Medical Director for pediatric oncology drug development at Roche Genentech

Position title: iPODD Associate Medical Director / Medical Director
Location: Basel / SF / Welwyn
Job description:

The Innovative Pediatric Oncology Drug Development (iPODD) team is situated in Roche's global late stage clinical development organization for oncology (PDO). Roche PDO is based in Basel, San Francisco (Genentech) and Welwyn UK. iPODD is a specialized pediatric team with the aim to improve outcomes for children with cancer by developing the Roche oncology portfolio using rational, science-driven and regulatory-compliant strategies. iPODD is currently responsible for the pediatric development activities of 8 Oncology molecules from our late stage portfolio. iPODD designs and executes the early and late development (Phase I - II – III) clinical strategies and plans, and also designs and implements the molecule regulatory strategies, including filing plans. iPODD delivers the basis for molecule clinical development plans (CDPs) by matching the mechanism of action of portfolio molecules with potential pediatric indications through analyses of preclinical proof-of-concept in pediatric models and by assessing the pediatric developability for each molecule considering nonclinical, pharmacologic, safety, and regulatory concerns. Additionally iPODD conducts cross-molecule projects and initiatives including the iMATRIX MASTER (a strategic initiative for early phase assessment and signal seeking in early phase pediatric trials) and the Adolescent and Young Adult project to increase early participation of adolescent cancer patients in 'adult' trials.

The Associate Medical Director / Medical Director will be responsible for the development and implementation of pediatric oncology CDPs and protocols, including early phase and pivotal trials. He/she will participate and/or can lead cross-functional global development teams to design and implement clinical development plans for several molecules. The medical director will also serve on iPODD study management teams as a medical monitor for clinical trials. The medical director will be a primary contributing author for regulatory submissions, including Pediatric Investigational Plans and Proposed Pediatric Study Requests. The medical director will also participate in global filing teams, when appropriate for the molecule program. Participation in health authority interactions will be an integral part of all above responsibilities.
Potential projects include:

- the pediatric atezolizumab combination strategy and trial design.
- the development of the iMATRIX MASTER protocol library for use as a "plug and play" tool in the design and implementation of iMATRIX trials.
- clinical development planning and phase I/II trial design and implementation for the 'next' pediatric molecule, such as idasanultin (MDM2-i), taselisib (PI3K-i) or ipatasertib (AKT-i).

Furthermore, he/she will contribute clinical pediatric oncology expertise to other clinical science team members to support CDP development, early and late stage trial designs and implementation, data analyses and reporting, filing plans and regulatory strategies. He/she will also contribute clinical and preclinical expertise, as appropriate, to support the MOA-based preclinical molecule prioritization for pediatric development through our PPP program with 'Target Actionability Reviews', 'in silico' target patterns in pediatric clinical series and preclinical Proof-of-Concept collaborations with CROs and academic investigators. Depending on experience and skills the Associate Medical Director / Medical Director can be responsible for the management of direct reports.

Job qualifications:

- M.D. Pediatric Oncologist with 4 or more years of relevant medical experience required
- 2 or more years experience with clinical trials across Phase I - II - III drug development is required
- Experience with assessing preclinical datasets for target identification+validation and molecule proof-of-concept testing is preferred
- 2 or more years pharma/biotech industry experience is a plus
- Academic/teaching background is a plus
- Experience working with the principles and techniques of data analysis, interpretation and clinical relevance (e.g., ISS, ISE, competitor data, etc.)
- Excellent project management skills, good interpersonal, verbal communication and influencing skills, works well within teams and is effective in collaborating with others internally and externally

Further information on Roche website: iPODD Medical Director *(crtl-click to follow)*