

# Study Start-Up Lead

Job ID  
REQ-10042923  
Mar 03, 2025  
China

## Resumen

-Planning, execution, and interpretation of clinical trials research, data collection activities and clinical operations. May interact with investigational sites, clinical consultants, Contract Research Organizations & other vendors. Collaborates with Country medical/clinical colleagues, global clinical teams and directs activities to execute and deliver the assigned studies. Monitors patient data and study-related information related to clinical study sites and clinical trial participation. Ensures the investigator adheres to research protocols, regulatory requirements and good clinical practices and provides input into data validation plan. Provides timely and accurate monitoring of patient data and study-related information from source documents, research records, and site visits where applicable. May monitor study sites and audit facility selection.

## About the Role

### Major accountabilities:

- Is a global clinical specialist overseeing all operational activities including planning, budgeting, implementing and completion of clinical trials in compliance with local and international regulatory requirements.
- Expert on monitoring processes, procedures, and systems.
- Prepare and collect study site documents.
- Perform Initiation Visit and continue to train study personnel as needed on study protocol, procedures, study drug handling and storage etc. -Perform Site Closeout activities per SOPs and applicable regulations.
- Is a seasoned, experienced professional with a full understanding of area of specialization; resolves a wide range of issues in creative ways.
- Works on problems of diverse scope -Networks with senior internal and external personnel in own area of expertise.
- Contributes to many cost center goals and objectives; may contribute to service line goals -May review and sign off Monitoring Visit Reports -Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

### Key performance indicators:

- Deliver customer satisfaction results for internal & external customers -Delivery of Clinical Trials to quality standards, agreed timelines, number of patients, costs and quality -Adherence to Novartis policy and guidelines and external regulations

### Minimum Requirements:

## Work Experience:

- Managing Crises.
- Operations Management and Execution.
- Collaborating across boundaries.
- Project Management.
- People Leadership.

## Skills:

- Budget.
- Clinical Monitoring.
- Clinical Research.
- Clinical Study Reports.
- Clinical Trial Management Systems.
- Clinical Trials.
- Collaboration.
- Data Analysis.
- Decision Making Skills.
- Financial Analysis.
- Health Sciences.
- Lifesciences.

## Languages :

- English.

**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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División

Development

Business Unit

Innovative Medicines

Ubicación

China

Sitio

Shanghai (Shanghai)

Company / Legal Entity

CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.

Functional Area

Research & Development

Job Type  
Full time  
Employment Type  
Regular  
Shift Work  
No  
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Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to [diversityandincl.china@novartis.com](mailto:diversityandincl.china@novartis.com) and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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