MEDSOURCE
Taking Relationships as Seriously as Science

Ensure your clinical trial is on the path to success.

MEDSOURCE – DELIVERING RELIABLE AND TRUSTED DATA ON TIME, EVERY TIME

DATA MANAGEMENT

Quality data is fundamental to the success of any clinical trial. For a pharmaceutical or biotech company seeking to move new therapies and treatments from first-in-human studies to market, working with compromised data can cause serious delays to the trial that can be costly and may even risk potential intervention by the FDA that suspends or stops the trial altogether.

Given the crucial role data management plays throughout each phase of the clinical trial, MedSource employs a dedicated team that understands the importance of having a rigorous data management process in place to ensure organizations move successfully through the drug development process.

As a full-service clinical research organization (CRO), MedSource prides itself on being a true strategic partner for clients, and we work to deliver services that suit each individual organization's needs and goals. Our Data Management Team exemplifies this commitment and becomes an extension of the client's internal team. We have the experience and flexibility to work within any electronic data capture (EDC) system or build a database from scratch. We never try to fit our software to your clinical trial; instead, we work to provide the best solution for your specific program.

The team has built a strong reputation for delivering relevant and reliable "clean" data for analysis and is trusted to fulfill specific data requests quickly and accurately. We are the last line of defense from a quality control perspective, which is why we are especially meticulous when it comes to certifying the integrity of our client's data. Available as part of MedSource's full CRO service, or as a stand-alone resource, with our experienced, esteemed team of specialists, our data management offering assures you of quality data, on time, every time.

ABOUT MEDSOURCE

MedSource is an award-winning, full-service CRO focusing on complex study designs and diseases with particular expertise in oncology and central nervous system disorders. MedSource has US offices in Boston, Houston, Raleigh, San Diego and UK offices in Newcastle.

HOW CAN WE HELP?

To find out more about how MedSource can assist your company with data management services, contact **877-269-2987** or **info@medsource.com.**

SERVICE OFFERING

MedSource's Data Management Team is responsible for monitoring, identifying and rectifying any anomalies with the data and ensuring it is cleaned regularly for statistical accuracy, from checking that each clinical trial site has entered the right dosage amount per patient to ensuring medical codes are applied correctly in the database and that terms are consistently categorized across various sites.

This attention to detail is paramount, as it gives clients the confidence that the data we have provided is reliable. Accurate and reliable data is especially important as it is used to make key decisions about the viability of a drug, take next steps based on the progress of a new therapy during the trial, or demonstrate results within reports or submissions to the FDA as part of the development and approval process.

We understand that good data management starts at the very beginning of the process, and our team of experts works with the client to ensure the database is set up correctly in the first instance. We can build a tailored database from scratch or work within any other EDC systems, whichever best suits the client and the needs of the trial.

Before a trial has started, the data manager can review the protocol and deliver recommendations and specifications for the best EDC system, taking into consideration key safety and efficacy data points and test that it is operating efficiently before it is pushed live.

Whether before or during a clinical trial, clients can choose any of the following data management services individually or as a full suite, depending on specific needs. These can include:

- **Protocol review and consultation.**
- **Case report form design.**
- **Database design and build.**
- **Serious adverse events reconciliation.**
- **Medical coding.**
- **Export data/status reports at specific intervals of the project or on an as-needed basis.**
- **Discrepancy management/data cleaning.**
- **Local/central laboratory data handling.**

Experience. Focus. Trust. Respect.

If these aren't words you typically associate with a CRO, perhaps it's time to consider MedSource.