

## Clinical Science Specialist

Job ID: 00412468

**Job Function**

Research

**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

#### Job Description (gRED ECD Onc Clinical Science Specialist [E4a])

Genentech is seeking a Clinical Science Specialist (CSS) with clinical and drug development experience in oncology to join the Genentech Research and Early Clinical Development (gRED) Oncology ECD organization and support Clinical Science deliverables for clinical trials and programs associated with the exploratory clinical development of novel anti-cancer agents within the Genentech portfolio. These programs span first-in-human Phase I studies through proof-of-concept Phase II studies in a variety of malignant disorders, and may involve collaborations with other Clinical Development teams at Genentech, corporate development partners, and external scientific/academic/clinical organizations. The optimal candidate will have the desire to proactively participate within a multi-disciplinary team of internal clinical and commercial colleagues and have the ability to interact with external experts and investigators.

#### **Job Duties and Responsibilities:**

##### Scientific Writing

- Draft Strategic Context Documents (SCD), Clinical Protocols, and Investigator Brochures, and coordinate the successful completion of documents with medical

editing.

- Conduct literature searches, draft abstracts, draft safety narratives, draft background sections of clinical documents, and ensure that standardized disease/molecule protocol language is incorporated (e.g., eligibility, dose-modification criteria, risk language, key scientific statements). Track items for inclusion in protocols and ICF amendments and work with Medical Editing to ensure the completion of the protocol and any subsequent amendments.

### Functional Activities

- Serve as a Clinical Science representative on cross-functional teams as assigned (i.e., Protocol Execution Team, Safety Sub-Team, Biomarker Sub-Team, cross-functional initiatives).
- Identify and implement processes to share clinical information across teams/molecules/indications.
- Develop study-specific listings with data management representatives and conduct frequent clinical data listing reviews.
- Working closely with the gRED medical monitor, serve as primary point of contact for, and triage, clinical study inquiries from site staff, CROs and site monitors regarding the study protocol, modifications to informed consent, and patient-specific questions. .
- Partner with Data Management for CRF design, instructions for unique CRFs, and data quality plan.
- In conjunction with a Medical Director, create and or review clinical slides for internal and external meetings (i.e. Investigator meetings, PSSV and SIVs, Study Coordinator and CRA training, Advisory Boards, scientific meetings). Develop and QC data tables with biostatisticians to support these activities.
- Participate in tracking/analysis of any potential safety events within a given trial and across trials for assigned program(s).
- In conjunction with Biostats and Medical Director review appropriate analysis and reporting documents (i.e. clinical study report, analysis plan, etc.).
- As assigned, participate in development of the long-range strategic plans for the assigned program(s).
- As assigned, participate in Clinical Science assessment of in-licensing opportunities.
- As assigned, mentor and/or train new Clinical Science Specialists

## **Who You Are**

### **Experience**

- Candidates should have an advanced clinical/science degree (e.g., PharmD, PhD, MSN, MPH, etc.).
- 6 or more years of industry/related experience (a focus on cancer cell biology or drug development is preferred).
- 4 or more years of clinical trial experience in industry
- 2 or more years of experience in, and appropriate therapeutic knowledge of, oncology
- Extensive knowledge of clinical research & successfully worked across Phase I – II drug development projects
- Experience working on cross-functional teams
- Experience authoring a full clinical trial protocol (Ph I or II)
- Broad experience in the principles and techniques of data analysis, interpretation and clinical relevance
- Comprehensive understanding of product and safety profiles
- Well-versed in medical aspects of GCP, ICH, FDA, EMEA, NICE and other relevant guidelines

- Preferred: Experience publishing clinical trial results in refereed journals

Genentech is an Equal Opportunity Employer.