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COLLICULUS

Case Study

End-to-End Data Management for a Phase 1 Dermatology Clinical Trial

Client's Business Influence

The project delivered measurable value to the client's clinical and regulatory strategy:

✅ Accelerated Development: Enabled rapid go/no-go decision for Phase 2 based on clean, validated data

📊 High Data Quality: >99% data accuracy at interim review; no major findings in QA audit

💼 Regulatory Readiness: Submission-ready SDTM datasets aligned with CDISC and FDA expectations

🧠 Strategic Advantage: Positioned the client to attract early licensing interest from dermatology-focused biotech firms

Project Scope:

A specialty pharmaceutical company focused on dermatological therapies and initiated a Phase 1, first-in-human (FIH) study to evaluate the safety, tolerability, and pharmacokinetics of a novel topical formulation for mild-to-moderate atopic dermatitis.
The study involved:

- 36 healthy volunteers
- Single and multiple ascending dose cohorts
- Conducted at 2 clinical sites in India

The client required end-to-end clinical data management (CDM) services to ensure high-quality, regulatory-compliant data for early decision-making and future IND submission.

Methodology/ Approach:

Study Setup

- Developed a comprehensive CDM Plan, Edit Check Specifications, and Data Review Guidelines
- Designed and built eCRFs in Medrio EDC tailored for dermatology-specific assessments (e.g., EASI score, IGA, TEWL)
- Integrated digital imaging data and local lab data from external vendors

Data Collection & Cleaning

- Real-time data entry and query resolution through EDC
- Implemented custom edit checks for dermatology endpoints (e.g., lesion count consistency, application site reactions)
- Conducted weekly data review meetings with clinical and safety teams

Medical Coding & SAE Reconciliation

- Used MedDRA 25.1 for AE and medical history coding
- Reconciled SAE data with Argus safety database on a rolling basis

Database Lock

- Performed interim data reviews after each cohort
- Final data cleaning and database lock achieved within 5 weeks of LPLV
- Delivered SDTM datasets, define.xml, and Data Management Report (DMR)