Immunology Japan Program Clinical Head

Job ID
395077BR
Mar 21, 2024
Japan

About the Role

Job Purpose:
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.

Major Activities:
1) Is an extended member of the GCT as representative of Clinical Development Japan (CD-J) and is a member of JPT and drive the clinical development in Japan
2) Play medical lead role in Japan initiated studies in collaboration with GPCH/CDMD
3) Post-Drug Development Point (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
4) 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)
5) 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
6) Contribute to development of Immunology strategies
7) Support Japan publication and clinical communication strategy in coordination with MA Japan and Medical Writing, and provides input into key external presentations. 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

8) 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
9) Provide on-boarding, coaching, and/or mentoring support; develop and foster Clinical Development culture
10) 100% timely delivery of all training requirements including compliance

Diversity & Inclusion / EEO

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

Role Requirements

Education:
• Advanced degree in life sciences/healthcare (or clinically relevant degree: MD or equivalent, PhD, PharmD degree is preferable) required.
Specialization in a subspecialty (Immunology) 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 (Immunology) 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 (important) 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

Why Novartis?
766 million lives were touched by Novartis medicines in 2021, and while we’re proud of this, we know there is so much more we could do to help improve and extend people’s lives.
We believe new insights, perspectives and ground-breaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working.

We believe our potential can thrive and grow in an unbiased culture underpinned by integrity, curiosity and

flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world’s toughest medical challenges. Because the greatest risk in life, is the risk of never trying!

Imagine what you could do here at Novartis!
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.

midcareer-r.japan@novartis.com

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

División
Development
Business Unit
CD&A GDD
Ubicación
Japan
Sitio web
Tokyo
Company / Legal Entity
Novartis Pharma K.K.
Functional Area
Research & Development
Job Type
Full Time
Employment Type
Regular
Shift Work
No
Apply to Job Access Job Account
Job ID

395077BR

Immunology Japan Program Clinical Head

Apply to Job Access Job Account

Source URL: *https://www.novartis.com/co-es/careers/career-search/job/details/395077br-immunology-japan-program-clinical-head*

List of links present in page

- https://www.novartis.com/about/strategy/people-and-culture
- https://talentnetwork.novartis.com/network
- https://sjobs.brassring.com/TGnewUI/Search/home/HomeWithPreLoad?PageType=JobDetails&partnerid=13617&siteid=5260&jobid=2816326&AL=1