› CASE STUDY

VERISTAT

Early Data Strategy: Building Today's Trial for Tomorrow's Scalable Success

Optimizing EDC Strategy and Data Collection for a Rare Disease Trial

Background

A small biotech sponsor preparing for a Phase II rare disease trial needed expert support to build an efficient, scalable data collection strategy. The trial design included complex eligibility criteria, custom assessments, niche endpoints, and multiple data sources, such as site-entered clinical data, local labs, and external imaging. Without an internal data management (DM) team and limited EDC and ePRO experience, the sponsor turned to Veristat for strategic guidance.

Challenges and Impact

CHALLENGES	IMPACT
No internal DM expertise	Risk of misaligned system choice and poor database structure
Complex protocol, custom data points	High potential for site burden and inconsistent data
Budget and timeline constraints	Needed a quick but robust solution
Limited familiarity with EDC platforms	Required expert-led system selection and configuration
Multi-source data requirements	Required future scalability for labs, imaging, and ePRO

Solution

Veristat's Data Management team was engaged early—during protocol finalization—to guide the sponsor through both strategic decisions and tactical execution. Our approach included:

EDC System Selection

We conducted a focused evaluation of three EDC systems based on study complexity, budget, and scalability. The final recommendation delivered strong functionality, intuitive site usability, and seamless scalability for later phases.

CRF Design & SDTM Alignment

Our team led the development of case report forms (CRFs) that emphasized data clarity, minimized redundancy, and ensured SDTM alignment to support future regulatory submissions and downstream analytics.

Streamlined Data Collection Strategy

We advised the sponsor on which data elements were essential and which could be deferred, focusing on endpoint-aligned capture that reduced site burden and simplified the data management process.

Planning for External Data Integration

Even though local labs and imaging were out of scope for Phase II, we developed a forward-looking roadmap for integrating these external sources in later stages—future-proofing the data ecosystem without complicating the current build.

Results

The collaborative approach delivered clear, measurable outcomes that positioned the sponsor for both immediate success and long-term scalability:

- The EDC system was selected, configured, and built within just 8 weeks—keeping the trial on schedule
- The database performed exceptionally during testing, with minimal queries and a clean validation process
- Clinical sites reported strong usability and ease of data entry, enabling efficient enrollment and data capture
- The sponsor gained confidence in both the database design and overall data strategy as they planned for Phase III

By involving Veristat's Data Management team early, the sponsor avoided common early-phase pitfalls, such as an unclear data strategy, inefficient CRFs, and delays caused by over-collection or misaligned systems. The final solution delivered clean, submission-ready data while laying the groundwork for scalable, multi-phase success.

ABOUT VERISTAT

Veristat's Data Management experts deliver flexible, customized solutions that optimize data accuracy, integrity, and regulatory readiness across the full clinical trial lifecycle. From EDC selection and SDTM-aligned CRF design to data cleaning, integration, and final submission, we proactively support every phase of your study. With nearly 200 trials supported globally by our data managers in the past five years, our integrated approach ensures speed, quality, and confidence from start to submission.

Contact Veristat Today

To learn more about Veristat's tailored data management solutions or how we can assist you in determining if our expertise meets your needs, reach out to us today.

veristat.com ›