# Job Title: Senior Director Biostatistics (Oncology)

London, United Kingdom; Berlin, Germany; Mainz, Germany; Munich, Germany | full time | Job ID: 8822

## 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
- Oversee and give statistical guidance on trials within a platform or portfolio
- Provide statistical guidance 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
- Provide input to database requirements and work closely with Clinical Data Manager to ensure data quality standards are met
- Provide guidance to Statistical Programmers on SDTM/ADaM and TLFs specifications development and programming
- Support and participate in initiatives to develop, implement and improve cross-functional standards, processes and infrastructure initiatives and evaluations
- Support and assist GBS Lead in both strategy developments and operations
- Mentors (Associate) Directors and/or assumes possible line management responsibilities of staff and is responsible for recruiting, developing, and retaining talent
- Collaborate with Safety and Pharmacovigilance in developing processes and standards to support safety assessment, signal detection and decision making
- Provide input into early risk management plan, blinded and unblinded safety monitoring (through internal safety review committees or DMC)
- Collaborate with Statistical Programming to ensure the data integration processes
- Lead aggregate safety analyses of clinical trials across the BioNTech portfolio
- Stay up to date with developing methodologies related to safety analysis and signal detection, including identifying adverse drug reactions per regulatory guidance

## What you have to offer:

- PhD or Masters in (Bio)Statistics, Mathematics or equivalent
- Minimum 12 years (15 years for masters) in the pharmaceutical industry and/or CRO
- At least 10 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
- Experiences in planning, conducting and analyses of **oncology** trials from phase I-IV, including scientific publications
- Experience in leading to answer health authority questions (FDA, EMA) and leading in statistics on regulatory submissions, including developing ISE/ISS packages
- Experience in leading integrated statistical analyses
- Excellent knowledge and experience of clinical development, study designs, advanced statistical methods (adaptive design and/or Bayesian is a Plus), regulatory guidelines (ICH, FDA, EMA)
- Excellent knowledge of statistical analysis software (SAS and/or R) and sample size calculation software (e.g., EAST and/or NQuery)

- Outstanding 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
- Awareness of the bigger picture, strong orientation to quality and timely manner, innovative and solution orientated thinking
- Excellent communication skills:
  - ability to express complex analysis in clear language
  - excellent command of written and spoken English

## 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.