# SSO Associate Clinical Project Manager

Job ID
REQ-10047678

4月 17, 2025

Japan

## 摘要

This is a newly created position regarding the establishment of a clinical translational research hub.
本募集はClinical Translational Research Hub設置に関して新設されるポジションです。

SSO Associate Clinical Project Manager(aCPM)は、ノバルティスのプロセス及び規制要件に準拠し、臨床試験の計画、実行、及び成果物に対して国レベルの責任を負います。
The SSO Associate Clinical Project Manager (aCPM) is accountable for the day-to-day planning, executing and reporting, (from first site initiation visit to and including study site close-out), of assigned Global Drug Development (GDD) studies in compliance with Novartis processes and regulatory requirements.
aCPM an entry level of CPM position and will be mainly focus on managing in-country study delivery. Like the CPM position, the aCPM is the single point of contact and study team lead, mainly within the country for the assigned studies. As part of their development, aCPM could also perform other development duties as assigned by management.
The aCPM is responsible for assuring aligned communication with Trial Lead and other CTT members, locally with Clinical Research Associates (CRAs), CRA Managers and other key associates on the execution and progress of their studies. The aCPM collaborates with the SSO Country Manager, SSO Country Head, SSO Feasibility Manager, SSO Study Start-up Manager and

SSO Site Partnership Manager in the planning, execution, and delivery of their assigned studies. Accountable for execution and reporting of assigned GDD studies in E2E product line Clinical Operations Program Head/Study Lead/CPM/aCPM - CRA. Can be assigned partially to participate in the review process of Site Monitoring Plans across Portfolio.

## About the Role

### Major Accountabilities

臨床試験及び治験実施医療機関のオペレーション戦略、臨床試験の開始と実施、品質の確保、予算管理、生産性の維持

### Study & Site Operations strategy

- Supports SSO Study Start-up Manager in the development of country study execution plans and timeline commitments
- Participates in the recruitment sub-team and supports the development of innovative solutions for site and patient participation to ensure the delivery of assigned studies on time
- Proactively identifies risk and opportunities for the assigned studies within the country and develops respective mitigation plans

### Initiation and conduct of trials

- When requested by the SSO Feasibility Manager supports the study feasibility by providing input to the study protocol, and operational aspects of the study
- Maintains a strong knowledge of the study protocol to answer standard operational questions from CRAs, sites and Country personnel
- Drives the conduct of the study, (tracks status, maintains relevant reporting systems, oversees forecasts, progress, and mitigation plans), to ensure all study operational aspects are on track
- Ensures recruitment targets are met and reviews enrolment at the site level including responsibility for getting approval from the STUDY LEADER on enrolling above site targets. Responsible to set up contingency plan to ensure recruitment targets are achieved in accordance with trial execution plan
- Oversees local study team activities to achieve study timelines and quality execution, (proposing and implementing corrective actions where appropriate), according to Novartis standards and relevant regulations
- Leads/chairs country study team meetings, participates in global clinical trial team meetings, as required and is the single point of contact for the conduct of assigned studies
- Maintains oversight of country level data management activities, including timely understanding of screen failure reasons and discontinuation rates, review of patient profiles, and proactively identifies data entry issues (on quality and timing) to mitigate queries, proactively identifies query resolution issues
- Coordinates the study handover process with CRAs and their managers to ensure proper documentation and communication, when necessary

- Tracks that all study close-out activities are performed in a timely manner, in collaboration with CRAs and key study stakeholders

**Delivery of quality data and compliance to quality standards**

- Conducts or coordinates training, as needed, for CRAs to support site readiness to recruit and study execution ensuring adherence to clinical data standards, prevailing legislation, GCP, Ethical Committee and SOP requirements
- Conducts or coordinates local investigator meetings as needed and ensures relevant documentation of training is archived in the Trial Master File
- Evaluates potential challenges/risks within the protocol and operational aspects of the study; assessing impacts, develops risk management plans and communicates/ escalates to global teams and SSO Country Head Portfolio, as appropriate
- Accountable for monitoring quality and issue resolution through timely review and approval of study monitoring visit reports to ensure quality trial oversight and appropriate issue escalation
- Promotes a compliance culture advocating the adherence to highest standards and ethical integrity, ensuring human subject protection and reliability of trial results at all times
- Escalation point for issues in monitoring visit reports (MVRs) for the assigned studies. Responsible for evaluating trends identified in MVRs and communicating/escalating to global teams, as appropriate. Communicates with CRAs and their managers to ensure issue resolution in a timely manner
- Provides feedback about the quality of monitoring activities to CRA Managers, MSOM, SSO Country Managers, FSP/BiS line managers (as propriate) and local QA (when required per Novartis SOPs)
- Supports inspection readiness and submission preparation for monitoring related activities and assists and coordinates with country Portfolio Execution and Quality Assurance for internal audits organization and HA inspections, as required, and ensures implementation of corrective actions within specified timelines
- Participates in multidisciplinary taskforces to support continuous improvement initiatives

**Budget and productivity**

- Monitors the status of site budget and contract negotiations as well as the collection and review of essential documents throughout study conduct
- Tracks study budget with appropriate study budget responsible in Country. Ensures timely TCF preparation and submission
- Processes invoiceable items for site level clinical study activities to allow timely payments

**Key Performance Indicators**

- Timely submission and delivery of high-quality clinical trial documentation/data
- Performance against study commitments at the country level, including delivery of studies per defined timelines (including study close out), number of patients and quality
- Delivery of study milestones in adherence to prevailing legislation, GCP, Ethical Committee and SOP requirements

**Work Experience**

- Minimum 3 years’ experience in clinical research in a role that oversees (project management) and/or with monitoring clinical trials
- Capable of leading in a matrix environment, without direct reports and working cross-border managing study in various countries
- Understanding of all aspects of clinical drug development with particular emphasis on monitoring and study execution
- Good project management capabilities with demonstrated ability to problem solve and mediate complex issues
- Thorough understanding of the international aspects of drug development process, including sufficient knowledge of international standards (GCP/ICH), health authorities (FDA/EMA), local/National Health Authorities regulations

**Skills**

- Demonstrated negotiation and conflict resolution skills both internal and external (site relationships)
- Communicates in a local/global ma

**Language**

- Native level Japanese, fluent in both written and spoken English

**Others**

- Currently resides in Japan

**福利厚生**

ノバルティスの福利厚生と報奨について必要な情報は、ノバルティスライフハンドブックに記載されています。

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**多様性と包括性へのコミットメント**

ノバルティスは患者さんや地域社会などに対して、 包括的かつ優れた職場環境、および
多様なチームを構築するよう取り組んでいます。

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ノバルティスは障害を持つ個々人に対して、 合理的配慮を提供し協働することをお約束します。

健康状態や障害に関して、 採用プロセスあるいは必須の職務を満たす
ために合理的配慮が必要な場合は midcareer-r.japan@novartis.com 宛てに電子メールをお送りください。その際ご依頼内容、ご連絡先、求人票の番号を明記してください。

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You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook.

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

**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 send an e-mail to midcareer-r.japan@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

**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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部门
Development

Business Unit
Universal Hierarchy Node

地点
Japan

站点
Toranomon (NPKK Head Office)

Company / Legal Entity
JP05 (FCRS = JP005) Novartis Pharma K.K.

Alternative Location 1

Fukuoka, Japan

Alternative Location 2
Osaka (Novartis Pharmaceuticals), Japan

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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