

Right Size. Right Reach. Right Team.

Let us support your infectious disease journey, the right way.

Linical is a public, mid-sized Contract Research Organization (CRO) headquartered in Japan with a significant presence across North America, Europe, and Asia-Pacific. Linical provides the full spectrum of drug development services from early stage to large-scale, multinational studies. Linical has vast experience in managing full-service, Phase I-IV infectious disease programs across the globe. During the past five years, globally we have managed 83 infectious disease programs spanning all major development regions. Of those 83 studies, 21 of them have been in the United States. Because of our extensive operational experience in the infectious disease space, Linical is your trusted provider for success, speed, efficiency, flexibility, and quality in clinical research. We:

- Engage with sites and vendors early to ensure smooth execution upon start-up
- Employ infectious disease experienced CRAs and project teams to ensure quality and on time delivery of your study results
- Fully understand vaccine and infectious disease regulatory requirements
- Evaluate preliminary immunogenicity, target disease epidemiology, and confirm dose levels are appropriately set
- Assure studies are properly conducted, adhering to FDA Toxicity Grading Guidance, ensuring pre-specified stopping rules are followed, conservative dose escalation schemes are instituted, and adverse events (i.e. SAEs, AESIs, MAEs, NOCIs) are monitored for adequate periods of time
- Use capacity modeling and pre-pooling of subjects for efficient on-site study conduct and on-time (or early) enrollment and study completion
- Effectively support the subject's journey, beginning with recruitment, moving to engagement, and assuring each subject's compliance and retention for successful study completion
- Integrate technology and identify key metrics up front to inform decisions including enrollment, laboratory parameters, subject diaries, safety management, data cleaning, risk mitigation, etc.
- Establish practical solutions to speed early-phase clinical development (e.g., incorporating early read-outs of key data)
- Manage the vaccine from packaging/delivery to destruction (or return)
- Integrate the entire team – Sponsor, Sites, Vendors & CRO – for a seamless end-to-end clinical program

A Global Partner for Full-Service Drug Development:

- Protocol Development
- Project Management
- Vendor Management
- Site Management
- Clinical Trial Monitoring
- Biostatistics
- Data Management
- Pharmacovigilance & Drug Safety
- Medical Monitoring
- Medical Writing
- Contact Center Solutions
- Regulatory Affairs, IND Services & FDA Meetings

Multiple Industry Honors

Linical's infectious disease experience and success have been recognized with our organization being awarded **Best Vaccine CRO** across multiple years at the World Vaccine Congress. Put our expertise and proficiency to work for you. Entrust Linical to lead all aspects of your infectious disease study through our integrated, accelerated, and cost-effective approach.

What We Bring to the Table

Proven experience across indications: Anthrax, C.diff, CMV, COVID-19, Dengue, Ebola, Equine Encephalitis, HBV, Hepatitis B, Hepatitis C, Herpes, HIV, HPV, Influenza (H1N1, H5N1, H9N2, H7N9, Swine Flu), Malaria, Meningitis, Plague, Pneumococcal, RSV, Smallpox, TDAP, and Typhoid.

Familiarity with varied routes of administration: Oral (pill/liquid), patch, electroporation, intranasal, intramuscular, intradermal, intravenous, microneedle, transdermal, and needle-free injection.

Established capability across diverse patient populations: Infant, adult, pediatric, elderly, niche, at risk, and varied therapeutic populations (e.g., oncology and hepatitis).

Sustained skill in Government contracts: Linical has successfully collaborated with Sponsors around the globe to secure funding from US Government agencies (e.g., BARDA, NIH, DoD, CDC, NIAID) for infectious disease development. Our experience is well known to these organizations, and our team is able to leverage our experience to advance your pursuit of these contracts to benefit your organization.

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Contact Linical:

information@linicalamericas.com

www.linicalamericas.com