

Safety Expert Statistician

At Sanofi, we chase the miracles of science to improve people's lives. We believe our cutting-edge science and manufacturing, fueled by data and digital technologies, have the potential to transform the practice of medicine, turning the impossible into possible for millions of people.

As Safety Expert statistician you will provide **leadership and guidance** as the lead statistician dedicated to safety on one or more safety monitoring team(s), you will be **accountable for all methodological and statistical aspects for safety** data analyses around pooled clinical trial data of project(s). You will act as statistical consultant within company for safety analyses, also on individual trial level.

Main job responsibilities

Lead safety signal detection, validation, charaterisation and reporting for several projects with minimal direction from group head, direct statistical support and provide statistical scientific leadership for clinical trial safety data within a project. Accountable for statistical aspects for safety analysis, including quality, relevance to external stakeholders (e.g. regulatory authorities, medical journals), and scientific validity.

Accountable for all safety statistical deliverables for complex projects

Promote teamwork, quality, operational efficiency, and innovation. Ensure safety monitoring team compliance with SOPs and departmental standards.

Plan and track project activities related to safety, timelines, and resource use. Provide justification for planned resource needs. Seek to optimize resource utilization thru efficient and well-managed resource allocation and across projects or areas. Capacity to respond to unscheduled increase in workload.

Lead discussion around definition and harmonization of quality standards also on individual trial level within and across therapeutic areas.

Provide technical guidance and mentoring to junior staff.

Ensure productive collaborations with other functions in the safety monitoring team and with other statistics project leaders and in communicating with senior leadership.

Represent statistics to participate (and lead if applicable) in scientific or technology working groups or cross function initiatives. Contribute to operation process optimization. Develop, promote state-of-the-art methodology and standards for safety analyses.

Main location: Germany (Frankfurt,

Berlin) _,

Second location: US (Bridgewater,

Cambridge)

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Job type: Permanent, Full time

Job ID: R2739100

50% Remote working



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About you

PhD/MS in statistics or related discipline with at least 6 years of pharmaceutical experience Knowledge of epidemiology methods and concepts in safety context

Demonstrated strong project/study management, interpersonal and communication skills

Broad knowledge and good understanding of advanced statistical concepts and techniques, including bayesian methodology

Broad experience in clinical development or post-marketing activities such a submissions, interactions with regulatory agencies or other external stakeholders

Experience safety signal detection desired

Ability to represent Sanofi in cross-company activities such a consortiums or professional associations

Ability and mindset to embrace change, innovate and continuously improve practice

Pursue progress, discover extraordinary

Better is out there. Better medications, better outcomes, better science. But progress doesn't happen without people - people from different backgrounds, in different locations, doing different roles, all united by one thing: a desire to make miracles happen. So, let's be those people.

At Sanofi, we provide equal opportunities to all regardless of race, colour, ancestry, religion, sex, national origin, sexual orientation, age, citizenship, marital status, disability, or gender identity.

Watch our ALL IN video and check out our Diversity Equity and Inclusion actions at sanofi.com

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