Clinical Development Director Japan

Job ID
REQ-10063806

12月 15, 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.

ノバルティスの製品は約8億人以上の患者さんに世界中で届けられています。

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。

ノバルティスファーマ株式会社は、スイス・バーゼル市に本拠を置く医薬品のグローバルリーディングカンパニー、ノバルティスの日本法人です。ノバルティスは、より充実したすこやかな毎日のために、これからの医薬品と医療の未来を描いています。詳細はホームページをご覧ください。https://www.novartis.co.jp

Japan

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.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.

ノバルティスは障害を持つ個人と協力し、合理的配慮を提供することをお約束します。

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。

Be aware of fake job advertisements and job offers

Novartis is aware of employment scams which make false use of our company name or leader’s names to defraud job seekers. Novartis does not make job offers without interview and never asks candidates for money.

All our current job openings are displayed here. If you have encountered a job posting or been approached with a job offer that you suspect may be fraudulent, we strongly recommend you do not respond, send money or personal information.

偽の求人広告や採用オファーにご注意ください

ノバルティスでは、当社名や幹部の名前を不正に使用して求職者をだます「採用詐欺」が発生していることを認識しています。

ノバルティスでは、面接なしに採用オファーを出すことはなく、候補者に金銭を要求することも決してありません。

現在の求人情報はすべてこちら
に掲載されています。詐欺の可能性がある求人広告や採用オファーに遭遇した場合は、返信したり

、金銭や個人情報を送ったりしないよう強くおすすめします。

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

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

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.

Job ID
REQ-10063806

Clinical Development Director Japan

Apply to Job

Job ID
REQ-10063806

Clinical Development Director Japan

Apply to Job

Source URL:

List of links present in page

1. https://www.novartis.com/jp-ja/careers
2. https://www.novartis.com/jp-ja/careers
3. https://www.novartis.com/about/strategy/people-and-culture
4. https://www.novartis.com/careers/benefits-rewards
5. mailto:midcareer-r.japan@novartis.com
6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Toranomon-NPKK-Head-Office/Associate-Manager--Clinical-Development-Director-JapanREQ-10063806-6
7. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Toranomon-NPKK-Head-Office/Associate-Manager--Clinical-Development-Director-JapanREQ-10063806-6