CASE STUDY

Turning A Stalled Healthy Sample Study Into a Sponsor Success Story

When a leading global pharmaceutical and diagnostics company saw U.S. enrollment stall on a healthy volunteer study, valuable samples and timelines were at risk. The sponsor turned to RDI for support, and within weeks, the trial was back on track. By aligning recruitment with clinical reality and streamlining execution, RDI's out-of-the-box thinking delivered results that traditional CROs couldn't.

Precision Cohorts, Tight Timelines, and Rising Stakes

The sponsor launched a healthy sample study to establish reference ranges critical for advancing its diagnostic pipeline. With multiple tightly defined cohorts including pediatric, adult, and pregnant participants, the study demanded precise recruitment and careful sample handling. While international enrollment was underway, U.S. participation ground to a halt. With timelines slipping and sample viability on the line, the sponsor called in RDI to turn the study around.

Proof That Simplicity Drives Success

RDI's results went beyond rescue, exceeding study expectations and delivering results within a tight timeline:

10 U.S. sites activated **in just three weeks**

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700+ participants enrolled with data locked in seven months

Timeline fully recovered, safeguarding valuable samples

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Sponsor engagement expanded as RDI's scope of work grew throughout the study

The Perfect Storm of Recruitment Barriers

Transitioning a complex study midstream is never simple. For this healthy volunteer trial, the obstacles stacked up quickly:

- **Midstream rescue:** When U.S. enrollment fell short, RDI stepped in as a sample vendor to deliver fast execution under pressure where a previous CRO's efforts had stalled
- **Highly specific cohorts:** With unique eligibility requirements for pediatric, adult, and pregnant subjects, the trial functioned more like several studies than a single pipeline, creating parallel recruitment challenges
- **Strict requirements for healthy subjects:** Narrow inclusion and exclusion criteria made it challenging to identify qualified participants
- **Seasonal ticking clock:** Certain cohorts could only be recruited during specific windows, meaning any delay would risk months-long setbacks
- **Time-sensitive samples:** Collected samples had a short stability window, making speed essential to avoid losing valuable data

How RDI Cut Complexity & Accelerated Enrollment

Where others saw obstacles, RDI delivered solutions:

- **Simple, standard-of-care-friendly execution:** Rather than layering on more complex processes, RDI cut through the noise and enabled doctors to integrate study activities into normal visits
- **Recruiting by cohort:** RDI used a tailored strategy for each cohort instead of lumping them together as healthy samples, unlocking the flexibility needed to actually reach the right patients
- **Data-driven site selection:** By combining claims and EHR analytics with targeted community engagement, including digital channels like social media, RDI identified the right sites with unparalleled precision
- **Maintaining momentum through the holiday season:** RDI obtained approvals over the holidays, pushing through IRB review over Christmas and New Year's with relentless follow-up
- **Adapting sample handling and logistics:** Where sites lacked -80° C freezers, RDI bought equipment or set up daily shipments so every sample stayed viable

As a result of RDI's efforts, sites were activated within weeks through a process that felt natural for providers and efficient for the sponsor.

Expertise and Persistence That Power Smarter IVD Trials

This rescue study demonstrated how RDI's ability to simplify complex protocols, think creatively about recruitment, and execute with speed can transform even the most time-sensitive challenges. For sponsors looking to accelerate timelines and strengthen trial execution, RDI offers the IVD expertise and practical approach to make it happen.

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