

Senior Medical Director, Clinical Development Sciences

Location, Barcelona, Spain.

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This is what you will do:

The Senior Medical Director, Clinical Development Sciences may lead the clinical sub-team or support the clinical sub-team and the global program team to build global clinical development plans and contributes to the development of asset level and therapeutic area strategies. Responsible for overseeing the clinical development strategy development and execution for 1 program, leading the clinical subteam to the GPT and represents clinical development on the GPT, contributing to the development of regulatory strategy, and representing the clinical program at regulatory meetings. May supervise 1-2 direct reports (Medical Directors for the program studies and/or Clinical Development Scientists) or provide medical oversight.

You will be responsible for:

- Lead or support the clinical sub team and oversee the design and execution of multiple clinical studies or clinical programs
- Represent Clinical Development on the Global Program Team (GPT) and in presentations at management and review committees (e.g., Clinical Document Review Committee, Development and Commercial Steering Committee)
- Supervise and develop Medical Directors and CDS and/or fellows; May lead a clinical subteam and oversee the preparation of a clinical development strategy. May lead one or more clinical study teams in the preparation of clinical study related documents including protocols, charters, statistical summary reports, meeting presentations, publications, and clinical sections of regulatory documents
- Determine appropriate advisory boards experts and lead the team in preparation for meetings
- Critically evaluate available information about diseases of interest to the therapeutic area and the competitive landscape and synthesize information succinctly to support dissemination and incorporation into clinical development programs, asset plans and therapeutic area strategy
- Lead the clinical sub team and oversee multiple studies for a given program. Serve as the Medical input to the Global Lead the clinical sub team and oversee multiple studies for a given program. Serve as the Medical input to the Global Development Team / Subteam and the Medical Expert for clinical study team.
- Liaise internally with other members of the clinical development team (including ClinDev Scientists) to drive overall program strategy and

development plans. Represent Clinical Development at the Global Program Team

- Maintain awareness of internal and external developments (scientific, clinical, competitive, and regulatory) that could impact the development plan, including attendance at major scientific conferences, participation in competitive intelligence activities, and periodic literature review
- Support business development activities, such as due diligence and research collaborations
- May serve as the Translational Science lead for one or more programs
- Critically evaluate available information about diseases of interest to the therapeutic area and the competitive landscape and synthesize information succinctly to support dissemination and incorporation into clinical development programs, asset plans and therapeutic area strategy
 - Determine appropriate advisory boards experts
- Working as part of a cross-functional team with colleagues representing, for example, biostatistics, data management, clinical pharmacology, commercial, regulatory and project management
- May supervise other medical monitors on individual studies

You will need to have:

- MD or equivalent
- 5-10 years of clinical experience preferably within industry (minimum of 3 years of industry experience may be acceptable for outstanding candidates)
- Experience as a medical monitor for clinical trials required
- Regulatory experience preferred
- Publication in peer reviewed journals
- Excellent written / oral communication skills
- Attention to detail and ability to think strategically
- Willingness to take on new responsibilities
- Interest and ability to learn about new therapeutic areas
- Interest in career progression and ability to take on a more senior roles in 1-3 years
- The duties of this role are generally conducted in an office environment. As is typical of an office-based role, employees must be able, with or without an accommodation to: use a computer; engage in communications via phone, video, and electronic messaging; problem solve; engage in complex and non-linear thought, analysis, and dialogue; collaborate with others; maintain general availability during standard business hours

We would prefer for you to have:

- Board Certification
- Preferred: Advanced knowledge of the assigned therapy area is desired, with the capability to interpret, discuss and represent trial or program level data.

- 5+ years of industry experience in clinical development is preferred
- Experience for medical responsibilities on a cross-functional team preferred
- Basic statistical knowledge preferred
- Understanding of general (and specific) therapeutic principles
- Experience designing and executing industry-sponsored clinical trials
- Broad experience in the principles of clinical trial methodology, statistics, data analysis and interpretation
- Expert in scientific literature searches and weighing of quality peer reviewed data
- Experience authoring study essential documents, Clinical Study Reports, and regulatory documents
- Strong relevant therapeutic area experience
- Ability to clearly communicate to internal and external stakeholders orally and in writing
- Experience interacting with varying levels of internal/external management and/or academicians and/or clinicians and/or scientists, etc.
- Strong business acumen: including in-depth knowledge of the multidisciplinary functions involved in a company's drug development process, e.g., clinical operations, biostatistics, regulatory, commercial operations, etc. and can proactively integrate multiple perspectives into the clinical development process for best end-results
- Ability to prioritize multiple tasks and goals to ensure completion in a timely manner within budget
- Ability to think both strategically and tactically
- Advanced knowledge of the assigned therapy area is desired, with the capability to interpret, discuss and represent trial or program level data
- 5+ years of industry experience in clinical development