	Description
Function	Clinical Lead
Location / Contact	AC Immune SA, EPFL Innovation Park, Building B, 1015 Lausanne hr@acimmune.com
Percentage	100 %
Reporting Line	Head of Clinical Development
Company Profile	• 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	Clinical Lead takes responsibility to lead the clinical development activities of one or more clinical programs. Current clinical programs focus on neurodegenerative diseases (eg., Alzheimer's disease, Parkinson disease). She/He develops the 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. The Clinical Lead is responsible to implement 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.
Key Responsibilities	• Leads the direction, planning, execution and interpretation of assigned clinical trials, with a focus in neurodegenerative diseases. • Takes part in the elaboration of clinical strategy and clinical communication, with a leading role in neurodegenerative diseases. • Leads the development of the assigned clinical development program and 5-year clinical plans in alignment with ACIU strategy. • Ensures/supervises the interpretation of the data from internal clinical trials and from competitors. • Establishes/reviews clinical study designs and implement clinical protocols, data collection systems and final clinical study reports. • Supervises, in respect with GCP, adherence to protocols and to clinical reports including medical/safety aspects. • Supervises/takes 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. • Takes part in the DSMB blinded meetings. • Prepare/takes part in investigator's meetings. • Generates presentations, publications and interfaces with KOLs, external experts, advisory boards, and health authorities. • Provides medical support to due diligences associated with in-licensing, acquisitions, and co-development agreements, under supervision of the head of clinical development and the CMO.

	• Ensures/handles clinical interfaces with external partners. • Ensures 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. • Supervises/provides 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. • Provides support to the clinical operation team and other stakeholders as needed.
Qualifications & Skills	*Required:* • MD or MD/PhD • Expertise or training in Neurosciences. • Experience in clinical development programs in Central Nervous System Diseases, Neurodegenerative Diseases. • 5+ years of experience in clinical development (academic and/or pharmaceutical or biotech companies) including preparation of key clinical study documents (e.g., but not limited to clinical study protocols, investigator's brochures). • Knowledge of clinical development process and related guidelines, GCP, ICH. • Experienced in the establishment and the maintenance of communication with KOLs, external experts and regulatory authorities. • Advanced communication skills, verbal and written. • Team player. • Demonstrated ability to synthesize, analyze and communicate key information. • Strong interpersonal skills for building networks with key experts and ensuring the interface with internal departments and project team members. • Ability to adapt priorities to meet company needs while maintaining effectiveness. • Leadership and project management skills. • Good spoken and written English. *Would be a big plus:* • Neurologist • Experience in pharmacovigilance. • Experience in translational sciences.