EUGENE A. TURNER

Summary of Professional Experience

Eugene Turner, a senior clinical data manager in the Clinical Research Informatics group at RTI International, has 22 years of experience in the pharmaceutical industry, with primary concentrations in project lead clinical data management (CDM). As a senior clinical data manager at RTI, Mr. Turner ensures database accuracy according to departmental operating procedures, performs a quality control (QC) review of the data and coordinates corrections to the database with the clinical sites, and designs case report forms (CRFs) for data acquisition and data entry. He also develops electronic case report forms (eCRFs) that do not require extensive programming, drafts data management plans, and monitors study metrics.

Education

BS, Business Administration, Strayer University, Arlington, VA, 1986.
AAS, Business Management, Northern Virginia Community College, Annandale, VA, 1984.
AS, General Studies, Northern Virginia Community College, Annandale, VA, 1984.

Certifications and Licenses

Certification, Good Clinical Practice for Clinical Trials, 2015.

Professional Experience

2016 to date	RTI International, Research Triangle Park, NC.
	Senior Clinical Data Manager 1. Ensures database accuracy according to departmental operating procedures. Performs a QC review of the data and coordinates corrections to the database with the clinical sites. Designs CRFs for data acquisition and data entry. Develops eCRFs that do not require extensive programming. Drafts data management plans and monitors study metrics.
2015 to 2016	Quintiles Inc., Durham, NC.
	Lead Data Manager. Provided leadership to the team in the area of project management. Was viewed as an expert in data management. Managed the delivery of projects through the full data management process life cycle by using Medidata RAVE as the primary data collection tool. Provided guidance for the design of new and revised forms in Medidata RAVE. Managed project timelines, quality issues, resources, and scope of work. Managed comprehensive data management tasks pertaining to the Data Management Plan. Managed comprehensive QC procedures. Established and maintained effective working relationships with coworkers, managers, and clients. Managed the data operations

coordinator in Bangalore, India, to ensure that project objectives were met. Developed project solutions and proposed these to the CDM team and the CDM Department. As required, negotiated with customers regarding timelines, resources, and other issues. Regularly monitored project status for changes and shifting priorities to ensure that objectives were met.

2014 to 2015 Planet Pharma, Durham, NC.

Lead Data Management Contractor at Quintiles. Served as the data team leader of a program. Manage data management internal and external customer relationships for the data management project team. Managed project timelines, quality issues, and resources by using Medidata RAVE as the primary data collection tool. Managed comprehensive data management tasks pertaining to the Data Management Plan. Managed comprehensive QC procedures. Developed and maintained good communication and working relationships with CDM, the project team, and a client. Demonstrated expert data management skills. When conducting work, applied comprehensive understanding of the clinical drug development process and knowledge of operating procedures and work instructions. Met objectives as assigned.

2008 to 2014 PPD Inc., Morrisville, NC.

Database Programmer 2. Served as a technical leader on study that involved Oracle Clinical Remote Data Capture (RDC) database design and build activities. Attended Medidata RAVE design and build training. Reviewed designs for compliance and feasibility within the database system and consistency with any current standards and/or sponsor specifications. Extracted SAS views for programming reviews and approvals. Regularly met with study teams during initial study setup to ensure effective communication and accuracy in design. Validated data checks. Coordinated the activities of other technical staff members who might assist in building studies to ensure that all jobs were completed and timelines were met. Updated annotations and production databases where required based on protocol amendments or other changes to trial designs. Performed core setup and supported processes for various peripheral systems. Provided basic technical support consultancy and end-user support. Worked with the Information Technology Department to troubleshoot, report, and resolve system issues. Represented the CDM Department within client and sponsor meetings and audit forums. Managed assignments to meet deadlines and produce high-quality deliverables. Remained familiar with relevant contractual obligations and sponsor expectations. Monitored own assignments, evaluating and shifting priorities and assignments to meet deadlines and deliver high-quality work. Proactively communicated with all project team members and regularly provided feedback to management about timelines and budget or resourcing constraints.

2002 to 2008 GlaxoSmithKline Inc., Research Triangle Park, NC.

Senior Clinical Data Scientist (2003 to 2008). Was responsible for managing all CDM activities for assigned Phase II through Phase IV studies. Provided technical expertise and support to the design, testing, and implementation of clinical trial databases in Clintrial 4.3, InForm 4.1, and 4.5. Created system-independent data specifications for Clintrial and Inform. Validated and extracted

InForm data to the Biostatistics Unix platform. Created system-independent data specifications for external vendor data not captured in InForm or Clintrial. Managed multiple external data vendors and interface applications. Merged and validated external vendor data into Clintrial and SAS. Validated and transferred external vendor data to the Biostatistics Unix platform. Designed and tested data validation check specifications. Provided input regarding the testing and validation of new computer systems and software applications. Participated in User Acceptance Testing of new and upgraded internal and external data interface software tools. Provided feedback about the development of data standards, including therapeutic standards. Effectively interacted and influenced colleagues and cross-functional project teams worldwide. Planned, negotiated, and managed project outcomes to meet established timelines. Ensured that milestones were met for deliverables to internal and external clients. Recommended project resource needs as necessary. Supervised, trained, coached, and, as necessary, mentored staff.

Clinical Data Scientist (2002 to 2003). Was responsible for managing all CDM activities for assigned projects for Phases II through III. Provided technical expertise and support to the design, testing, and implementation of clinical trial databases in CT-GOLD and Clintrial 4.3. Created system-independent data specifications for CT-GOLD and Clintrial 4.3. Performed program ad hoc SQL data checks and listings as needed in CT-GOLD and Clintrial 4.3. Merged and validated external vendor data into Clintrial and SAS. Conducted database management programs and performed data maintenance and validation procedures. Ensured that databases for assigned studies were consistently defined and documented and that quality data were provided for regulatory submissions. As a representative of the Data Management Department, provided status updates and information to the various cross-functional teams involved with studies being conducted within the Department. Provided input regarding the testing and validation of new computer systems and software applications. Communicated project status to the study team and management. As necessary, participated in the review of contract research organization (CRO) and external data supplier bid packages. Supervised, trained, coached, and, as necessary, mentored staff.

1998 to 2002 ClinForce Inc., Research Triangle Park, NC.

CDM Contractor at GlaxoSmithKline. Coordinated all CDM activities for assigned studies. Used technical expertise in the design, set up, testing, and implementation of clinical trial databases in GOLD. Managed and supported GOLD database performance throughout the study life cycle. Created specifications for external data transfer. Managed the external data transfer process. Worked with the project team to design non-standard CRF pages. Wrote effective specifications for data validations. Resolved validation reports. Worked with Clinical and Biostatistics Departments to resolve data discrepancies. Worked closely with a project programmer to ensure that project objectives were met. Supervised, mentored, and trained data management staff assigned to assist with designated projects. Coded drugs and diseases. Transcribed responses to data management queries on CRFs. Ensured high standards of quality efficiency and timeliness of data management work for assigned projects. Supervised, trained, coached, and, as necessary, mentored staff.

1994 to 1998 PPD Inc., Morrisville, NC

Clinical Data Analyst (June to November 1998). Designed CRFs to ensure that relevant protocol-specified data were collected on the form. Used technical expertise in the design, set up, testing, and implementation of clinical trial databases in PPD Clinical Information System (CIS). Managed and supported PPD CIS database performance throughout the study life cycle. Provided technical expertise and support to the design, testing, and implementation of clinical trial databases in Clintrial 3.2. Ensured the timely delivery of CRFs to the sites. Designed coding and database manuals. Wrote effective specifications for data validations. Applied knowledge of medical and clinical trial terminology. Supervised, mentored, and trained data management staff assigned to assist with designated projects. Ensured customer satisfaction by establishing high standards for the quality, efficiency, and timeliness of the CDM work for assigned projects. Used CRF tracking and project status reports to monitor work progress. Worked closely with project programmers to ensure that project objectives were met. Presented an overview of the CDM Department to current and potential clients. Assisted in marketing the services of the Biostatistics and Data Management Division.

Clinical Data Associate (1996 to 1998). Read and understood project protocols and CRF review guidelines. Understood, updated, filed, and distributed project-specific coding and database manuals. Compared, resolved, and updated entry files. Generated, tracked, and resolved data clarifications and queries. Analyzed and resolved data validation data management reports. Reviewed data listings for accuracy and consistency. Coded drugs and diseases. Manually proofread the entire CRF and key variables. Regularly produced project-specific status reports for the supervisor and clients. Communicated with clients and wrote contact reports.

Document Management Supervisor (1995 to 1996). Hired, trained, supervised, motivated, and evaluated Document Management and CRF design staff. Organized and managed work flows. Monitored and coordinated immediate, short-term, and long-range resource requirements for Document Management staff. Was responsible for planning to help ensure adequate resources to meet project timelines and for managing the daily operations of the Document Management and CRF design staff. Was responsible for conducting QC audits and reviewing and revising, as necessary, standard operating procedures (SOPs) and working with project managers and Document Management staff to establish procedures that comply with company and sponsor SOP requirements.

Document Control Specialist (1994 to 1995). Was responsible for monitoring, tracking, and filing CRFs. Prepared and maintained files for project documentation, providing accurate, document management through the CRF tracking database. Generated and reviewed computerized tracking reports daily. Assured security of the Biostatistics and Data Management Division's Document Control Room.