Japan Program Clinical Head

Job ID
REQ-10019692
Mar 13, 2025
Japan

Summary

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 is responsible for one or more clinical programs across indications, involving one or multiple compounds. The JPCH closely works with Japan Project Head (JPH) as well as Global Program Clinical Head (GPCH) and inputs the risk benefit assessment for the program(s), and as the member of Global Clinical Team(s) (GCT) provides the inputs regarding the design, implementation, and execution of a clinical development program(s) including post approval commitment to support decision milestones, regulatory requirements, and market access from Japan point of view. The JPCH may contribute to disease area strategy.

About the Role

1．Is an extended member of the GCT as representative of Clinical Development Japan (CD-J)

2．Is a member of JPT and drive the clinical development in Japan

3．Play medical lead role in Japan initiated studies in collaboration with GPCH/CDMD

4．Post-DDP, 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

5．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) with high quality and consistency with CDP and TPP. Support registration, market access, commercialization, and maintenance of product licenses (e.g., Core Data Sheet, Periodic Safety Update Report, J-RMP, clinical benefit-risk assessment for license renewals) for the compound(s)

６．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, GDO/Trial management, Research, Translational Medicine, Medical Affairs, Marketing, Pharmacovigilance (PV), Health Economics & Outcomes Research, etc.), and internal decision boards lead clinical related health authority (HA) activities including development of briefing book and answers for questions from HA

７．Contribute to development of TA strategies (Rheumatology area)

８．　Provide on-boarding, coaching, and/or mentoring support; develop and foster Clinical Development culture

９．　Ensure adequate reporting of adverse events / technical complaints / compliance issues in accordance with company procedures

１０．100% timely delivery of all training requirements including compliance

Key Performance Indicators

The indicators below are applied for clinical related activities in Japan

- **Excellence in establishing clinical development and Re-examination strategy across various indications and programs with alignment across functions**
- **Apply effective clinical research methodology, including trial design/analyses, efficacy endpoints, safety assessments, and risk management across disease area**
- **Robust evidence of quality medical/clinical review of trial data, development of CSRs**
- **Support TA through high quality contributions to CDP and protocol reviews**
- **Timely development of quality disease/program clinical standards, publications, and internal/external presentations**
- **Timely delivery and submission of high-quality clinical program data in a cost-effective manner**
- **External acceptance of clinical data and risk-benefit assessments by key decision makers including Health Authorities, pricing, and reimbursement bodies**
- **Well contributed, effective, and engaged GCT(s) and GPT (as needed)**
- **Clearly demonstrate Novartis Values and Behaviors**

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 (Rheumatology 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/or 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 (or intermediate) oral and written English**

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Japan

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