Clinical Development Partner Linical

Vaccines Overview

Accelerate. Advance. Achieve.

Speed & Success in your Vaccine trial with Linical Accelovance.

Linical Accelovance has vast experience in vaccines, including over 500 treatment and prophylaxis trials involving more than 750,000 subjects. Headquarted in the United States with offices in Asia, and Europe, we are a full-service CRO conducting Phase I-IV programs across the globe. Because of our extensive operational experience in the vaccine space, Linical is your trusted provider for success, speed, efficiency, flexibility, and quality in vaccine clinical research. We:

- Engage with sites and vendors early to ensure smooth execution upon startup
- Employ vaccine experienced CRAs and project teams to ensure quality and on time delivery of your study results
- Fully understand vaccine regulatory requirements
- Evaluate preliminary immunogenicity, target disease epidemiology, and confirm dose levels are appropriately set
- Assure trials 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 mangment, 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
- Patient Enrollment & Engagement Solutions
- Regulatory Affairs, IND Services & FDA Meetings

Multiple Industry Honors

Linical Accelovance's vaccine 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 Accelovance to lead all aspects of your vaccine trial through our integrated, accelerated, and cost-effective approach. We are confident in our results and offer performance guarantees on our contracted work.

What We Bring to the Table

Proven experience across vaccine types: Anthrax, C.diff, CMV, Dengue, Ebola, 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 Accelovance has successfully collaborated with Sponsors around the globe to secure funding from US Government agencies (e.g., BARDA, NIH, DoD, CDC, NIAID) for vaccine 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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Speed & Success in your vaccine clinical trial.

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