

# Director, Translational Medicine Expert, Clinical Pharmacology

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Индия

## Сводка

As a Director, Translational Medicine Expert (TME), Clinical Pharmacology (CP TME), you will serve as the primary medical and scientific leader for FiH and Clinical Pharmacology studies. You will partner closely with cross functional Clinical Pharmacology Trial Teams, project level TMEs, and CRO collaborators to ensure the highest standards of medical supervision, participant safety, and scientific quality.

TM Clinical Pharmacology is a cross-functional expert group responsible for the design, execution, and reporting of First-in-Human (FiH) and Clinical Pharmacology studies across all therapeutic areas. Operating through a strategic outsourcing model, we partner with qualified CROs while maintaining strong sponsor oversight of all strategic elements, including study design, regulatory engagement, and timelines.

## About the Role

### Role Overview

As a **Director, Translational Medicine Expert (TME), Clinical Pharmacology (CP TME)** you will serve as the primary medical and scientific leader for FiH and Clinical Pharmacology studies. You will partner closely with cross-functional Clinical Pharmacology Trial Teams, project-level TMEs, and CRO collaborators to ensure the highest standards of medical supervision, participant safety, and scientific quality.

This role directly shapes early and full development programs across the BR portfolio and plays a critical part in delivering high-quality data that informs program decisions and regulatory submissions.

### Your Responsibilities

#### 1. Clinical Pharmacology Portfolio Leadership

- Lead and manage multiple FiH and Clinical Pharmacology studies simultaneously with medical, scientific, and operational excellence
- Provide expert Clinical Pharmacology input into Study Concept Sheets, protocols, Informed Consent Forms, Statistical Analysis Plans, and TLF shells
- Oversee medical and safety aspects of studies, including Site Initiation Visits, ongoing safety reviews, medical coding, and safety reporting
- Drive development of Clinical Study Reports and contribute to dissemination of study results (e.g., abstracts, posters, manuscripts, plain-language and technical summaries)

#### 2. Clinical Pharmacology Strategy & Cross-Functional Collaboration

- Provide strategic Clinical Pharmacology guidance to ensure optimal study design aligned with program objectives
- Partner with project-level TMEs to align on compound background and program strategy
- Lead or contribute to strategic initiatives, process optimization, and capability-building efforts within TM Clinical Pharmacology
- Strengthen collaborations with internal stakeholders across early and full development, as well as with external CRO partners

### Impact of the Role

This role significantly influences the success of the Novartis development pipeline by:

- Enabling efficient and high-quality execution of FiH and Clinical Pharmacology studies
- Delivering key data supporting program milestones and regulatory submissions
- Strengthening Clinical Pharmacology as a Novartis Center of Excellence across all BR therapeutic areas
- Elevating scientific and medical expertise within TM and across development teams

### Minimum Requirements

- Medical degree (MD) combined with a PhD/post-doctoral training, board certification, or relevant Clinical Pharmacology research experience
- Significant experience in FiH and Clinical Pharmacology studies—either in biotech/pharma, as a PI/sub-investigator at a CRO, or at an academic medical center
- Proven track record of contributions to drug development, regulatory submissions, or high-quality scientific publications
- Experience within a TM therapeutic area is an asset
- Full professional proficiency in English (spoken and written)

### Work Experience

- Strategy Development
- Project Management
- Collaborating across boundaries
- Operations Management and Execution
- Representing the organization

### Skills

- Clinical Trials
- Cross-Functional Teams
- Data Analysis
- Data Monitoring
- Drug Development
- Drug Discovery
- Medical Research
- Medical Strategy
- People Management

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 Functional Area  
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 Job Type  
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 Employment Type  
 Regular  
 Shift Work  
 No

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