icnarc intensive care national audit & research centre

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Data Manager

Job Description

Purpose	Responsible for implementing and maintaining effective data management processes primarily across ICNARC's clinical trials unit, in order to ensure the accuracy of data.
Responsible to	Head of Research
Direct reports	None
Internal relationships	The Data Manager will work primarily within the Clinical Trials Unit with some ad hoc support activity for the Audit teams and will liaise with other members of ICNARC.
External relationships	To represent ICNARC when dealing with data queries from participating sites (hospitals and critical care units) and other relevant individuals, bodies or groups; and to represent ICNARC at meetings and off-site monitoring visits for CTU studies as required.
Location/Environment	The ICNARC office along with site visits and meetings, external conferences and training venues as required.

Principal duties and responsibilities.

- Lead in development of relevant policies, Standard Operating Procedures, dataset specifications, dataset flows, case report forms and data management plans, and review as required.

- Lead in the development of data collection/validation systems, including:
  - produce detailed functional specifications for data collection application development;
  - provide insights on other internal stakeholders and applications to ensure efficient design of final products which can meet the individual needs of multiple projects whilst maintaining rigorous data collection and validation procedures.
  - coordinate system testing, log and clearly communicate issues, and make modifications where appropriate;
  - define, programme and test validation systems to ensure accuracy of data;
  - develop written instructions and provide support and guidance on the collection and validation of data to both internal and external users of the systems.
  - assist in manual entry of study questionnaires and other data and with other trial related activity when required.

- Ensure data meet the standards of accuracy expected for reporting both internally and to regulatory bodies and trial committees in accordance with the standards of Good Clinical Practice and other relevant legislation:
    - monitor incomplete or missing data, raise data discrepancies and liaise with staff in participating sites to resolve issues;
    - monitor the accuracy of the data against the validation queries and work with colleagues to resolve issues of concern in a timely manner;
    - process any Serious Adverse Event reports and contribute to resolving issues;
    - prepare for, and undertake, monitoring visits at participating sites;
    - track data collection/patient recruitment progress against agreed milestones and provide regular updates to the relevant project manager and relevant regulatory bodies.

- Work closely with the project team when locking databases for the purpose of:
    - providing reports and interim analyses to a range of oversight committees/groups;
    - producing presentations and publications, including final reports to funding bodies.

- Attend internal project meetings, leading discussions on data management and clearly document and circulate actions/decisions relating to datasets/data management.

- Prepare/complete data accuracy updates and ensure, where possible, that legacy datasets are updated in line with new data integrity decisions. Use data interrogation and analytical skills to investigate potential data integrity errors and propose updates and safeguards to existing and new datasets.

- Work with project teams to provide ad hoc reports and solutions for routinely required information/tasks.

- Review of outputs prior to publication to ensure the quality and integrity of reports.

- Provide Training / Workshops for our Research Programmes.

As a member of the ICNARC team, you will be expected to play a part in all its general activities.

General duties and responsibilities as an employee

- To work as part of a team and contribute to the overall aims and objectives of the organisation
- To be an advocate for the organisation
- Attend staff meetings and training as required
- All staff are required to operate in accordance with ICNARC's values, policies and procedures, including but not limited to, Health and Safety, and Data Protection

The above list of duties and responsibilities is not exhaustive and you may be required to undertake other responsibilities and training as requested and as appropriate to your role level.

Person specification

Requirements	Essential	Desirable
Educational attainment	A-Levels or equivalent	Undergraduate degree, preferably in scientific field
Knowledge required	Knowledge and interest in the role of Data management within clinical research and audit projects.	Data management process and Dataset specification experience
Experience required	Experience working with data and able to think analytically about requirements for implementing and maintaining data management processes.	Planning, developing, implementing and maintaining data management processes for clinical trials or national clinical audits.
Skills and aptitudes required	Can demonstrate working understanding and skill of MS Office (Word, Excel, Outlook, Power Point). Experience of data interrogation	Knowledge of SQL/T-SQL Experience of electronic data capture software for clinical research e.g. MACRO. Experience using MS Visio.

Personal qualities required	**Communication:** has the ability to communicate effectively with a variety of people, on the telephone, face-to-face and through written correspondence. **Conscientious:** works steadily, efficiently and dependably; checks work thoroughly for errors/omissions. Maintains a high level of detail in all aspects of work. **Achievement orientation:** demonstrates motivation to achieve results by agreed deadlines; perseveres with plans. **Analytical skill:** ability to assimilate and interpret information and to identify and investigate observed anomalies. **Initiative:** proactive in identifying potential problems, seeks solutions and opportunities to improve work procedures. Self-motivating and able to undertake self-directed learning. **Organised:** has experience of managing a number of projects at the same time with the ability to plan ahead and deal with any issues as they arise. Ability to prioritise workloads within timescales and meet deadlines. **Customer service orientation:** is courteous and helpful to collaborators. Shows understanding for their concerns and acts to accommodate their needs where possible. **Relations with others:** is cooperative and gets along well with others. Keeps manager informed, reports problems promptly and seeks guidance when needed.	