Kandance Cooper, MBA

SUMMARY

- Clinical Data Management professional offering over 20 years of experience
- 10 years of managerial experience
- 7 Years of EDC experience (Medidata Rave, Oracle-RDC, Inform)
- 10 Years of CRO Management experience
- Multiple NDA and BLA Submissions
- Multiple therapeutic areas (Oncology, CNS, Vaccines)
- Experience is Phases I-IV

PROFESSIONAL EXPERIENCE

10/2012 Present — **Principal Clinical Data Manager (contract) – Pharma Data Associates, Piscataway, NJ**

Provide Data Management Support for Clinical Studies

- Oversee EDC and data management activities
- eCRF design and review, DMP and edit check specifications review
- EDC and IWRS UAT
- Data review and reconciliation, protocol deviation review

02/2013 Present — **Associate Director, Clinical Data Management Consultant– Daiichi Sankyo, Edison NJ**

Coordinate Data Management deliverables for NDA Submissions

- Working with service providers to facilitate the development of STDM Datasets
- Review and approve datasets for inclusion in the submission to ensure they are CDISC compliant
- Facilitate the creation of PDF's of the subjects eCRF for inclusion in the submission
- Track, and facilitate responses to FDA Request
- Facilitate the creation of annotated CRFs for inclusion in the submission
- QC the datasets and other Data Management components of the eCTD submission

11/2011 01/2013 — **Senior Clinical Data Manager - Targacept, Inc, Winston Salem, NC**

Development of the Data Management infrastructure and performance of data management activities for a small Biotech company

- CRO Oversight and management
- Development of Data Management SOPs
- eCRF Development, User Acceptance Testing, Edit Check Development, Development of Data Management Plan and eCRF completion Guidelines, Data Review/cleaning, Coding and database lock

05/2011-11/2011 — **Senior Data Management Consultant – Sunovion Pharmaceuticals, Fort Lee NJ**

Provide Data Management expertise in the initiation of 2 phase III Trials

- Provide CRO and vendor management. Reviewed and approved contracts, Data Transfer Agreements.
- Contributed to the development of the Protocol, CRF, Clinical Database, Edit specifications, CRF Completion instructions, Data Management Plan, and other Data Management Study Documents
- Investigator meetings presentation

11/2010-04/2011 — **Senior Project Manager, Clinical Data Management Endo Pharmaceuticals (contract)**

As a consultant contributed to the development of the internal Data Management infrastructure.

- Assisted in the implementation of Medidata RAVE.
- Developed Standardize Data Review Plan, and standard data review reports in J-Review
- Performed Data Management activities (CRO oversight and management, UAT, Data Review, Document Development Program data listings Coding).

09/2010-
11/2010 **Senior Data Management consultant, Clinilabs, Inc., New York, NY (3-Month contract)**

- Providing Data Management services for a small – Start-up CRO
- Database development, Edit check programming, UAT, Development of Study Documentation, Site Training. Development of SOPs and training
- Working with an EDC System on a Phase II CNS study

4/2010-
7/2010 **Data Management Consultant, Advanced Clinical Services (3-month contract)**

- Home-based Senior Data Manager performing DB Lock Activities for a CRO
- Data Review, Writing Queries, Reviewing submission datasets for Quality and accuracy
- Attendance at project team meetings

12/2007-
04/2010 **Manager Clinical Data Management, Novartis Pharmaceuticals Corporation, Florham Park, NJ**

- Provided Oversight of Data Management personnel and Data Management activities for multiple drug programs within Novartis Oncology
- Managed CRO's and other vendors; was an active member on a Strategic Outsourcing Committee; Contributed to development of new outsourcing strategy.
- Participated in the successful submission of two NDAs
- Recruited, trained, developed, and provided guidance to Data Management personnel to ensure top performance and regulatory compliance (7 Direct Reports)
- Ensured adequate resources were assigned to projects to meet Data Management deliverables and organizational goals
- Provided Data Management Expertise to project teams
- Contributed to the development of the Data Management organization by participating in process improvement initiatives

01/2006-
09/2007 **Data Management Consultant, MGI PHARMA, Inc., Baltimore, MD (18 Month Contract)**

- Development of Data Management infrastructure
- CRO Management and oversight
- Recruit, Direct and provide guidance to Data Management personnel (13 Direct reports)
- Development of Data Management SOPs and Work Practices
- Actively participate in MGI and Guilford integration efforts
- Oversee Data Management Activities for MGI Sponsored Clinical trials
- Advise and Provide Data Management expertise to project teams
- eCRF Development, User Acceptance Testing, Edit Check Development, Development of Data Management Plan and eCRF completion Guidelines, Data Review cleaning, Coding and database lock
- Successfully prepared the data for two NDA Submissions

09/2002-
09-2005 **Senior Manager, Clinical Data Management, MedImmune, Inc., Gaithersburg, MD**

- Managed Data Management group of 35 (16 Direct reports)
- Strategic CRO and Vendor Management; Developed and implemented a new outsourcing strategy for the Data Management Organization. Developed new billing guidelines for vendor contracts.
- Overall Department budget management and forecasting
- Participated in the successful submission of a BLA
- Developed an automated tool used to forecast the number of FTEs need for a project
- Developed and implemented a training program for Data Management personnel
- Developed and implemented over 50 standard operating procedures and work practices
- Facilitated the development, validation and implementation of clinical trial databases to ensure standardization. Reviewed and approved all data management documents and deliverables. Served as an advisor to all project teams.
- Active participant on several committees (standard CRF, Standard Timeline, Statistical analysis plan, and the SOP committee)
- Successful upgrade and validation of Oracle Clinical
- Successful implementation of MedDRA

- Developed job descriptions
- Responsible for a 37% departmental growth
- Developed a standard Data Management Plan, a standard edit specifications template, and status/metric reports

01/1999-
09/2002 **Senior Clinical Data Manager, Pfizer Global Research and Development, La Jolla, CA**

- Managed seven employees, responsibilities included providing performance evaluations, goal setting, training, coaching, recruiting, developing SOPs and work practices.
- CRF Development, Database Development, Edit Check Development, Development of Data Management Plan and Data Entry Guidelines, Coding, SAE Reconciliation, Data cleaning and database lock. I was responsible for managing resources to ensure adequate support for each trial.
- Responsible for evaluating and managing CROs for our outsourced projects.
- Actively participated on a taskforce that evaluated and implemented new technologies and strategies for continuous business process improvements.
- Oracle-Clinical Validation
- MEdDRA Implementation
- EDC-Implementation and Pilot study.
- Successfully lead a team of data managers in an effort to clean out a backlog of discrepancies that existed on a critical trial.
- Developed a standard query form to aid in the SAE reconciliation process.
- Lead the successful completion of an oncology drug program of 24 individual protocols.

01/1995-
01/1999 **Training Manager, Clinical Data Management, Quintiles Pacific, Inc., Mt. View CA**

- Developed and implemented a Data Manager training program for the Clinical Data Management Organization.
- Participated in BID meetings and gave presentations to prospective clients.
- Developed a Training Database and maintained training records for all Data Management personnel.
- Developed training modules for the various data processing tasks in Clinical Data Management.
- Developed SOPs, guidelines, and working procedures. Presented training modules to employees.
- Actively participated in the development of project teams, budgets, and timelines.

01/1992-
01/1995 **Clinical Data Manager**

- Managed several trials (Phases I-IV). Worked on a number of NDA submissions. Effectively managed resources to meet project deliverables and deadlines. Participated in an FDA Audit.
- Worked with Database Programming group to build databases and develop edit checks.
- Trained and coordinated data management staff to perform data entry, to write queries, to update the database and to perform various data processing tasks.
- Developed and maintained a Data Management Plan.

01/1991-
01/1992 Contractor-Database Development **Coherent Medical, Inc.,** Palo Alto, CA
Database development for clinical trials (Medical Devices)

COMPUTER APPLICATION EXPERIENCE

Oracle Clinical, Oracle – RDC, ClinTrial, Medidata Rave, InForm, Paradox, SQL, SAS, TMS, MedDRA, DS Navigator, DATATRAK EDC system, Medrio EDC system, Timeaus EDC system, Integrated review, J-Review, Cognos Impromptu

EDUCATION

American Intercontinental University
MBA, Project Management

American Intercontinental University
Bachelors, Business Administration, Management

American Intercontinental University
Associates, Business Administration

University of California-Santa Cruz
Certificate in Training and Human Resource Development

Association of Clinical Research Professional
Certified CRA -1998