Associate/Manager, JPCH

Job ID
REQ-10063886

10月 05, 2025

Japan

摘要

・The Japan Program Clinical Head (JPCH) is responsible for clinical program activities for approval and post approval commitment for Re-examination in Japan
・The JPCH leads disease area strategy discussion and the risk-benefit assessments for the programs(s) that are required for approval in Japan
・The JPCH is accountable for the study design, implementation, and execution of clinical development program(s) including post approval commitment to support decision milestones, regulatory requirements, and market access from Japan point of view, as a member of Global Clinical Team(s) (GCT) and the leader of Japan Clinical Team(s) (JCT)

About the Role

1) Lead the JCT and represent Clinical Development on the JPT to achieve

valuable clinical program strategy, drive innovation, ensure regulatory approval, and post approval commitment for patients
2) Is the single integrative leader for clinical programs to establish clinical trials excellence, high performing JCT & LTT, integrated CD/GCO/Analytics WoW
3) Is a member of the GCT as representative of Clinical Development Japan
4) May serve as the CD-J Representative on NIBR clinical/project teams in Japan (EAGLE: Early AGile LEadership Team in pharma), JPT: Japan program team in oncology) to drive transition of pre-FIH (First In Human) projects to Transition Decision Point (TDP) for clinical development strategy in Japan
5) Play medical lead role in Japan initiated studies in collaboration with GPCH/CDMD
6) Post-TDP, lead the development and execution of Japan clinical strategy. Provides Japan inputs to GPCH for developing an endorsed Clinical Development Plan (CDP) in line with the Target Product Profile (TPP) which is designed for successful regulatory approval/market access for one or multiple treatment indications and/or multiple programs in Japan
7) Is responsible for Japan input to the creation of clinical components of key documents (e.g., Clinical Trial Protocols (CTPs), Investigator's Brochures, Clinical Study Reports (CSRs), regulatory documents including maintenance of product licenses, registration dossiers, Re-examination application dossier, value dossiers, pharmacoeconomic dossiers, Core Data Sheet, Periodic Safety Update Report, J-RMP, and clinical benefit-risk

assessment for license renewals) with high quality and consistency with CDP and TPP
8) Together with Patient Safety, provide GPCH with Japan input regarding continuous evaluation of drug safety profile, including safety monitoring of clinical studies and signal detection from post-marketing surveillance (PMS)
9) As the medical/scientific expert, contribute interactions with Japan external stakeholders (e.g., regulatory authorities, key opinion leaders, data monitoring committees, advisory boards, patient advocacy groups), Japan internal stakeholders (e.g., JPT, GCO/Study & Site Operations, Research, Translational Medicine, Medical Affairs, Marketing, Pharmacovigilance (PV), Health Economics & Outcomes Research, etc.), and internal decision boards
10) Gather latest clinical trial/drug development trend/information and enhance innovative approach in clinical development and post approval commitment to maximize the product value
11) Lead clinical related health authority (HA) activities including development of briefing book and answers for questions from HA
12) Lead discussion for post approval commitment strategy in JPT and Japan submission team (JST) and contribute to Team for Re-examination excellence (TREE) for PMS and Re-examination activities including the review of Re-examination dossier
13) Support JCDH with leading the peer-review of CDPs, CTPs, and other clinical documents across various indications and programs; and with driving excellence across clinical trial strategy, design, and execution as a delegator of regional reviewer
14) Contribute to development of TA strategies

15) Support/author Japan publication and clinical communication strategy in coordination with MA Japan and Medical Writing, and provides input into key external presentations
16) Responsible for medical/scientific training of relevant Japan stakeholders on the disease area and compound/molecule. May serve as speaker for medical/scientific training in Japan
17) Lead or serve on Japan process improvement work streams, act as Subject Matter Experts for standard operating procedures or trainings, and/or contribute to other cross-functional or Clinical Development line function initiatives
18) Provide on-boarding, coaching, and/or mentoring support; develop and foster Clinical Development culture
19) Ensure adequate reporting of adverse events / technical complaints / compliance issues in accordance with company procedures
20) 100% timely delivery of all training requirements including compliance
21) May serve as CDD-J concurrently depending on project size or resource allocation

Education:

- Advanced degree in life sciences/healthcare (or clinically relevant degree: MD or equivalent, PhD, PharmD degree is preferable) required.
Specialization in a subspecialty may be needed. Advanced clinical training/knowledge in medical/ scientific area aligned with TA required.

Experience/Professional requirement:
- ≥5 years of involvement in clinical research or drug development in an industry environment spanning clinical activities in Phases I through III/IV, including submission dossiers (In case MD holder, equivalent medical experience is needed)
- Advanced knowledge of assigned therapeutic area required, with the capability to innovate in clinical development study designs that provide relevant evidence to decision-makers, and to interpret, discuss and present clinical trial or section program level data
- Thorough knowledge of GCP and GPSP, clinical trial design, statistics, and regulatory/clinical development process
- Experience with submissions and health authorities required
- Demonstrated ability to establish strong scientific partnership with key stakeholders
- Demonstrated leadership and team management skills with a documented track record of delivering high quality projects/submissions/trials in pharmaceutical or biotech industry
- Considerable organizational awareness including extensive

experience working cross-functionally and in clinical teams
- Excellent management, interpersonal, communication (both written and oral), and problem-solving skills
- Excellent negotiation and diplomatic skills

English Skill:

- Fluent oral and written English

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Japan
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部門
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.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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