# **India Jobs Expertini®**

#### **Clinical Data Manager II**

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Company: Caidya

Location: India

Category: other-general

Job Title: Clinical Data Manager II (CDM II) Job Location: Home-based Job Overview: The Clinical Data Manager II participates in the clinical data management activities for a project within a data management project team; including processing of case report form (CRF) and electronic data in accordance with Caiya SOPs, Good Clinical Practice, ICH Guidelines and sponsor requirements. Job Duties and Responsibilities: The specific job duties of a Clinical Data Manager II may include but are not limited to: For specified projects performs start-up activities including: Developing data management guidelines and study documentationAssists in developing core study documents for data management including DMP, DVP, CRF completion guidelines, and other study documentation as neededReview of CRF design against protocolReview of database setupFor specified projects performs some data management activities as detailed below and performs activities in accordance with our SOPs, Good Clinical Practice, ICH Guidelines and study documentation. Study status tracking and associated metricsData EntryReview and reconciliation of data listingsIdentification of data issues and query generationUpdating of database with query resolutions (paper studies only)Ownership and proactive management of the data reconciliation activities documented in the DVP, DMP, etc. Provide input for Database closeout and lock activities and timelinesArchiving of critical documents on an ongoing basisProvide support to deliver DM specifications for CRF counts and associated details for proposal needs. Awareness of the CAPA process and provide input for audit responses regarding assigned tasksParticipate in User Acceptance Testing for assigned projectsFor specified projects performs study finalization activities including: Database close-out Critical item review

and Quality control support as needed, per platformData review and reconciliationQuality ControlArchivingSupports and tracks budget adherence in cooperation with Finance to ensure the assigned studies are meeting targeted margins and utilizationContinuous improvement of departmental processes and procedures to ensure DM is consistently maximizing efficiencies, leveraging technology and incorporating innovation to optimize deliveryMaintains working knowledge of regulatory requirements/guidance as well as industry leading best practices to ensure Caidya DM procedures are in line with industry expectationsOther duties as assignedSupervisory Responsibilities:No supervisory responsibilities.Job Requirements: Education College graduate with a life science, computing or nursing qualification or 3 to 4 years equivalent experience. Experience Minimum of 2 years of experience with demonstrated experience supporting data management work. Experience working in pharmaceutical and/or Contract Research Organization (CRO) industry preferredWorking knowledge of EDC studiesSkills/CompetenciesStrong organizational skillsStrong written and verbal communication skillsExceptional attention to detailKnowledge of clinical research including regulatory requirements GCP/ICHStrong computer skills, including Microsoft Office and clinical data management systemsDemonstrated problem-solving skillsCapabilitiesFlexibility - willing to change assignments and work focus to accommodate project demandsTeam player – effective proactive participant as a team memberDedicated home office environment for home-based employees, as applicable

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