Medical Director - Dermatology Translational Medicine

Job ID
392731BR
Aug 02, 2024
Schweiz

Summary

350 million! That is the estimated number of patients worldwide suffering of atopic dermatitis or psoriasis. Join Novartis to help find the right drugs to transform and improve patient's lives all around the world.

About the Role

You will provide medical and scientific leadership and expertise in a role that significantly impacts the entire Novartis Dermatology drug development pipeline.

• Drive success of early global programs, develop and implement strategies to achieve clinical Proof of Concept or Proof of Mechanism to enable transition to further development
• Drive success of late global programs when appropriate by developing and implementing strategies that lead to clinical pharmacology, design of mechanistic studies and profiling packages that meet regulatory requirements and support differentiated and competitive drug labeling
• Provide scientific expert assessments and support for in-licensing opportunities, including due diligences

Your responsibilities:
Translational Medicine early clinical projects:
In collaboration with your Translational Medicine Therapeutic Area Head or other Translational Medicine Experts
• Develop high value decision-strategies for the Translational Medicine component of drug development projects from Research to clinical Proof of Concept or Proof of Mechanism in a single or multiple indications, including Parallel Indication Expansion-Proof of Concepts
- Represent TM and lead global project teams through First in Human and Proof of Concept phase to drive strategy that enables development
- In collaboration with research scientists, contribute to the proposal of new targets or indications for existing compounds; identify, develop, and implement strategy for preclinical support of clinical program-related scientific objectives. This includes assessment of medical need, proposal of clinical development pathways, and review of preclinical data for clinical implications, and other relevant activities
- Responsible for implementing studies during the Proof of Concept phase by providing medical and scientific leadership and expertise to all line functions on the project team. This may include methodology studies to identify and validate novel endpoints for early decision making.
- Responsible for clinical portions of the Integrated Development Plan, including the Clinical Development Plan and Clinical Pharmacology Plan
• Accountable for compound and disease related biomarker strategies, working closely with Biomarker Experts

in implementation
• Develop and implement study protocols for different types of clinical studies (First in Human, Proof of Concept, mechanistic and safety studies), and other documents such as investigators brochures.
• Responsible for clinical monitoring and integrated safety data review during and after the live phase of a study
• Provide medical and scientific leadership and expertise to all line functions on the study team
• Leadership
- Lead study-specific teams/ clinical trial teams
- Represent TM or lead BR project teams
• Represent clinical Translational Medicine aspects to Health Authorities and other stakeholders (e.g. payers, patient advocacy groups)
• Represent clinical Translational Medicine in reviews of external opportunities
• Oversee publication and external presentation of study results
• Innovation: Champion and drive new clinical compound characterization opportunities and profiling approaches
• Contribute to initiatives that drive innovation, quality, and efficiency across Translational Medicine

Translational Medicine late-stage clinical projects:
In collaboration with your Translational Medicine Disease Area Head:
• Drive analysis of studies and present results to relevant decision boards
• Communicate clinical team matters to Global Project Teams, relevant Novartis BioMedical Research and Global Development boards, and other Novartis Boards as required.
• Evaluate clinical centers and foster communication with crucial collaborating investigators, regulatory authorities, and other stakeholders
• Provide support for dose selection, design and other clinical pharmacology matters throughout the development cycle
• Responsible for content and authoring of documents needed for submission documents with Translational Medicine input (CO, SCE, SCS, SCP, SBP) of NDAs, sNDAs, MAAs, BLAs from regulatory submission through drug registration, including advisory committee and scientific advice group meetings

Key Performance Indicators:
• Delivery of proposed Development Candidates, Integrated Development Plan Approval and Development transition point milestones, and early clinical study results, according to timelines
• Team leadership skills that create high performing teams and drive efficient conduct of innovative, interpretable clinical results
• Strong adherence to and modeling of Novartis values and behaviors
• Quality of contribution to disease area strategy discussions and contribution to Clinical Pharmacology plans / Profiling strategy discussions and external collaborations

Matrix people responsibility per project: 5-8 cross-functional members from within Translational Medicine plus other line functions per project team

Impact of this role?
• Design and implementation of early Clinical Development Plan and studies according to the Integrated Development Plan / Clinical Development Plan / Clinical Pharmacology Plan enabling efficient and rational decision-making, high probability of fast drug registration, favorable drug label and high competitiveness of compounds
• This role has a key impact on the entire Novartis pipeline, transitioning programs from preclinical through

early clinical and ultimately to full development via First in Human, Proof of Concept, and driving the program after Proof of Concept by delivering key Profiling data to support regulatory submissions
• Recognized Expert in field, drives project team clinical strategy. Works globally across Novartis as well as country organizations as appropriate

What you'll bring to the role:
• Medical Degree and additional PhD/post-doctoral equivalent immunology research
• Specialized further training (board certification) and / or clinical research experience in dermatology / immunology preferred
• Advanced / business-level / fluent English (oral and written)
• Recognized for medical expertise: demonstrated excellence and clinical / patient expertise in dermatology / immunology
• Recognized for scientific expertise: respected by colleagues internally and externally, you've made significant contributions to your field and created / established new concepts; record of high quality publications in international scientific journals.
• Previous relevant & significant clinical study experience: either from pharma/biotech leading early phase clinical trials; a senior role within a CRO responsible for leading the medical relationship with Sponsors; from a relevant academic medical center with PI & co-PI clinical trial experience. You are used to working independently and within teams including scientists and non-scientists on study planning and execution, demonstrating competence in a broad range of project and more strategic planning skills
• Excellent written and oral communication/presentation skills, used to distilling and effectively conveying significant messages to different audiences

Your behavioral characteristics
• Demonstrated passion for treating patients and science
• Strategic thinker: you have created major innovations, networked with and influenced external medical leaders with your clear and logical presentation of complex strategic issues
• Innovation: a curious mind and a natural instinct to seek out new clinical discovery opportunities and clinical study approaches
• Results-driven self-starter and decision taker; good planning, prioritization, problem solving and organizational skills; strong cooperative team player, flexible in a changing environment; Resilient, energetic and enthusiastic; responding constructively to challenging new ideas and input

This position is written for Director - we can hire Executive Director for those with significant Pharma careers, or Associate Director if you have limited clinical study experience or a less established scientific record but have already demonstrated impactful new thinking and innovative clinical & scientific approaches within your career.

ABOUT TRANSLATIONAL MEDICINE:
Translational Medicine is a global group of scientists and Physicians working at the pre-clinical and early clinical stage of drug discovery. Our Physician-Scientist Discovery & Profiling group drives innovative and cutting–edge science from Discovery to the market through the selection, profiling and effective global development of successful medicines. The group closes the gap between preclinical research and clinical development and integrates clinical science into the discovery and preclinical development phase. Our Translational Medicine concepts are driven by medical needs of the patient and the concept of personalized medicine, tailoring the drug, its dose and dosing regimen in such way to the patient that the clinical response is optimal in terms of efficacy and safety.

We focus from identification of drug targets (molecular pathways relevant to disease) up to the completion of Proof of Concept (Phase IIa studies). Our Translational Medicine Experts are part of preclinical project teams in all drug discovery phases and help design the pathway for First in Human studies (healthy volunteer) that bridge to studies in the patient population. They have the comprehensive responsibility for designing and executing the early clinical drug development phase together with a project team from researcher, biomarkers, biostatistics, modeling and simulation, toxicology, technical experts and the clinical trial teams.

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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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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Biomedical Research
Business Unit
Pharma Research
Standort
Schweiz
Site
Basel (City)
Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

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