

## Clinical Trial Manager II, gRED

Job ID: 00413880

### 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

Purpose:

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

Primary Accountabilities and Responsibilities:

- Independently lead cross-functional Study Team within Clinical Operations with minimal oversight from the CPL
- Accountable for Clinical Operations deliverables to achieve study objectives and milestones within timelines and budgets
- Responsible for vendor selection and management including CRO, IVRS, central lab, imaging vendor
- Provide input to the program budget and is accountable for managing overall study budget
- 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
- 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
- Conduct protocol and site feasibility assessments
- Provide drug supply assumptions to clinical planning team
- Delegate and oversee study activities assigned to Clinical Operations as applicable
- 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

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:

- 6+ 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:

- Highly experienced in managing early development phase clinical studies and generally experienced in clinical research/development
- Effective leadership of cross-functional teams
- Extensive experience in planning, risk mitigation strategies, trial budgets, site selection, clinical supplies management, sample management, conduct and monitoring of clinical

studies

- Demonstrated experience in various therapeutic areas
- 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. \*LI-EK1

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