

JOB DESCRIPTION CLINICAL DATA MANAGER

Job Purpose

To lead all activities related to the Data Management of clinical trials managed by 4Clinics.

Scope

Will work closely with the Sponsor, the Clinical Sites and the Statistical department in order to coordinate all activities related to the DM of clinical trials.

Key Responsibilities

- Author the Data Management Plan
- Author the Data Management Report
- Request access to the clinical database for team members
- Define the data validation plan
- Initiate the clinical study instance in the Clinical Data Management System
- Coordinate and control data collection, data cleaning and data reporting activities
- Apply QC to each stage in the data handling to assure that the data are reliable and processed correctly
- Send Data Clarification Forms to clinical sites
- Update clinical data in the clinical db according to the DCF
- Lock the clinical database
- Perform the medical coding
- Define clinical study timelines and workflow
- Interact with sponsor and clinical sites
- Conduct the reconciliation of SAEs
- Archive clinical study data

Qualifications

- Master's Degree in Sciences preferably in Computer Science, Life Sciences or related fields or Pharmacist
- Understanding of Regulatory Guidelines for the use of computer systems in clinical studies.
- Demonstrated technical abilities and skills in the use and management of computer databases.
- Excellent technical and analytical skills
- Good communication skills in English, both written and verbal
- Good team player and flexible to work on diverse projects in various disease areas

