

## Study Start-Up Clinical Research Associate

Job ID  
REQ-10055557

6月 18, 2025

India

### 摘要

#LI-Hybrid  
Location: Mumbai, India

The Study Start-Up Clinical Research Associate (SSU CRA) plays a critical role in ensuring efficient and compliant trial start-up activities at clinical sites. This position is responsible for site selection, preparation, and activation for Phase I-IV clinical trials. SSU CRA acts as the primary liaison between the sponsor and the site during the start-up phase, ensuring all regulatory, ethical, and operational requirements are met to achieve site readiness.

### About the Role

#### Key Responsibilities:

- Lead and execute site selection and start-up activities from country allocation to site

greenlight.

- Serve as the main point of contact for trial sites during start-up, including IRB/IEC and Health Authority submission preparation.
- Ensure timely collection and submission of site-specific documents (e.g., CVs, GCP certificates, financial disclosures).
- Support the preparation of country-specific documents and patient-facing materials.
- Coordinate vendor setup and assist with financial contract negotiations with investigational sites.
- Maintain accurate and up-to-date documentation in Trial Master File (TMF) and internal systems.
- Collaborate with internal stakeholders to ensure seamless handover to execution CRAs and readiness for audits and inspections.

#### Essential Requirements:

- Bachelor ' s degree in a scientific or health discipline; clinical operations experience preferred.
- Minimum 3 years of experience in clinical operations, particularly in site management or monitoring.
- Strong knowledge of ICH/GCP guidelines, local regulatory requirements, and clinical trial processes.
- Excellent interpersonal, negotiation, and conflict resolution skills.
- Proven ability to manage multiple priorities and adapt to fast-changing environments.
- Willingness and ability to travel for site visits and meetings.

#### Commitment to Diversity and Inclusion / EEO paragraph:

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#### Accessibility and Accommodation:

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部门

Development

Business Unit

Innovative Medicines

地点

India

站点

Mumbai (Head Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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