



Senior - Biostatistician M/F

Belgium, France, Italy, Portugal, Spain

Reference Number: SBA

You are a highly skilled professional with passion for the world of life sciences and clinical research? You want to thrive in a dynamic and collaborative international environment where your expertise directly impacts people lives? Come and join Aixial Group to contribute to shaping the future of clinical research!

Who Are we ?

- We are one of the world's leaders in CRO (Contract Research Organisation) with the commitment, expertise, and flexibility needed to deliver efficient clinical trials.
- We work with global, pharmaceutical, biotech, cosmetic, medical device, and many other companies around the globe, providing them with innovative and scalable solutions.
- We are operating in 10 countries across 3 continents, bringing together over 1000 talented professionals dedicated to make a positive impact in the life sciences industry.
- We have been part of ALTEN Group since 2014 and are continuously exploring new opportunities to expand our activity worldwide.

Why Join Us ?

- Make a positive impact and be at the forefront of project : You will be part of groundbreaking advancement in clinical research that has positive impacts on millions of people's lives globally.
- Career Development : People are our biggest asset. We are committed to empower our team continually and build a positive and supportive environment that fosters growth, flexibility, and teamwork. At Aixial Group, you will be coached and mentored throughout your journey to help you advance your professional and personal growth.

- Our commitment to Diversity, Equality, and Inclusion : We aim to create a workforce which promotes dignity and respect, where individual differences are recognized and valued, and where each employee can give their best. Gender equality is at the core of the development strategy of Aixial Group.

Aixial Group continues to grow, and to recruit in the clinical trial professions.

For more information: <https://www.linkedin.com/company/aixialgroup/about/>

We are currently looking for a **Senior - Biostatistician M/F** to carry out the following tasks (*non-exhaustive list*) :

- Participate in the development of working hypotheses in collaboration with physicians and the clinical studies team.
- Select a statistical model and define the statistical methodology for clinical studies
- Determine the number of subjects to be studied
- Create the statistical analysis plan
- Participate in protocol drafting and validation
- Set up randomization plans
- Validate evaluation criteria
- Validate data consistency in collaboration with the Data Management team
- Observe the consequences on the model of variations in a local parameter
- Produce data reviews
- Perform and program analyses
- Write statistical sections of study reports
- Present statistical results
- Monitor and propose new statistical tools and methodologies through scientific and technical reading.
- Participate in exchanges on technical subjects with members of the research team.
- Complete Risk Management Plan
- Manage submissions to the FDA (Food and Drug Administration) / EMA (European Medicines Agency)

Your profile :

- You have a BAC+5 or PhD in statistics, applied mathematics, computer science or other equivalent field of study.
- You have at least 5 years experience as a Biostatistician in clinical trials in CROs (Contract Research Organizations) and/or pharmaceutical laboratories
- You have experience in early and late phase
- You are familiar with CDISC and/or SDTM standards.

- Knowledge of SAS programming and R would be a plus
 - Able to carry out complex tasks within defined deadlines, you are rigorous and organized
 - Experience in phases 2 and 3 of clinical trials would be appreciated
 - Ability to work with multidisciplinary teams
 - You are fluent in written and spoken English
 - Speaking French would be a plus
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Your contact person

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