Pharm-Olam™
Helping Create A Healthier World

CASE STUDY

Rescue and Transfer of a Bioequivalence Breast Cancer Study:

How Pharm-Olam Met Aggressive Enrollment Timelines and Objectives

Study Overview:

Pharm-Olam rescued a bioequivalence Breast Cancer study from multiple CROs and independent contractors. To meet rapid patient recruitment goals, Pharm-Olam both assumed management of already-activated sites and added new sites. Pharm-Olam's Regulatory experts also worked directly with regulatory authorities to clarify paperwork, communicate priorities and resolve open issues with submissions.

Study Details:

- **Indication:** Breast Cancer
- **Patients:** 111
- **Sites:** 26
- **Countries:** USA, Bulgaria, Georgia, Hungary, Moldova, Poland, Romania, Serbia, Singapore, and Ukraine
- **Services Provided:**
  - Regulatory
  - Monitoring
  - Project Management
  - Data Management
  - Medical Monitoring

Key Achievements:

- Successful transition of study from multiple CROs and independent contractors.
- Patient enrollment objective met in 4 months.
- Enrollment objectives achieved ahead of schedule, using fewer sites than scoped (18 actual vs 41 targeted).
- Data cleaning completed on time or ahead of schedule for both the Interim Database Lock and Final Database Lock, despite aggressive setup deadlines.
- Study passed five external site audits with no critical findings.

Study Challenges & Solutions:

Challenge # 1: Transition of Study Knowledge and Materials

The incumbent trial team included 4 CROs and a series of independent contractors. As a result, components of the study—including materials, product knowledge and data—were scattered across numerous sites and organizations. The sponsor expressed concern about capturing critical information and maintaining its integrity during the transfer process.

Solution: Pharm-Olam refrained from contacting the incumbent trial team. Instead, Pharm-Olam coached the sponsor's project team through the transition. During the transition period, Pharm-Olam was tasked with Site Start-up, Site Management including Monitoring, Drug Management, TMF Maintenance, Project Management, Data Management and Medical Monitoring.

Challenge # 2: Regulatory Submissions

Once the transfer of knowledge and administration was complete, Pharm-Olam reviewed the Regulatory notifications submitted by the trial's former CRO. After review, Pharm-Olam discovered duplicate submissions, a redundancy error which delays approvals.

Solution: Pharm-Olam's Regulatory experts worked directly with regulatory authorities to clarify paperwork, communicate priorities and resolve open issues with submissions. Further delays were prevented, allowing rapid patient recruitment to resume. Ultimately, recruitment thresholds were met prior to the originally contracted date.

Challenge # 3: Patient Recruitment

The handover process was ultimately successful, although it resulted in some delays in the patient recruitment process. It was necessary to reactivate sites in some countries that had been initiated by the preceding trial team. Several of sites that were reactivated as part of a catch-up recruitment process had yet to enroll a patient.

Solution: To accelerate the patient recruitment process, Pharm-Olam activated sites in Georgia, Hungary, Serbia and the Ukraine. Georgia, Ukraine and Moldova each enrolled nearly double their patient quota, all in a shorter timeline than budgeted. Pharm-Olam worked closely with the reactivated study sites in order to motivate them to continue participating in enrollment efforts.

Conclusion

Despite the challenges presented by its initial design and structure, this bioequivalence Breast Cancer study was rescued by Pharm-Olam to the sponsor's satisfaction. Pharm-Olam was able to overcome regulatory and recruitment challenges, maintain data integrity and exceed sponsor expectations with respect to original timelines and budgets. Pharm-Olam's global coverage resolved gaps in the patient recruitment mix, allowing the study to benefit from new sites in countries that were not included by the original investigators.

Pharm-Olam is currently in conversations with the sponsor about conducting the next phase of this trial.

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