

	<b>Description</b>
<b>Function</b>	Clinical Project Manager (CPM)
<b>Location / Contact</b>	AC Immune SA, EPFL Innovation Park, Building B, 1015 Lausanne <a href="mailto:careers@acimmune.com">careers@acimmune.com</a>
<b>Percentage</b>	100 %
<b>Reporting Line</b>	Head of Clinical Operations (HCO)
<b>Company Profile</b>	<ul style="list-style-type: none"> <li>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</li> <li>150+ Employees, 20+ nationalities, IPO in 2016, listed on NASDAQ</li> <li>AC Immune SA is a progressive, equal opportunity employer</li> </ul>
<b>Job description</b>	The Clinical Project Manager will be responsible, under the supervision of the Head of Clinical Operations, of the management of regional and/or international studies, alone or in collaboration with a senior CPM, according to time, cost and quality standards.
<b>Key Responsibilities</b>	<ul style="list-style-type: none"> <li>Manage international clinical studies according to time, cost and quality standards</li> <li>Negotiate, implement and maintain contracts with study partners (study vendors, sites)</li> <li>Manage activities of study partners, support clinical CRO in managing the sites</li> <li>Review and approve submission packages for submission to Ethics Committees/Institutional Review Boards</li> <li>Supply proper documentation to the Regulatory department for submission to Regulatory Authorities</li> <li>Contribute to the generation of SOPs/WIs</li> <li>Participate in clinical study design</li> <li>Create and maintain operational plans</li> <li>Prepare study budgeting and forecasting</li> <li>Global budget management of studies</li> <li>Ensure the accurate planning and ordering of clinical study drug supply</li> <li>Lead study protocol development</li> <li>Write and update clinical study documents</li> <li>Participate to review and approval of the Clinical Trial Report</li> <li>Be responsible for the Trial Master File</li> <li>Participate in study specific core team meetings</li> </ul>
<b>Qualifications &amp; Skills</b>	<p>Required:</p> <ul style="list-style-type: none"> <li>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</li> <li>Minimum of 4 years of experience in clinical research (preferably with 2 years coordinating international or leading regional studies)</li> <li>Knowledge in international standards (GCP/ICH) as well as in international (FDA/EMA) and local regulations</li> <li>Hands on experience in writing clinical study documents</li> <li>Good spoken and written English</li> </ul> <p>Personal features include:</p> <ul style="list-style-type: none"> <li>Advanced understanding of timelines, budget and resource management</li> <li>Planning, tracking and solving skills for maintaining project timelines</li> <li>Networking skills</li> <li>Working both independently and in a cross-functional team setting</li> </ul>

