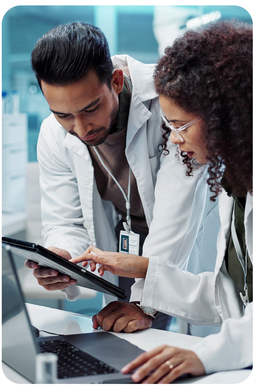
RAPID STUDY START-UP

Six Steps to Success

in Vaccine and Infectious Disease Trials

- Every dollar invested in immunization programs in low- and middle-income countries yields a return of $52[1]
- Licensed vaccines exist for 26 pathogens out of over 1,400 known human pathogens[2,3]
- Immunization prevents 3.5 to 5 million deaths every year around the world[4]
- 10 manufacturers provide 75% of vaccine doses (excluding COVID-19 vaccines); more than 80 manufacturers serve the remaining market[5]



Clinical development, especially for infectious disease vaccines, faces urgent pressures—from fierce competition to global health crises—that make speed essential for commercial success.

At VaxTrials, we've identified six critical factors to streamline study start-up timelines to ensure rapid market entry.

1 Rely on in-country staff

Local staff understand their local healthcare systems, epidemiology, regulatory environment, and cultural nuances to prevent delays and optimize trial locations.

2 Identify and engage key study personnel early on

Effectively communicating with potential sites regarding their capabilities and the protocol requirements ensures both the identification of suitable sites for participant recruitment and alignment on study goals and responsibilities.

3 Obtain regulatory and ethical approvals efficiently

By leveraging local partners to recommend optimal strategies for approval pathways, you can efficiently streamline timelines, select the appropriate country mix, anticipate complications, and ensure precise compliance with submission requirements.

4 Develop and implement a robust operational plan

VaxTrials utilizes a Quality Management Model to assess and mitigate potential risks to the start-up timeline. Alongside that, it's important to establish clear communication channels with study team members and site personnel to share updates and address issues.

5 Develop effective recruitment strategies

Effective recruitment strategies start with thorough feasibility assessments. Complemented by our expanding AI analysis capabilities for site performance and demographics, and bolstered by direct site communication, we can better confirm site experience and resources, meet diversity targets, and ensure teams are primed for enrollment success.

6 Harness technology to accelerate building the trial database

Choosing the right technology can cut database build timelines by more than half, reducing study start-up timelines by four weeks or more. VaxTrials is innovating in this area through:

1. Using AI to digitize trial protocols, transforming unstructured text into structured elements, to support automated creation of electronic case report forms (eCRFs).
2. Leveraging machine learning (ML) to identify and reuse relevant data validation checks from a library of previous trials.

Implementing these rapid study start-up approaches leads to faster study initiation, reduced timelines, and improved overall trial efficiency.

To learn more, visit www.vaxtrials.com

[1]Sim SY, et al. Immunization against 10 pathogens in 94 low- and middle-income countries 2011-30. Health Aff., Aug 2020. https://doi.org/10.1377/hlthaff.2020.00010
[2]Kennedy RB, Ovsyannikova IG, Palese P, Poland GA. Current Challenges in Vaccinology. Front Immunol. 2020 Jun 25;11:1181. doi: 10.3389/fimmu.2020.01181. PMID: 32670279; PMCID: PMC7329983.0
[3]Balloux F, van Dorp L. Q&A: What are pathogens, and what have they done to and for us? BMC Biol. 2017 Oct 19;15(1):91. doi: 10.1186/s12915-017-0433-z. PMID: 29052511; PMCID: PMC5648414.
[4]https://www.who.int/health-topics/vaccines-and-immunization#tab=tab_1
[5]World Health Organization Global Market Report, 2023. Accessed at: https://www.who.int/publications/m/item/global-vaccine-market-report-2023