IDDI

PASSION. SCIENCE. EXPERIENCE.

Your Guide to Smarter Data Management Partnership

Stronger Data, Stronger Trials

Driving quality, confidence, and speed

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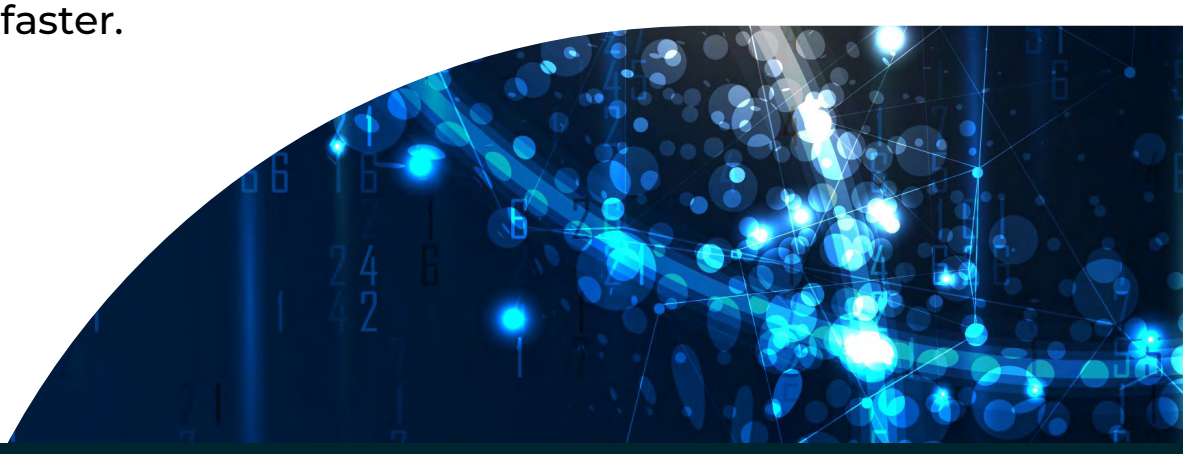
Clinical trials generate vast amounts of data, and the quality of that data determines the reliability of every conclusion drawn.

When data are incomplete, inconsistent, or poorly structured, the impact is felt across the trial: timelines slip, analyses are delayed, and regulators are more likely to raise questions—making the path to approval longer and riskier.

In contrast, when data management is recognized as a strategic function from the outset, data quality improves, risks are reduced, and trial close-out moves faster.

This guide

- Highlights the most common challenges sponsors face in managing data.
- Provides a checklist to evaluate whether a potential partner can deliver the quality and experience your trial requires.



Setting your trial up for success

A strong grasp of protocol and study design is the foundation of excellent data management.

Clinical trials rarely run exactly as planned. Protocol amendments, unexpected results, and site deviations are common. If data management is treated as an administrative task, these realities can lead to errors, duplication, and wasted time cleaning.

Data management must be a strategic safeguard:

- Ensuring data are collected correctly from the outset.
- Ensuring all data required by the statistical analysis are collected.
- Anticipating deviations and preventing problems at the source.
- Protecting data integrity throughout the trial.

Close collaboration between data managers and statisticians is critical.

Case report forms should be designed with the analysis plan in mind, standards like CDISC embedded from the beginning, and outputs prepared for regulatory submission without costly rework.

Sponsors who maintain strong control of their data throughout the trial achieve:

- Fewer surprises at the end.
- Faster database lock.
- Smoother analysis.
- More reliable results.

Key areas of data management excellence

Protocol and study design expertise

Excellence in data management begins with a deep understanding of the protocol and study design.

When data managers approach the study scientifically—rather than simply executing forms—they can identify mistakes early, and reduce risks at the source.

Scientific rigor in operations

Instructions to sites and monitors must reflect scientific accuracy, not just data entry convenience.

Otherwise, data may appear correct in the database but fail to support biostatistical needs—leading to re-entry, deletion, and weeks of delay.

Transparency and accessibility

Daily access to clean, up-to-date data makes it possible to spot and fix risks immediately, instead of discovering issues after they are embedded in the database.

SDTM as a critical function

The Study Data Tabulation Model (SDTM) is the backbone of regulatory submissions. It provides a standardized format for organizing clinical trial data, ensuring consistency, transparency, and regulatory compliance. The FDA expects CDISC-compliant datasets at submission.

When SDTM is a data management responsibility, it ensures alignment with downstream analysis. That is why, successful SDTM implementation requires only technical rigor but also close collaboration with biostatistics teams.

Risks of late SDTM implementation:

- Data flagged as incomplete or inconsistent by Pinnacle 21.
- Queries unresolved after site closure.
- Analyses based on flawed or truncated datasets.

Benefits of early SDTM implementation:

- Progressive, biostatistics-oriented data cleaning.
- Reduced rework and delays.
- Earlier site closure.
- Lower risk of inaccurate results.

Datasets not built to CDISC standards from the start cannot be quickly corrected later. Waiting until database lock introduces avoidable risk, rework, and regulatory pushback.

Integrated data management & biostatistics collaboration

Effective Data Management and Biostatistics team collaboration is more than periodic check-ins—it is an interaction across the trial lifecycle:

- **Protocol design stage:** An eCRF that looks fine on paper but fails to capture the right endpoints in the right structure can compromise a trial. Biostatisticians define primary/secondary endpoints; DM translates them into eCRF fields and data structures.
- **Database build:** Joint review of eCRF design, edit checks, and CDISC mapping.
- **Trial conduct:** Regular review of SDTM builds, query resolution, and progressive data cleaning.
- **Database lock and beyond:** SDTM datasets are submission-ready with minimal residual issues.

Efficiency gains:

Involving data management and biostatistics early ensures:

- Every field in the eCRF supports downstream analysis.
- Critical information is not missed.
- Data collection aligns seamlessly with statistical objectives.
- Risks of “analysis gaps” are minimized.

Redundant work is reduced; trial teams spend less time “fixing” and more time analyzing.

Experience and stability

Continuity is a key safeguard in clinical data management. Low turnover means you benefit from a stable, experienced team that ensures:

- Consistency from first patient in to final analysis.
- Accumulated knowledge that sharpens study decisions.
- Flexibility to adapt as trials scale or extend over many years.

Choosing the right partner:

Seven criteria for data management excellence

By evaluating potential partners against these seven criteria, sponsors can:

- Reduce risk.
- Shorten timelines.
- Increase confidence in their results.

1 Deep understanding of protocol and study design

The team must fully grasp the scientific and operational intent of your study and translate it into robust data processes.

2 Integrated data management and biostatistics collaboration

Are Data Management and Biostats teams working seamlessly to anticipate downstream needs and ensure data integrity?

3 Regulatory experience and CDISC compliance

Will study design and data handling be aligned with CDISC standards and regulatory expectations from the outset?

4 Fit-for-purpose methods and tools

Are the platforms, processes, and statistical approaches appropriate —And is the team skilled in applying them effectively?

5 Transparency and accessibility

Can you access clean, up-to-date data and intuitive dashboards in real time?

6 Scientific rigor in operations

Does the partner apply critical thinking and scientific context to data decisions, not just process execution?

7 Stable and experienced team

Is the team stable enough to provide focused, hands-on support? Will it provide consistency from the first patient into the final analysis?

Safeguarding trial integrity

Strong data management is not just about database setup and cleaning.

It is about embedding reliability and scientific rigor into every stage of the trial, from the first patient enrolled to the final analysis.

The right partner doesn't just manage data—they protect the integrity of your trial.

- Maintaining high-quality data throughout the study minimizes corrections at the end, accelerates database lock, and ensures statisticians work with reliable datasets.

The outcome is clear: faster delivery of the final analysis package, with fewer risks along the way.

About IDDI

IDDI is the center of excellence in **regulatory statistics and clinical data science** with deep expertise in handling complex data challenges from **Pre-IND through to regulatory submission.**

We support pharmaceutical, biotech, and medical device/diagnostic companies with:

- Regulatory affairs and early development
- Regulatory statistics
- Clinical development strategy
- Clinical trial design
- Randomization and Trial Supply Management (RTSM)
- Clinical data management
- Electronic Data Capture (EDC)
- Biostatistical services

With 1400+ Phase I-IV clinical trials, we are a therapy-focused CRO working mainly in CNS diseases, oncology, ophthalmology, and orphan drugs.

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