Head CD Pediatric CoE

Job ID
REQ-10006146
Juni 13, 2024
USA

Zusammenfassung

When we put our heads together, we can do brilliant work. And when we do brilliant work, we can achieve remarkable things for patients as we positively transform healthcare. We are looking for a Head Clinical Development, Pediatric COE.
• The Head CD Pediatric CoE is the functional leader of the Pediatric Clinical Group. The mandate is to raise awareness, strategy, and skills to enhance Pediatric Drug Development across all Therapeutic Areas; in particular educate the Global Program Teams (GPTs) to drive integrated partnership between research, clinical and operations to enable early planning for most efficient, strategic and feasible development of pediatric projects.
• The Head CD Pediatric CoE is responsible for the implementation of the cross-functional Pediatric organization to provide expert clinical and strategic advice, shared learnings, educational tools/resources to Development and Biomedical Research (BR) global teams pursuing pediatric drug development across the entire Novartis portfolio and to realize a culture change to optimize our Pediatric obligations and opportunities.
• The Head CD Pediatric CoE serves as a key contact with major external stakeholders and non-governmental stakeholders including academic societies and institutions and non-governmental agencies, key opinion leaders, clinical networks, and patient advocacy groups. The Head CD Pediatric CoE may consult across multiple franchises, as needed, based on therapeutic or scientific expertise, and may also be required to represent Novartis externally to key stakeholders including scientific societies and academic groups.

About the Role

Major accountabilities:

Your responsibilities include, but are not limited to:

- In alignment with the Head of CD Advanced Clinical Methods and CoE, leads the multi-stakeholder Pediatric Clinical Group, its structure, resources, processes, and implementation plan, as a focal point for pediatric expert knowledge development, expert advisory body, and dissemination of best practices/shared learnings/peds curriculum.
- In concert with Early Phase-Global Program head (EP-GPH), identifies early programs/indications with potential pediatric use to ensure pediatric programs are prepared for regulatory requirements and to reduce cycle times for pediatric development to make important drugs available efficiently and expeditiously. These activities would coincide with early portfolio tollgates.
- Leads the development of the pediatric clinical strategy in partnership with the Global Clinical Program Head (GPCH) to ensure efficient parallel development is feasible. Develops an endorsed pediatric plan within the Clinical Development Plan (CDP) in line with the Target Product Profile (TPP) which is designed for successful global regulatory approval/market access/Compliance Check for one or multiple

treatment indications and/or multiple programs
- Leads the Pediatric Sub-team within the GCT for priority programs, represents the pediatric Clinical Development on the (early) Global Program Team (GPT)
- Leads the strategy behind key pediatric clinical components of key documents (CTP, regulatory documents including PIP(s), IPSP (s), and WR(s) with high quality and consistency with CDP and TPP in collaboration with clinical team.
- Provides oversight of processes for review through ISRC (protocol review committee or equivalent), infrastructure, resources, capabilities, and culture to facilitate all teams to plan early, design innovative and efficient, feasible pediatric studies and deliver quality pediatric clinical trials on realistic timelines. Provides directly, or through the Pediatric Clinical Group support to GPTs in developing sound pediatric regulatory plans and responses to feedback/discussions with revelant Authorities.
- Accountable for oversight related to direct Pediatic Clinical Group support staff including performance management process, annual objectives and performance appraisals for functional direct reports as required. Ensure efficient on-boarding, training, and mentoring of new associates, and mini-sabbaticals within pediatrics.
- Serves as an internal scientific and clinical consultant in his/her areas of specialization
- Customer facing representation of Novartis to the relevant scientific, academic, and patient advocacy groups. Develops and maintains key external relationships with academia, health authorities, trade organizations and other stakeholders. Writes review articles and publications in collaboration with academic researchers.
- May attend and present at key HA-related meetings per team request. Provides expert contributions to Franchise Strategic Plan in collaboration with other members of the CD team.
- Leverages knowledge, expertise, understanding of external stakeholders, internal team capabilities and portfolio needs to develop a compelling innovative vision and strategy for the program/portfolio and subsequent impact on overall Development and Pharma strategy
- As the medical expert, may lead interactions with external stakeholders (e.g., key opinion leaders, DMC’s, advisory boards, patient advocacy groups) internal stakeholders and internal decision boards.
- Key contributor to CD organization including CDP/IDP reviews, development and implementation of clinical development and support the Peds CoE in talent management and peer review in areas of expertise
- Proactively shape the external environment to defend and improve Novartis position relevant to the project by development strong evidence and trust-based relationship with key stakeholders (e.g., KOL, patient groups, scientific societies, global pediatric networks)

What you'll bring to the role:

- MD or MD/PhD required with advanced knowledge and clinical training in a pediatrics with advanced training in sub-specialty) preferred. Medical Board certification required; Clinical practice experience ≥ 6 years (including completion of medical residency/fellowship) required
- Fluent oral and written English
- Min 10 years of drug development or relevant clinical research experience
- Proven track record of R&D leadership and management
- Clinical background relevant to the pediatric programs in Development Franchises
- Experience in product registration and major Health Authority interactions preferred
- Considerable organizational awareness including significant experience working cross-functionally and in global teams
- Excellent communication skills, written and oral
- Strong interpersonal skills
- Excellent negotiation and diplomatic skills, experience with submissions and health authorities required

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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