BIOCARTIS

BIOSTATISTICIAN

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Publication date: 20 December 2023

Location: Mechelen

Country: Belgium

Workplace type: Hybrid

Travel percentage: 0%

Department: R&D - Bio IT

Function type: Full-time

Contract type: Employee

Experience required:

Experience in the IVD Diagnostic, Pharmaceutical or Biotechnology industry is a plus but not mandatory.
FDA related experience is a serious plus.
Good understanding of medical statistics, study design and regulatory reporting;
Good understanding of molecular detection techniques (PCR) and oncology clinical trials;
Knowledge of basic statistical concepts in clinical trials;
Excellent technical writing and documentation skills;
Knowledge of international regulatory and quality guidelines for clinical laboratory methods (ISO, FDA, CLIA);
GLP and GMP working knowledge;
Experience with writing scripts in R and RStudio (including version control - Git) or willingness to learn.

Education:
MA or MSc in (Bio)Statistics is preferred or equivalent through experience and/or training.

The biostatistician will ensure that appropriate and sound statistical methods are used throughout the entire product development cycle. He/she will provide statistical expertise in analytical and clinical validation study design, writes statistical analysis plans and reports, perform statistical analysis and programming.

In addition, the biostatistician will also assist in preparation of experimental designs and quality control release strategies.

Accountabilities

Consult product development teams in statistically supported test strategies during product development (i.e. DOE);
Propose statistical methods for analytical validation strategies, in line with international standards;
Write statistical plans and reports for clinical validation studies;
Propose statistical supported strategies for quality control release methods;
Prepare analysis datasets, generate and/or validate data, and tables/reports;
Ensure scientific integrity and data quality of experimental and clinical designs;
Provide statistical data analysis and reporting;
Provide accurate and timely answers to project stakeholders in or outside the company;
Clearly communicates (orally and written) statistical concepts to non-statisticians;
Carry out all activities according to appropriate Biocartis SOP's, working within the framework of the Quality Management System and to GCP.

Profile requirements

MA or MSc in (Bio)Statistics or equivalent through experience and/or training;
Experience in the IVD Diagnostic, Pharmaceutical or Biotechnology industry is a plus;
FDA related experience is a plus;
Good understanding of medical statistics, study design and regulatory reporting;
Good understanding of molecular detection techniques (PCR) and oncology clinical trials;
Knowledge of basic statistical concepts in clinical trials;
Excellent technical writing and documentation skills;
Knowledge of international regulatory and quality guidelines for clinical laboratory methods (ISO, FDA, CLIA);
GLP and GMP working knowledge;
Experience with writing scripts in R and RStudio (including version control - Git) or willingness to learn;
Ability to collaborate and communicate efficiently within a multidisciplinary team;
Goal oriented and problem solving mindset;
Independent and proficient in handling multiple and varied tasks simultaneously;
Able to work under pressure and have a flexible approach
Thrives in a fast paced and changing environment;
Excellent knowledge of English (written and spoken), any other European language is a plus;
MS Office (Word, Excel, PowerPoint, Outlook).

Our offering

We offer you an exciting career in a fast growing international and innovative environment where you can work with top entrepreneurs in the biotech industry. You can be part of a very dynamic, young and growing team.

You will have freedom to shape your work and shape your job where you deem it necessary: we value your input.

Of course we offer you an appropriate compensation package with many [illegible]nge benefits including a Flexible Income Plan.

Our hybrid way of working offers flexibility and a better Work/Life balance.

Interested ?

We look forward to receiving your CV and motivational letter.

APPLY NOW

First name *

Last name *

Email *

Phone

+32 470 12 34 56

UPLOAD CV *

Choose file

One file only. 5 MB limit. Allowed types: pdf.

MOTIVATIONAL LETTER *

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One file only. 5 MB limit. Allowed types: pdf.

Message *

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