Associate Director Pharmacometrics

Job ID
REQ-10013609
Sep 03, 2024
Vereinigtes Königreich

Summary

-Designs and conducts absorption, distribution, metabolism and excretion (ADME) research on compounds, drug agents and metabolites in pre-clinical and/ or clinical development. Using a physicochemical approach, attempts to compile various data such as absorption and excretion rates and drug agent halflife in order to establish pharmacokinetic profiles of new chemical and/or molecular entities as well as determining the optimum and safe dosage forms for compounds that have been determined to have indications for various disease groups. Responsible for developing protocols and/or preparing study documentation and findings to support domestic and inte national submissions of new drugs. May include modeling and simulation. May conduct studies using parametric optimization approach. Manages research related to absorption, distribution, metabolism, and elimination of drugs in both animals and humans for a therapeutic area, product line or program. Works closely with toxicology to document drug exposure in safety studies. Conducts bioanalytical research on drug agents and metabolites in clinical studies, including management of studies conducted in outside labs. Using pharmacokinetics, compiles data such as absorption and excretion rates in order to establish optimal and safe dosage rates. Serves as liaison with marketing, conducting analytical and kinetic studies on new dosage regimens and/or new dosage forms. -Associate Director levels:Provides strategic and broad team leadership on drug discovery and/or early development projects and initiatives throughout the lifecycle, and/or leads broad technology development areas within department and Division. Widely recognized as a strong team leader and/or a deep expert in her/his area ; assesses impact, limitations, and added value of scientific activities in order to define team's strategic objectives, advance related projects, and/or significantly expand scientific/technical knowledge within one or several related areas of deep expertise and relevance to Division. -Senior Principal Scientist levels:Establishes and leads novel projects in emerging strategic scientific/technical/development areas. Widely recognized as a key expert in her/his area, develops ideas with team members and collaborates across multiple different therapeutic areas, modalities and/or initiatives. Leads and connects a team to enable project progression, and/or identifies key connection points with own area(s) of deep expertise to progress department and Division strategic priorities. Recognizes and leverages external collaboration opportunities.

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.

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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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