



MEDSOURCE

Taking Relationships as Seriously as Science

Biostatistics you can trust to deliver a successful clinical trial

MEDSOURCE – DEPENDABLE DATA ANALYSIS

CLINICAL TRIAL BIOSTATISTICS

Every successful clinical trial needs an experienced biostatistician to develop the protocols, establish the design of the trial, and provide a detailed analysis and assessment of what each data point means in the overall context of the clinical trial's goals and objectives.

With particular expertise in oncology and central nervous system disorders, MedSource is a well-established clinical research organization (CRO) with a proven record of assisting biotech and pharmaceutical companies throughout the drug-development process. Biostatistics is a vital part of our service to clients, from designing the trial to providing the research and analysis needed to ascertain a new drug's safety and efficacy before it is released on the market. Our clients make key decisions about the viability of a trial, the success of a new drug, and whether protocols need to be amended based on the analysis and recommendations of our biostatistics department.

Unlike other CROs, the lead statistician working on a client's clinical trial has expertise not only in mathematics and data, but also has direct experience in clinical and medical statistics. This added expertise brings enormous value to a project, as it means the MedSource team has a thorough understanding of the disease being trialed from a patient safety and efficacy perspective, which encourages a more holistic understanding of how the data relates to the broader context of the trial and patient considerations.



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 clinical trial biostatistics, contact **877-269-2987** or **info@medsource.com**.



SERVICE OFFERING

A critical part of what makes a trial successful, the biostatistics team is involved in every step of the process. This is the team that will, in working with the data management team, provide the client with advice on the best clinical trial design to meet the client's clinical end points. During a trial, once quality data is mined and cleaned, it is up to the biostatistics team to analyze, assess and understand what each data point means, so the client can make informed decisions and understand the progress of the new drug or agent.

As a full-service CRO, we understand what is needed to advance a therapy through each stage of the clinical development process, and at every step, our biostatistics team has the expertise to assist in a broad range of statistical and biometrics services.

Pre-clinical trials and R&D

Our biostatisticians collaborate with MedSource's scientific development department to help drug developers take assets from the post-discovery stage into the clinic. Services at this pre-clinical stage include assisting with the research and strategy required to complete a clinical development plan, such as indication prioritization and biomarker selection, where the team conducts data mining and data collection exercises to confirm clinical scientific evidence.

Clinical trial services: Phase I-Phase IV

From phase I to phase IV clinical trials, our team can assist in any of the following statistical and biometrics services.

- Develop and design statistical sections of protocol
- Run simulations and ensure client understanding of trial design
- Develop Statistical Analysis Plan
- Study randomization schemes
- Advance Frequentist and Bayesian study designs
- Analyze real-world outcome data
- Calculate sample size and power
- Produce and submit SDTM and ADaM
- Produce tables, listings and figures
- Deliver statistical analysis and reporting
- Prepare statistical sections of the clinical trial report
- Provide data safety monitoring board (DSMB) support
- Offer annual safety report support
- Provide interim analysis support
- Integrate safety and efficacy summaries
- Conduct pharmacokinetic (PK) and pharmacodynamics (PD) analysis
- Ensure dataset standard compliance (CDASH and CDISC)
- Assist in the design of case report forms (CRFs) and electronic case report forms (eCRFs)
- Conduct data-cleaning activities and confirm that the final datasets are aligned with reporting processes and meet all statistic needs

Experience. Focus. Trust. Respect.

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

