Roles, Key Performance Expectations, and Competencies for CRE Clinical Data Managers (CDM) I-IV

**Role:** Clinical Data Managers ensure the integrity, validity, and accuracy of CRE's clinical data.

**Key Performance Expectations**

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| **Key Performance Expectation** | **CDM I** | **CDM II** | **CDM III** | **CDM IV** |
| **All study database builds are completed within agreed upon timelines** | * Reviews and provides feedback on study protocols, aims and data collection processes * Builds data collection forms in alignment with study event structure * Drafts the Data Management Plan |  | * Provides expert advice on study protocols, aims and data collection processes * Defines study event structure and builds data collection forms in alignment with study aims * Creates the Data Management Plan | * Key contributor on study protocols, aims, and data collection processes |
| **All study datasets are complete and accurate** | * Maintains and adheres to Data Management Plan * Writes simple queries and resolves discrepancies in data with guidance * Provides simple reports to assist in data monitoring * Works with study team and sites to resolve data issues * Manages data within a risk-based framework | * Independently writes queries and resolves discrepancies in data * Provides reports to assist in data monitoring | * Writes complex queries and resolves discrepancies in data * Suggests methods to check and monitor study data | * Expert in writing queries and resolving discrepancies in data * Proposes and implements methods for examining and validating study data |

**Competencies**

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| **Competency** | **CDM I** | **CDM II** | **CDM III** | **CDM IV** |
| **Technical Knowledge** | * + Introductory knowledge of SQL   + Familiarity with EDCs (e.g. REDCap) | * + Basic knowledge of SQL   + Basic understanding of relational databases | * + Intermediate knowledge of SQL   + Intermediate understanding of relational databases | * + Intermediate knowledge of SQL   + Solid understanding of relational databases |
| **Communication** | * + Uses clear and consistent language in spoken and written exchanges   + Gives and receives constructive feedback | * + Familiar with writing study specific procedures, data entry guidelines, and other study documents | * + Proficient in writing study specific procedures, data entry guidelines, and other study documents | * + Expert in writing study specific procedures, data entry guidelines, and other study documents |
| **Relationship Management and Teamwork** | * + Demonstrates team-building skills that enhance the learning environment   + Assists others as needed   + Provides excellent customer service   + Freely shares expertise with others |  |  |  |
| **Ownership** | * + Independently completes all assigned tasks within agreed upon timeframes   + Manages project work and timelines   + Contributes to study risk assessment and risk monitoring plan and helps ensure that risks are monitored on the agreed upon schedule   + Accepts responsibility for assigned work | * + Manages and successfully negotiates project work and timelines | * + Key contributor in project deliverables | * + Creates new or updates processes or tools under the direction of the CDM director. |
| **Critical Thinking** | * + Identifies ways to reduce redundancy   + Makes decisions within authority and escalates to higher authority when needed   + Prioritizes data validation and other data management activities using a risk-based paradigm | * + Proposes improvements to standards, tools, and processes | * + Proposes novel approaches to addressing study needs | * + Proposes and implements novel approaches to addressing study needs |
| **Leadership** |  |  | * + Teach CDM I-II the research process   + Mentor CDM I-II in their roles | * + Teach CDM I-III the research process   + Supervise CDM I-III work   + Mentor CDM I-III in their roles |