



OPEN POSITION: Senior Biostatistician in Cancer Immunotherapeutics

CONTEXT

Within the Biostatistics & Data Management team of GSK Biologicals, biostatisticians provide statistical expertise and support in the development of prophylactic or therapeutic vaccines. Amongst the 75 statisticians part of an international team and devoted to the discovery and development of vaccines, an expanding small team of about 5 statisticians are providing statistical expertise to the cancer immunotherapeutics clinical development. Currently two Phase III studies are ongoing in non-small cell lung cancer and melanoma (www.gsk-asci.com).

We are a growing team sharing and learning from each other. We are creative, always looking for new and better ways to do our job. We focus on performance but recognize there is no achievement without integrity. Come and join our team and help us make a difference at our vaccine headquarters located in Rixensart, Belgium (www.gsk-bio.com).

KEY RESPONSIBILITIES:

As senior biostatistician in the oncology statistical team, you will:

- participate in the cancer immunotherapeutics development plan (trial designs, sample sizes, interim analysis, etc.) in collaboration with clinical development managers, safety physicians and clinicians. In particular, provide strategic, statistical, and scientific input into clinical development planning
- be responsible for the statistical designs of clinical trials, creating statistical sections for study synopses and protocols
- input in study set up (case report forms, database, randomization)
- explore new statistical approaches and methodologies through innovative and creative thinking
- interact with regulatory authorities
- propose and evaluate the performance of statistical methods in order to prepare statistical analysis plans
- write and execute SAS programs to analyse the data and to report results creating tables and standard listings
- perform statistical analysis, run simulations and discuss with internal and external experts
- support scientific writers and clinicians to correctly interpret the statistical results and align them with the clinical report conclusions
- write the statistical sections of clinical study reports, statistical publications and prepare materials for publications and create statistical text for clinical study communications
- input in standard processes (review of Standard Operating Procedures, guidelines, definition of new processes needed)



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QUALIFICATIONS/EXPERIENCE REQUIRED:

- M.Sc. or Ph.D. degree in Biostatistics
- At least 5-7 years of experience in Statistics
- Good knowledge of statistical approaches applied in cancer clinical trials with a focus on survival analysis techniques
- Comprehensive understanding of applied statistical principles and modeling in the design and analysis of clinical trials
- Experience in statistical or clinical trial methodology research and presentations on statistical methods, clinical trial design, and analysis
- Proficiency in SAS (knowledge of other statistical software is an asset)
- Good skill in written and spoken English
- Ability to easily communicate with different functions: clinicians, scientists, data managers, scientific writers, commercials, etc. in an international, multi-cultural environment
- Compliance with internal Standard Operating Procedures and regulatory guidelines
- Previous experience in a vaccine company or oncology department is an asset.

Interested? send your C.V. to Bart Spiessens bart.spiessens@gskbio.com or François Beckers francois.beckers@gskbio.com