

Biostatistician

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Company: Galapagos

Location: Mechelen

Category: computer-and-mathematical

Pleased to meet you, we are Galapagos, a dynamic growing Biotech company with offices across Europe and in the US, headquartered in Mechelen, Belgium.

We're in the business of changing lives. We go where no one has ever gone in our quest to discover and develop life-improving medicines. In every challenge we face, we see new opportunities. We pioneer for patients. We need thought leaders and rapid thinkers, entrepreneurs in spirit and status quo-fighters: collaborative innovators and perseverant idealists. We need the best-in-class. In other words, we need you: The 'make-it-happener'.

We are looking for a **Biostatistician - Mechelen, BE or Leiden , NL (remote contractor position of 12 month)**

Scope of the job

The biostatistician is a functional expert in the field of clinical trial biostatistics, and as such supports the Clinical Study Team (CST) through design, set-up, analysis and reporting of clinical trials.

Your role

Participate in CST and in Biometrics oversight meetings as Biostatistics representative, and closely interact with Data Management, Statistical Programming, MWR, Clinical Operations and other functional representatives

- Provide statistical input in the design of phase 1-3 clinical trials
- Write statistical analysis plans
- Provide input to the the draft eCRF
- Perform regular quality checks on the relevant datasets during study conduct phase, in

collaboration with the Statistical Programmer

- Organize blinded test runs prior to database lock, and perform QC together with the Statistical Programmer
- Review of regulatory documents, as per internal procedures, such as the Clinical Study Report
- Manage the production of high-quality topline results in a timely manner
- Oversee activities in regards to randomization of the trial
- Organize a Blind Data Review Meeting prior to database lock
- Gain insight in the specific disease area and the competitive landscape through focused literature search and summarizing of publicly available data

Ensure proper and timely filing of function-related documents and files in the Trial Master File or in other secured dedicated environment

- Actively participate in Biostatistics and Biometrics team meetings
- Adhere to relevant policies and procedures and ensure timely completion of relevant training
- Keep abreast with recent innovative developments in regards to design an analysis of clinical trials

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