

Infectious Disease and Vaccine Study Support for Clinical Development

Infectious disease studies and development of vaccines are diverse, dynamic and complex areas of research that require a thorough understanding of many different indications, as well as populations and environments, to create safe, effective therapies and vaccines. Due to the continuing evolution of new strains and re-emerging pathogens, the timing and seasonal preparedness can be critical.

Pharmaron's specialist team has an in-depth understanding of the complexities of vaccine trials and is committed to helping clients make fast and accurate decisions about clinical development programs, while providing ongoing regulatory guidance.

Patient Recruitment

- Clinical trials conducted at 96+ bed Clinical Pharmacology Center in Baltimore, MD
- 30,000+ volunteer database, diverse population including ages 65+
- 100% subject recruitment rate
- 98% retention rate
- Ethnobridging studies of Japanese populations
- Close collaboration with local practitioners and local clinical centers for access to patients/healthy subjects for multiple study types

Vaccine Development Studies

- 50+ vaccine studies completed, targeting viral and bacterial infections
- Utilized controlled human infection models in studies including Campylobacter, Cryptosporidium, Cholera, Enterotoxigenic E coli, Norovirus and COVID.
- Outpatient vaccine center staffed by board-certified infectious disease physicians, alongside full-time nurses, pharmacists and laboratory support staff

Challenge Studies

- Challenge studies (Phase 2a) or controlled human infection models are useful for the study of pathogenesis and immune response and to accelerate the development of vaccines and therapeutic interventions
- Challenge studies have been conducted in our isolation unit since 2008
- Access to multiple challenge strains

Site & Subject Safety

- Clinical facility layout allows for the isolation of subjects enrolled for vaccine and infectious disease studies to ensure volunteer safety and integrity of clinical data

Bioanalysis

- On-site central laboratory and co-located bioanalysis lab in nearby Germantown, MD, provides prompt bioanalytical and biomarker sample analysis for rapid progression of vaccine development programs
- For data that is used for regulatory filings in support of NDA/BLA/ANDA applications, FDA/EMA/NMPA/ICH regulatory guidelines (GLP/GCP/GCLP) are followed