Medical Director/Exec. Director, Gastrointestinal (GI) Immunology (Translational Medicine)

Job ID
REQ-10048222

8月 22, 2025

Switzerland

摘要

Ulcerative colitis and Crohn's disease, along with other gastrointestinal ailments, represent a diverse array of conditions impacting millions globally. These afflictions have significant unmet medical needs and often lead to a diminished quality of life. Novartis stands at the forefront of pharmaceutical innovation in immunology, leveraging advanced scientific research to develop transformative treatments that enhance patients' lives worldwide. We are seeking a Medical Director or Executive Director of Gastrointestinal (GI) Immunology in Translational Medicine Immunology. Join us in this endeavor!

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

1. Drive success of early global programs, develop and implement strategies to achieve Transition Decision Point (TDP)
2. Drive success of late global programs by developing and implementing strategies, which lead to clinical pharmacology and profiling packages that meet regulatory requirements and support

differentiated and competitive drug labeling.
3. Support Translational Research in developing new indications, endpoints and biomarkers, using in vitro, in vivo, or in silico methods.
4. Provide scientific expert assessments and support for in-licensing opportunities, including due diligences.

About the Role

Major Accountabilities

Early clinical projects (Phase I / II, "Discovery"):

Develop, in collaboration with TM TA Head and work with teams to carry out, strategies for the Translational Medicine component of drug development projects from Research to TDP in single or multiple indications, including post-indication expansion projects.

- Lead global project teams through phase I/IIa to drive implementation of the development strategy.
- Convene relevant (internal and external) experts to consider the proposed approach to reach TDP; present plans for approval at relevant decision boards.
- Be responsible for clinical portions of the Integrated Development Plan (IDP, including the Clinical Development Plan and Clinical Profiling Plan)
- Evaluate clinical centers and foster communication with crucial collaborating investigators, regulatory authorities, and other stakeholders.

Late-stage clinical projects (post-TDP, "Profiling"):

In collaboration with TM TA Head or Translational Medicine Profiling Head:

- Act as a key leader in developing the Ph2-3 and post-approval profiling strategy for drug programs, representing TMDP on Global Project Team (GPT) along with other TM line functions.
- Provide support for dose selection, study design and other clinical pharmacology matters throughout the development cycle.
- Oversee conduct and interpretation of studies prioritized by the to support the pivotal trials, such as special populations, drug-drug interactions, mechanism of action assessments, Pediatric Investigational Plan, etc.
- Drive analysis of studies and presents results to relevant decision boards.
- Communicate clinical team matters to GPTs and relevant BR and Development boards [and other Novartis Boards]
- Evaluate clinical centers and foster communication with crucial collaborating investigators, regulatory authorities, and other stakeholders.
- Be responsible for writing TM portion of documents needed for regulatory submission through drug registration (including advisory committee and scientific advice group meetings)

Translational Research (TR; indication seeking, endpoint and biomarker development):

In collaboration with TM TA Head, BR Research scientists, other TM line functions (BMD, CS&I, PCS, PKS), develop strategies to identify initial or expansion (PIE) indications, and to obtain sufficient evidence to fund these ideas.

- In collaboration with research scientists, 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.
- This may include methodology studies to identify and validate novel endpoints for early decision making in Phase IIa studies.
- Be accountable for compound-related biomarker strategies; works closely with Biomarker Expert in implementation.

Business Development and Licensing (BD&L; in-licensing and outlicensing compounds):

Participate on BD&L teams as the TM representative.

- In collaboration with BD&L team, evaluate the risks and benefits of potential in-licensing opportunities, identifying the strengths and weaknesses of external programs in terms of TM ' s scope of responsibility.
- Participate in teams carrying out out-licensing of BR programs, as subject matter expert for the disease indication, molecule, and clinical trial experience.

Leadership:

- Lead study-specific teams/ clinical trial teams in partnership with other line functions.
- Lead BR-sub-team(s) on Global Project Teams for late-phase programs
- Collaborate closely with other TM (especially CS&I) and non-TM (especially Project Management) line functions to ensure operational excellence, continued urgency, and close attention to timelines, costs, and subject burden in balance with high scientific stand- ards and innovation.

Key Performance Indicators

Delivery of proposed Development Candidate ((B)DC) and Integrated Development Plan Approval (IDPA) milestones, and results driving decision-making for/against transition into later phase development (TDP), according to defined timelines. Delivery of Clinical pharmacology and profiling strategy including execution of studies according to timelines to support regulatory submissions and approvals. Delivery of TR plans, whether in vitro, in vivo, or in silico, to drive program strategy and clinical trial efficiency. Team leadership skills that create high performing teams and drive efficient conduct of innovative, interpretable clinical results and a focus on operational excellence at all levels. Strong adherence to and modeling of Novartis values and behaviors.

Impact of this role?

Design and implementation of early Integrated Develop- ment Plan (IDP) and design and implementation of studies according to the IDP, 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 the TDP mechanism, and driving the program after TDP by delivering key Profiling data to support regulatory submissions.

Recognized Expert in field, drives project team clinical strategy. Works globally across Novartis.

Role Requirements :

Education

Doctoral degree, MD required in most cases. PhD or relevant scientific experience with academic track record preferred

Demonstrated excellence and clinical expertise in relevant medical subspecialty.

Experience/Professional Requirement:

At least 5 years ' experience in a pharmaceutical/biotech company, CRO, or academic medical center, or related experience.

Recognized medical expertise, as evidenced by publication of significant contributions to a field over time.

Excellent written and oral communication/presentation skills.

Independence: Able to work independently as outlined above, commensurate with level of role.
Innovation: Seeks out new clinical discovery opportunities and approaches to reach TDP.
Demonstrated passion for science.

Recognized expert in field, driving success for individual studies and projects; respected by colleagues across R&D, Development, and externally.

Languages:

Fluent English (oral and written).

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

Commitment to Diversity and Inclusion:

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

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to all

individuals. If, because of a medical condition or disability, you need a reasonable

accommodation for any part of the recruitment process, or in order to receive more detailed

information about the essential functions of a position, please send an e-mail to diversity.inclusionch@novartis.com 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 hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

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: https://www.novartis.com/careers/benefits-rewards

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Biomedical Research

Business Unit
Pharma Research

地点
Switzerland

站点
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

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