JOB PROFILE

Job title:	(Senior) Clinical Trial Associate (USA)
Reporting to:	Senior Clinical Study Manager
Department:	Clinical Operations
Nº of Direct reports:	0
Location:	Providence, RI or Burlington, MA
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. Due to expansion within its Clinical Operations Department, the Company is now 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 as well as assist the general day-to-day administrative tasks required for the US office locations. The CTA will become involved in all aspects of clinical drug development from site selection through to clinical study report, 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 including: • US office administrative tasks such as stationary orders, expense report management and organisation of team travel • Coordinating internal review of site agreements • Maintaining constructive relationships with the site staff as well as with colleagues within the organisation • Tracking site budgets, including invoices, raising purchase orders, tracking payments etc • Document tracking (contracts, financial agreements, patient informed consent forms, insurance certificates etc) • Creation of agenda and minutes for internal meetings • Organising the printing and dispatch of clinical study documents to sites • Maintenance and updating of the Trial Master File (and preparation for relevant QC checks when applicable) • Coordinating the shipment of IMP supplies and ancillary products to study sites • Coordinating the translation of site documents where necessary • Collecting and tracking data required for IRB and regulatory submissions

	• 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.	
Person Specification		
Qualification/ Experience required	**Essential**	**Desirable**
	• Minimum qualifications of an Associate Degree in a life science field	• Prior experience in cardiovascular (stroke), ophthalmology or oncology therapeutic areas would be desirable
	• Minimum of 2 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: