

# Director Biostatistics Medical Affairs, Real World Data Expert

Job ID  
REQ-10011224  
Jul 11, 2024  
United Kingdom

## Summary

Biostatistics -Influences and drives statistical strategy/innovation at advanced expert-level directly taking part in cross-functional collaboration & decision making for multiple programs, across multiple indications/therapeutic/disease areas within (pre/early/full) clinical development and/or medical affairs. Responsible for leading and integrating input from different quantitative scientists, impacting clinical development, health authority interactions. Represent the function at internal and external decision boards, develop and mentor other statisticians, and provide strategic, technical, operational and scientific leadership and solutions. -CDS -Supports Head CDS in setting the standards and automation strategy across Novartis. Manage a global team(s) responsible for executing data standards / automation objectives across DO. Responsible for ensuring quality, scalable, reusable, (CDISC and regulatory) compliant data standards and technologies are transparently deployed across GDO in close collaboration with external industry peers and internal stakeholders delivering stellar customer focus. Responsible for planning and overseeing KPIs/metrics, frameworks, policies, business rules and processes for development, maintenance, deployment. Responsible to ensure Novartis fulfills a ROI across the standards and automation landscape.

## About the Role

Our Development Team is guided by our purpose: to reimagine medicine to improve and extend people's lives.

To do this, we are optimizing and strengthening our processes and ways of working. We are investing in new technologies and building specific therapeutic areas and platform depth and capabilities – all to bring our medicines to patients even faster.

We are seeking key talent, like you, to join us and help give people with disease and their families a brighter future to look forward to.

Apply today and welcome to where we thrive together!

## The Role:

Are you ready to take your career in biostatistics to the next level? Novartis are seeking a highly skilled and motivated individual to join our team as Director Biostatistics supporting Medical Affairs as a Real World Data Expert. You will be required to influence and drives statistical strategy/innovation directly taking part in cross-functional collaboration and decision making for program(s) medical affairs. Responsible for leading and integrating input from different quantitative scientists impacting, clinical development, health authority interactions. Represent the biostatistics function at internal and external decision boards, develop and mentor

other statisticians, and provide strategic, technical, operational and scientific leadership and solutions to the organization.

May serve as:

- Individual contributor who is a thought leader in Real World Data analysis, drug development biostatistics across related indications/areas
- Lead statistician for a mid to high complexity project and/or multiple late phase clinical projects supporting Medical Affairs
- Team leader in matrix organization of a small team of up to 8.

This role offers hybrid working, requiring 3 days per week or 12 days per month in our London Office.

**Key requirements:**

- Ensure expert level contribution to strategy (design, analysis/synthesis, interpretation and reporting, health authority response, negotiating with pricing agencies, influence and implement publication strategy, quantitative decision making) for critical studies in a program, with emphasis on analysis and interpretation of Real World Data
- Accountable for strategic statistical input and influence into one or more projects (development plan, dose-finding strategy, regulatory strategy, publication strategy, pricing & reimbursement strategy, statistical deliverables, Real World Data).
- Lead collaborations with strategic functions to drive quantitative decision making in drug development and enable successful impact on robust drug development plans.
- Facilitate flawless transition of projects from early to late development. Also proposing and implementing innovative designs and methods to optimize drug development.
- Plan, prioritize and oversee project level activities and ensure efficient re-source management within or across franchise and effective partnership with vendors.
- Represent Biostatistics and Pharmacometrics line function at internal and external decision boards (e.g. regulators).
- Lead or significantly contribute to initiatives at global line function level, or cross-functional franchise level, requiring coordination of diverse of team members.

**Your Experience:**

- MS Statistics or equivalent with 12+ years' work experience or PhD (in Statistics or equivalent) with 8years + work experience with expertise in Real World Data analysis methodology.
- Fluent in English with strong communication and presentation skills, with the ability to articulate complex concepts to diverse audiences.
- Influences decisions that directly impact the project and department's ability to deliver objectives.
- Has advanced knowledge of applying statistics and innovative approaches Expert knowledge in a variety of statistical areas.

- Record of successful implementation of novel methods and/or innovative strategies in drug development.
- Extensive knowledge of drug development and Health Authority guidelines.
- Strong understating of at least one disease area.
- Proven leadership ability with excellent collaboration skill and ability to mentor up to 10 associates.

**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>

Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve.

Join our Novartis Network:

Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: <https://talentnetwork.novartis.com/network>

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Division

Development

Business Unit

Innovative Medicines

Location

United Kingdom

Site

London (The Westworks)

Company / Legal Entity

GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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

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