

Function	Senior Clinical Project Manager (Senior CPM)
Location / Contact	AC Immune SA, EPFL Innovation Park, Building B, 1015 Lausanne hr@acimmune.com
Percentage	100 %
Reporting Line	Group Leader Clinical Operations (GLCO)
Company Profile	<ul style="list-style-type: none"> 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 140+ Employees, 20+ nationalities, IPO in 2016, listed on NASDAQ AC Immune SA is a progressive, equal opportunity employer
Job description	AC Immune is seeking for an expert Clinical Project Manager who will be responsible, under the supervision of the GLCO, of the management of an international vaccine study in the Parkinson's Disease indication.
Key Responsibilities	<ul style="list-style-type: none"> Manage international and/or complex clinical studies 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/WIs and share experience and expertise when reviewing documents created by other members of the clinical team Participate in clinical study design Create and maintain operational plans Prepare study budgeting and forecasting Global budget management of studies Ensure the accurate planning and ordering of clinical study drug supply Lead study protocol development Write and update clinical study 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 Serve as a mentor and as a dedicated point of contact for operational related questions for junior team members within the clinical team
Qualifications & Skills	<p><i>Required:</i></p> <ul style="list-style-type: none"> Minimum of 6 years of experience in clinical research (with 4 years coordinating international or leading regional studies) 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