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SENIOR BIOSTATISTICIAN

Pharma / Biotech

Permanent contract / Paris

The company, conducting a multiple major international clinical development programs 1 phase I, 3 phases II & 8 phases III), is looking for a Senior Biostatistician to strengthen its biometrics teams.

Missions

- Author the Statistical Sections of Protocol
- Propose and Review the Study design
- Calculate the sample size
- Review the Case Report Form (CRF) and the Edit Check Document (specifically for critical modules like RECIST 1.1 etc.)
- Write the randomization specifications and coordinate and finalize all the randomization activities with the IWRS vendor
- Author Statistical Analysis Plan (interim and final as appropriate)
- Perform the Statistical Analysis (Efficacy and Safety (key safety like Adverse Events)) using SAS
- Ensure quality of all the outputs developed
- Perform the role of validator as appropriate
- Provide Statistical Consultancy on an ongoing basis for projects
- Perform Futility and Efficacy analysis as appropriate for interim analysis and interact with third party independent Statistician
- Defend the Statistical Analysis at the IDMC meetings as appropriat
- Write the specifications for the efficacy analysis. Review the Specifications for the Safety Analysis
- Organize Data Review Meetings (equivalent to Blinded Data Review (BDR) or Dry Run) and lead all the statistical discussions
- Work Collaboratively with the data management, Clinical Operations, Medical Writing and the Pharmacovigilance team as appropriate
- Provide inputs to the regulatory affairs for all the discussions with the health authorities (e.g. ANSM, EMA, FDA)
- Review the Clinical Study Report and provide statistical inputs as appropriate
- Perform exploratory analysis as appropriate

Profil

- Female or male
- Ph.D. in Statistics with minimum 3 years of relevant pharmaceutical (or CRO) industry work experience or Masters in Statistics or equivalent with minimum 5 relevant pharmaceutical (or CRO) industry work experience
- Good Knowledge of SAS, preliminary working knowledge on R, good Understanding of CDISC Concepts
- Good understanding of ICH guidelines
- Decent written and verbal English communications skills
- Good team player, innovative mindset, good interpersonal skills, good time management.

Terms and conditions

- Permanent contract (CDI) to be filled as soon as possible, Paris based post office
- Salary to be defined according to profile and experience
- The company sponsors the EU work visa if needed

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