

## Global Clinical Operations- Study Start-Up CRA

Job ID  
REQ-10032137

12月 04, 2024

China

### 摘要

监控与临床研究网站和临床试验参与相关的患者数据和学习相关信息。确保调查员遵守研究协议、法规要求和良好临床实践，并为数据验证计划提供投入。提供及时和准确的监测患者数据和研究相关信息，从源文件，研究记录和现场访问(如果适用。)可以监控学习地点和审计设施的选择。

### About the Role

Key Responsibilities :

- Supports country SSU strategy in close collaboration with SSO Study Start-Up Team Lead, SSO Study Start-Up Manager, SSO Feasibility Manager as well as SSO Site Partnership Manager
- Collaborates with SSO Study Start-Up Manager, SSO Study Start-Up Team Lead and global study team to ensure Study Start-Up timelines and deliverables are met according to country commitments

- Accountable for timely start-up activities from country allocation until site greenlight at assigned sites
  - Conducts site selection visits, verifies site eligibility for a specific study
  - Main contact for trial sites during site selection, study start-up and IRB/IEC and HA submission preparation
  - Ensures that milestones (KPIs) and time schedule for study start-up are met as planned
  - Facilitates the preparation and collection of site and country level documents
  - Collects submission relevant site-specific documents (e.g., FD, CV, GCP certificates, DSL...) for all relevant site personnel within agreed timelines
  - Supports SSU Manager in preparation of country-specific documents, e.g., ICF, patient facing materials, etc.
  - Supports SSO Study Start-Up Manager and assigned sites in vendor set-up activities
  - Prepare and finalize site specific documents for submission
  - Negotiates investigator payments as needed
  - Supports preparation of financial contracts between Novartis and investigational sites and investigators as needed
  - Updates all systems until site Green Light on an ongoing basis
  - Supports preparation of audits and inspections as applicable
  - Supports reduction of formal site-specific IRB/IEC deficiencies
- Ensures timelines, accuracy, and quality of country and site TMF documents in study start-up to ensure TMF inspection readiness
  - Ensures adherence to financial standards, prevailing legislation, ICH/GCP, IRB/IEC, Health Authority and SOP requirements
  - Implements innovative and efficient processes which are in line with Novartis strategy
- Ensures sites are prepared for “Green Light” and is accountable to send the Green Light to SSU Manager for review and approval

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

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

#### Essential Requirements:

- A degree in scientific or health discipline, preferably with clinical operations experience (or, for United States: 4-year degree plus relevant, related healthcare experience)
- Fluent in both written and spoken English, local language as needed
- Minimum 3 years ' experience in clinical operations in a monitoring / site management role

#### Desirable Requirements:

- Advanced understanding of all aspects of clinical drug development with particular emphasis on trial set-up, execution, and monitoring
- Central/in-house monitoring or field monitoring experience is desirable

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?

Benefits and Rewards: Go to Novartis career website to learn about all the ways we'll help you thrive personally and professionally.

Accessibility and Accommodation:

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 tell your relevant request to our hiring managers.

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up. You can follow us via the official account and video account of Novartis Recruitment.

Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up. You can follow us via social media account of Novartis Recruitment.

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>

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: <https://talentnetwork.novartis.com/network>

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

部门  
Development

Business Unit  
Innovative Medicines

地点  
China

站点  
Beijing (Beijing)

Company / Legal Entity  
CN06 (FCRS = CN006) Beijing Novartis Pharma Co., Ltd

Functional Area  
Research & Development

Job Type  
Full time

Employment Type  
正式

Shift Work  
No

[Apply to Job](#)

## 无障碍及便利设施

诺华承诺与残障人士共事并为他们提供合理的便利设施。如果您由于健康状况或残障在招聘过程的任何环节需要合理便利设施或者为了履行职位的基本职能请发送电子邮件至 [diversityandincl.china@novartis.com](mailto:diversityandincl.china@novartis.com) 告知您的需求和联系方式,并在邮件中附上您的职位申请编



Job ID  
REQ-10032137

Global Clinical Operations- Study Start-Up CRA

[Apply to Job](#)

---

Source URL:

<https://www.novartis.com.cn/careers/career-search/job/details/req-10032137-global-clinical-operations-study-start-cra-zh-cn>

List of links present in page

1. <https://www.novartis.com/about/strategy/people-and-culture>
2. <https://talentnetwork.novartis.com/network>
3. <https://www.novartis.com/careers/benefits-rewards>
4. <https://platform.moseeker.com/m/customize/page/novartis?jobnumber=REQ-10032137>
5. <mailto:diversityandincl.china@novartis.com>
6. <https://platform.moseeker.com/m/customize/page/novartis?jobnumber=REQ-10032137>