

Job Description and Person Specification

Last updated: 10 March 2023

JOB DESCRIPTION

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|------------------------|---|--------|---|
| Post title: | Head of Data Management [DM] and Information Systems [IS] | | |
| School/Department: | Cancer Sciences Division, Southampton Clinical Trials Unit (SCTU) | | |
| Faculty: | School of Medicine | | |
| Career Pathway: | Management, Specialist and Administrative (MSA) | Level: | 5 |
| Posts responsible to: | Head of Operations, SCTU (level 6) | | |
| Posts responsible for: | Senior Clinical Data Manager (level 5) Database Programmers (level 5) Clinical Trials Data Managers (level 4) Clinical Data Coordinators (level 3) | | |
| Post base: | Hybrid working (approximately 3 : 2 - SCTU offices : Working From Home) | | |

| Job purpose |
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| <p>Southampton Clinical Trial Unit (SCTU) is a Cancer Research UK core funded and UKCRC registered CTU which designs, initiates, conducts and analyses high quality national and international clinical trials and other well-designed studies to directly influence routine clinical practice. The SCTU study portfolio includes phase I (first-in-human) to phase 3 clinical trials, complex intervention mixed-methodology studies, observational studies (including large cancer early diagnosis community-based studies) and translational studies.</p> <p>The role requires the successful candidate to lead the Data Management (DM) group within SCTU, providing leadership and direction for the development and continued improvement of data governance, data management services (e.g. Rave and other solutions), incorporating routine NHS data into trials (e.g. NHS DigiTrials), digital solutions (e.g. e-Trial Master File [eTMF], e-Patient Reported Outcomes [e-PROs], e-CONSENT, Clinical Trial Management Systems [CTMS], Secure Data Environment [SDE]) and contributing to the development of IS as part of the planned strategic development of SCTU over the coming years.</p> |

| Key accountabilities/primary responsibilities | % Time |
|--|--------|
| <p>1. To provide senior professional leadership for the data management team (including data manager and database programmer staff). To line manage and mentor the data management team, ensuring effective resource strategies and allocation. To set training standards and required competencies for staff and act as an accessible resource to support delivery as and when required by the SCTU. Manage the prioritisation, with steer from the Director and Head of Operations, of activities within the Data Management Function.</p> | 30% |

| Key accountabilities/primary responsibilities | | % Time |
|---|---|--------|
| 2. | To lead on data management and data lifecycle management (including storage and final repository) on behalf of the SCTU and other stakeholders as appropriate. Ensure necessary strategies and process are in place for data curation, stewardship, performance reporting of sites etc and e-archiving of electronic data. Act as an advisor for complex or new data issues relevant to the design of new clinical trials and other well-designed studies through to end of study and on-going data release. Scope and steer SCTU in improved practice with regard to technological tools including CTMS, e-PRO, sample tracking systems and the sharing and storing of trial data (with associated omic, image and routine NHS data linkage) using secure data environments (SDE) and other databases storing translational assets, in close collaboration with other SCTU groups, including but not limited to, trial management, statistics, translational and bioinformatics. | 25% |
| 3. | To chair data sharing meetings and act as an advisor to the SCTU Directorship Committee with regards to data sharing, SDE access and data protection within SCTU. Input into protocols with regards to the data management and sharing aspects. Assist the SCTU with regards to review of data sharing clauses in contracts and ensuring compliance with such clauses. Assisting and supporting staff where DPIAs and applications to access NHS outcome data are required. | 5% |
| 4. | To identify and lead initiatives relevant to data management and information system solutions within SCTU (and as requested across the UK Clinical Trial Unit network (Cancer Research UK/UKCRC)) to improve current practice by ensuring data management and other digital solution provision is fit-for-purpose, flexible, efficient, competitive and meets the varied needs of the SCTU portfolio (including the ability for hybrid working of all SCTU staff). | 5% |
| 5. | To maintain an excellent knowledge of regulatory requirements for clinical trials data management systems and digital technology, to ensure SCTU processes are regulatory compliant. Develop, produce and maintain SOPs, quality systems and clinical audit of research activity, and adhere to all SCTU and University policies and procedures. | 10% |
| 6. | Ensure the effective management of relevant financial activities regarding digital technology solutions and data management functions across the SCTU, including input to bids for further grant incomes and budget management. To be the business lead for procurement for any requests/tenders/negotiations regards data management and digital technology solutions. Assisting with due diligence of new e/digital suppliers. To ensure that there is good vendor selection and oversight of new systems implemented by SCTU. To work with the University Finance and the Procurement teams to ensure we follow the correct Public Procurement and UoS processes | 10% |
| 7. | Take in leading role in discussion with industry and international partners for database requirements when developing collaborative academically sponsored studies. | 5% |
| 8. | Represent and promote SCTU at an international, national and local level; with contributions that make a difference, at relevant working group meetings and conferences. | 5% |
| 9. | Any other duties as allocated by the Head of Operations or Director following consultation with the post holder. | 5% |

| Internal and external relationships |
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| <p>Other staff (including Heads of SCTU Group) within Southampton Clinical Trials Unit, including but not limited to the Directorship committee, operations, trial management, QA/PV, statistics, translational and bioinformatics.</p> <p>UHS and UoS sponsorship office (or other sponsors of SCTU trials as appropriate)</p> <p>Maintain a relationship with external database provider(s)</p> <p>UoS iSolutions staff</p> <p>University Hospital Southampton and University of Southampton Clinical Informatics Research Unit (and other parties where appropriate) in the development of a SCTU SDE</p> <p>External software and digital technology providers</p> <p>Other Clinical Trials Units - Cancer Research UK (CRUK), NCRI & UKCRC</p> <p>Funders e.g. CRUK</p> |

| Special Requirements |
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| Based in or around Southampton General Hospital within the SCTU offices. Travel to external meetings will be required on an ad-hoc basis. |

PERSON SPECIFICATION

| Criteria | Essential | Desirable | How to be assessed |
|--|---|---|--------------------|
| Qualifications, knowledge and experience | <p>BSc Hons and proven level of expertise in the fields of clinical operations, data management and associated digital technology.</p> <p>Proven management skills in the specialist field of clinical operation systems, data governance, data stewardship, the data management lifecycle, data management etc.</p> <p>Knowledge in ICH GCP and regulatory landscape relevant to digital platforms.</p> <p>Experience in leadership.</p> <p>Good communication skills and proven interdisciplinary team working.</p> | <p>Expertise in Medidata Rave (or equivalent) and secure data environments or other associated data management platforms.</p> <p>Knowledge of various systems for randomisation.</p> <p>Previously worked in a UKCRC Clinical Trials Unit or equivalent.</p> <p>Understanding of industry data standards for licencing.</p> | |
| Planning and organising | <p>Able to plan and shape the direction of the DM group and information governance on behalf of the SCTU.</p> <p>Proven experience of managing significant change and organising major new changes, such as vendor management and implementation of new platforms and technology for data curation, electronic data capture, mobile health and digital solutions, executing relevant due diligence.</p> | | |
| Problem solving and initiative | <p>Able to develop solutions and solve problems under own initiative in order to ensure the DM group continues to provide a flexible and fit for purpose service across the entire SCTU portfolio.</p> | | |
| Management and teamwork | <p>Able to proactively develop team dynamics and performance, ensuring quality standards are consistently achieved.</p> <p>Able to foster positive relationships both within and outside of the SCTU with key stakeholders.</p> <p>Able to proactively work with senior peer group within the SCTU to achieve key deliverables in line with the SCTU overarching strategic vision.</p> | | |
| Communicating and influencing | <p>Able to negotiate effectively on behalf of the SCTU on key issues.</p> | | |

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| | <p>Able to effectively communicate with the Data Management Team and other senior managers and Directors within SCTU.</p> <p>Able to develop and lead key communications strategies as required and in line with the SCTU overarching strategic vision.</p> | | |
| Other skills and behaviours | <p>Strong team player able to demonstrate an ethos of support for delivery for the strategic vision of the SCTU.</p> <p>Experience in the tender process and the grant application process.</p> <p>Experience managing budgets.</p> | | |
| Special requirements | <p>Travel to external meetings will be required on an ad-hoc basis. With occasional engagement with Cancer Research UK funder raisers/donor visits.</p> | | |

JOB HAZARD ANALYSIS

Is this an office-based post?

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| <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 | | | |
| 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 | | | |