Transforming Complexity into Success: A Large-Scale Global Phase III Biosimilar Dermatology Trial

Streamlining Regulatory Processes, Site Management, Patient Selection, Retention and Investigational Product (IP) Management

Infinite Scientific Innovations

Background

A leading global pharmaceutical company, recognized for its generics and specialty drugs, partnered with COD to manage a Phase III, multicentre, double-blind Biosimilar study. The trial aimed to compare the efficacy, safety, and immunogenicity of an injectable Biosimilar with a reference product, targeting patients with a chronic dermatological condition who had not responded adequately to standard care. The trial required an efficient strategy and streamlined approach to ensure success across multiple regulatory environments, clinical sites, and patient populations.

Our Approach: A Comprehensive, Results-Driven Strategy

1. Accelerating Regulatory Approvals for Timely Study Initiation

Navigating regulatory requirements swiftly and precisely was key to this global trial's success.

- **Rapid Submissions:** Our team ensured fast, detailed submissions, covering the investigational product (IP), study protocol, patient safety, and ethics, meeting strict standards to prevent delays.
- **Proactive Communication:** We closely monitored approval progress, responding promptly to queries and ensuring timely approvals, facilitating recruitment in India, US, Europe and Jordan.

2. Strategic Site Selection & Activation Across Key Regions

Site selection and activation were executed in parallel with the regulatory submission process, ensuring that patient recruitment could begin immediately after approvals.

- **Multicenter Site Selection:** We identified clinical sites in India, US, Europe and Jordan based on their capabilities, experience with Biosimilar trials, and access to the appropriate patient populations. By leveraging local knowledge and expertise, we ensured that each site was equipped to meet the study's specific needs.
- **Efficient Site Activation:** Ethics committee approvals were secured swiftly, and site initiation visits were conducted to confirm that each site was fully prepared for patient recruitment. By streamlining the site activation process, we minimized delays and ensured that each site could begin recruitment promptly upon receiving regulatory approval.

3. Precise Patient Selection to Uphold Study Integrity

Ensuring the right patient population was critical to the trial's scientific rigor and participant safety.

- **Rigorous Criteria:** Detailed inclusion/exclusion criteria were set to define eligible patients based on disease history, symptom severity, and prior treatments, ensuring data integrity and minimizing variability.
- **Ongoing Safety Monitoring:** Continuous patient monitoring throughout the trial ensured safety and enhanced data quality, contributing to robust findings for regulatory review.

4. Advanced Investigational Product (IP) Management

To manage the high cost and limited shelf life of the IP, COD employed precise practices to prevent waste and ensure product integrity.

- **Optimized IP Logistics:** We coordinated shipments to match patient recruitment, minimizing wastage and ensuring efficient use of IP.
- **Strict Packaging & Shipment:** Two separate cartons were used to maintain blinding, and temperature-controlled shipments preserved IP integrity throughout transit.
- **Sample Collection & Management:** We implemented rigorous protocols for the collection, storage, and shipment of PK, PD, and ADA samples, ensuring sample integrity for future analysis.

Key Study Highlights

Recruited **600** subjects with timely start-up, sites activation across **4** regions

12,000 PK, PD, and ADA samples were successfully managed

The sites performed exceptionally well in competitive recruitment, demonstrating excellent patient retention and providing auditable data

Conclusion: Delivering Excellence Across Every Step

COD's methodical and integrated approach ensured the successful execution of this Phase III Biosimilar dermatology trial. By streamlining regulatory approvals, managing site activation efficiently, and executing precise patient selection and retention strategies, we helped the client stay on track to meet critical milestones and deliver high-quality data.

Our robust IP management practices, along with constant monitoring and support, played a crucial role in maintaining both the scientific and operational integrity of the study In the end, COD's dedicated efforts not only supported the trial's smooth execution but also ensured patient retention, data integrity, and a seamless transition to the next phase of development. Our comprehensive, results-driven approach helped our client achieve success on a global scale, reinforcing our reputation as a trusted partner in complex clinical trials.

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