BIOSTATISTICIAN PROJECT LEADER – Early phases
(Permanent Contract)

Company

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions. With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe. Sanofi, Empowering Life

At Sanofi diversity and inclusion is foundational to how we operate and embedded in our Core Values. We recognize to truly tap into the richness diversity brings we must lead with inclusion and have a workplace where those differences can thrive and be leveraged to empower the lives of our colleagues, patients and customers. We respect and celebrate the diversity of our people, their backgrounds and experiences and provide equal opportunity for all.

Main Responsibilities:

• In collaboration with the members of the project team in an international context (eg, clinical, pharmacovigilance, regulatory affairs, marketing), contribute to the elaboration of the early development strategy, participate in the management of the project, take part in the preparation of the associated submission dossier, provide quantitative elements for decision-making.

• In interaction with the therapeutic units, carry out the project by acting as statistician of a study and/or coordinating the statisticians in charge of the different studies from the protocol to the study report.

• Appropriately integrate the translational approach strategy into development plans and implement it

• Actively participate in writing clinical study synopsis/protocols, interpreting statistical analyses, and presenting results oReview or produce the Statistical Analysis Plans and the statistical part of the study reports

• Define, produce, review, and integrate reports on project safety, pharmacodynamics or efficacy.

• Participate in meetings with regulatory authorities; prepare submission dossier

• Provide/develop statistical expertise within the team, department or crossfunctions with pharmacology, pharmacokinetics or pharmacometry teams.

•Make proposals to improve designs, analyses and, more broadly, the efficiency and effectiveness of the department through continuous bibliographic monitoring.

Education and experience

• PhD or Master in mathematics /statistics, with specialization in Biostatistics.

• Professional experience : Statistician with significant experience in the pharmaceutical industry (> 8 years) in the field of early clinical studies (up to and including Phase II), with experience as a biostatistics project manager. Experience in biomarker development, Phase IIb/III and submission would be appreciated.

Profile

• High proficiency of clinical research and business strategy in this field; mastery of general regulatory guidelines, and specific to at least one therapeutic area

• Ability to understand clinical, regulatory and marketing issues and propose innovative/state-of-the art development plans, trial designs and analyses

• High proficiency of statistics used in the pharmaceutical industry in clinical development including statistical methods used for flexible designs as well as simulation technics; modeling and biomarker data mining skills o Successful experience as a project manager; strong capacity for anticipation, organization and coordination; leadership, including

supervision of contractors; ability to work as a team player and interact with all stakeholders.
• Familiar with state of the art study designs and statistical methods

• Very good communication skills and good popularization skills for explaining the statistical methods used.

•Good level of English mandatory for writing and speaking; experience in presentations

•Very good skills in SAS ; practice of R

•Scientific and operational rigor o Autonomous in the management of your activities; organized, able to efficiently manage multiple and variable deadlines.

Apply

IVIDATA is in charge to find candidates for this position

Send your candidature to Camille CALAS, IVIDATA Manager associate : camille.calas@ividata.com