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Temporary Clinical Data Programmer

Department/Division/Faculty:	Imperial Clinical Trials Unit/ School of Public Health/ Faculty of Medicine
Campus/Location:	Stadium House, White City Campus/ Hybrid
Job Family/Level:	Professional Services 3b, (Salary Scales)
Responsible to:	Deputy Head of Clinical Data Systems
Line management for:	N/A
Key working Relationships (Internal):	Imperial Clinical Trial Unit (ICTU), Research Governance and Integrity Team (RGIT), staff within other schools, institutes and departments across Imperial College London.
Key Working Relationships (External):	NHS Trusts, Industry Sponsors and Funders, national and international research units, and critical care settings. Trial funder, contracted service providers, Trial Committees
Contract type:	Full time, temporary post available for 3 or 6 months

Background

ICTU is a UK CTU Network-registered clinical trials unit that brings together academic, clinical, and trial management expertise from across Imperial College London and Imperial College Healthcare NHS Trust to deliver world class clinical trials of all phases and designs. The Unit also collaborates with members of the designated Academic Health Science Network for North West London, Imperial College Health Partners, other national clinical and scientific key opinion leaders, other CTUs and with Industry.

The Unit leads primarily on the design, conduct and analysis of national and international multi-centre trials, has staff with specialist disease and methodological knowledge, and has input at all stages of the trial lifecycle; thus, ensuring all activities are conducted according to the principles of ICH GCP and in compliance with the appropriate regulatory and ethical requirements. Current therapeutic areas of expertise include Cancer, Cardiovascular, Respiratory, Emergency and Critical Care, Infectious Diseases, Surgery and Child Health.

This post is jointly funded by multiple clinical trials and projects that offer an opportunity to contribute to cutting-edge approaches to trial delivery, with potential to influence future best practice in clinical research.

Purpose of the post

This is a new and exciting post that reflects the demands of contemporary clinical data management, particularly in the context of adaptive platform trials and the use of routinely collected healthcare data.

You will ensure that the full spectrum of data management activities across these studies is conducted to the highest scientific, ethical, and regulatory standards, making extensive use of data handling and programming skills to support these aims. The role is suitable for an experienced data programmer who is comfortable taking ownership of complex data management activities, working with a high degree of autonomy, and providing expert advice to trial teams on data-related issues. The post is particularly suited to an individual who combines traditional clinical data management expertise with strong technical skills in areas such as Python programming, SQL, electronic data capture systems, and the use of application programming interfaces (APIs) for system integration.

You will support data management activities throughout the entire trial lifecycle for assigned studies, from input into protocol development and study database design through to routine data cleaning, validation, reporting and database lock, in accordance with approved clinical trial protocols and under the direction of senior colleagues where appropriate. This will include supporting the design, build and maintenance of study databases and data pipelines; working with structured data from electronic health records and other health data sources; and developing and applying data extraction, transformation and loading processes. In doing so, the post holder will be expected to design and implement robust extract–transform–load (ETL) workflows using appropriate tools to work confidently with data in variety of formats, transformation to Clinical Data Interchange Standards Consortium Operational Data Model where appropriate, and to automate routine data management tasks where this can enhance efficiency and data quality.

A key aspect of the role will be to work with the unit's electronic data capture (EDC) systems, currently OpenClinica & REDCap, developing a strong understanding of their configurations and capabilities and to use this to address the challenges posed by complex trials. The role will involve writing and maintaining scripts to implement data validation and quality control procedures and to generate routine and ad hoc data listings, reports and metrics that support trial conduct, monitoring, and oversight. Basic web technologies (such as JavaScript) may be used to support the design and optimisation of electronic case report forms and related data capture workflows including integration with international data providers and navigating all local regulations.

You will work closely with trial teams and senior data management colleagues to plan and coordinate data management activities across the trial lifecycle, ensuring that key milestones and timelines for trial completion are met. You will contribute to activities that support compliance with Good Clinical Practice (GCP) guidelines and relevant data protection requirements, ensuring that agreed standards, methodologies, and standard operating procedures are followed, and that EDC and other data systems are configured and used in line with these frameworks.

You will be encouraged and supported to develop skills in relevant technologies, for example, data standards, scripting languages, database technologies, and EDC platforms; and to translate these into practical improvements in ICTU's data management processes. This will include opportunities to deepen expertise in the configuration and backend use of EDCs and related tools. There will be opportunities to contribute to methodological development, to present work internally and externally, and to shape data management practices within the ICTU. The role would suit an individual with a strong interest in the intersection of data, methodology and implementation, who is motivated by improving the quality, efficiency, and impact of clinical trials through rigorous and innovative data management.

Key Responsibilities

Data Management:

- Maintain an up-to-date understanding of clinical data management within the electronic database environment, including reviewing and, where appropriate, adopting new and recommended approaches.
- Support the application of a consistent, fit-for-purpose approach to data management is applied across trials, in line with best practice and trial needs, with detailed planning and documentation.
- Contribute to discussions on the most appropriate data management approach for each trial, taking into account the trial's requirements and challenges and constraints of the academic environment, including where trials are embedded within electronic health record (EHR) systems and routine care pathways.
- Support the design, development, testing and maintenance of trial electronic databases and associated data pipelines. This will include configuring OpenClinica and REDCap databases and forms; specifying and implementing validation rules and edit checks; developing ETL processes to move data between systems and other data sources; and designing processes to support interim analyses and ongoing trial work.
- Prepare data management documentation and other supporting materials (for example, data management plans, data handling guidelines, and user guides). Where automated scripts or other technical solutions are used, ensure that they are appropriately documented, version-controlled and maintained, in collaboration with information technology colleagues where relevant.
- Act as the day-to-day data management contact for allocated trials, working directly with trial teams under the guidance of senior colleagues to help ensure that trial design and data collection processes reflect data management best practice.
- Work closely with trial teams, statisticians, and data managers to contribute to protocol development and to translate trial requirements into robust electronic case report forms (eCRFs), ensuring that eCRF design is consistent with the protocol and analytical need.
- Contribute to the evaluation and implementation of new solutions for eCRF engines, reporting tools, integrations or data transformation utilities and data management systems when the need arises, including assessing suitability, feasibility, and impact.
- Identify opportunities to improve operational processes and recommend changes that enhance efficiency, data quality, and compliance with Good Clinical Practice (GCP), regulatory requirements, and relevant procedures.

Project Management:

- Support the planning and delivery of timelines for data management activities for allocated trials, ensuring that these are realistic, documented, communicated, and escalated where necessary in a timely fashion.
- Identify and record assumptions, risks and issues associated with data management activities as early as possible and escalate or mitigate them appropriately.

- Establish and maintain excellent working relationships with all key stakeholders, including regular liaison with study teams regarding timelines, deliverables, and priorities to ensure that expectations are clear and well managed.
- Investigate and support resolution of complex incidents or problems associated with data capture and data management, using appropriate investigative techniques and tools.
- Ensure that challenging or unresolved issues are escalated in a timely manner to Deputy/Head of Clinical Data Systems (CDS) or appropriate senior colleague), with clear documentation of findings and proposed solutions.
- Lead on documenting solutions and lessons learned to support knowledge transfer and to reduce the likelihood of recurrence.
- Lead on documenting solutions to ensure that knowledge is transferred to prevent issues recurring.

Regulatory

- Apply the principles of the International Conference on Harmonisation – Good Clinical Practice (ICH-GCP) guidelines, applicable clinical trial regulations, and ICTU Standard Operating Procedures (SOPs) across all data management activities.
- Maintain familiarity with, and ensure adherence to, all relevant ICTU SOPs and Work Instructions.
- Contribute subject-matter expertise to the development, review and update of data-management-related SOPs and Work Instructions, helping to ensure that they remain current, practical, and aligned with best practice.
- Participate in internal and external audits and inspections as defined by the audit plan, and support responses to any corrective and preventive actions (CAPA) or incident management processes related to data management activities.

General:

- Attend and/or deliver training which ensures compliance with regulatory requirements and guidance by self or other team members.
- Raise any areas of concern with the Head or Deputy Head of CDS in a timely manner.
- Perform any other duties which may be required that are consistent with the nature and grade of the post as required.
- To observe and comply with all College policies and regulations, including the key policies and procedures on Confidentiality, Conflict of Interest, Data Protection, Equal Opportunities, Financial Regulations, Health and Safety, Imperial Expectations (for new leaders, and supervisors), Information Technology, Private Engagements and Register of Interests, and Smoking.
- To undertake specific safety responsibilities relevant to individual roles, as set out on the College Website Health and Safety Structure and Responsibilities page ((https://www.imperial.ac.uk/safety/safety-by-topic/safety-management/health-and-safety-management-system/structure-and-responsibilities/)

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Person Specification

Requirements Candidates/post holders will be expected to demonstrate the following:	Essential (E)/ Desirable (D)
Education	
• Bachelor's degree or equivalent in computing/health informatics, data science, or relevant experience	E
• Postgraduate qualification relevant field (e.g. clinical trials, data science, health informatics) or equivalent experience	D
Experience	
• Hands-on experience with clinical data management systems and EDC platforms used in clinical trials (e.g. OpenClinica, REDCap or equivalent), including database requirements and eCRF design, implementation of user acceptance testing and ongoing maintenance.	E
• A solid understanding of clinical trials and data management practices, associated regulations (Clinical Trials Regulations, Good Clinical Practice, Data Protection Act, Research Governance Framework, Human Tissue Authority)	E
• Experience of designing and implementing data extraction, transformation and loading (ETL) processes and data pipelines, including working with structured data from multiple sources (e.g. electronic health records, registries, routinely collected health data) and formats, and integrating these into trial databases or analysis-ready datasets.	E
• Experience of configuration, rules/edit checks, imports/exports to support merging/integrating/aligning datasets across EDCs in complex or adaptive trial designs.	D
Knowledge	
• Understanding of how clinical and health research data are collected, curated and used by researchers, including implications for study design, analysis, and reproducibility.	E
• Experience with working with routinely collected health data and linkage.	D
• Experience of analysing and solving complex problems. Experience of using project management techniques, systems, and software	E
• Awareness of approaches to integrating systems and data sources in a regulatory-compliant way.	D

Skills & Abilities

• Able to show initiative and proactiveness to plan for complex database changes.	E
• Proficiency in SQL, Python, and JavaScript	E
• Strong motivation for continuous learning and improvement, including willingness to undergo any training necessary for trial duties (e.g. new EDC features, programming tools, data standards, GCP updates).	E
• Ability to communicate technical and data management concepts clearly to non-technical colleagues, through participation in meetings at all levels.	E
• To work both independently and as part of a team with high attention to detail, good project management skills, and the ability to manage conflicting priorities and meet demands of a dynamic portfolio.	E

Further Information

Please note that job descriptions cannot be exhaustive, and the post-holder may be required to undertake other duties, which are broadly in line with the above key responsibilities.

Our values are at the root of everything we do and everyone in our community is expected to demonstrate Imperial:

- Respect
- Collaboration
- Excellence
- Integrity
- Innovation

Employees are also required to comply with all Imperial policies and regulations.

We are committed to equality of opportunity, to eliminating discrimination and to creating an inclusive working environment for all. We encourage candidates to apply irrespective of age, disability, marriage or civil partnership status, pregnancy or maternity, race, religion and belief, gender reassignment, sex, or sexual orientation. You can read more about our commitment on our webpages.

Imperial is a proud signatory to the San-Francisco Declaration on Research Assessment (DORA), which means that in hiring and promotion decisions, we evaluate applicants on the quality of their work, not the journal impact factor where it is published. For more information, see https://www.imperial.ac.uk/research-and-innovation/about-imperial-research/research-evaluation/

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