



Position Description: Clinical Research Associate

POSITION DETAILS

Title	Clinical Research Associate
Upward Reporting	Clinical Research Director
Company Location	Clinuvel Pharmaceuticals AG, Hauserstrasse 14, Zuerich, Switzerland
Core Responsibilities	Management of clinical trials
Working Hours	8.30am – 5.00pm, Monday to Friday. Some overtime as required
Travel	Travel (domestic and/or international) required for trial monitoring

PURPOSE OF THE ROLE

To manage the conduct of clinical trials in accordance with the protocol, ICH GCP guidelines, applicable local and international regulations and company SOPs to ensure the timely delivery of clinical trial reports within budget.

MAIN INTERFACES

Internal: Chief Scientific Officer, CEO, VP Scientific Affairs, Clinical Research Director, Senior Clinical Project Manager, Project Team

External: Clinical trial investigators and other trial staff, regulatory agencies

KEY RESULT AREAS

Study Feasibility Assessments	<ul style="list-style-type: none"> ○ Liaise with internal and external experts regarding proposed protocol scope, budget and timelines ○ Identification, assessment and selection of appropriate investigators/sites and other service providers according to project requirements and company SOPs
Study Set-up	<ul style="list-style-type: none"> ○ Ensure site feasibility and preparation and execution of study initiation and associated meetings
Investigational Medicinal Product and Study Supplies	<ul style="list-style-type: none"> ○ Ensure all study materials including investigational medicinal products are procured appropriately and available on site when required ○ Ensure all labeling requirements are met ○ Assist in securing import documentation if necessary ○ Arrange adequate storage and dispatch of investigational medicinal product and study materials to the investigational site
Document Management	<ul style="list-style-type: none"> ○ Collect and compile Essential Documents (according to ICH GCP guidelines and company SOPs)
Ethics Committee Documentation	<ul style="list-style-type: none"> ○ Prepare required HREC/IEC applications in a timely manner
Study Site Staff	<ul style="list-style-type: none"> ○ Train study staff in all study related processes / procedures ○ Coordinate meetings with investigator as study site staff
Monitoring	<ul style="list-style-type: none"> ○ Monitoring the progress of clinical trials through regular visits and correspondence to ensure satisfactory conduct of trials including: <ul style="list-style-type: none"> ○ monitor recruitment and consenting procedures ○ adherence to the study protocol ○ completion of CRFs and review of source data ○ collection of data as specified in project plans ○ review site files and accountability logs ○ ensure reporting of visit occurs in a timely manner and according to company SOPs



Pharmacovigilance	<ul style="list-style-type: none"> ○ Report adverse events in compliance with regulatory requirements and company SOPs
Site Closure	<ul style="list-style-type: none"> ○ Ensure all data queries are resolved ○ Ensure all essential documents are complete and filed appropriately ○ Ensure accountability and reconciliation of study materials and investigational medicinal product

COMPETENCIES (KNOWLEDGE, SKILLS AND ATTRIBUTES)

<ul style="list-style-type: none"> ○ Establish and maintain relationships with internal/external contacts ○ Prepare high quality documents for submission to Ethics Committees and Regulatory Authorities ○ Track and plan regulatory activities to meet agreed timelines ○ Maintain a current awareness of ethical and regulatory requirements ○ Report writing skills ○ Effective verbal and written communication in individual and group settings ○ Ability to create and maintain relationships with internal/external contacts ○ Deliver high quality customer services to internal/external customers ○ Ability to source information, research skills ○ Ability to analyse and interpret data ○ Problem solving skills ○ Excellent attention to detail ○ Ability to work in a team environment ○ Ability to plan, organise and follow up ○ Effective time management of multiple tasks ○ Negotiation skills ○ Presentation skills ○ Computer literacy

QUALIFICATIONS / EXPERIENCE REQUIREMENTS

Required Qualifications:	<ul style="list-style-type: none"> ○ Graduate qualifications in Biological Sciences, Nursing, Pharmacy or related discipline ○ Post-graduate qualifications desirable
Required Experience / Knowledge:	<ul style="list-style-type: none"> ○ At least 2 years experience as a CRA ○ Excellent working knowledge of ICH GCP guidelines
Desirable Experience / Knowledge:	<ul style="list-style-type: none"> ○ Management of clinical trials/projects in Europe