

Clinical Trial Manager II-gRED

Job ID: 00410981

Job Function

Clinical Operations

Schedule

Full-time

Location

United States-California
South San Francisco

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Experienced

Who We Are

At the Roche Group, about 80,000 people across 150 countries are pushing back the frontiers of healthcare. Working together, we've become one of the world's leading research-focused healthcare groups. A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 30 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. The headquarters for Roche pharmaceutical operations in the United States, Genentech has multiple therapies on the market for cancer and other serious illnesses. Please take this opportunity to learn about Genentech, where we believe that our employees are our most important asset and are dedicated to remaining a great place to work.

The Position

The Genentech Research and Early Development (gRED) Clinical Trial Manager (CTM) provides support and/or leadership to one or more global Study Teams within an early development program(s). The CTM is accountable for activities ensuring high quality deliverables are within budget and timelines.

Primary Accountabilities and Responsibilities:

- Support cross-functional Study Team within Clinical Operations with minimal oversight from the Sr. CTM and/or CPL
- Responsible for Clinical Operations deliverables to achieve study objectives and milestones within timelines and budget
- Responsible for vendor selection and management including CRO, IVRS, central lab and imaging vendor
- Provide input to the study budget and is responsible for managing assigned vendor

budget(s)

- Under the leadership of the Sr. CTM, takes responsibility for agreed operational aspects (e.g., vendor management, drug supply management)
- Identify and track timelines, milestones, critical study activities, issues and budget and provide regular updates to the Study Team and CPL as appropriate
- Partner with CPL to develop and/or present at project teams and management review bodies
- Conduct protocol and site feasibility assessments
- Provide support, mentoring, and study-specific training to Clinical Operations staff
- Network and share best practices with colleagues to ensure optimal efficiency and consistency in Clinical Operations
- Participate in initiatives and/or activities as assigned

Responsibilities and Accountabilities When Leading a Study:

Depending on skill level and study design, CTM may lead Study Team, including obtaining agreement on project timelines, study objectives and goals.

- Ensure relevant functional groups provide input to and participate in developing and finalizing Study Team level documents and meet Study Team level deliverables within timelines
- Accountable for Clinical Operations deliverables to achieve study objectives and milestones within timelines and budgets
- Provide input to the program budget and is accountable for managing overall study budget
- Delegate and oversee study activities assigned to Clinical Operations Study Team as applicable
- Provide drug supply assumptions to clinical planning team

These statements are not intended to be an exhaustive list of all responsibilities, duties, and skills required of people assigned to this job, but are instead intended to describe the general nature and level of the work. Different levels of responsibilities and accountabilities may be

assigned to take account of the skills capabilities and experience of the individual.

Who You Are

Minimum:

- 3+ years study management experience in clinical and drug development
- Bachelors degree or equivalent required (scientific or healthcare discipline preferred)
- Working knowledge of international regulatory and ICH GCP guidelines

Experience, Skills, Knowledge:

- Experienced in clinical trial management
- Aptitude for leadership of cross-functional teams, including delegation of tasks
- Experience in planning, risk mitigation strategies, trial budgets, site selection, clinical

supplies management, conduct and monitoring of clinical studies

- Familiar with global trial requirements
- Demonstrated creativity and innovation to support projects and initiatives
- Excellent planning and organizational skills
- Flexible and solution focused
- High level of initiative and ability to work independently
- Strong analytical skills
- Strong customer focus
- Highly effective verbal and written communication skills in English

Other (e.g. Travel):

Willingness to travel domestically and internationally, and work across cultures.

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