MEDPACE

CASE STUDY

GLOBAL PHASE III RARE DISEASE STUDY EXCEEDS DATABASE LOCK TARGET DURING COVID-19

CHALLENGES

Due to the COVID-19 pandemic, a key Medpace Sponsor was facing delays that would affect their clinical trial timeline and lead to potential interruptions in treatment as well as unexpected budget overruns. COVID-19 restrictions caused unplanned challenges in getting patients to sites and put the timing for database lock at risk.

Key challenges included:

- LIMITED ONSITE PATIENT STUDY AND MONITORING VISITS
- MANY STUDY SITES NOT ALLOWING REMOTE SOURCE DATA VERIFICATION
- SITE STAFF NOT ONSITE AND THEREFORE NO ACCESS TO STUDY DOCUMENTS

RESULTS

Database Lock Target for Critical Data Points was 70%

We achieved **92%**

Database Lock Target for all forms was 40%

We achieved **91%**

SOLUTION

To overcome these challenges, the study team updated the protocol to allow remote monitoring. Key tactics included:

- Utilized ClinTrak®, Medpace's proprietary web-based clinical trial management software, to track site specific COVID-19 restrictions — provided updates to the study team on what each site permitted on a weekly basis
- Developed site specific plans for remote based monitoring and source data verification and ensured site source documentation process forms (SSDPFs) were updated for source sharing
  - Use of ClinTrak's Site Source Portal which allowed sites to upload source documents for CRA's to review remotely
  - Video-based monitoring
  - Sites emailed redacted certified copies
- Updated protocol language to allow for COVID mitigations with regulatory submissions globally
  - Increased visit windows
  - Allowed for home health visits
  - Allowed for telehealth visits
  - Allowed for local lab testing when site didn't allow subject visits
- Developed remote consenting guidance for both sites and subjects
- Developed source data verification plan that allowed for focus on critical data for primary endpoints
  - Set required % source data verification for critical data and overall source data verification
- Added detailed language to the Monitoring Plan – defining the source data verification plan and provided detailed guidance to CRAs
- Developed Database Lock Plan to detail timelines, source data verification plan, roles and responsibilities for database lock, and contingency planning
- Created detailed metrics reporting and reviewed weekly as it related to the database lock to prioritize sites of concern and necessary follow-up

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.