MERCK

Start your journey of
DISCOVERY!
Bring your curiosity to life.

Director Biostatistician Phase I (m/f)

A career at Merck is an ongoing journey of discovery: our 52,000 people are shaping how the world lives, works and plays through next generation advancements in healthcare, life science and performance materials. For 350 years and across the world we have passionately pursued our curiosity to find novel and vibrant ways of enhancing the lives of others.

Your role:

You will join a department that plays a key role in the success of drug development at Merck. As a Director in Biostatistics in early development, you will provide statistical contribution to the development of new products and life cycle management of established products, in complex high priority therapeutic indication(s) through the statistical designs of phase I studies (PK, PD, FIM); the CRO oversight in delivering proper statistical contributions; ensuring adequate statistical analyses, reporting, objective interpretation of the results and publication(s).
Defend statistical design and results interpretation towards Health Authorities and Key External Experts.
Ensure that all functional activities supporting are performed to meet the defined timelines and quality specifications.
Demonstrate leadership in delivering in a matrix organization towards both the Project (including Statistical Programming and other Statisticians involved in the program) and the Global Biostatistics Function (support the best practices and adhere to processes).

Who you are:

- Ph.D. or MS in Statistics, Mathematics or related discipline.
- At least 10 years' experience in the Pharmaceutical/Biotechnology industry in clinical development with at least 5 years of experience in PK, PD and Phase I. Profound knowledge in the PK/PD area.
- Experience of project management as global statistical leader, preferably exposed to a multi-cultural environment.
- Comprehensive expertise in drug development, including knowledge of interfaces and interdependencies of clinical development with other functions.
- Excellent knowledge of ICH and other relevant Guidance documents (from ICH, FDA, EMEA, Etc.). Use them pro-actively to impact the performance or find alternative solutions
- Experience supporting global regulatory submissions is required

What we offer:

At Merck, there are always opportunities to break new ground. We empower you to fulfil your ambitions, and our diverse businesses offer various career moves to seek new horizons. We trust you with responsibility early on and support you to draw your own career map that is responsive to your aspirations and priorities in life. Join us and bring your curiosity to life!

Curious? Apply and find more information at come2merck.com with number 175539