

	Description
Function	Clinical Lead
Location / Contact	AC Immune SA, EPFL Innovation Park, Building B, 1015 Lausanne careers@acimmune.com
Percentage	100 %
Reporting Line	Head of Clinical Development
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 (ACIU) is a progressive, equal opportunity employer
Job description	<p>The Clinical Lead takes responsibility to lead the clinical development activities of one or more clinical programs.</p> <p>Current clinical programs focus on neurodegenerative diseases (eg., Alzheimer's disease, Parkinson disease).</p> <p>She/He develops clinical development plans and clinical project strategy, including a translational biomarker strategy. The Clinical Lead participates notably to the clinical study team and core team, representing the clinical development. As a key contributor she/he takes responsibility for developing study plans and protocols according to the agreed company's strategy. She/He is also responsible for implementing the clinical and biomarker development strategy notably based on data from the competitive landscape and from the most recent state of the art, medical and scientific knowledge. She/He takes part in and supervises all the key steps related to the preparation, the conduct and the completion of the clinical studies, including the medical and safety monitoring, associated to the related clinical program sponsored by ACIU. She/He also provides appropriate support to the clinical operations team and other key stakeholders.</p>
Key Responsibilities	<ul style="list-style-type: none"> Lead the direction, planning, execution and interpretation of assigned clinical trials, with a focus in neurodegenerative diseases. Take part in the elaboration of clinical strategy and clinical communication, with a leading role in neurodegenerative diseases. Lead the development of the assigned clinical development program and 5-year clinical plans in alignment with ACIU strategy. Ensure/supervise the interpretation of the data from internal clinical trials and from competitors. Establish/review clinical study designs and implement clinical protocols, data collection systems and final clinical study reports. Supervise, in respect to GCP, adherence to protocols and to clinical reports including medical/safety aspects. Supervise/take part in the medical and safety monitoring and reports promptly serious adverse events or any safety concerns considered of medical significance according to internal SOPs. Take part in the DSMB blinded meetings. Prepare/take part in investigator's meetings. Generate presentations, publications and interfaces with KOLs, external experts, advisory boards, and health authorities. Provide medical support to due diligence associated with in-licensing, acquisitions, and co-development agreements, under supervision of the head of clinical development and the CMO.

	<ul style="list-style-type: none"> • Ensure/handle clinical interfaces with external partners. • Ensure competitive intelligence in the related field in order to implement a state-of-the-art approach for the related clinical development program and clinical studies. • Supervise/provide support on the preparation, the review and the finalization of key clinical documents including, but not limited to, clinical development plan, clinical protocols and related amendments, clinical study reports, investigator's brochures, DSURs, and other key study documents as appropriate. • Provide support to the clinical operation team and other stakeholders as needed.
Qualifications & Skills	<p>Required:</p> <ul style="list-style-type: none"> • MD or MD/PhD with board certification in neurology or psychiatry or both • 8+ years of pharma/biotech R&D experience. Strong experience in early-stage drug development is essential, preferably in the field of Neuroinflammation/Neuroimmunology • Health Authority Interaction experience, e.g. with FDA and EMA • Strong interpersonal skills: <ul style="list-style-type: none"> ▪ Outstanding interpersonal, verbal, and written communication (English) and influencing skills ▪ Proven ability to influence internal partners and stakeholders, thought leaders, national advocacy organizations, national standard-setting bodies, and other relevant external parties ▪ Able to establish seamless collaboration with colleagues/other parts of the organization