JOB PROFILE

Job title:	Senior Clinical Trial Associate
Reporting to:	Senior Director of Clinical Operations
Department:	Clinical Team
Nº of Direct reports:	
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. The company is seeking an experienced and highly motivated individual to support its clinical development programmes. The Clinical Trial Associate will play a pivotal role within the Clinical Operations department. The CTA will become involved in all aspects of clinical drug development, whilst also having the rare opportunity to work with cutting- edge Advanced therapy Medicinal Products (ATIMPs). This position represents an excellent opportunity for an individual with high levels of initiative seeking excellent development opportunities.
Main areas of responsibility:	Working and liaising closely with department colleagues to support the completion and coordination of various logistical and administrative tasks within the Clinical Operations Department including: • Document tracking (contracts, financial agreements, patient informed consent forms, insurance certificates etc) • Collecting and tracking data required for REC and regulatory submission • Tracking site budgets, including invoices, raising purchase orders, tracking payments etc • Assisting in financial reconciliation and budget tracking for vendors and patient fees • Organising the printing and dispatch of clinical study documents to sites • Maintaining constructive relationships with the site staff as well as with colleagues within the organisation • Maintenance and updating of the Trial Master File (and preparation for relevant QC checks when applicable) • Coordinating the translation of site documents where necessary • Distribution of SUSAR/Safety reports within the required timelines to RECs • Supporting Investigator meetings including the development of presentation materials under the direction of Clinical Study Manager • Drafting and producing letters, reports, minutes and other documents and processing them accordingly (including photocopying, scanning and distribution)

	• Contributing to Clinical Operations team activities, initiatives and providing as-hoc support as appropriate. • Other tasks delegated by either Chief Medical Officer, Senior Director, Clinical Operations or Clinical Study Managers	
Person Specification		
Qualification/ Experience required	**Essential**	**Desirable**
	• Minimum qualifications of 'A' levels or equivalent	• Prior experience in cardiovascular (stroke), ophthalmology or oncology therapeutic areas would be desirable
	• Minimum of 3 years' of clinical research experience gained with CRO or pharmaceutical company	
	• A good working knowledge and understanding of the clinical trials environment along with regulatory issues and SOPs	
	• Good Clinical Practice knowledge (certified to a basic standard)	
	• Strong working knowledge of MS Word, Excel, PowerPoint and Outlook	
	• Fluent in written and spoken English	
Skills and Competencies required	• Excellent organisational, written and verbal communications skills • Ability to juggle and prioritise multiple completing tasks and demands • Ability to work independently in a fast paced environment	

• 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: