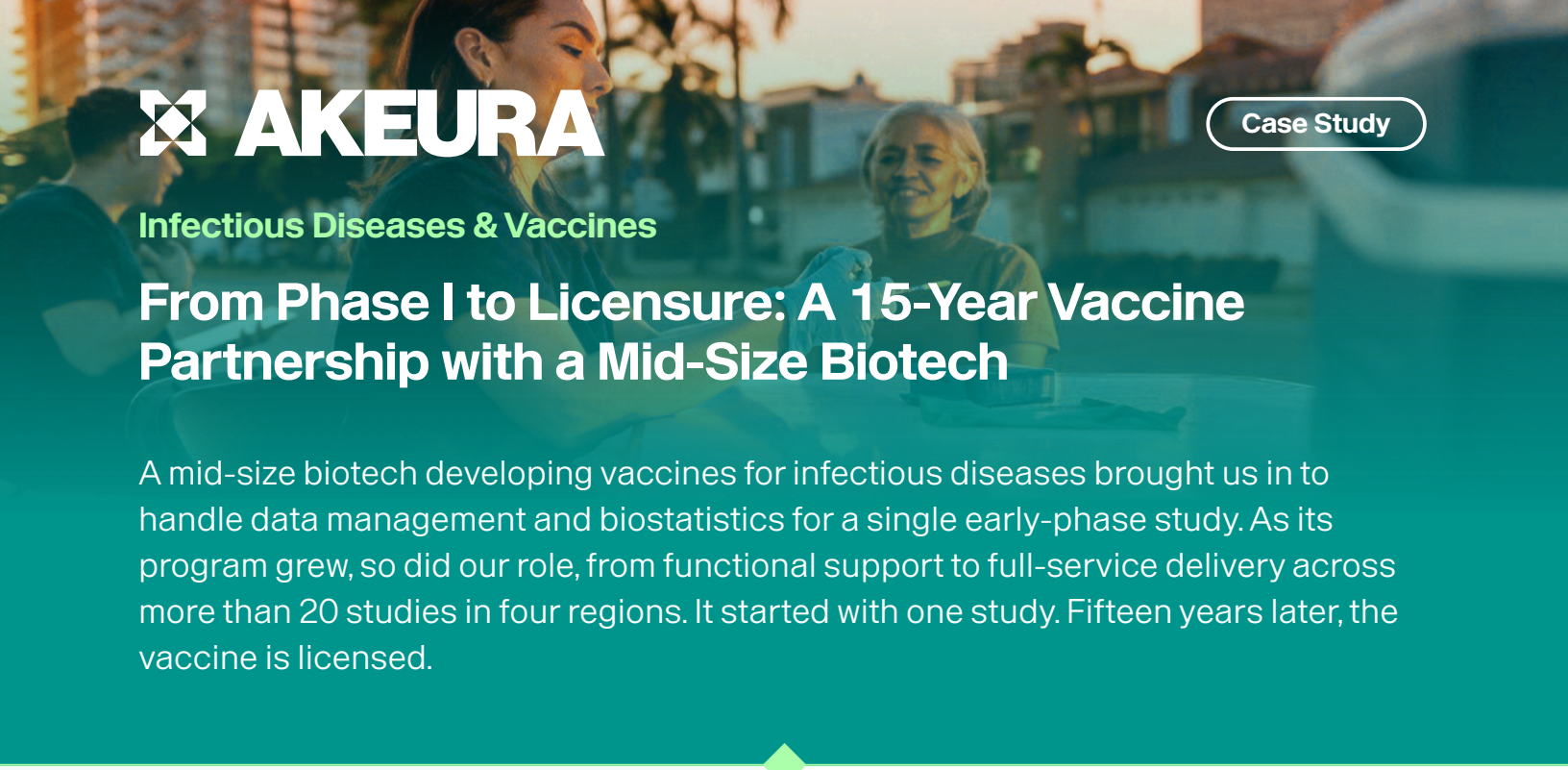


AKEURA

Case Study

Infectious Diseases & Vaccines

From Phase I to Licensure: A 15-Year Vaccine Partnership with a Mid-Size Biotech

A mid-size biotech developing vaccines for infectious diseases brought us in to handle data management and biostatistics for a single early-phase study. As its program grew, so did our role, from functional support to full-service delivery across more than 20 studies in four regions. It started with one study. Fifteen years later, the vaccine is licensed.

The Study

CONTRIBUTION
Functional service partnership that grew into full-service delivery

DESIGN
Multi-study vaccine development program, from Phase I through post-marketing

GEOGRAPHY
North America, Latin America, Europe, and Asia-Pacific

SCALE
20+ studies over 15 years, with 10+ active at once

The Challenge

As the sponsor's vaccine program expanded, so did the pressure. Timelines were shrinking, regulatory demands kept evolving, and regular analyses added a steady stream of deadlines. With multiple vendors involved, coordination got harder with every new study.

The sponsor needed a partner who could keep momentum, starting with data and statistical deliverables but flexible enough to grow with the program. That meant working well alongside other vendors, adjusting fast when priorities changed, and taking on more studies without sacrificing speed or consistency. And with licensure as the goal, every deliverable had to hold up to regulators across multiple authorities, often on tight turnarounds for post hoc analyses and regulatory requests.

The Approach

We started small, earned trust, and grew our role as the program grew, without losing speed along the way.

A Consistent Foundation

Data management and biostatistics for early-phase studies set statistical design and analytical standards that carried through the whole program.

Multi-Vendor Partnership

We worked as a strategic partner alongside other vendors, adding pharmacovigilance and monitoring oversight as needs changed.

Problem-Solving

When a new regulatory requirement came up mid-trial, our senior experts got on a call and modified the protocol within days.

Scaling to Full Service

Delivery models flexed for growth, speed, and cost, expanding to full-service support for multiple studies and post-marketing commitments.

The Impact

- **Vaccine licensure supported, with submissions to EMA, FDA, Health Canada, ANVISA, and UK MHRA**
- **20+ studies supported over 15 years, from Phase I through post-marketing**
- **10+ active studies managed at once, globally**
- **Post-marketing commitments fulfilled in multiple regions**

The Difference

Going the Distance

Some partnerships last a study. Ours has lasted a vaccine program, from first dose to licensure.

Every Study, Shaped Around You

When priorities shifted, so did we. New services, new regions, and new delivery models, added as the program needed them.

From First Dose to the Real World

More than 100 clinical vaccine studies and 140+ after licensure. One team, from first dose to real-world effectiveness.

Looking for a partner to grow with your vaccine program?

Contact us at info@akeura.com to discuss how we can support your next study.