Pharm-Olam
Helping Create A Healthier World

CASE STUDY

Accuracy & Compliance in a Phase I/II Trial Involving Preterm Neonates

Study Overview:

Pharm-Olam was contracted to provide clinical research services on a Phase I/II pediatric Respiratory Distress Syndrome study involving neonates with a gestational age between 27 and 33 weeks. This first-in-human study required a single intratracheal administration within 24 to 48 hours of birth.

Study Details:

- Phase I/II
- **Patients:** 40
- **Sites:** 12 sites in 3 countries—Great Britain, Germany, and Czech Republic
- **Services Provided:**
  - Regulatory
  - Monitoring
  - Project Management
  - Pharmacovigilance
  - Data Management
  - Biostatistics
  - Medical Writing
  - Medical Monitoring
- Management of Data and Safety Monitoring Board (DSMB), required for each cohort within 48 hours of birth
- Management of Safety Monitoring Board (SMB) assessments

Study Challenges & Solutions:

Challenge # 1: Potential Delays with Enrollment

Study protocol required patient data to be reviewed and approved by the SMB 7-10 days after collection. Once the data was collected, additional time was required to organize a meeting of the voting members of the SMB. Since patients could not be enrolled until an SMB-approved positive result was secured, recruitment efforts could be potentially delayed.

Solution: To ensure enrollment protocol was followed, Pharm-Olam instituted a check-in procedure, obligating CRAs to verify patient safety and provide training to investigators at each site. Pharm-Olam's Data Management team actively monitored and maintained records within the electronic monitoring system eCRF, helping sites to comply with recruitment protocol and stop recruiting efforts when thresholds were met.

Challenge # 2: Informed Consent

As the patients were preterm neonates, informed consent form signatures were required from the parent(s) and/or guardian(s) both before and after birth. Furthermore, follow-up was required if the subject was transferred to another care facility and so it was imperative that the mother's data was maintained in the master file.

Solution: Pharm-Olam was able to educate and train investigators and site staff with regards to the unique requirements of this study. Real-time tracking of all patients by investigators and site staff resulted in successful retention and maintenance of all subjects for the duration of the study.

Challenge # 3: Differences in Standards of Care

Different countries, and even different geographies within the same country, often had different standards of patient care. The use of 12 sites in three countries presented site-level challenges in following study protocol.

Solution: Pharm-Olam accounted for discrepancies by using source data worksheets, pocket cards with inclusion/exclusion criteria and required lab values, and labels for patient medical files that documented the Informed Consent Form (ICF) procedure, study participation and screening failures. Only sites agreeing to follow the protocol procedures were selected for the study. It is important to have the freedom to reject sites, even key opinion leaders, if they insist on using local treatment procedures rather than to implement local protocol amendments.

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