UNIVERSITY OF LEICESTER

Job Summary

Job Title: Clinical Database Developer
Grade: 5
Salary: £26,707 to £31,236 per annum
Department: Leicester Clical Trials Unit (LCTU)
Hours/Contract: Full time fixed term contract for 12 months
Job Family: Technical and Experimental
Reference: 12977

Role Purpose

You will be primarily responsible for the design, build and testing of clinical trial databases developed using one of the following Electronic Data Capture (EDC) solutions; REDCap, OpenClinica, ENNOV MACRO (or equivalent) off the shelf clinical data management systems. You will work with enthusiastic investigators to advise on available data collection tools, coordinate the drafting of Case Report Forms (CRFs) alongside drafting a database specification, developing the database and providing ongoing support for the life of the trial.

You will also be responsible for drafting testing plans for the databases and supporting peers by testing their databases and following their testing plans.

You will act as a source of knowledge for the trial team around the best way to electronically capture their data, demonstrating the functions of REDCap, OpenClinica, ENNOV MACRO (or equivalent) to support the teams in their goal to collect accurate, complete and high-quality datasets.

Throughout the lifetime of the trial database, you will support the trial team with any modifications, troubleshooting or training needs.

Main Duties and Responsibilities

Database Design

- Coordinate the creation of CRFs, either paper-based or electronic, following LCTU Standard Operating Procedures (SOPs). Act as a source of knowledge for the capabilities of the EDCs which LCTU utilises, to positively influence the data capture tools' design and improve the quality and safety of the trial
- Support the trial team to identify suitable validation rules to apply to the database and create the database design specification
- Develop trial databases and subsequent modifications using REDCap, OpenClinica, ENNOV MACRO or equivalent EDC software. Ensure the standardisation of data fields and coding, to capture the data as defined in the database design specification. Compile a set of standard database modules, and design database output records for routine tracking and monitoring purposes

Database Testing

- Development of a test plan for the database once created

- Testing of databases to test plans for databases created by peers, log errors, and suggest modifications to the database design
- Document all software developments to ensure all are fully validated in order to meet the current regulatory and Good Clinical Practice (GCP) requirements
- Work with trial teams to understand any requirements they have for modifications to the database and facilitate their modification in line with LCTU Standard Operating Procedures
- Train end users on 'End User Acceptance Testing' and facilitate their testing of the database

Data Management

- Contribute to the Data Management / Validation Plans for the trial, working as part of the trial team and act as a source of information about the database the team have created
- Collaborate with senior colleagues to test data import procedures and validate imported data

Database Maintenance

- Manage user access to systems as required, creating accounts, making databases live etc
- Create, run and enable reports / extractions for the trial team as defined in the Service Level Agreement
- Work with senior data managers and/or statisticians to ensure that the database is locked prior to data extraction and transfer, and to create appropriate documentation
- Cleanse and lock data as required in line with the Service Level Agreement
- Archive databases in line with LCTU Standard Operating Procedures
- Import / cleanse / map external datasets to LCTU built databases

General Duties

- Participate as an active member of the trial team at LCTU to review and improve quality systems and working practices, and to develop procedural documentation to support these. Adhere to all LCTU and University / external sponsor policies and procedures

Internal and External Relationships

- Chief Investigators and their teams
- Data entry clerks and clinical researchers at sites
- IT programmers and statisticians at LCTU, and externally
- Trial managers, administrators and monitors at LCTU, and externally
- Digital Services & IT staff in the University database services group

Planning and Organising

Set and monitor the data management service objectives. Maintain and improve operational efficiency and quality of service by development and application of process improvements. Prioritise own work load to meet clinical trial target timelines and milestones, in line with LCTU strategy. Plan own work activities against the agreed quality standard and specification, to ensure operational quality and efficiency.

Have a high degree of organisation with good attention to detail including high standards of accuracy.

Communicate and liaise with trial teams, including Chief Investigators representing LCTU in a professional manner at all times.

Qualifications, Knowledge and Experience

Essential

- A Levels or NVQ3 or equivalent in subjects relating to IT*

OR:

- Broad vocational experience acquired through a combination of job-related vocational training and progressively more demanding roles providing considerable relevant work experience in a healthcare, pharmaceutical or University research capacity*

AND:

- Detailed operational experience of relevant tools in terms of functionality and capability i.e. experience of relational database development and management*
- Experience of working under a Quality Management System with Standard Operating Procedures*
- Experience of planning and progressing work activities using initiative without recourse to seniors

Desirable

- Previous experience of working in a healthcare, pharmaceutical or University research capacity, with specific experience in a clinical trials position with data management involvement*
- Educated to degree level in a subject relating to IT
- Thorough working knowledge of the standards and regulations required for the conduct and output for the role, including the requirements of the EU Clinical Trials Directives, the Medicines for Human Use (Clinical Trials) Regulations 2004 and amendments, the principles of GCP, EU guidance documents on computerised systems, and other relevant legislative and research governance requirements*
- Familiarity with medical terminology and coding dictionaries*
- Experience of using Research Electronic Data Capture (REDCap) and/or OpenClinica and/or ENNOV MACRO or equivalent EDC. Please state if this applies*

Skills, Abilities and Competencies

Essential

- Ability to work on own initiative and as part of a team, using judgement to set data management objectives and to resolve queries in a consistent manner
- Good interpersonal skills with evidence of ability to interact with or provide training to team members*
- Ability to communicate clearly verbally and in writing to ensure effective data collection and query resolution

- Evidence of good organisational skills with proven ability to maintain attention to detail and accuracy of data handling under pressure*
- Ability to undertake basic programming to query databases

Criteria to be used in shortlisting candidates for interview

Reason for Fixed Term Contract

The reason for the fixed term contract is stated in section 1.9 in the summary of contractual terms in your contract of employment.

Criminal Declaration

If you become an employee, you must inform your manager immediately, in writing, if you are the subject of any current or future police investigations/legal proceedings, which could result in a criminal offence, conviction, caution, bind-over or charges, or warnings.

Supporting University Activities

As a University of Leicester citizen, you are encouraged to support key university activities such as clearing, graduation ceremonies, student registration and recruitment open days. We encourage all staff as citizens to work flexibly across the University if required. If supporting these activities is likely to affect your workload, please speak to your line manager in the first instance

University Values

Inclusive - We are diverse in our makeup and united in ambition. Our diversity is our strength and makes our community stronger.

Inspiring - We are passionate about inspiring individuals to succeed and realise their ambitions. We challenge our community to think differently, to get involved, and to constantly embrace new ideas.

Impactful - As Citizens of Change we will generate new ideas which deliver impact and empower our community

Freedom of Speech

The University is committed to upholding freedom of speech and academic freedom within the law throughout our recruitment processes. We ensure that all candidates are considered based on merit and suitability for the role, without regard to their lawful viewpoints or the expression of challenging or controversial ideas. Our recruitment policies and practices are designed to protect applicants from discrimination or adverse treatment on the basis of their opinions, and to foster an environment where open debate and diverse perspectives are valued as essential to our academic mission.

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Job Summary

Equity and Diversity
We believe that equity, diversity and inclusion is integral to a successful modern workplace. By developing and implementing policies and systems that challenge stereotypes across all aspects of our work, we have a culture that recognises and values the diverse contributions of our staff which benefits everyone. Our strong values of inclusivity and equality support our efforts to attract a diverse range of high quality staff and students, and identify our University as a progressive and innovative workplace that mainstreams equality, diversity and inclusion.