

Role Summary

Indianapolis Oritavancin Team

Position Title: Director, Medical

Reporting to: Vice President of Clinical Development & Medical Science Team Leader

Position Summary:

The Director, Medical is a director level position that reports to the Vice President, Clinical Development & Medical Science Team Leader.

This position will lead the clinical development team for additional clinical indications. They are responsible for the clinical study design, selecting CRO and ensuring excellent scientific rigor into the design and implementation of the clinical trials. They are responsible for the safety of patients in the clinical trials. This person will also contribute to the medical sections of the initial NDA to be coordinated with other team resources.

Key Responsibilities:

- Lead Physician for the design, CRO selection, successful implementation of additional clinical trials.
 - Sponsor physician monitor for safety in additional clinical trials. Responsible for insuring the accurate and timely reporting of safety notification through CRO.
 - Develop with team regulatory strategy for FDA negotiations regarding NDA, additional studies (including the protocol design), and label with team.
 - Physician contributor to medical, regulatory, and pharmacovigilance parts of the initial NDA. Responsible for substantial contributions for the medical sections of the initial NDA to be coordinated with other team resources.
 - Work closely with regulatory colleagues and consultants in preparation and delivery of regulatory documents, meetings, and the NDA submission.
 - Responsible for the coordination of the safety evaluation reporting of oritavancin.
 - Key team member in developing the clinical strategy for the sNDA, additional human studies.
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Qualifications required:

- M.D. with Internal Medicine and Pulmonary or Critical Care Boards.
- More than 5-7 years work experience in medicine.

- Clinical Trial experience preferred.
- Strong scientific and medical judgement.
- Excellent written and verbal communications skills.
- Discretion, confidentiality, professionalism, ability to prioritize, problem solve and make decisions, and well organized.
- Entrepreneurial spirit.

Approved By: _____

Approved By: _____

Date: _____