COVID-19 projects require a flexible approach that responds to the ever-changing epidemiology and evolving knowledge base. Our team is experienced at rapid start-up and management of complex clinical research at clinical sites diverse in geographic area and research capacity. We have the experience to rapidly initiate large multicenter research projects, yet we are agile enough to fill gaps and respond to urgent needs, working within parameters required to maintain sound management structures.



**6-8 week**  
start-up times possible with  
FHI Clinical involvement

## GLOBAL, RESEARCH-READY SITES

Adapting to the ongoing situation also requires access to a ready pool of qualified sites that can be quickly matched against the capabilities and populations needed for your protocol requirements. Our proprietary database contains thousands of established, high-quality sites spanning 72 countries in the Americas, Asia, Africa and Europe.

**Based on feedback from our site network as well as our own experience, sites are ready and able to handle both vaccine and therapeutic COVID-19 studies:**



As cases decrease to manageable levels globally, there is greater capacity to run studies.



Stipends have helped incentivize enrollment and patient retention.



Experience with decentralized clinical trials (DCTs), including telemedicine and home visits, has increased.



Many sites have separate entrances and designated treatment areas for COVID-19 patients.



Lockdowns/restrictions have not posed a challenge for recruitment and enrollment.



Many sites are interested in being involved in healthy volunteer studies.



Sites are more comfortable managing COVID-19 patients.



Sites are also interested in conducting vaccine studies.



Outpatient COVID-related studies benefit from site availability in the evenings and on weekends.



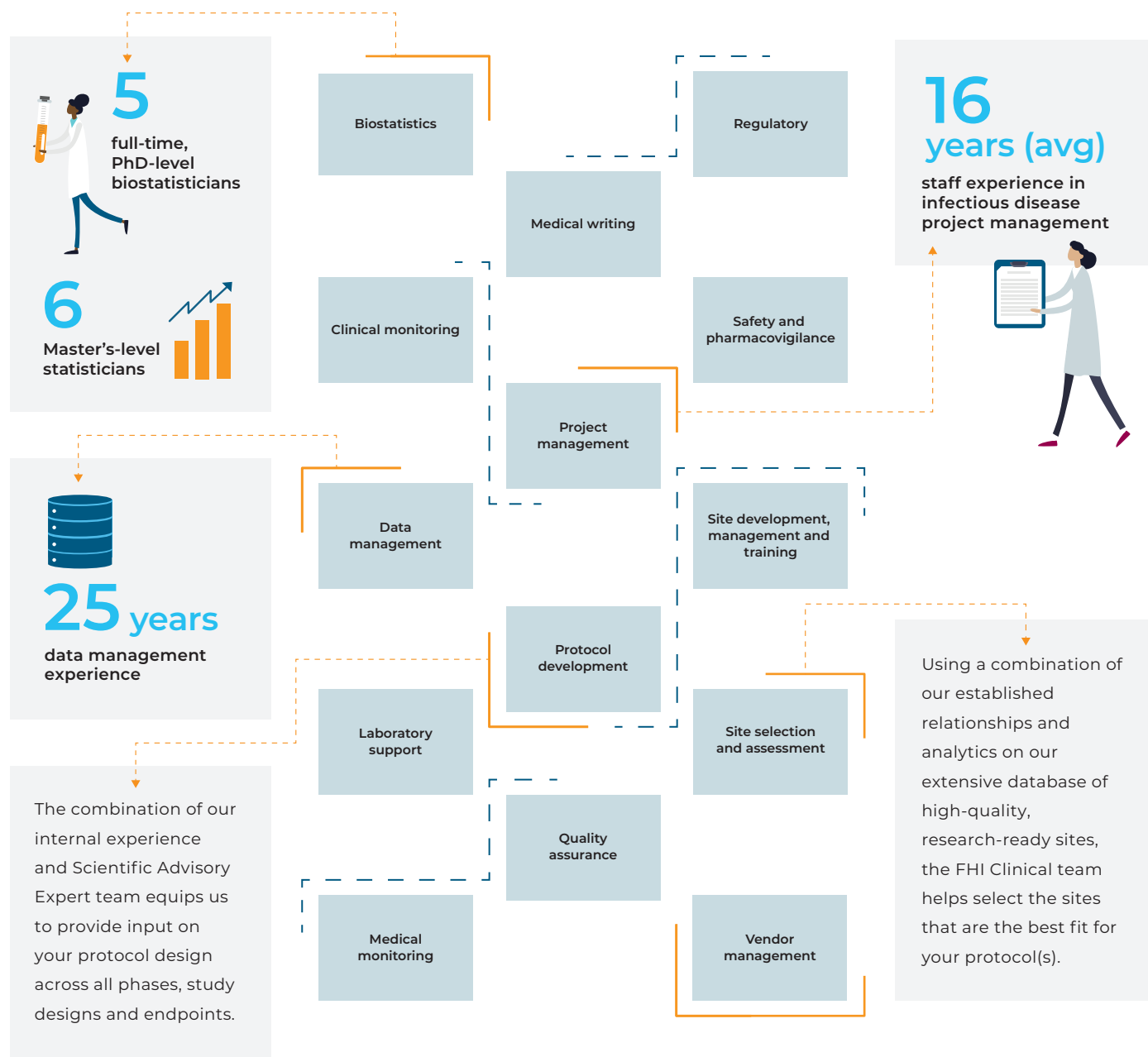
## FOLLOWING THE EPIDEMIOLOGY

We anticipate the next location with a surge of potentially eligible patients for an investigational treatment through careful monitoring of:

- COVID-19 case counts
- Locations with the more contagious viral variants
- Changes in local policies such as mask mandates, indoor dining capacities, indoor gathering guidelines, school policy and age eligibility for vaccines
- Reactions of the local population to the policies and mandates
- Vaccine administration rates
- Evidence of vaccine hesitancy

# SERVICES AND CAPABILITIES

High-quality studies require proven, flexible services that support the entire research lifecycle. Leverage our expertise and services to conduct your entire study or fill the gaps in your capabilities.



Leverage our high-quality, end-to-end clinical trial services in this rapidly evolving public health crisis. Visit [fhiclinical.com](https://fhiclinical.com), email us at [info@fhiclinical.com](mailto:info@fhiclinical.com) or call **919.321.3321**.