

Associate Director Pharmacometrics

Job ID REQ-10013609 Sep 03, 2024 Vereinigtes Königreich

Zusammenfassung

Leads the execution and delivery of pharmacometrics tasks on assigned projects within (early/full) clinical development. Together with the leadership, s/he is responsible for the discussion and implementation of pharmacometric methodologies that optimally address the research and development objectives on assigned projects.

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 area 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

As an Associate Director Pharmacometrics you will drive the pharmacometrics strategy for clinical programs in multiple indications or a disease area. As well as organizing the strategy for addressing pharmacometrics issues in regulatory submissions and integrated evidence generation directly influencing drug development and adoption decisions with internal and external partners.

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

Key Accountabilities:

- You will provide global strategic pharmacometrics leadership for clinical development programs of medium to high complexity, based on relevant technical and disease area knowledge.
- You will Represent the Global Project Teams internally and externally as the pharmacometrics expert.
- You will develop, write, and execute pharmacometrics analysis plans, and deliver reports on results.
- You will define and drive pharmacometrics contributions to regulatory/submission strategy and related

documents (e.g. briefing books, summaries of clinical pharmacology/efficacy/safety, responses to Health Authority questions).

- You will represent PMX on all pharmacometrics aspects of the programs at global regulatory hearings/advisory committee meetings and other global regulatory interfaces.
- You will drive and coordinate the synthesis and integration of pharmacometrics information to support transition of drug development milestones / decision boards. As well as Identify alternative strategic options to mitigate risk on clinical programs.
- You will lead and contribute to Integrated Evidence generation by leveraging disease progression and PKPD modeling techniques using varied data sources, including Real World Data.
- You will contribute to various internal and external initiatives on use of PMX techniques in support of Evidence Generation.
- You will ensure that the Analytics team (biometrician, data management, database programming, programming, medical and scientific writing) are aligned on the pharmacometrics strategy, execution, and delivery of assigned projects.

Your Experience

- Ph.D. in pharmacology, biology, engineering, mathematics, statistics, or a field with significant modeling-related content (or equivalent).
- More than 6 years' experience in applying model-based methods in pre-clinical and clinical drug development.
- Track record of contributions to external whitepapers/ policy shaping best practice in pharmacometrics. Internally and externally established track record of developing/establishing pharmacometrics excellence.
- Experience in contributing to global scientific improvement/change initiatives.
- Scientific leadership skills demonstrated in facilitating and optimizing the clinical development strategy.
 Track record for global scientific leadership in the development and evaluation of modern program/trial design methodologies.

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.

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Abteilung

Development

Business Unit

Innovative Medicines

Ort

Vereinigtes Königreich

Website

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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