

Clinical Scientist Specialist - TDM1

Job ID: 00411567

Job Function

Clinical Development

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

Provides clinical oversight for a variety of projects, in consultation with his/her Medical Director or Senior Medical Director :

- Works with a host of internal and external partners and stakeholders in the implementation of clinical trials for assigned drugs/indication
- Provides scientific input into and/or coordinates the development of specific clinical trial documents for review and discussion with Medical Directors* (e.g., protocols, charters, safety monitoring plans, process documents, etc.) including disease and/or treatment registries
- Participates in the identification of appropriate external investigators
- Oversees the clinical trial implementation, ongoing monitoring and evaluation, working closely and regularly with external investigators and Clinical Operations. Active Member in Study Management Team for assigned drugs/indications
- Develops and cultivates relationships with external partners such as clinical investigators, clinicians, scientists and KOLs, as well as cross-functional partners in Clinical

Development, Commercial, Legal and Regulatory.

- Supports his/her manager in developing clinical components of presentations* for clinical trial investigator meetings
- In collaboration with his/her manager, coordinates the preparation and reviews data outputs for reporting documents* where appropriate (e.g. clinical study reports, analysis plans, etc.) with the CRO, the Medical Affairs Biostatisticians and his/her Medical Directors
- Monitors project progress and is expected to proactively identify any issues or challenges and recommend and implement strategies to effectively resolve such once approved with his/her manager
- Works closely with his/her manager, the publication team and Clinical Operations to complete associated publications, reviews draft publications*.
- Keeps all partners abreast of projects progress throughout all applicable intervals
- May also participate/coordinate collaborations with external stakeholders

(e.g. cooperative groups, other companies, etc.) on development and implementation of approved clinical projects.

- May coordinate, liaise with internal and external providers for data mining activities
- Helps his/her manager provide data outputs requested for safety and/or other relevant sections of IND annual reports, if these sections and reports relate to assigned drugs and/or indications*.
- May interact with NCI or other agency, as appropriate, with supervision from his/her manager

¿ Stays abreast of internal and external developments (scientific, clinical, commercial, competitive, legal, regulatory and like) as such developments may implicate or otherwise impact the implementation of the medical plan of the assigned drug(s)/indication(s). Includes attendance at major scientific conferences, participation in competitive intelligence activities, and review of published literature

Who You Are

Strong scientific Academic background, PhD or PharmD preferred, Advanced nursing degree with some additional post graduate training will be considered.

- Must demonstrate 2 or more years' clinical trial experience relevant to biotech/pharmaceutical molecules or drugs Experience working with the principles and techniques of data analysis, interpretation and clinical relevance
- Strong, relevant experience in the therapeutic area (as typically measured by 5 or more years' relevant experience)
- Must demonstrate understanding of late-stage drug development, in particular Phase

IV

programs

- Must demonstrate understanding of product and safety profiles
- Versed in medical aspects of FDA regulations with regards to conduct of clinical trials
- Business travel is required

ABILITIES:

- Outstanding attention-to-detail
- Demonstrable abilities to work more independently (with limited guidance and supervision) in implementing and overseeing clinical plans, trials and other programs
- Excellent project management skills: can prioritize multiple tasks and goals to ensure the

timely, on-target and within-budget accomplishment of such. Works well within multi-disciplinary teams and has proven abilities to coordinate and drive projects in a matrix organization.

- Sound business acumen; has knowledge of the multi-disciplinary functions involved in a company's drug development process, e.g., clinical operations, biostatistics, regulatory, commercial, etc. and can proactively integrate the relevant functions into projects for best end-results
- Strong interpersonal and influencing skills: has established strong relationships with key internal partners and stakeholders, as well as thought leaders, cooperative groups and disease organizations.
- Sound communication and business presentation skills: communicates in a timely, thorough and concise manner and is comfortable presenting information to others at varying organizational levels
- Good negotiation skills: knows how to complete deliverables by working effectively with others internally and externally
- Proven track record of effective decision-making: makes good business decisions and exercises sound judgment. Consistently and effectively balances decisions with imperatives for ethics and efficacy
- Demonstrates behaviors and values consistent with Genentech's Good Operating Principles *LI-EK1

Genentech is an Equal Opportunity Employer.