

<b>Title:</b>	European Clinical Program Lead
<b>Department:</b>	Clinical Operations
<b>About MAPS Europe:</b>  <p>MAPS Europe and MAPS Public Benefit Corporation (MAPS PBC) are wholly-owned subsidiaries of the Multidisciplinary Association for Psychedelic Studies (MAPS). Their primary work is completing Phase 3 clinical trials required to develop MDMA-assisted psychotherapy into an approved treatment for PTSD. More information about MAPS Europe can be found: <a href="https://mapseurope.eu">https://mapseurope.eu</a></p> <p>MAPS Europe committed to the evolution of psychedelic healing modalities. We are building a diverse and inclusive workplace where we learn from each other. We value transparency, autonomy, experimentation, and kind, direct feedback. We welcome applicants who thrive in the midst of a growing organization that values science and healing.</p> <p>We believe in diversity and inclusion of people of all backgrounds, genders, races, ethnicities, sexual orientations, educational backgrounds, military and veteran status, religions, abilities, and perspectives. MAPS PBC values and seeks applicants who are people of color, queer, transgender, gender non-conforming, and gender fluid people. MAPS PBC strives to establish a supportive, equitable and accessible work environment.</p>	
<b>Call for Candidates:</b> <p>MAPS Europe is seeking an enthusiastic, focused, and organized person to join our Clinical Operations Department. The Clinical Program Lead to be creative and enjoy working within a small, entrepreneurial environment that is mission-driven, results-driven and research-oriented. Suitable candidates are able to work well in a fast environment and adept at organizing and managing lots of information virtually.</p> <p>The Clinical Program Lead will ensure that clinical trials are conducted in a timely manner and in accordance with Standard Operating Procedures (SOPs), General Data Protection Regulation (GDPR), the principles of ICH/Good Clinical Practice (GCP) and all applicable regulations governing the conduct of clinical trials in Europe. The Clinical Program Lead is responsible for managing the clinical operations of the group they are assigned, implementing and maintaining oversight of clinical studies and those working on them in a team setting. The ideal individual will have the ability to lead a team, exercise good judgment in a variety of situations, with strong written and verbal communication, organizational skills, and the ability to maintain a realistic balance among multiple priorities. The Clinical Program Lead must be able to work under pressure at times to handle a wide variety of activities. The focus of the Clinical Program Lead role is to oversee assigned clinical programs and protocols, and the teams for those studies, guide Clinical Trial Leader, CRAs and CTAs, contribute to all clinical documents, track timelines, review invoicing and budgeting, ensure a plan for clinical supplies and contribute to clinical operation documents (e.g. SOPs, work instructions).</p>	
<b>Location:</b> Contract position  <p>This is a remote position from a suitable home office with a private and quiet area to work. Secure internet and reliable phone reception are required. This position requires frequent phone and internet meetings.</p>	
<b>Hours:</b> 32-40 hours per week	
<b>Minimum requirements:</b> University Degree	

Eight (8) years (at least) of Clinical Research experience in the CRO/Pharmaceutical industry managing clinical studies and teams and after gaining excellent knowledge in developing work organization models  
 Strong knowledge of clinical trial operations and monitoring in Europe, GCP/ICH Guidelines and other applicable regulatory requirements.

Fluent in English and local language(s) as needed

Proficiency in Microsoft Office (e.g. Word, Excel, Outlook)

Willingness to travel

**Position duties:**

- Provides strategic input and expertise on MAPS Europe clinical operations matters (i.e. feasibility, protocol design, study management, patient recruitment, study execution timelines, personnel & site management, and risk mitigation) for assigned clinical trials being conducted including study quality matters
- Escalates issues/obstacles of strategic importance and study quality to the MPBC Leadership team for review, discussion and mitigation planning
- Coordinates provision of resources required in support of all MAPS Europe clinical trials
- Oversees and ensures the timely and quality execution of assigned studies according to the study protocols, study execution plans, and GCP and GDPR guidelines (including SOPs, ICH, FDA, EMA and other health authorities)
- Ensures compliance with GCPs as promulgated by ICH E6 and other relevant local, regional or national regulations regarding clinical study conduct and protection of human subjects
- Contributes to the development and maintenance of the MAPS Europe clinical development strategy and execution planning
- Escalation point for any MAPS Europe clinical operations issues that have a significant impact on overall study or program timelines, other functions, budget or quality
- Oversees the development of cross-functional efforts to define enrollment strategies of studies
- Communicates key study and program metrics to executives and cross-functional stakeholders
- **Program Conduct:**
- Oversees and provides guidance to clinical sites and the sponsor clinical team, holding them accountable for achieving assigned deliverables within timelines & budget, and in accordance with quality standards
- Reviews and confirm risk identification and mitigation planning is in place for each clinical site as well as for the overall program
- Ensure timely and effective communication among the MPBC Leadership, MAPS Europe Clinical Operations, and clinical sites, as appropriate
- Review and recommend MAPS Europe site payments in alignment with budgets
- Ensures accurate and up-to-date information of MAPS Europe project management and tracking systems and timelines
- Contribute to and review MAPS Europe protocol and protocol related documents, ensuring proper timelines are kept
- Coordinate with the Training Team to ensure appropriate MAPS Europe site staff are available
- Coordinate with researchers to conduct clinical trials, providing support in their efforts and coordinating communication between key players in all functions
- Maintain effective communication and facilitate the exchange of information within the Clinical Department, MPBC/MAPS Europe staff and external groups including CRAs, Medical Monitors, Department Heads, CRA's, Site Staff, Data Management, Finance, Logistics, Adherence Raters and other collaborators
- Mentor and manage and lead MAPS Europe CRAs, CTAs and Interns
- Participate in the identification and selection of CROs, new hires or contractors, as required
- Liaise with doctors/consultants/investigators on conducting the trial
- Ensure proper clinical trial site oversight

- Review monitoring trip reports, as required in collaboration with CTL, status of each of the studies and make any necessary recommendations for contingency or risk mitigation planning
- Oversee set up of the MAPS Europe study centers, which includes ensuring each center has the trial materials and training on trial-specific industry standards
- Manage and, if needed, monitor (from SIV through COV) of the trial throughout its duration according to the monitoring plan in collaboration with the CTL
- Review the trending of monitoring findings (deviations/data listings/communications) taking the lead on resolution of compliance issues at centers including risk mitigation and site and staff retraining
- Guide sites through the controlled substance process, drug ordering, receipt, storage, packaging and import logistics in coordination with the IMP Supply Manager and CTL
- Oversee or as needed complete verification of data, plan data audits and oversee database lock activities
- Ensures the quality of study data by reviewing or overseeing review of data listings, managing data entry, completion of data base lock and organizing audits, ensuring reviews are occurring and action items are followed up on in collaboration with the CTL
- Ensure and oversee proper filing to eTMF system
- Review procedures for and coordinate with the media group on news stories, postings, documentaries in coordination with the communications group

**Vendor Management:**

- Oversee MAPS Europe vendor relationships for studies as appropriate
- Ensure appropriate vendor management activities are occurring across all studies
- Escalate any vendor issues that may impact study or program
- Contribute to vendor selection decisions as appropriate
- Ensure appropriate functional or cross-functional governance is in place for any vendors that support multiple studies or functions

**Cross- Functional Representation**

- Facilitate timely and effective communications from MPBC Leadership to MAPS Europe Staff, Sites, and Contractors including decisions and progress, as well as communicating significant decisions and issues (including those of any functional area sub-teams or committees) from to MAPS Europe Staff, Sites, and Contractors back to MPBC Leadership
- Facilitate timely and effective communications of MPBC Leadership decisions and progress to MAPS Europe Staff, Sites, and Contractors, as well as communicating significant decisions and issues (including those of any functional area sub-teams or committees) from to MAPS Europe Staff, Sites, and Contractors back to MPBC Leadership
- Contribute to the establishment of Clinical Development Timeline goals that are aligned with Corporate and Global Clinical Development goals and that clinical sites and other functional teams are executing to optimally achieve those goals.
- Provides updates on MPBC perspectives and ensure alignment of goals with MAPS Europe Staff, Sites, and Contractors

**People Management:**

- Oversee, train, and mentor all MAPS Europe Clinical Operations contractors and staff contributing to European studies supporting the Clinical Development Program
- Plans, monitors and manages the workload of MAPS Europe clinical operations staff and contractors
- Contribute to departmental and cross-functional improvement activities
- Identifying competencies and skills required, selecting and recruiting MAPS Europe staff, defining appraisal, skills, and pathways for potential career path development
- Ensures that MAPS Europe Clinical Operations contractors staff works efficiently in matrix environment

<ul style="list-style-type: none"> <li>• Collates feedback from the MAPS Europe clinical team in order to plan career progression and assess training requirements</li> <li>• Builds the MAPS Europe team by proper communication and motivation as well as organizing regular meetings</li> <li>• Reviews MAPS Europe project needs and allocate resources</li> <li>• Periodically assesses the performance of MAPS Europe Clinical Operations contractors and staff based on feedback from MPBC Directors and other relevant roles</li> <li>• Supports the MPBC Directors in analyzing performance, identifying root causes of non/poor performance and implementing corrective actions</li> <li>• Review factors related to evaluation, development, and retention of the MAPS Europe Clinical Operations contractors and staff</li> <li>• Monitors and enforces compliance with systems, processes and policies and all applicable regulations</li> <li>• Provides input to process and SOPs review/design</li> <li>• Identifies and proposes process and system improvements to maintain quality and effective deliverables</li> <li>• Leads by example, living and enforcing company values</li> </ul>
<b>General Responsibilities:</b> <ul style="list-style-type: none"> <li>• Communicate and collaborate with key players, internal and external staff</li> <li>• Check in regularly with supervisor and complete assignments by agreed deadline</li> <li>• Document processes and provide regular updates</li> <li>• Proactively seek methods of improvement, streamlining workflows and building efficiencies in individual work and project outcomes</li> </ul>
<b>FLSA Status:</b> n/a contract position
<b>Compensation:</b> disclosed upon request.