Job Title: Director Statistical Programming (Oncology)

London, United Kingdom; Mainz, Germany; Munich, Germany | full time | Job ID: 8854

Your main responsibilities are:

- Work alongside with Head of Statistical Programming to implement a comprehensive strategy to maximize efficiency in statistical analysis and reporting that encompasses vendor management, technological innovation, process automation, and adherence to industry standards
- Oversee a team of FSP programmers or vendor CROs to ensure timely, high-quality delivery of analysis datasets, tables, listings, and figures (TLFs) across multiple clinical trials
- Align programming strategies with compound/platform objectives and regulatory requirements (e.g., CDISC standards, FDA/EMA guidelines)
- Drive the creation, review, and validation of SAS/R programs for clinical data analysis, including SDTM/ADaM datasets, efficacy/safety outputs, and integrated summaries
- Ensure adherence to SOPs, regulatory standards, and reproducibility
- Partner with Biostatistics, Clinical Development, Data Management, and Regulatory Affairs to shape clinical study designs, statistical analysis plans (SAPs), and submission strategies to meet project deliverables and timelines for statistical data analysis and reporting
- Represent programming in clinical study team and other key meetings (e.g., protocol reviews, submission readiness)
- Lead the programming contribution to global regulatory submissions (e.g., NDAs, BLAs, MAAs), ensuring compliance with eCTD requirements
- Manage the production of submission-ready datasets, TLFs, and documentation (e.g., define.xml, reviewers' guides)
- Champion the adoption of advanced analytics, automation tools (e.g., SAS macros, Python), and new technologies (e.g., AI/ML) to enhance programming efficiency
- Develop standardized processes and mentor teams on emerging industry trends (e.g., RWE, decentralized trials)
- Develop and establish efficient processes, innovative solutions, and standards to enhance the delivery of statistical analysis and reporting; this may include optimizing work flow and infrastructure of the statistical programming environment, and also author relevant Standard Operating Procedures (SOP) to document and communicate these processes
- Actively participate in continuous improvement activities and processes reengineering to contribute to BioNTech's global clinical initiatives that enhances its clinical operation, data analysis, and overall efficiency infrastructure of the statistical programming environment

What you have to offer:

- Bachelor's degree in Statistics, Mathematics, Computer Science or related discipline, advanced degree preferred
- 15+ years (10+ years for advanced degree) experience in a pharmaceutical industry, CRO or another clinical research setting, with a focus on oncology
- Excellent knowledge of statistical programming in SAS including Base, macro, STAT, GRAPH, SQL
- Solid understanding of FDA, EMA, ICH, and global regulations and guidelines
- Solid understanding of industry standards applicable to clinical study data and reporting on clinical trials, including CDISC standards
- Solid understanding of the drug development process from early to late-stage development and submission
- Expertise in the requirements and technology to support electronic submissions
- Strong interpersonal skills in addition to exceptional written and oral communication skills commensurate with the need to work closely with CROs, investigators, consultants, and team members across functions
- Strong analytical, project management, and problem-solving skills
- Ability to work in a fast-paced and dynamic environment

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.