JOB PROFILE

Job title:	Clinical Study Manager I
Reporting to:	Senior Director of Clinical Operations
Department:	Clinical Operations Team
Nº of Direct reports:	None
Location:	Frimley, Surrey
Job Details	
Job Purpose:	This is an exciting opportunity to work within a fast paced, busy environment in a leading, clinical-stage stem cell biotechnology business whose primary objective is the development of novel stem cell therapies targeting areas of significant unmet or poorly met medical need. Having successfully completed its FIH early phase clinical trials, the Company is now looking for a highly talented and motivated individual to support its Phase II programs. Our Clinical Study Managers act as the functional lead from Clinical Operations with responsibility for delivery of all Clinical Operations aspects of clinical trials ensuring consistency with Company SOPs/Procedures, contracts, budgets and timelines.
Main areas of responsibility:	• Operational site management of assigned clinical trials • Ensuring major trial milestones are met • Management/oversight of external service providers e.g. CROs, PV, data management etc • Ensure high performance and efficiency of the CRO clinical team through the scheduling of co-monitoring /accompanied site visits Oversee IEC/IRB submissions and associated activities including collation of essential documents • Track and manage budget and timelines • Contribute to the production, review and update of key clinical documents e.g. clinical protocol/amendments, IBs, PIS-ICFs, trial plans etc • Development and maintenance of SOPs in conjunction with QA • Prepare monthly progress reports • Set up and/or maintain trackers using Excel, software and any other reporting tools • Ensure Trial Master File maintenance, compliance and review • Attendance at site initiation, monitoring and close out visits, where required • Support of Investigators, research coordinators and other site personnel. • Perform adhoc tasks to support Clinical Operations activities

Person Specification		
Qualification/ Experience required	**Essential**	**Desirable**
	• Minimum of a Bachelor's degree in life science, medical or related field • 4+ years' of clinical research experience gained with a CRO or pharmaceutical company working on Phase II to III clinical trials • Demonstrated ability to use their initiative • Demonstrated ability to prioritise multiple projects • Ability to work independently as well as part of a multidisciplinary team in a fast paced environment with demonstrated ability to juggle multiple competing tasks and demands • Good understanding of ICH GCP and applicable local and national regulations for the conduct of clinical trials • Willing to spend up to 25% of working time on travel to UK and/or US to participating centres • Fluent in written and spoken English • Strong written and spoken communication skills	• Previous CRA/monitoring experience • Strong scientific background and prior experience in ophthalmology, neurology/stroke or oncology • Prior experience with ATIMPs • Previous experience working on USA based trials
Skills and Competencies required	• Strong working knowledge of MS Word, Excel, PowerPoint and Outlook • Full, clean current UK driving license	

• To carry out any other tasks or duties within post holders capability as requested by the Company to meet business needs.
• The Company reserves the right to vary or amend the tasks and responsibilities of the post holder at anytime according to the needs of the Company's business. • Information contained therein is not exhaustive but describes key elements of the function.

Author:	Date:
Revised:	Date: