Sarah M. Kelly

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Clinical Data Associate

Data Management ~ Data Reconciliation and Trending ~ Documentation

CAREER ACCOMPLISHMENTS

- Improved client visibility through the creation and delivery of weekly and monthly performance metrics and analysis of client deliverables increasing client satisfaction levels significantly.
- Assisted in increasing department efficiencies by 80% through the detailed analysis of individual performance levels.
- Improved individual team performance through the creation and updates of existing process and procedures.
- Assisted Director in daily responsibilities including but not limited to client deliverables, employee monitoring, development and training of department procedures.
- Participated in weekly client operations meeting providing real time updates on operations increasing client's confidence level in team abilities to meet project timelines without difficulty.

PROFESSIONAL EXPERIENCE

Kendle International - Old Lyme, Connecticut July 2009 – Present
Clinical Data Management
Clinical Data Associate

- Review and monitor ongoing clinical trial data to ensure the accuracy and consistency of clinical databases. Other clinical study work activities include: CRF tracking, CRF/eCRF review, reconciliation and validation of clinical data from EDC systems.
- Using extensive knowledge of Microsoft Excel, create automated tools to assist with data listing review, increasing speed and efficiency of review and minimizing errors due to manual review.
- Operate and update laboratory and clinical databases, design and testing of database procedures, generation of reports.
- Design and write clinical study documentation such as eCRF Completion Guidelines, Standard Operating Procedures, and assist in eCRF design.
- Maintains internal CDM QC documentation.
- Track and reconcile data received for in-house review through use of existing CRF tracking tools.
- Apply corrections and/or updates to the clinical database that are identified through query resolution, text review, study conventions, data validation, and/or data importing.
- Perform reconciliation of similar data between multiple data sources.
- Perform internal CDM QC audits of the clinical database; assist in production of QC audit report including calculating accuracy rate.

- Completes tasks within timelines by appropriately prioritizing multiple tasks within or across projects, minimizing backlog and managing time constraints across projects. Seeks direction from management as required.
- Adapt to timeline or priority changes by reorganizing daily workload.
- Proactively communicate to CDM Management/DM accurate estimates on time to complete tasks, availability to take on new assignments and resourcing conflicts.
- Demonstrate customer-oriented communication skills responding to management and team correspondence promptly and within agreed upon timeframes, cooperating with requests and utilizing appropriate method of communication based on urgency and type of information being communicated.

BLC Pro - New London, Connecticut April 2008 – July 2009
Study Operations Group
Closeout Team Lead

- Responsible for internal daily reporting and data trending analysis for study verification closeout.
- Extensive involvement with coordinating and facilitating the delivery of services in support of call center and data verification.
- Assist in the implementation of new process and procedures through document creation.
- Develop procedural documentation including but not limited to training guides, work instructions, standard operating procedures and reference documents under quality guidelines.
- Responsible for coordinating and facilitating department trainings for updates and changes to policies and procedures.
- Attend weekly client meetings and provide operational status updates.
- Create and maintain extensive data spreadsheets in Microsoft Excel.
- Liaison between Study Operations department and client to resolve discrepancies and escalated issues that arise during the verification process.
- Responsible for providing weekly and monthly trending reports to client.

BLC Pro - New London, Connecticut February 2007 – April 2008
Study Operations Group
Clinical Verification Specialist

- Responsible for reviewing, assessing, and verifying subject data, indexes, and mandatory CRFs compiled on data CDs.
- Responsible for burning complete verification of casebooks, ensuring that each Study Closeout Casebook File is an accurate representation of the study data as it appears in Pfizer electronic data capture programs.
- Accountable for the review and approval of the data CD, ensuring completed sites provide their regulatory documents in accordance with FDA Regulations.
- Extensive experience with Client applications including but not limited to EDC Trial Manager, GCDS Track, Info Share, Right Track II, I*Net and I*Net Study Manager Oracle Clinical Citrix RDC, Eclipse.

- Responsible for fielding calls regarding site closeout activities during study closedown and provide high quality customer service.
- Update spreadsheets posted in shared environment with individual performance details in order to provide metrics to client.

U.S. Forest Service Durham, New Hampshire August 2003 – February 2007
Center for Research on Ecosystem Change
Analytical Lab Technician

- Responsible for receiving and cataloging incoming study samples from multiple sites and individual researchers.
- Preparation of samples for testing; conducting tests using state-of-the-art analytical instruments.
- Responsible for data collection, data analysis, and the development of formal test results reports submitted to the various research scientists.
- Experienced in laboratory equipment including but not limited to Shimadzu TOC, ASI-V Combustion Catalytic Oxidation, GC Spec Gas Chromatography, and Metrohm-Peak Ion Chromatography.
- Work with multiple researchers that use our laboratory for sample analysis.
- Required to have the ability to learn quickly on new analytical methods, utilize my highly developed organizational skills, and my strong professional communication ability.

PROFESSIONAL SKILLS

- Experience in developing procedural documentation including training guides, work instructions, standard operating procedures and reference documents under quality guidelines.
- Extensive knowledge on Microsoft Office including Excel, Power Point, Word, Publisher and Outlook, Adobe Acrobat Writer, Photoshop.
- Experienced in Framemaker / Visio / Graphic Design / Web content / HTML / FrontPage.
- Efficient problem/issue solver, highly organized, dedicated and motivated, with an ability to communicate effectively and utilize negotiation skills when necessary.

EDUCATION AND CERTIFICATIONS

University of New Hampshire 8/2003 – 12/2007
Chemistry B.S., English B.A. (Both degrees are in progress but currently on hold)

References are available upon request.

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