

# Job Description and Person Specification

Last updated: 28MAR2025

## JOB DESCRIPTION

Post title:	Senior Clinical Data Manager		
Academic Unit/Service:	Southampton Clinical Trials Unit {SCTU}		
Faculty:	Medicine		
Career Pathway:	Management, Specialist and Administrative (MSA)	Level:	5
*ERE category:	n/a		
Posts responsible to:	Head of Data Management		
Posts responsible for:	Clinical Trials Data Managers (level 4) Clinical Data Coordinators (level 3) Clinical Data Assistants (level 2a)		
Post base:	Hybrid		

Job purpose
<p>SCTU is a UKCRC registered CTU which designs, initiates, conducts and analyses high quality national and international clinical trials to directly influence routine clinical practice.</p> <p>The purpose of the Senior Clinical Data Manager role is to manage and coordinate the provision of professional services within data management.</p> <p><b>The post holder will be responsible for:</b></p> <ul style="list-style-type: none"> <li>• Providing a leadership role, in either the <i>[i] Database Build and Acquisition function</i>, or <i>[ii] Data Management Conduct function</i>, or across both functions for specific portfolios within SCTU.</li> <li>• The delivery of clinical data management activities across multiple projects.</li> <li>• Providing input into Data Management and IT strategy.</li> <li>• Driving continuous improvement of Data Management and IT processes.</li> <li>• Training and coaching new staff</li> </ul> <p>The individual will act as one of the primary sources of information governance and technical expertise and liaise with University of Southampton central IT services on relevant aspects of IT provision for SCTU. They will line-manage members of the data management to ensure data are managed effectively according to required regulations, standards and timelines.</p>

Key accountabilities/primary responsibilities		% Time
1.	To provide senior professional leadership and act as an accessible resource on SCTU IT systems, including [where relevant to the role] data collection and data management software and randomisation services	15 %
2.	Effectively project manage all SCTU data management activities, including [where relevant to the role] programming and validation of databases, completing data management documentation, ongoing data cleaning, and provision of high quality data for interim and final analyses to meet trial targets.	20 %
3.	To identify and lead in continuous improvement initiatives relevant to clinical trials data management and IT provision within SCTU. Including [where relevant to the role] oversight of best practices in the data life cycle including database build, data conduct, data reporting, data governance. and data standardisation (including the maintenance of SCTU's global libraries).	15 %
4.	To line manage and mentor members of the data management group, and ensure effective resource allocation. To set training standards for staff.	15 %
5.	To be an active member of the SCTU senior management team, taking a lead on data management and IT strategy, and ensuring communication of key messages relating to IT and data management to all SCTU staff and other stakeholders as appropriate	10 %
6.	Liaise with trial statisticians and trial teams to oversee central monitoring and regular quality control checks of data, and to ensure all data is entered onto the trials database in a timely and accurate way as required for each trial.	5 %
7.	To maintain an excellent knowledge of regulatory requirements for clinical trials data management, ensure SCTU processes are compliant and that SCTU staff adhere to SOPs.	5 %
8.	Participate in the development and maintenance of SOPs, quality systems and clinical audit of research activity, and adhere to all CTU and University policies and procedures. Identify areas of deficiency requiring SOPs or guidelines and develop and execute a plan to rectify them.	5 %
9.	Represent and promote SCTU on national and local committees and working groups.	5 %
10.	Any other duties as allocated by the line manager following consultation with the post holder.	5 %

Internal and external relationships
<p>Other staff within University of Southampton Clinical Trials Unit, to ensure good working relationships</p> <p>iSolutions staff at all levels for IT provision</p> <p>External software providers to ensure service delivery.</p> <p>Other Clinical Trials Units and similar groups establishing and maintaining regular links to ensure data management systems and processes are consistent nationally.</p> <p>CRUK and NIHR and other funders to develop cooperation, collaboration and improve infrastructure nationally.</p>

Special Requirements
<p>The Senior Data Manager will be based at Southampton General Hospital within the CTU. Travel to external meetings will be required on an ad-hoc basis.</p>

## PERSON SPECIFICATION

Criteria	Essential	Desirable	How to be assessed
Qualifications, knowledge and experience	<p>Skill level equivalent to achievement of a professional qualification or postgraduate degree providing experience of a clinical trials environment</p> <p>Expert knowledge of statutory clinical trial regulations, GCP and research governance requirements.</p> <p>Detailed knowledge of data protection, compliance and regulations</p> <p>Experience of database design and implementation</p> <p>Experience of medical data, data entry and validation techniques.</p> <p>Highly IT literate</p>	<p>Evidence of continuing professional development</p> <p>Knowledge of quality management systems.</p> <p>Working knowledge of Medidata RAVE applications</p>	Application or interview
Planning and organising	Able to plan and manage major new projects or significant new activities, ensuring plans complement broader organisational strategy.		Application or interview
Problem solving and initiative	<p>Able to identify broad trends to assess deep-rooted and complex issues.</p> <p>Able to apply originality in modifying existing approaches to solve problems.</p>		Application or interview
Management and teamwork	<p>Able to manage team dynamics, ensuring any potential for conflict is managed effectively.</p> <p>Able to formulate development plans for own staff to meet current and future skill needs.</p> <p>Able to provide expert guidance and advice to colleagues to resolve complex problems.</p>		Application or interview
Communicating and influencing	<p>Able to persuade and influence in order to foster and maintain relationships.</p> <p>Able to resolve tensions and difficulties as they arise.</p>		Application or interview
Other skills and behaviours			
Special requirements			

# JOB HAZARD ANALYSIS

## Is this an office-based post?

<input checked="" type="checkbox"/> 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.
<input type="checkbox"/> 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			
<b>EQUIPMENT/TOOLS/MACHINES USED</b>			
## 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)			
<b>PHYSICAL ABILITIES</b>			
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			
<b>PSYCHOSOCIAL ISSUES</b>			
Face to face contact with public			
Lone working			
## Shift work/night work/on call duties			