

	Description
Function	Clinical Project Manager (CPM)
Location / Contact	AC Immune SA, EPFL Innovation Park, Building B, 1015 Lausanne hr@acimmune.com
Percentage	100 %
Overview	<p>AC Immune is a clinical stage Swiss biotech company focused on the development of innovative therapeutics and diagnostics for Alzheimer's and other neurodegenerative diseases.</p> <p>AC Immune is seeking a clinical project manager responsible for the implementation and execution of international clinical trials.</p>
Job description	<ul style="list-style-type: none"> • Manage international clinical trials according to time, cost and quality standards • Negotiate, implement and maintain contracts with study partners (study vendors, sites) • Manage activities of study partners, support clinical CRO in managing the sites • Review and approve submission packages for submission to Ethics Committees/Institutional Review Boards • Supply proper documentation to the Regulatory department for submission to Regulatory Authorities • Contribute to the generation of SOPs • Participate in clinical study design • Create and maintain operational plans • Prepare study budgeting and forecasting • Global budget management of trials • Ensure the accurate planning and ordering of clinical trial drug supply • Lead study protocol development • Write and update clinical trial documents • Participate to review and approval of the Clinical Trial Report • Be responsible for the Trial Master File • Participate in study specific core team meetings • Report to Head of Clinical Operations
Qualifications	<p>The candidate should have the following qualifications:</p> <ul style="list-style-type: none"> • Minimum of 4 years of experience in clinical research (preferably with 2 years coordinating international or leading regional trials) • Previous monitoring experience and knowledge in international standards (GCP/ICH) as well as in international (FDA/EMA) and local regulations • Hands on experience in writing clinical study documents • A scientific degree is required as well as the ability to work in a start-up environment, handling multiple demands and strong planning and organizational skills • Personal features include: <ul style="list-style-type: none"> - Advanced understanding of timelines, budget and resource management - Planning, tracking and solving skills for maintaining project timelines - Networking skills - Working both independently and in a cross-functional team setting - Good spoken and written English are required; a 3rd language is asset