Delivering Clinical Trial Continuity During a Global Crisis:

A Case Study in Rapid Enrollment for an IV Biosimilar Study

Executive Summary

The COVID-19 pandemic presented unprecedented obstacles for clinical research organizations (CROs) worldwide. Enrollment rates plummeted, timelines slipped, and study continuity was at risk. This white paper presents a case study of how AXIS Clinicals partnered with a top three global CRO to rescue a complex multicenter trial for an intravenous (IV) biosimilar drug. Despite pandemic-era restrictions, AXIS successfully recruited, enrolled, and dosed 50 subjects within 90 days—directly enabling the sponsor to meet regulatory and contractual commitments.

Background and Study Design

Drug and Objectives

The investigational product was an IV biosimilar administered based on subject body weight. The primary objectives were to evaluate pharmacokinetics (PK), receptor binding, and pharmacodynamics (PD), with secondary endpoints including safety, tolerability, and immunogenicity.

Trial Structure

- **Study Type:** Multicenter, stratified by subject weight
- **Sample Size:** 360 total subjects, with a goal of 327 evaluable
- **Sites:** Planned across 5 centers in the EU and US
- **Confinement:** 8 days of inpatient participation
- **Follow-Up:** Ambulatory visits through Day 85, with full PK/PD and safety monitoring at each checkpoint

The trial was awarded to a leading global CRO, which initiated operations in early 2020. However, enrollment stalled due to COVID-19 restrictions, creating significant delays and jeopardizing sponsor timelines.

AXIS Engagement

In Q2 2020, the global CRO identified AXIS Clinicals as a rescue site, tasked with enrolling up to 50 volunteers to recover lost recruitment momentum.

- **Contract Awarded:** July 16, 2020
- **Screening Initiated:** July 27, 2020
- **First Dosing:** August 18, 2020
- **Enrollment Completion:** November 16, 2020

This three-month timeline demonstrated not only operational agility but also the ability to maintain quality under pressure.

Recruitment Challenges

The height of the COVID-19 pandemic posed unique enrollment barriers:

1. **Safety Protocols**
   - All volunteers required **two negative SARS-CoV-2 PCR tests** prior to check-in.
   - Negative antibody screening was mandated to exclude prior infections.
2. **Volunteer Hesitancy**
   - Potential participants were cautious about hospital and clinical site visits during the pandemic.
   - Additional education and reassurance were necessary to alleviate concerns.
3. **Regulatory Compliance**
   - All processes required strict alignment with evolving local and international COVID-19 safety guidance.

Despite these constraints, AXIS leveraged established community engagement, streamlined pre-screening, and strict infection-control procedures to ensure subject safety and trial continuity.

Results

AXIS exceeded expectations by successfully enrolling and dosing all 50 subjects within the sponsor's required timeline. This was achieved while adhering to rigorous pandemic-era safety protocols and without compromising data quality.

Key Outcomes:

- Full enrollment of rescue cohort (50 subjects) within 90 days
- Continuity of trial timelines for sponsor and CRO
- Maintenance of data integrity across PK, PD, safety, and immunogenicity endpoints
- Demonstrated resilience in clinical trial operations during a global health crisis

Lessons Learned

This case study highlights several key lessons for clinical research organizations. Agility during times of disruption proved critical. The ability to adapt rapidly to unforeseen global events enabled AXIS to contribute meaningfully to the continuation of a large-scale trial. This flexibility demonstrates the value of smaller, responsive organizations in complementing the operations of larger CROs when challenges arise.

Equally important was the implementation of safety-first protocols that built trust among participants. Clear communication and rigorous infection-control measures provided reassurance during a period of heightened concern, supporting both participant retention and data integrity. Prioritizing safety not only safeguarded volunteers but also ensured compliance with evolving regulatory expectations.

Finally, the success of the trial depended on effective collaboration across stakeholders. Close coordination among the global CRO, the sponsor, and AXIS aligned study operations, timelines, and scientific objectives. This cooperative approach illustrates how strategic partnerships can mitigate risks and maintain trial momentum, even under the most adverse conditions.

Conclusion

This case study illustrates how adherence to protocol and adaptive enrollment strategies can help preserve study continuity in the face of global challenges. While large CROs may provide infrastructure and global reach, smaller, agile organizations bring flexibility, responsiveness, and community trust. By enrolling 50 subjects during the height of COVID-19, AXIS enabled the sponsor to stay on track with trial timelines, demonstrating resilience, reliability, and operational excellence.

For sponsors, the implication is clear: diversifying partnerships across CRO types can help safeguard study progress during unforeseen crises.
For regulators, the findings underscore the importance of maintaining operational feasibility without compromising data quality or participant safety. Looking ahead, the integration of adaptive strategies into trial design may represent a practical step toward ensuring continuity in future large-scale clinical investigations.