Westat®

Improving Lives Through Research®

Clinical Trial Services in Support of SARS-CoV-2 Research

Westat supports clinical research in emerging infectious diseases, such as COVID-19, Zika, and influenza as well as chronic and infectious diseases, including HIV/AIDS, cancer, and tuberculosis. We are a leader in designing, managing, monitoring, and delivering advanced clinical trials and epidemiologic studies, and supporting vaccine and gene therapy research.

Our interdisciplinary teams, with expertise in biostatistics, data management, and regulatory affairs, partner with and support our clients in advancements that prevent, diagnose, and treat infectious and chronic diseases—improving lives through research.

Why Westat

Nimble Project Management	Risk-based project plans ensure required tasks for end-to-end trial management meet on-time mile-stones, with quality assurance and subjects' protection
Expert Protocol Design and Statistical Services	Innovative and adaptive study designs; selection of estimand(s); sample size and power estimates; statistical analysis plans; report production and interpretation
Unified Platform of Data Services and Data Management	Interoperable Medidata Rave solutions for trial management include electronic trial master file, randomization and trial supply management, electronic data management
Informed Site Selection, Management, and Monitoring	Full-service support for selecting, managing, and monitoring clinical sites; negotiating agreements and site budgets
Comprehensive Regulatory Support Services	Regulatory strategies for traditional and compressed timelines; preparing and submitting content to regulators; preparing briefing packages and managing meetings with regulators; international network of relationships

Photo is for illustrative purposes only. Any person depicted in the photo is a model.

RELEVANT WORK EXPERIENCE

Westat Provides Clinical Support for New Treatment Trial for Severe COVID-19

Westat is supporting a multicenter, double-blinded, randomized-controlled study for a commercial client that is showing positive results for a treatment for Severe COVID-19. We are recruiting and readying sites to participate in a COVID-19 clinical trial as quickly as possible. This is a 2-stage study. Stage 1 will enroll 22 patients, and Stage 2 will enroll 60 additional patients at 19 sites in the United States and Europe.

Westat staff are responsible for project management; data management, including case report form development; site management and monitoring, including site contracts and payments; procedures manual development; support for the investigators meeting; safety reporting; medical monitoring; biostatistical services; support for the data monitoring and mortality adjudication committees; regulatory support; and preparation of the clinical study report.

Monitoring Zika in Mexico

As in so many countries, Mexico faces a variety of mosquito-borne viruses, including Zika, chikungunya, and dengue. Westat helps conduct research in Mexico, sponsored by the National Institute of Allergy and Infectious Diseases and the Mexican Emerging Infectious Disease Clinical Research Network, on how many people are infected with one or more mosquito-borne virus and what their symptoms look like.

Westat provides administrative and technical support to the study's clinical sites in southern Mexico; trains site staff on regulatory requirements, study protocol, and protocol implementation; oversees regulatory and protocol compliance; provides data management; and helps the staff write and publish research papers on the study findings.

Our support of the Network sites and coordinating center will help researchers better understand the frequency of infections with multiple mosquito-borne viruses in Mexico, the impact of these infections, especially on vulnerable populations, and how to develop rapid diagnostic tests.

Human Papilloma Virus Vaccine Efficacy Trial in Costa Rica

For the National Cancer Institute, Westat provided regulatory support; conducted site monitoring and auditing visits; and coordinated development activities with the Costa Rican investigators and subcontractors. The HPV-16/18 Vaccine Efficacy Trial was a double-blind, placebo-controlled clinical trial to evaluate the prophylactic efficacy of an HPV-16/18 virus-like particle-based vaccine. A total of 7,462 women (aged 18-25) in the Guanacaste region of Costa Rica were enrolled into the trial and randomized into an experimental arm and a placebo arm. Data collection included in-person interviews, clinical histories, and reports on reactions or side effects.

Influenza Therapeutic Pilot Trial

In 2015-16, Johns Hopkins University School of Medicine conducted a single-site, phase 4, randomized-controlled trial that demonstrated success using the adult emergency department (ED) as a clinical recruitment venue for patients at risk for complications from influenza. Westat supported a similar trial in 2016-17 at two U.S. clinical sites to determine the feasibility of enrolling subjects in the ED setting. Project staff administered one of two influenza antivirals and followed subjects for medical outcomes and safety for up to 28 days. Westat was responsible for study planning, development, and reporting; regulatory support; site management; data management; biostatistical services; and medical writing.

CONTACT

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