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COLLICULUS

Case Study

End-to-End Data Management for Phase 1–3 Pulmonology Clinical Trials

Client's Business Influence

The data management strategy delivered significant value across the development lifecycle:

✅ Accelerated Timelines: Enabled Phase 2 to Phase 3 transition within 6 months due to clean, high-quality data

📊 Data Quality: >99.5% data accuracy at final lock; zero critical findings in regulatory audits

🌎 Global Compliance: Submission-ready datasets aligned with CDISC, FDA, and EMA standards

💼 Strategic Impact: Supported successful NDA submission and approval within 12 months of Phase 3 completion

Project Scope:

A global pharmaceutical company developing a novel inhaled therapy for moderate to severe chronic obstructive pulmonary disease (COPD). The company conducted a full clinical development program:

- Phase 1: Safety, tolerability, and PK in healthy volunteers
- Phase 2: Dose-ranging study in COPD patients
- Phase 3: Multinational, randomized, double-blind, placebo-controlled efficacy trial

The client required end-to-end clinical data management (CDM) services across all phases, including:

- Study startup and EDC build
- Real-time data cleaning and query management
- Integration of spirometry, imaging, and ePRO data
- Regulatory submission-ready datasets (SDTM + ADaM)

Methodology/ Approach:

Study Setup

- Developed CDM Plans, Edit Check Specifications, and Data Review Guidelines for each phase
- Built eCRFs in Medidata Rave and Veeva Vault CDMS for global Phase 3
- Integrated third-party data: spirometry, CT imaging, ePRO, and central labs

Data Collection & Cleaning

- Implemented custom edit checks for pulmonary endpoints (e.g., FEV1, FVC, exacerbation events)
- Real-time data review dashboards for safety and efficacy monitoring
- Weekly data review meetings with clinical, safety, and biostatistics teams

Medical Coding & SAE Reconciliation

- Used MedDRA 26.0 and WHO-DD for AE and concomitant medication coding
- Reconciled SAE data with Argus safety database across all phases

Database Lock & Submission

- Conducted interim locks for DSMB reviews and regulatory milestones
- Delivered SDTM and ADaM datasets, define.xml, and Reviewer's Guides
- Supported eCTD submission for NDA filing with the US FDA and EMA