U NOVARTIS

Associate Director Pharmacometrics (PhD/PharmD)

Job ID REQ-10054511 Jun 09, 2025 USA

Summary

#LI-Onsite East Hanover, New Jersey Cambridge, Massachusetts

About the role:

We are 60 quantitative scientists supporting more than 80 clinical development projects in 10 therapeutic areas every day. As the Associate Director Pharmacometrics, you will drive the pharmacometric strategy for clinical programs in multiple indications or a disease area. In this role, you will perform or supervise execution of the pharmacometrics strategy in those programs with focus on implementing model-informed drug development (MIDD) approaches. You may manage a portfolio of projects at the disease area or indication level. You will set the strategy for addressing pharmacometric issues in regulatory submissions and integrated evidence generation directly influencing drug development decisions with internal and external partners.

About the Role

Your Key Responsibilities:

- Provide global strategic pharmacometrics leadership for clinical development programs of medium to high complexity, based on relevant technical and disease area knowledge
- Develop, write, and execute pharmacometrics analysis plans, and deliver reports on results
- Lead and drive PMX contributions to integrate relevant technical and scientific knowledge in the planning and execution of robust quantitative development programs with focus on MIDD strategies
- Lead and optimize the provision of pharmacometric contributions to regulatory/submission strategy and related documents: (e.g. briefing books, summaries of clinical pharmacology/efficacy/safety, and responses to Health Authority questions).
- Represent the Global Project Teams internally and externally, including interactions with Health Authorities and external key opinion leaders, as the recognized Novartis pharmacometrics expert within the Development Unit (or equivalent). Represent PMX at global regulatory hearings/advisory committee meetings and other global regulatory interactions
- 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
- Lead and contribute to Integrated Evidence generation by leveraging disease progression and PKPD modeling techniques using varied data sources, including Real World Data
- Ensure that the Analytics team (biometrician, data/panagement, database programming, programming,

medical and scientific writing) are aligned on the pharmacometrics strategy, execution, and delivery of assigned projects

• Represent PMX in due-diligence teams to evaluate in-licensing opportunities.

Video Link https://www.youtube.com/watch?v=ggbnzRY9z8w

The ideal location for this role is the Cambridge, MA or East Hanover, NJ site. This role offers hybrid working, requiring 3 days per week or 12 days per month in the Office.

Role Requirements: Essential Requirements:

- Ph.D. in pharmacology, biology, engineering, mathematics, statistics, or a field with significant modelingrelated content (or equivalent) with 6+ years' experience in clinical drug development applying modelbased methods using NLME methods and its application in Dose-exposure-response analysis, population PK/PD modeling, disease progression modeling and clinical trial simulation in academia and/or industry
- Clinical pharmacology, statistics and therapeutic knowledge in one or more disease areas
- Diverse experience in pharma industry on incorporation of MIDD strategies into drug development plans across all phases and answering challenging questions on dose and regimen justification, study design, safety analysis among others
- Track record of contributions to external whitepapers/ policy shaping best practice in pharmacometrics. Internally and externally established track record of developing/establishing pharmacometrics excellence
- 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

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between \$152.600 and \$283,400 per year. The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

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

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

Accessibility and Reasonable Accommodations: The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or in order to perform the essential functions of a position, please send an e-mail to tas.nacomms@novartis.com call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to learn 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

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

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

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to <u>us.reasonableaccommodations@novartis.com</u> or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Division Development Business Unit Innovative Medicines Location USA State

Massachusetts Site Cambridge (USA) Company / Legal Entity U014 (FCRS = US014) Novartis Pharmaceuticals Corporation Alternative Location 1 East Hanover, New Jersey, USA **Functional Area Research & Development** Job Type Full time **Employment Type** Regular Shift Work No Apply to Job

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