Associate/Manager, Clinical Development Director Japan

Job ID
REQ-10063785

10月 05, 2025

Japan

摘要

The Clinical Development Director Japan (CDD-J) is the clinical/scientific and clinical development expert and provides leadership and support to clinical development deliverables and activities within a clinical trial (e.g. clinical trial protocol) including post approval commitment study, under the leadership of the JPCH. The CDD-J hasresponsibilities for post approval phase activities and may also contribute project level activities.

About the Role

1) Supports and if assigned leads delivery of all assigned clinical deliverables in the assigned trial including post approval commitment study. Clinical deliverables may include clinical sections of individual protocol/related documents, clinical data review, interim/final study report (CSR), trial related clinical components of regulatory documents/registration dossiers, and publications
2) Provides input into final analyses and interpretation including the development

of the Clinical Study Report(s) (CSRs), publications and internal/external presentations.
3) Lead discussions regarding assigned trial and study, in Japan Project Team (JPT), Japan Clinical Team (JCT), Japan Submission Team (JST), Clinical Trial Team (CTT), Local Trial Team (LTT), Post-marketing Study Team (PST), and Team for Re-Examination Excellence (TREE)
4) Contribute to development of clinical sections of project level documents (e.g., Investigator's Brochures clinical development plan, briefing books to PMDA consultation, safety updates, submission dossiers, interim/final study report (CSR), J-RMP, Re-examination application dossiers, a report for lifting of "all patient surveillance" as approval condition and responses to Health Authorities)
5) Create study concept in collaboration with JPCH.
6) Drive execution of the clinical program in partnership with responsible line functions including CSMs, Global Trial Directors (GTDs), PMS TMa, if applicable
7) Conducts ongoing clinical data review of the clinical trial data (including post approval commitment study) with appropriate oversight from Medical Lead. Work in close collaboration with the data management and statistics teams to ensure proper data quality and analysis of clinical trial results.
8) Inspection Readiness and interaction with QA - risk assessments, audit preparation, mock interviews and presentation prep; Author and/or review

presentations and manuscripts of answer for accuracy of clinical data and content
9) Support overall program safety reporting (e.g., Periodic Safety Update Reports (PSURs), Drug Safety Update Reports (DSURs), and other safety related documents) in collaboration with Patient Safety in Japan
10) As a clinical development expert, support the JPCH in interactions with Japan external stakeholders (e.g., regulatory authorities, key opinion leaders, data monitoring boards, advisory boards, patient advocacy groups), internal stakeholders (e.g., JPT, JBT/JDT, CTT, Research, Translational Medicine, Japan Medical Affairs, Marketing, HE&OR, PS-J), and internal decision boards
11) Provide on-boarding, training, & mentoring support
12) Contribute to medical/scientific training of relevant Novartis stakeholders on the disease area and compound/molecule. May serve as speaker for medical/ scientific training
13) Contribute to initiatives (e.g., process improvement, training, SOP development, other Clinical Development line function initiatives)
14) May be assigned to lead clinical trial(s) as Clinical Scientific Lead and provide leadership and guidance for all clinical aspects of a clinical trial in close collaboration with JPCH and/or CDMD.
15) Identify candidate of CDD-Js and contribute to coach/support CDD-Js, and cultivate their talent & career development
16) Comply with PMD Act(Pharmaceutical and Medical Device Act), GPSP (Good Post-marketing Study Practice), SOPs and other related procedures (including performing all provided training)
17) Ensure adequate reporting of adverse events / technical complaint / compliance issue in accordance with company procedures
18) 100% timely delivery of all training requirements including compliance
19) Lead or serve on Japan process improvement work streams, act as Subject

Matter Expert for SOP or trainings, and/or contribute to cross-functional initiatives.
20) Expand our external network and an awareness of industry trend and benchmark.

Education:

- Relevant degree in life sciences/healthcare (or clinically relevant degree) is required

Experience/Professional requirement:
- ≥ 5 years of involvement in clinical research or drug development in an academic or industry environment spanning clinical activities in Phases I through IV, and PMS. ≥ 5 years of contribution and accomplishment in all aspects of conducting clinical trials or PMS (e.g., planning, executing, reporting and publishing) in a global/matrix environment in pharmaceutical industry.
- Advanced knowledge of assigned therapeutic area
- Demonstrated ability to establish strong scientific partnership with key internal and external stakeholders
- Thorough knowledge of ICH, GCP and GPSP, clinical trial/PMS design and methodology, statistical analysis methodology, and regulatory/ clinical development process≥ 2 years people coaching/supporting experience required, this may include management in a matrix environment.
- Demonstrated leadership and team management skills.
- Excellent communication skills, written and oral
- Strong interpersonal skills
- Excellent negotiation and conflict resolution skills

English Skill:

- Capable oral and written English

Why consider Novartis?

817million. That ' s how many lives our products touch. And while we ' re proud of that fact, in this world of digital and technological transformation, we must also ask ourselves this: how can we continue to improve and extend even more people ' s lives?

We believe the answers are found when curious, courageous and collaborative people like you are brought together in an inspiring environment. Where you ' re given opportunities to explore the power of digital and data. Where you ' re empowered to risk failure by taking smart risks, and where you ' re surrounded by people who share your determination to tackle the world ' s toughest medical challenges.

We are Novartis. Join us and help us reimagine medicine.

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約10万の社員が世界中のノバルティスで働いており、その国籍は約147カ国に及びます。

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Japan

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健康状態や障害を理由に採用プロセスのいかなる部分においても、あるいは職務の必須事項を果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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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

部門
Development

Business Unit
Development

地点
Japan

站点
Toranomon (NPKK Head Office)

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

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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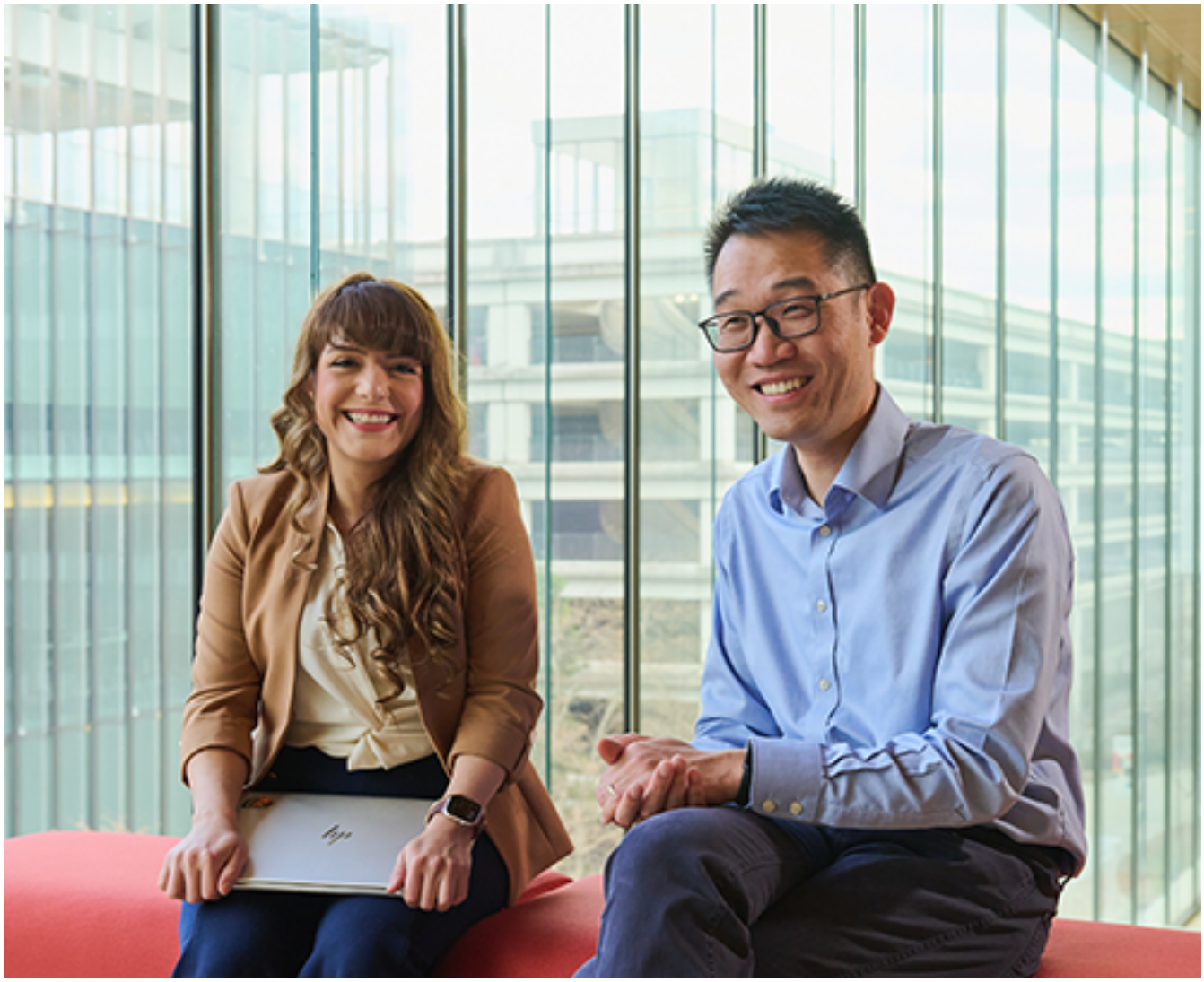
Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.



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