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Accelerating Study Startup. Protecting Execution. Delivering Results.

A CASE STUDY

How **Clinovo's Dedicated SSU Team** Enabled a Sponsor's Global Phase 3 Launch Ahead of Schedule

A biopharmaceutical sponsor specializing in rare diseases, oncology, and neurology faced a pivotal moment: three early-phase studies were transitioning into in-human trials, and a first-of-its-kind global Phase 3 was on the horizon.

But with limited headcount approvals, rising operational pressure, and no margin for error, internal teams were stretched thin.

Rather than disrupt ongoing study execution or risk costly startup delays, the sponsor partnered with Clinovo to implement a **dedicated Study Startup (SSU) team**—injecting specialized expertise, preserving internal bandwidth, and accelerating timelines.

Key Results Delivered

Clinovo's targeted SSU deployment created immediate, measurable results:

- **8 SSU experts embedded,** from Clinical Project Manager through Associate Director—each selected for global regulatory expertise and sponsor alignment across APAC, LATAM, EU, and US[1]
- **Zero attrition over 24 months,** preserving continuity, institutional knowledge, and execution consistency[2]
- **All early-phase studies launched on time and on budget,** despite constrained headcount and aggressive timelines[1]
- **Global Phase 3 initiated ahead of schedule,** with no regulatory queries returned—reflecting flawless documentation, proactive authority engagement, and seamless site activation[1]

THE CHALLENGE

Growth Without Bandwidth

- Headcount constraints blocked permanent hires, even as the pipeline expanded across multiple therapeutic areas and regions
- Internal teams were fully committed to executing active trials, leaving no bandwidth to absorb startup complexity without risking quality or timelines
- Global Phase 3 launch required flawless execution, navigating diverse regulatory requirements across APAC, LATAM, EU, and US[3]
- Startup delays posed strategic risk, threatening milestone delivery, investor confidence, and competitive entry

THE CLINOVO SOLUTION

Strategic Segmentation + Embedded Expertise

Clinovo designed a **sponsor-aligned SSU model** that preserved internal bandwidth, accelerated global startup, and protected execution quality:

- **Dedicated SSU team segmented from core operations** preventing resource cannibalization and enabling internal teams to stay focused on active trials
- **Specialized global regulatory** expertise across APAC, LATAM, EU, and US delivered proactive authority engagement, faster document turnaround, and seamless site activation
- **Structured leadership and escalation protocols** ensured tight alignment with sponsor SOPs, while enabling rapid issue resolution and cross-functional coordination
- **Sponsor control without overhead**—Clinovo's embedded model delivered full transparency, flexible scaling, and execution discipline without the drag of permanent headcount or CRO disruption

Strategic Impact

For the sponsor, Clinovo's SSU team delivered more than accelerated startup—it created lasting operational stability and competitive advantage.

Operational discipline investors expect
On-time launches, zero disruption[3]

Therapeutic and regulatory alignment
Accelerated approvals, smoother site activation[1]

Workforce stability that protects timelines
0% attrition avoided costly turnover[2]

Scalable oversight without CRO disruption
Sponsor control without the burden of permanent headcount[2]

The result: a faster path to Phase 3 and greater confidence in global execution—without compromise.

Ready to Optimize Your Study Startup?

Let's talk about how Clinovo's sponsor-aligned SSU model can accelerate your timelines and protect your pipeline—without compromise.

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