

Director Quantitative Safety Statistician

Job ID

391255BR

Apr 17, 2024

Ireland

About the Role

1 in 10,000 is the frequency of a rare safety event! The science of detecting, quantifying and communicating adverse drug reactions as well as designing measurable risk minimization activities – this is quantitative safety science. Providing patients with more benefits than risks is Novartis' top priority.

As Director Quantitative Safety Statistician you will shape the quantitative safety strategy for multiple programs across multiple indications during the whole life cycle. You will set innovative scientific and functional standards for excellence in signal detection, safety evaluation and benefit-risk assessment to inform internal and external evidence-based decision-making.

Location: Ireland (hybrid) / UK (remote) / Spain (hybrid) #LI-Hybrid

Your responsibilities:

Your responsibilities include, but are not limited to:

- Establishing the quantitative safety science strategy for assigned programs during the full life cycle, including early and full development, pre-, peri- and post- regulatory submissions
- Expert level contribution to strategy (design, analysis/synthesis, interpretation and reporting, health authority response, influence and implement publication strategy, quantitative decision making) for complex, critical studies across programs/indications
- Leading collaborations and effective partnerships with medical safety, epidemiology, clinical, regulatory and other quantitative scientists to ensure quantitative decision-making based on data from different sources in a pro-active manner
- Proposing and implementing modern and innovative statistical methods to support safety signal detection, safety risk and benefit-risk assessment. Promoting their use and acceptance within and outside of the organization through presentations, publications and scientific collaborations.
- Identifying and leading cross-functional scientific improvement and change initiatives providing strategic, technical, operational, and scientific solutions to the organization
- Representing Quantitative Safety & Epidemiology at internal and external decision boards
- Mentoring others in developing strategic quantitative frameworks

Diversity & Inclusion / EEO

We are committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Role Requirements

- University degree in statistics or mathematics or related area (PhD preferred)
- 10+ years (or 8+ years for PhD) of relevant experience in positions with growing responsibility in the Pharmaceutical Industry
- Expert knowledge and substantial experience of statistical methods applied to drug development and post-marketing safety and benefit-risk assessments with impact on company and/or health authority decisions. Hands-on experience in interactions with regulatory agencies.
- Demonstrated experience in developing and evaluating modern quantitative safety methodologies. Computing ability and experience with different data sources.
- Scientific curiosity combined with strong communication skills bridging scientific and business needs over different expertise areas
- Proven successful experience in leading global scientific improvement/ change initiatives. Natural modern leadership style building partnerships and collaborative environments

Why Novartis: Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here:

<https://www.novartis.com/about/strategy/people-and-culture>

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. <https://www.novartis.com/careers/benefits-rewards>

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: <https://talentnetwork.novartis.com/network>

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? <https://www.novartis.com/about/strategy/people-and-culture>

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Division

Development

Business Unit

Patient Safety & Pharmacovigilance

Location

Ireland

Site

Dublin

Company / Legal Entity

Novartis Ireland Limited

Alternative Location 1

United Kingdom
Alternative Location 2
Spain
Functional Area
Research & Development
Job Type
Full Time
Employment Type
Regular
Shift Work
No
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Job ID
391255BR

Director Quantitative Safety Statistician

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