Job Title:	Research Data Manager/ Officer
Job Description Version:	Version 2.0/ Feb 2021
Location:	Site Based
Position Type:	

Job Purpose:

Responsible for entry of clinical data, data query resolution and Investigator Site File content management at the clinical study site according to study protocol(s), ICH-GCP and local regulations and requirements. You will be a key interface amongst site-staff and external stakeholders, and perform a key role to enabling successful study performance at site.

Main Responsibilities:

- To conduct data entry accurately and completely in a timely manner, aiming to minimise data entry queries while ensuring confidentiality and security of the data at all times.
- To support the study team(s) with missing data/ quality checks as appropriate and to perform follow-up data collection where required.
- To facilitate sponsor representative/ CRA during initiation and monitoring visits and assist with query resolution as appropriate.
- To effectively communicate and develop strong collaborative relationships with personnel across study sites, external stakeholders and the office/field based O4 Research team.
- To coordinate and support the study team at site(s) to meet study requirements and ensure the study is conducted to the highest standard.
- To facilitate in quality control and quality assurance audits of clinical study documentation.
- To comply with the requirements for the timely and accurate reporting of all Adverse Events.
- To ensure standard working practices are followed in order to provide an effective professional clinical trial administration service for the site.
- To track and maintain study information and to report internally within the site and to report study progress and weekly activity to O4 Research.
- To ensure that internal/external enquiries are dealt with professionally and effectively.
- To contribute to study site team efficiency and process improvement, including contributing to the development of best practices and appropriate tracking tools and templates.
- To be aware, understand and comply with all applicable standard procedures, Regulatory and Legal requirements (ICH-GCP, Statutory Instruments and SOPs) requirements.

Qualifications & Experience:

- A minimum of one year's experience working in a Clinical Research investigative site environment within a clinical data entry role with query resolution and data quality experience.
- Experience in using EDC system(s)
- Working knowledge of clinical trials and associated regulations (EU Clinical Trials Directive, Statutory Instruments, ICH-GCP, EU General Data Protection Regulation and Data Protection Act 2018).
- Life Sciences/Scientific Degree preferred.
- Experience in oncology based studies preferred.
- Knowledge of medical terminology would be beneficial.

Personal Characteristics/ Key Competencies:
• Self-motivated with ability to work independently, take initiative and problem solve, yet also work cooperatively as part of a team. • Excellent organisation skills and time management skills, with proven ability to prioritise workload and work calmly under pressure. • Strong interpersonal skills (both written and verbal communication) with the ability to interact well with all levels of management and staff (internal and external). • Approach tasks with great tenacity combined with a quality focused, attention to detail, positive and enthusiastic attitude. • The ability to work across multiple clinical studies at different research sites. • Flexible and responsive to new ideas in a changing environment. • Demonstrate professionalism and present a positive image of O4 Research and the hospital site to the study wide stakeholders. • Open and transparent working style. • Desire for success and highly results focused. • Approachable, personable and supportive of others.

Job Description agreed by:	
Employee Signature:	Date:
Line Manager Signature:	Date: