

| | Description |
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| Function | Clinical Project Manager (CPM) |
| Location / Contact | AC Immune SA, EPFL Innovation Park, Building B, 1015 Lausanne hr@acimmune.com |
| Percentage | 100 % |
| Reporting Line | Head of Clinical Operations (HCO) |
| 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 150+ Employees, 20+ nationalities, IPO in 2016, listed on NASDAQ AC Immune SA is a progressive, equal opportunity employer |
| Job description | The Clinical Project Manager will be responsible, under the supervision of the HCO, of the management of regional and/or international studies, alone or in collaboration with a Lead CPM, according to time, cost and quality standards. |
| Key Responsibilities | <ul style="list-style-type: none"> Manage international 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 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 |
| Qualifications & Skills | <p>Required:</p> <ul style="list-style-type: none"> 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 Minimum of 4 years of experience in clinical research (preferably with 2 years coordinating international or leading regional studies) Knowledge in international standards (GCP/ICH) as well as in international (FDA/EMA) and local regulations Hands on experience in writing clinical study documents Good spoken and written English <p>Personal features include:</p> <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 |