Job Title: Associate Director Biostatistics (Oncology)

Mainz, Germany; London, United Kingdom; Munich, Germany | full time | Job ID: 8824

Your main responsibilities are:

- Represent Statistics in all assigned cross-functional clinical study teams and other projects and holds him/herself accountable for all statistical aspects
- Work as part of a collaborative, cross-functional team with members from other disciplines
- Provide statistical input into clinical development plans, clinical study protocols, clinical study reports, regulatory submission documents, and publications ensuring accurate deliverables
- Perform and/or verify sample size calculations
- Lead development of statistical analysis plans and TLFs, perform statistical analyses and validate analysis results
- Participate in planning for health authority meetings, development of associated documents, and the preparation of associated responses
- Oversee outsourced statistical CRO activities and deliverables ensuring highest quality and in a timely manner
- Support and participate in the development of departmental strategies
- Provide guidance to Statistical Programmers on SDTM/ADaM and TLFs specifications development and programming
- Provide input to database requirements and work closely with Clinical Data Manager to ensure data quality standards are met

What you have to offer:

- PhD or Masters in (Bio)Statistics, Mathematics or equivalent
- Minimum 5 years (8 years for masters) in the pharmaceutical industry and/or CRO
- At least 3 years of work/leadership experience, overseeing statistics staff (internal as well as outsourced) and in representing Biostatistics in a matrix organization and in a multidisciplinary team
- Experienced in planning, conducting and analyses of **oncology** trials from phase I-IV, including scientific publications
- Experience in answering health authority questions (FDA, EMA) and in leadings statistics on regulatory submissions, including developing ISE/ISS packages
- Good knowledge and experience of clinical development, study designs, advanced statistical methods (adaptive design and/or Bayesian is a Plus), regulatory guidelines (ICH, FDA, EMA)
- Good knowledge of statistical analysis software (SAS or R) and sample size calculation software (e.g., EAST and/or NQuery)
- Very good understanding of special topics like Diagnostics, Biomarker, PK/PD, PRO, RWE, is a plus
- Very Good analytical skills, ability to analyze complex issues to develop relevant and realistic plans, programs, recommendations, risk mitigation strategies, and the ability to communicate them to cross functional colleagues
- Strong drive for achieving high quality working results in a timely manner, while always safeguarding ethical standards in work and behaviors
- Very good communication skills:
  - ability to express complex analysis in clear language
  - an excellent command of English written spoken

Your Benefits:

BioNTech is committed to the wellbeing of our team members and offers a variety of benefits in support of our diverse employee base. We offer competitive remuneration packages which is determined by the specific role, location of employment and also the selected candidate’s qualifications and experience.

Note: The availability, eligibility and design of the listed benefits may vary depending on the location. The final requirements for the individual use of our benefits are based on the company's internal policies and applicable law.

How to apply:

Apply now by sending us your application documents including Curriculum Vitae, copy of ID, copies of degree certificates and professional certificates, motivation letter as well as your contact details via our online form.

Please note:
Only applications sent via our online form shall be considered. By submitting your application, you acknowledge that a background check will be conducted as part of the recruitment process in accordance with applicable laws and regulations. If you are considered for the position, BioNTech will conduct the background check through our service provider ‘HireRight’. You will be informed accordingly by your BioNTech-Recruiter.

We are looking forward receiving your application.