Global Development Leader, Product Development
Ophthalmology (PDS with Ranibizumab)

Job ID: 202103-106167

Job Function
Clinical Operations

Location
South San Francisco, California

Company/Division
Pharmaceuticals

Schedule
Full time

Job type
Regular

Job Level
Manager with direct reports

The Position

Roche’s Clinical Development organization is structured by therapeutic area and is responsible for developing and executing the late development (Phase IB – III) clinical strategies and plans that provide meaningful improvement to patients. The PD Global Development Leader (GDL) is a core member of the Lifecycle Team Leadership Team (LCT LT) and is responsible for overseeing and developing global Clinical Development (CD) molecule and disease strategies and ensuring effective and efficient execution for one or more molecules/indications/programs. PD GDLs guide the development of molecules and programs, approve Clinical Development Plans (CDPs) and priorities, and lead the design and final interpretation and completion of clinical studies. PD GDLs are members of the PD Clinical Science organization, have a medical (M.D.) background, and can manage a team of PDC Medical Directors and Clinical Scientists. PD GDLs interact with the highest levels of management and serve as scientific, medical, product development, and strategic experts both internally and externally. The GDLs serve as internal consultants for Roche committees as well as represent the therapeutic area’s CD strategy, plans, objectives, and interests to health authorities (HAs) and prominent thought leaders worldwide. PD GDLs are expected to provide critical insights and contributions to the overall development and effectiveness of the assigned therapeutic/disease area(s), including therapeutic area scientific strategies and plans, including acting as a key collaborative partner with gRED, pRED, Chugai, and partner companies. The TA and Franchise Heads may delegate the following depending upon the GDLs level of scientific and technical expertise: protocol approval, protocol amendment approval, ICF approval (Informed Consent Form), IBs, PBRERs, and clinical overview approval.

JOB DESCRIPTION – PRIMARY DUTIES AND RESPONSIBILITIES:

Cross-Functional Team Leadership

- A key member of the Lifecycle Team’s LT (GDL, LCL and IBL), representing Product Development (PD)
- Leads cross-functional, fit-for-purpose team(s) with a focus on product development, molecule or disease strategy (Development Working Groups, Clinical Science Team
CST, as appropriate and assigned by the LCT LT)

- Represents PD/CD for assigned portfolio at the highest management/expert levels inside and outside Roche; includes championing and sponsoring the work of his/her staff
- Represents PD/CD on cross-functional strategic workstreams and initiatives as well as with internal (REDS, PD functions) and external (Business Development, Partnering, Scientific and Medical Societies, Therapeutic Area Experts, Regulatory Authorities) interactions
- Oversees one or more Clinical Development Plans (CDPs), disease strategies, molecules and/or indications, as well as associated clinical trial programs and studies. Guides direct reports to ensure cross-functional integration, coordination, and alignment to enable effective and efficient CDP execution
- As member of the LCT, provides input and leadership regarding key decisions for molecules, Disease Areas, and Therapeutic Areas, including decisions regarding prioritization of activities.
- Ensures direct reports and their staff are actively and appropriately aligning with sub-teams (e.g., Study Management Teams), to ensure on-time and on-target results
- As needed, provides leadership guidance and direction in ongoing enhancements/development of core and sub-team processes, structures, systems, tools and other resources

**Staff Leadership & Development**

- Works with manager and peers to identify and ensure the appropriate infrastructure – clear roles and responsibilities, learning and development, technology, other tools, vendor partners and operating budgets
- Where applicable, may participate in the negotiation with and commissioning of external vendor partners to support certain elements of the therapeutic area’s CD function
- Assigns direct reports their projects and programs and guides direct reports in their assignment of projects and programs across their staff
- Cascades strategic and other relevant goals and objectives as well as expense budgets to direct reports
- Leads recruitment, hiring and training for his/her staff member roles
- Provides direct reports with ongoing coaching, development and leadership; includes holding regular staff meetings, check-ins, and 1:1 meetings
- Oversees staff members’ work to ensure on-time, on-target and within-budget results
- Plays a leadership role in all formal and informal performance management and career development activities for his/her staff members
- Actively participates in leadership and skill development programs for continued professional development
- Initiates and develops cross-functional projects, programs or other initiatives that can carry broad and important impact to multiple Product Development objectives and activities
- Consistently complies with all governing employment laws, regulations and company HR policies & procedures and ensures the same across his/her staff

**Global Clinical Development Leadership**

- Stays abreast of internal and external developments, trends and other dynamics relevant to the work of CD to maintain, at all times, a fully current view and perspective of internal/external influences and/or implications for the assigned therapeutic and disease area(s). Ensures the same across his/her staff
- Provides CD leadership guidance and direction regarding competitive intelligence and/or other market/industry assessment activities and projects
Maintains the highest standards and levels of scientific and clinical knowledge in the specific therapeutic and disease area(s) of assignment. Ensures the same across his/her staff.

Educates others internally and externally on relevant clinical developments as these may implicate the assigned therapeutic area’s CD strategies, plans and programs.

Collaborates with a variety of internal and external partners and stakeholders, such as HAs, clinical investigators, clinicians, scientists and key opinion leaders (KOLs). Has extensive interactions with these external parties, subject matter experts and influencers. Supports his/her direct reports and/or other CD staff members in their communications and interactions with these external parties.

Works across Roche at all levels and with various groups and functions, such as other groups in PD, research, business development, manufacturing, commercial operations, legal, etc.; providing ongoing leadership expertise and guidance on the assigned therapeutic area’s clinical strategy.

Plays a leadership role in providing clinical science input into the relevant therapeutic area clinical scientific strategy, as well as into relevant cross-functional and enterprise-wide plans, strategies and initiatives. Helps Research and PD groups to ensure consistency of scientific and late-development strategies with target label claims and corporate goals. As appropriate/needed, performs or delegates clinical assessments on relevant drug discovery projects.

As needed, ensures his/her staff members support internal partners in transitioning new drugs/indications into Phase IIIB or publication studies. Expected to provide expert leadership CD guidance, when needed, on Phase IIIB and Medical Affairs protocols.

Consults to, and/or assigns staff members to consult to, pharma partnering on relevant acquisitions, joint ventures or other strategic partnerships, as these potentially relate to the assigned therapeutic/disease area(s). Serves on joint executive committees, which include other Roche functions as well as external partner personnel, and/or assigns such responsibilities to direct reports.

Leads global CD strategy development for the assigned portfolio. Acts as a regular reviewer/presenter to various internal committees.

Acts as an expert advisor and consultant to various internal committees, other Roche management and teams regarding CD strategies, priorities, implementation and the like. Leads interactions with internal and external fit-for-purpose Advisory Forums and groups, in close collaboration with other LCT LT members.

Leads global development of clinical science input into annual and strategic Lifecycle Plans (LCPs) and the Integrated Development Commercialization Plan (IDCP). Acts as an expert advisor to others regarding CD strategic alignment with and implications for LCPs for the assigned portfolio.

Oversees creation and implementation of global CD plans for all molecule(s)/indication(s) and/or other programs across the assigned portfolio:

- Accountable to ensure strategic and operational alignment of CD plans with the relevant CD strategy, Disease Area Strategy and LCPs.
- Guides CSTs in developing all CD plan components (e.g., analytics/data strategy, KOL development, publications strategy, etc.).
- Reviews budget and other resource requirements necessary to implement and execute CD plans. Provides leadership guidance and direction to ensure the optimal use of resources.
- Supports direct reports, as needed, to ensure they gain alignment with various internal partners/stakeholders on goals and resource needs. Includes guiding direct reports and other team leads.

As needed, or otherwise appropriate, supports direct reports and/or other team members in their communications with HAs. Accountable to ensure his/her team members ethically, effectively and professionally represent the interests of Roche and
Global Clinical Plan Development Implementation

- Accountable for the design, execution and medical/scientific data interpretation of global clinical studies and other evidence generation programs across the assigned portfolio:
  - Manages across multiple, often large-scale and highly complex projects
  - Provides guidance to direct reports in the strategy, design and implementation of clinical studies and other programs
  - Reviews various items and activities and provides leadership guidance and direction to ensure successful execution and completion of clinical studies and other programs: study protocols, incorporation of cross-functional strategies and input into programs, product safety profiles, etc.
  - Oversees development of clinical sections of investigator brochures, other external presentations, information and materials
  - As needed, guides others in the identification and selection of appropriate external investigators and sites
  - Guides others in patient registry design and development (including strategies for patient registry recruitment)
  - Advises direct reports and others on development of study analytics and data management plans for their key, large-scale studies
  - Reviews and approves clinical components of presentations for clinical trial investigator and other relevant meetings
  - As needed, supports direct reports in conducting investigator or other external presentations, meetings and other communications
  - Provides ongoing guidance to direct reports, cross-functional teams, internal committees and company executives regarding the overall strategy, implementation and prioritization of CD activities across the assigned portfolio
  - Regularly reviews medical/safety data
  - Measures and monitors study progress against objectives and plans, including any variances. Proactively guides other team members on identifying, communicating and addressing any issues, challenges and potential strategies to resolve such
  - Reviews and approves various interim study reporting prior to further dissemination
  - Serves as a resource for issue management and resolution. Anticipates issues and helps prevent and/or resolve these
  - Oversees clinical study, database and study reporting completion. Approves final study reporting prior to further dissemination
  - Accountable to ensure correct medical/scientific data interpretation for interim and final study reporting
  - Guides direct reports in their assimilation and translation of safety and efficacy data for regulatory submissions
  - Oversees clinical science input for completion and submission of regulatory filings and other regulatory documentation. Advises direct reports and other team members in their development of clinical science information and input into regulatory submissions and other regulatory processes. Includes guiding others, as necessary, on development of labeling and packaging language, etc.
  - Keeps partners and stakeholders abreast of developments relative to the work of CD and the assigned portfolio and ensures same approach is consistently taken across his/her staff
  - As needed, advises direct reports and other team members regarding
communications strategies to support existing and concluded studies. Includes interactions with Therapeutic Area Experts (TAEs), advisory boards (internal and external), Independent Data Monitoring Committees (IDMCs), Data Review Board (DRB), major medical meetings, congresses and other events, publications and other materials used to communicate Roche’s clinical view and position on clinical development plans and study results for molecules/indications across the assigned portfolio.

- Develops and delivers key presentations, both internally and externally, to convey the CD perspective and provide updates on strategies, plans and other activities. Includes regularly acting as an expert participant and contributor on advisory boards and other relevant external forums representing Roche.
- Drives and integrates ongoing evidence/data generation, including clinical trials, Medical Affairs studies, Real World Evidence (RWE), Patient-Centered Outcomes Research (PCOR) and other types of evidence. Plays a lead role within the assigned therapeutic area(s) to identify significant opportunities for unmet medical needs.
- Accountable to ensure that CD plans, objectives, and deliverables are consistently accomplished on-time and on-target.
- Leads other special projects. Expected to proactively identify opportunities to continuously improve CD processes and operations and Roche’s leadership position in CD.
- Consistently complies with, and ensures the same among relevant functional and cross-functional team members, all governing laws, regulations, Roche Standard Operating Procedures (SOPs) and other guidelines.

**SELECTION CRITERIA:**

Candidates for this position should hold the following qualifications, have the following experience, and be able to demonstrate the following abilities to be considered as a suitable applicant. Please note that except where specified as “preferred,” or as a “plus,” all points listed below are considered minimum requirements.

**QUALIFICATIONS & EXPERIENCE:**

- Experience working in ophthalmology preferred
- M.D. degree is preferred but not required
- Experience submitting NDAs/BLAs to regulatory authorities in Europe and the U.S.
- 4 or more years experience managing medical/clinical/scientific staff
- 8 or more years experience with clinical trials (exact number of years depending on level)
- 4 or more years experience authoring global clinical development plans (exact number of years depending on level)
- 4 or more years experience publishing results of clinical drug trials in referred journals (exact number of years depending on level)
- In-depth understanding of Phase I – IV drug development Multidisciplinary experience in the pharma/biotech industry is strongly preferred (e.g., research, regulatory, clinical operations, business development, commercial operations, etc.)
- Broad experience in the principles and techniques of data analysis, interpretation and clinical relevance (e.g., ISS, ISE, etc.)
- Comprehensive understanding of product and safety profiles
- In-depth knowledge of medical aspects of GCP (Good Clinical Practice), ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use), FDA, EMEA, NICE and other relevant guidelines and regulations
- In-depth understanding of competitive activity in the field
ABILITIES:

- Strong influencing skills; proven abilities to get things done without formal authority
- Strong Collaboration and Communication
- Strong conflict management and resolution skills; proactively minimizes situations where conflict may arise
- Strong negotiation skills; is highly adept at identifying solutions that will meet the needs of all parties involved
- Strategic agility: has in-depth knowledge and broad experience in the pharma/biotech industry and is able to bring this to bear in accomplishing strategic goals and objectives
- Strong Leadership abilities
- Has impeccable ethics. Demonstrates, or proven abilities to demonstrate, Roche Values
- Clinical leadership: is recognized as a subject matter expert in his/her field (includes external recognition as an expert); able to evaluate, interpret and present highly complex data for a series of studies (prospective and retrospective); has made significant contributions to an organization’s drug development (whether for Roche or another organization); has identified and created clinical development strategies that have led to label-enabling product definitions
- Proven abilities to plan and resource multiple development projects on short-, medium- and longer-term bases
- Considerable comfort around all levels of management; has regularly demonstrated the managerial courage necessary to succeed at higher-levels within the organization
- Outstanding interpersonal skills; proven track record of building strong and sustainable relationships with internal & external partners/stakeholders
- Strong communication & presentation skills; exhibits professional maturity, confidence and competence. Knows how to summarize and communicate the key points and business case for others to effectively and expeditiously make important business decisions
- Outstanding financial acumen: has a proven track record of achieving qualitative and quantitative results across multiple, often large-scale and complex clinical development projects
- Ability to travel globally (<30%)
- Drug Development Expertise
- Scientific, Medical and Disease Expertise in ophthalmology
- Innovator and Competitive mindset
- Creative Mindset
- Portfolio/Enterprise View

Who We Are

Genentech, a member of the Roche group and founder of the biotechnology industry, is dedicated to pursuing groundbreaking science to discover and develop medicines for people with serious and life-threatening diseases. To solve the world’s most complex health challenges, we ask bigger questions that challenge our industry and the boundaries of science to transform society. Our transformational discoveries include the first targeted antibody for cancer and the first medicine for primary progressive multiple sclerosis.

Diversity and Inclusion (D&I) are critical to the success of our company and our impact on society. We believe that by championing diversity of background, thought and experience, we can foster a sense of belonging and provide an environment where every employee feels valued, included, and able to contribute their best for the patients we serve. We’re focused on attracting, retaining, developing and advancing our people to their full potential by rewarding bold ways of thinking and integrating inclusive behaviors into every aspect of our
work.

Genentech is an equal opportunity employer & prohibits unlawful discrimination based on race, color, religion, gender, sexual orientation, gender identity/expression, national origin/ancestry, age, disability, marital & veteran status. For more information about equal employment opportunity, visit our Genentech Careers page