Job Description and Person Specification

Last updated: 17/07/2017

JOB DESCRIPTION

Post title:	**Clinical Trials Data Manager**		
Academic Unit/Service:	Southampton Clinical Trials Unit		
Faculty:	Faculty of Medicine, Cancer Sciences Division		
Career Pathway:	Management, Specialist and Administrative (MSA)	Level:	4
*ERE category:	n/a		
Posts responsible to:	Head of Data Management		
Posts responsible for:	Clinical Data Coordinator		
Post base:	Office-based (see job hazard analysis)		

Job purpose
The Southampton Clinical Trials Unit (SCTU) is a UKCRC registered CTU with expertise in the design, conduct and analysis of multicentre interventional clinical trials, who work in partnership with investigators to deliver high quality trials that will directly influence routine clinical practice. The appointed person will take responsibility for the development of clinical trial databases and clinical trial data management processes across all clinical trials within SCTU. This includes the design and implementation of GCP [Good Clinical Practice] compliant data capture solutions, automation and standardization of database development processes and ongoing data management activity.

Key accountabilities/primary responsibilities		% Time
1.	Design and build EDC [electronic data capture] tools and applications, define validation checks and create rules programming	40%
2.	Prepare or support the preparation of data management specific study documentation, e.g. Database Scoping and Specification Documentation, Validation Plan, Data Test Plan & UAT, Validation Report, eCRF Data Entry Guidelines and Data Management Plan	20%

Key accountabilities/primary responsibilities		% Time
3.	Contribute to the development, review and implementation of processes, policies, SOPs and associated documents affecting Clinical Data Management in SCTU and participate in the development and maintenance of quality systems and clinical audit of research activity, and adhere to all CTU and University policies and procedures	10%
4.	Oversea and line manage staff conducting data clean-up activities e.g. data review, query generation, SAE reconciliation activities with the Quality and Regulatory team; deliver 'fit for purpose' data sets to statistics for analysis	10%
5.	If required, support team members with preparation for on-site monitoring visits, central monitoring data currency and quality reports and data safety review updates.	5%
6.	To attend internal and external meetings to ensure that departmental issues are appropriately represented and reported.	5%
7.	To train new starters in use of data capture tools and processes and provide technical support for EDC software. Organise and maintain training databases and training material.	5%
8.	Any other duties as allocated by the line manager or senior management team following consultation with the post holder.	5%

Internal and external relationships
• Other staff within University of Southampton Clinical Trials Unit, to ensure good working relationships • Departmental IT staff and external electronic database services to develop and manage databases. • Trial specific groups (Management groups, Trial Steering Committees, Data Monitoring Ethics Committees) to provide and discuss trial data. • Staff at participating sites, to secure trial documentation and resolve data queries • Cancer Research Networks across the UK; providing regular updates and trial information as appropriate. • Trial funders, to provide trial data.

Special Requirements
The Clinical Trials Data Manager will be based at Southampton General Hospital. Travel to other CTUs within the UK may be required in some instances.

PERSON SPECIFICATION

Criteria	Essential	Desirable	How to be assessed
Qualifications, knowledge and experience	Skill level equivalent to achievement of HND, Degree, NVQ4 or basic professional qualification. Knowledge and experience of using data collection forms and knowledge of database design and implementation Experience of medical data, data entry and validation techniques. Knowledge and experience of medical research methodology and statutory clinical trial regulations, GCP and research governance requirements. Proven experience of planning and progressing work activities within broad professional guidelines and/or broad organisational policy. Understanding of how the specialist/professional services provided by the post-holder support the objectives of the University. Able to apply an awareness of principles and trends in a specialist or professional field and an awareness of how this affects activities in the University. General IT Literacy – MS Office applications	Membership of relevant professional body. Experience of a clinical trials environment Knowledge of quality management systems (EDC) Programming skills specific to data management e.g. SQL, SAS, C#, Excel, Business Objects	
Planning and organising	Able to seek opportunities to progress a broad range of activities within professional guidelines and in support of University policy.	Experience of successful project management.	
Problem solving and initiative	Able to develop understanding of long-standing and complex problems and to apply professional knowledge and experience to solve them.		
Management and teamwork	Able to proactively work with colleagues in other work areas to achieve outcomes. Able to delegate effectively, understanding the strengths and weaknesses of team members to build effective teamwork. Able to formulate development plans for own staff to meet required skills.	Experience of successfully managing and developing staff.	
Communicating and influencing	Able to provide accurate and timely specialist guidance on complex issues. Able to use influencing and negotiating skills to develop		

	understanding and gain co-operation.		
Other skills and behaviours			
Special requirements			

JOB HAZARD ANALYSIS

Is this an office-based post?

☒ Yes	If this post is an office-based job with routine office hazards (eg: use of VDU), no further information needs to be supplied. Do not complete the section below.
☐ No	If this post is not office-based or has some hazards other than routine office (eg: more than use of VDU) please complete the analysis below. Hiring managers are asked to complete this section as accurately as possible to ensure the safety of the post-holder.

- HR will send a full PEHQ to all applicants for this position. Please note, if full health clearance is required for a role, this will apply to all individuals, including existing members of staff.

ENVIRONMENTAL EXPOSURES	**Occasionally** (<30% of time)	**Frequently** (30-60% of time)	**Constantly** (> 60% of time)
Outside work			
Extremes of temperature (eg: fridge/ furnace)			
## Potential for exposure to body fluids			
## Noise (greater than 80 dba - 8 hrs twa)			
## Exposure to hazardous substances (eg: solvents, liquids, dust, fumes, biohazards). Specify below:			
Frequent hand washing			
Ionising radiation			
EQUIPMENT/TOOLS/MACHINES USED			
## Food handling			
## Driving university vehicles(eg: car/van/LGV/PCV)			
## Use of latex gloves (prohibited unless specific clinical necessity)			
## Vibrating tools (eg: strimmers, hammer drill, lawnmowers)			
PHYSICAL ABILITIES			
Load manual handling			
Repetitive crouching/kneeling/stooping			
Repetitive pulling/pushing			
Repetitive lifting			
Standing for prolonged periods			
Repetitive climbing (ie: steps, stools, ladders, stairs)			
Fine motor grips (eg: pipetting)			
Gross motor grips			
Repetitive reaching below shoulder height			
Repetitive reaching at shoulder height			
Repetitive reaching above shoulder height			
PSYCHOSOCIAL ISSUES			
Face to face contact with public			
Lone working			
## Shift work/night work/on call duties			