



## only your success counts

MSOURCE is a full-service Contract Research Organization and part of the TÜV SÜD Group of companies. For 16 years we have provided ISO certified clinical development services to the pharmaceutical, biotechnology, and medical device industries for products targeting cardiology, oncology, neurology and infectious diseases. Our clinical trial management, data management, statistics, medical writing, quality assurance, regulatory and safety management services are designed to ensure our client's success.

To ensure MSOURCE clients succeed our team of 250 people is focused on continuous improvement. We invest in our employees and we train them in the skills they need to deliver high quality services for our clients.

Every day we strive to create an environment in which all employees can contribute to their full potential and at the same time allow the company to develop and grow with them. With MSOURCE you will be able to participate in challenging projects and achieve your professional goals.

Sounds interesting?

Currently we are looking for a dedicated, enthusiastic and motivated employee to join the MSOURCE Team in D-Aachen or NL-Vianen as:

### Senior Statistician

#### Responsibilities:

- Providing statistical input for protocol writing (including randomization and sample size calculation) to ensure that the protocol reflects the GCP and ISO guidelines on biostatistics in clinical studies
- Developing detailed statistical analysis plan in order to pre-specify the statistical analysis according to the study protocol
- Performing complete statistical analysis of a clinical study in order to make it compliant with the statistical analysis plan and protocol (including programming of the inferential analysis, tables, listings and figures in SAS)
- Organizing and performing of a quality control review of the tables, listings, figures, inferential analysis and statistical text to ensure compliance with the protocol and SAP
- Writing statistical reports and/or statistical sections for the integrated study report and reviewing the draft integrated study report, ensuring that all data presented are correct, that conclusions are consistent with the statistical analyses performed and that the statistical part of the report is in accordance with regulatory guidelines
- Contributing to the development and implementation of the quality system for biostatistics guaranteeing best quality services of the department
- Coaching and mentoring junior statisticians and SAS programmers and providing training to MSOURCE personnel regarding statistical analysis of clinical studies in order to continuously increase the quality of the services provided by the department and MSOURCE
- Taking responsibility for clear and effective communication with all internal and external parties involved in the clinical studies to allow for smooth and GCP compliant processes

#### Qualifications:

- Higher education in sciences with substantial statistics component
- At least five years of experience as a statistician in life science/pharmaceutical environment
- Ability and knowledge to use SAS and preferably also "R"
- Fluent in English and local language(s) and good communication skills
- Driving licence and flexibility to travel to other MSOURCE locations

#### MSOURCE offers:

- Dynamic working environment, large diversity in working assignments
- A market conform salary adjusted to your qualifications and experience,
- Coaching and training system

Are you interested? Please send your application (including English CV) via email to:

#### Rita Nerstheimer

Human Resources

Email: [RNerstheimer@msource-cro.com](mailto:RNerstheimer@msource-cro.com)

#### MSOURCE Medical Development GmbH

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CLINICAL TRIAL MANAGEMENT & MONITORING  
CLINICAL CONTRACT HIRE & STRATEGIC RESOURCING  
CLINICAL DATA MANAGEMENT, BIostatISTICS & MEDICAL WRITING  
QUALITY ASSURANCE & REGULATORY CONSULTING  
SAFETY MANAGEMENT & MEDICAL AFFAIRS