propharma

CASE STUDY

Keeping Research Moving Under Pressure: Delivering Data Integrity at Speed

When rapid enrollment outpaces expectations, clinical trials can face mounting operational pressure, putting timelines, data integrity, and regulatory milestones at risk.

A mid-size biotech sponsor conducting parallel Phase 2 studies encountered accelerated patient enrollment across high-performing regions, creating an urgent need for rapid data cleaning, site coordination, and consistent oversight to support multiple compressed data cuts.

Challenge

Customer: Mid-Size Biotech Company

Therapeutic Area & Development Stage: Phase 2 Concurrent Respiratory Studies

Background: Mid-size Biotech Sponsor with parallel enrolling studies in respiratory with exacerbation in emergency settings. Both studies experienced rapid enrollment (outside the US), far exceeding original enrollment projections by more than 300%, necessitating multiple data cuts in quick succession.

Key Challenges:

- **Rapid Data Cuts:** High volume of case report forms (CRFs) needed cleaning in a short timeframe. The sponsor wanted all data cleaned before the data cut.
- **Accelerated enrollment velocity**: Higher than anticipated concentration of patients enrolled within the data cut timelines, resulting in a surge of data concentrated in a single region.
- Site Data Quality: Inconsistent and incomplete electronic data capture (EDC) data entry, driven by variable site responsiveness, competing site priorities due to rapid enrollment, and site expectations of data entry.
- Need to utilize data for pivotal sponsor decisions: The quality of data was essential to address systemic and rapid decisions across regions.

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Solution

- **Targeted CRA Deployment:** ProPharma rapidly deployed specialized SWAT CRA resources to execute targeted onsite and remote monitoring. A focused deployment strategy prioritized the highest-enrolling sites with the greatest impact on data integrity, ensuring that monitoring activities were tightly aligned with accelerated data cut timelines. Centralized training and rigorous oversight ensured consistent, high-quality data review and deliverables across all monitoring activities.
- **Enhanced Site Communication and Engagement**: To provide the necessary outreach to the sites to achieveing the data cleaning, ProPharma created a Data Cut Rapid Response Team by leveraging dedicated regional oversight with Project Managers and Clinical Leads to identify rapid identification and regional trends impacting data completeness and provide real-time issue resolution. The Rapid Response Team augmented the Communication Plan to provide continuous outreach to sponsors and sites to address gaps, reinforce urgency, and recognize progress.
- **Streamlined Operational Coordination and Governance**: ProPharma established strong cross-functional alignment across Clinical Operations, Data Management, and Clinical Monitoring to support accelerated timelines and critical data milestones. This integrated operating model ensured consistent and coordinated communication to investigational sites, clear prioritization of data critical to interim and final analyses, and rapid escalation and resolution of persistent data quality risks.

Result

- Delivered consistent, decision-ready data across multiple rapid data cuts, achieving target data cleanliness metrics despite accelerated enrollment velocity.
- Enabled confident downstream analyses by ensuring 100% completion of critical data pages prior to each data cut.
- Substantially reduced EDC backlog and variability, improving overall data completeness and reliability across high-enrolling sites.
- Established a scalable, repeatable operating model for managing parallel studies with frequent data cuts—maintaining sponsor confidence through predictable, high-quality data delivery.

100% completion of critical data points across multiple rapid data cuts

Through a targeted, cross-functional approach, ProPharma enabled consistent, decision-ready data while significantly reducing backlog and variability across high-enrolling sites.

Beyond immediate execution, this model established a scalable, repeatable framework for managing parallel studies under compressed timelines, supporting both data integrity and confident downstream decision-making.

Because advancing clinical research requires more than execution alone, it depends on maintaining momentum, quality, and oversight when it matters most.

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