

## Biostatistician

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Company: Keyrus Life Science

Location: Belgium

Category: other-general

### Job Description

The Biostatistician we're looking for would be responsible for a whole study from design to execution for different study designs:

Use statistical methodology to establish study strategy (e.g. power modelling of different scenario, set up power).

Monitoring, set up mitigation plan to minimize risk of stat failure.

Provide input to protocol (design, objective, endpoint, randomization strategy, sample size, stat analysis).

Provide input to study set up (CRF review, randomization, DMP plan including specification for subset, important protocol deviation).

Develop Statistical Analysis Plan/Additional Analysis Request (involving sensitivity analysis to support robustness of result) and coordinate review.

Review the Tables Figures and Listings (TFL), to coordinate review with the stat analyst, to approve the TFL.

Do the QC of the statistical analysis methodology.

Validate study specific dataset & analysis programming specification.

Approve deviation from TFL format.

Propose Statistical Analysis Results conclusion.

Prepare answer to study specific stat question (e.g. inspection, regulatory question).

## **Profile**

You have 3 to 5 years experience in the field of Biostatistics in a pharmaceutical/Contract Research Organization environment.

You are familiar with SAS software.

You have a strong knowledge of international scientific and regulatory guidelines (ICH, EMA, FDA, ...).

You have a good level of English.

You have good interpersonal skills and a good global vision of the study process, which allows you to ensure an efficient interface with the project teams (project leader, data managers, medical writers,) and other external stakeholders (scientific experts, methodologists, etc.).

A good knowledge of CDISC standards (ADAM) is a plus.

## **Who we are**

Keyrus Life Science is an international Consulting, Contract Research Organisation and Functional Services provider with a reputation for transparency and integrity, highly focused on being able to deliver with excellence. Our 'human' approach to service provision is what differentiates us from our competitors. Combined with our high caliber staff, this approach has allowed us to become a key player in clinical research.

At Keyrus Life Science we're proud of our commitment to delivering services of the highest quality, not only skillfully, efficiently and reliably, but also with sincerity and genuine care for our clients' projects, priorities and reputation. Thus we maintain and advance our vision and our standards, all the while ensuring that we serve your interests better

From early- to late-stage drug development, our range of services includes: Project Management, Clinical Operations, Pharmacovigilance, Quality Assurance (GxP), Regulatory Affairs Strategy & Support, Data Management, Medical Review & Coding, Biostatistics, Medical Writing & Medical Information, Real World evidence services.

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