

Clinical Data Management

Clinical trial data management services:

- CRF design
- Database specification, programming, and validation
- Data management plan development
- Data entry
- Query management
- Medical coding
- Data Integration

Axio's clinical data management team delivers solutions that address **all aspects of the clinical trial process**—from development of the protocol through report writing—with uncompromising accuracy and adherence to the highest data management standards. Our work pivots on industry-recognized and **FDA-compliant** data management systems that enable us to deliver high-quality output with confidence. Our team has **extensive data management experience** spanning preclinical through Phase IV development as well as a broad range of therapeutic areas, using both **paper and EDC systems**. To facilitate decision-making, we **customize data metrics and study management reports** to your needs.

Our team has extensive data management experience spanning preclinical through Phase IV development as well as a broad range of therapeutic areas including cardiovascular disorders, infectious diseases, and respiratory diseases.

Representative Studies

Indication	Phase	# Patients
Atrial Fibrillation Therapy	3	4,100
Coronary Events Study	4	4,000
Hyperlipidemia	4	3,400
Personalized medicine and lab-developed test	4	2,300
Anemia	3	750
Cystic Fibrosis	3	350
RSV Vaccine	3	300
Rheumatoid Arthritis	2	225



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Clinical Data Management Systems

You can count on Axio's adherence to the highest data management standards. Our personnel follow standard specifications and collaborate with in-house biostatisticians and SAS programmers to develop case report forms (CRFs) and databases with an eye to how these elements affect your downstream processes. Your study's processes for data extraction and preparation are designed to make the database useful for SAS analyses.

We will also work with your team to identify key areas for edit checks and cross-form checks. To support your team's decision-making activities, we will customize data metrics and study management reports to your needs.

PAPER STUDIES: For paper-based studies, we will build and maintain your clinical database using Clintrial™ (Phase Forward). After CRFs are final, the database is typically ready for data entry in two weeks, while edit checks are programmed and validated in approximately four weeks.

ELECTRONIC DATA CAPTURE (EDC) STUDIES: Axio has more than 13 years of experience with EDC. To further upgrade our EDC capabilities, we have partnered with BioClinica® to adopt its Express EDC solution. We selected BioClinica® based on the product's flexibility and ease of use, and the company's shared commitment to customer service and quality.

Adverse Event Coding

We will work with you to develop best practices in creating coding guidelines and conventions. Our services include preparation of a detailed plan for your study that addresses:

- How to code procedures properly
- Defining protocols for coding symptoms versus diagnoses
- MedDRA versioning over time
- Under what circumstances to query the sites about adverse events

You can depend on fast turnaround times and a flexible, service-oriented team.

Data Standards

Axio is a corporate member of the Clinical Data Interchange Standards Consortium (CDISC); our staff members have

been trained in the Study Data Tabulation Model (SDTM) and Analyst Data Model (ADaM) standards. In addition, our data management team members are active participants in the SDTM, ADaM, and Clinical Data Acquisitions Standards Harmonization (CDASH) standards groups. We have assisted clients in creating CDISC/SDTM data sets from their clinical data and have conducted training for biotechnology companies in CDISC/SDTM.

Additional Services

For studies that require highly complex data management solutions, we have answers. Axio's data management experts have successfully built custom systems for many companies such as:

- A web-based application to track the incidence, reporting, and follow-up of SAEs. This encompassed ongoing cross-checks with CRF data, generating reports that included both CRF and safety data to assist with the preparation of narratives, and generating real-time reports that enabled clinical sites to see discrepancies between safety data and CRF data.
- An MRI scan tracking system for remote readers to grade scans and communicate with site personnel if and when scan results indicated a problem.
- Tools to incorporate lab data transfers and scan reading center data to study databases. Because of our deep experience with mid-study DMC reports, we excel at detecting and scrubbing unclean data from disparate sources. We have validated macros for lab unit conversions and common terminology criteria for adverse events (CTCAE) grading.
- Web-based custom patient randomization schemes based on algorithms generated by our biostatisticians. Simple or adaptive designs, with or without blocks or strata, are all within our capabilities.
- A Survey Tool to support to several large registries, along with electronic patient-reported outcomes (ePRO). This tool features customizable edit checks and web-page formatting, options for double data entry, cross-browser compatibility, and extraction of data to SAS. The Survey Tool has been used in more than a dozen applications, including surveys of clinical practitioners, patient symptom diaries, and medication experiences.



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