

Case Study

Remote Clinical Data Management Using MEDRIO EDC for a Phase 2 Trial

Client's Business Influence

The remote data management approach using MEDRIO EDC delivered significant operational and strategic benefits:

✔ Business Continuity: Enabled uninterrupted trial execution during pandemic-related travel restrictions

🕒 Faster Timelines: Reduced site setup and data entry delays by 30%

📊 High Data Quality: >98% query resolution rate within 5 days

💰 Cost Efficiency: Saved ~25% in monitoring and travel costs

🌐 Scalability: Client adopted MEDRIO for 4 additional global studies based on success

Project Scope:

A global pharmaceutical company conducting a Phase 2 clinical trial for a novel oral treatment targeting mild to moderate asthma.

The study was conducted across multiple sites in India and Southeast Asia during a time when travel and on-site monitoring were limited. The client required a fully remote data management solution that ensured:

- ❖ Real-time data capture and cleaning
- ❖ Seamless collaboration across geographies
- ❖ Regulatory compliance and audit readiness

The chosen platform for this project was MEDRIO EDC, selected for its cloud-based, user-friendly interface and rapid deployment capabilities.

Methodology/ Approach:

Study Setup

- ❖ Designed and built eCRFs in MEDRIO EDC within 3 weeks
- ❖ Configured custom edit checks, visit schedules, and dynamic forms for asthma-specific endpoints (e.g., FEV1, symptom scores)
- ❖ Integrated ePRO modules for patient-reported outcomes and central lab data feeds

Remote Data Collection & Cleaning

- ❖ Enabled role-based access for sites, CRAs, and data managers
- ❖ Conducted virtual training sessions for site staff and CRAs
- ❖ Used MEDRIO's query management system for real-time issue resolution
- ❖ Weekly data review dashboards and automated alerts for missing or inconsistent data

Monitoring & Oversight

- ❖ Integrated remote monitoring tools for SDV (source data verification)
- ❖ Used audit trails, data export logs, and e-signatures to ensure compliance
- ❖ Conducted bi-weekly virtual data review meetings with cross-functional teams

Database Lock & Reporting

- ❖ Performed interim data reviews and dry-run locks
- ❖ Final database lock achieved 100% remotely
- ❖ Delivered SDTM datasets, define.xml, and Data Management Report (DMR) for regulatory submission