Job Description and Person Specification

Last updated: February 2016

JOB DESCRIPTION

Post title:	Clinical Data Coordinator		
Academic Unit/Service:	Southampton Clinical Trials Unit		
Faculty:	Faculty of Medicine		
Career Pathway:	Management, Specialist and Administrative (MSA)	Level:	3
*ERE category:	n/a		
Posts responsible to:	Clinical Trials Data Manager		
Posts responsible for:	None		
Post base:	Office-based		

Job purpose
The Southampton Clinical Trial Unit (SCTU) designs, initiates, conducts and analyses high quality national and international clinical trials to directly influence routine clinical practice. To take responsibility for the data management of one or more clinical trials within SCTU; which includes some aspects of database build and all stages through the conduct phase of a trial up until database lock.

Key accountabilities/primary responsibilities		% Time
1.	To manage, deliver and take accountability for activities within the trial conduct phase of allocated trials; such as the generation of manual and auto queries via the EDC [electronic data capture] tool, reconciliation of the trial data between in-house and external systems, medical coding of medical conditions, adverse events and drugs using MedDRA and WHO coding criteria, central monitoring, performance management and metrics reporting on trial delivery and conducting data base lock process steps.	30 %
2.	Contribute to the development of the electronic case record form [eCRF] and using the current EDC [electronic data capture] tool, build aspects of the eCRF, such as forms and simple rules.	20 %
3.	Work with clinical data manager(s), and other SCTU staff, on user acceptance testing to validate the database prior to use. Identify issues in design and recommend modifications	15 %
4.	To contribute to trial specific documentation delivery such as the Trial Specific Data Management Plan (DMP), Trial Schedule, Trial Database Design Specification and UAT [user acceptance testing] of the trial specific EDC	10 %
5.	To manage data received from third party suppliers such as central labs, bio banks etc.	10 %

Key accountabilities/primary responsibilities		% Time
6.	Design and deliver bespoke validation or status reports to aid management and delivery of allocated trials.	5 %
7.	To review standard operating procedures [SOPs] and processes, ensuring they are fit for purpose and maximise efficiency; making recommendations for improvements to process where identified and implementing agreed change to the process.	5 %
8.	Any other duties as allocated by the line manager following consultation with the post holder.	5 %

Internal and external relationships
Other staff within Southampton Clinical Trials Unit iSolutions Trial specific groups (Management groups, Trial Steering Committees, Data Monitoring Ethics Committees) Staff at participating sites Cancer Research Networks across the UK Trial funders

Special Requirements
Special Requirements: The Clinical Trials Data Officer will be based at Southampton General Hospital within the CTU. Travel to participating centres 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 HNC, A-Level, NVQ3 with proven work experience acquired in relevant roles and job-related training. Knowledge and experience of using data capture tools and knowledge of database design Experience of medical data Good IT Literacy – MS Office applications	Relevant degree (or equivalent qualification or experience). Evidence of continuing professional development Experience of a clinical trials environment Knowledge and experience of validation techniques, medical research methodology and statutory clinical trial regulations, GCP and research governance requirements. Knowledge of quality management systems	Application or interview
Planning and organising	Able to plan and prioritise a range of one's own, and the team's, standard and non-standard work activities. Ability to successfully plan and deliver projects over a period of several months.(e.g. to co-ordinate a trial)		Application or interview
Problem solving and initiative	Able to identify and solve problems by applying judgement and initiative to tackle some situations in new ways and by developing improved work methods.		Application or interview
Management and teamwork	Able to solicit ideas and opinions to help form specific work plans. Able to positively influence the way a team works together. Ability to effectively allocate to, and check work from SCTU staff supporting you in an activity e.g. UAT; coaching/ training and motivating staff as required.		Application or interview
Communicating and influencing	Able to elicit information to identify specific customer needs. Able to offer proactive advice and guidance. Ability to deal with sensitive information in a confidential manner.		Application or interview
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			