

**NOTES**

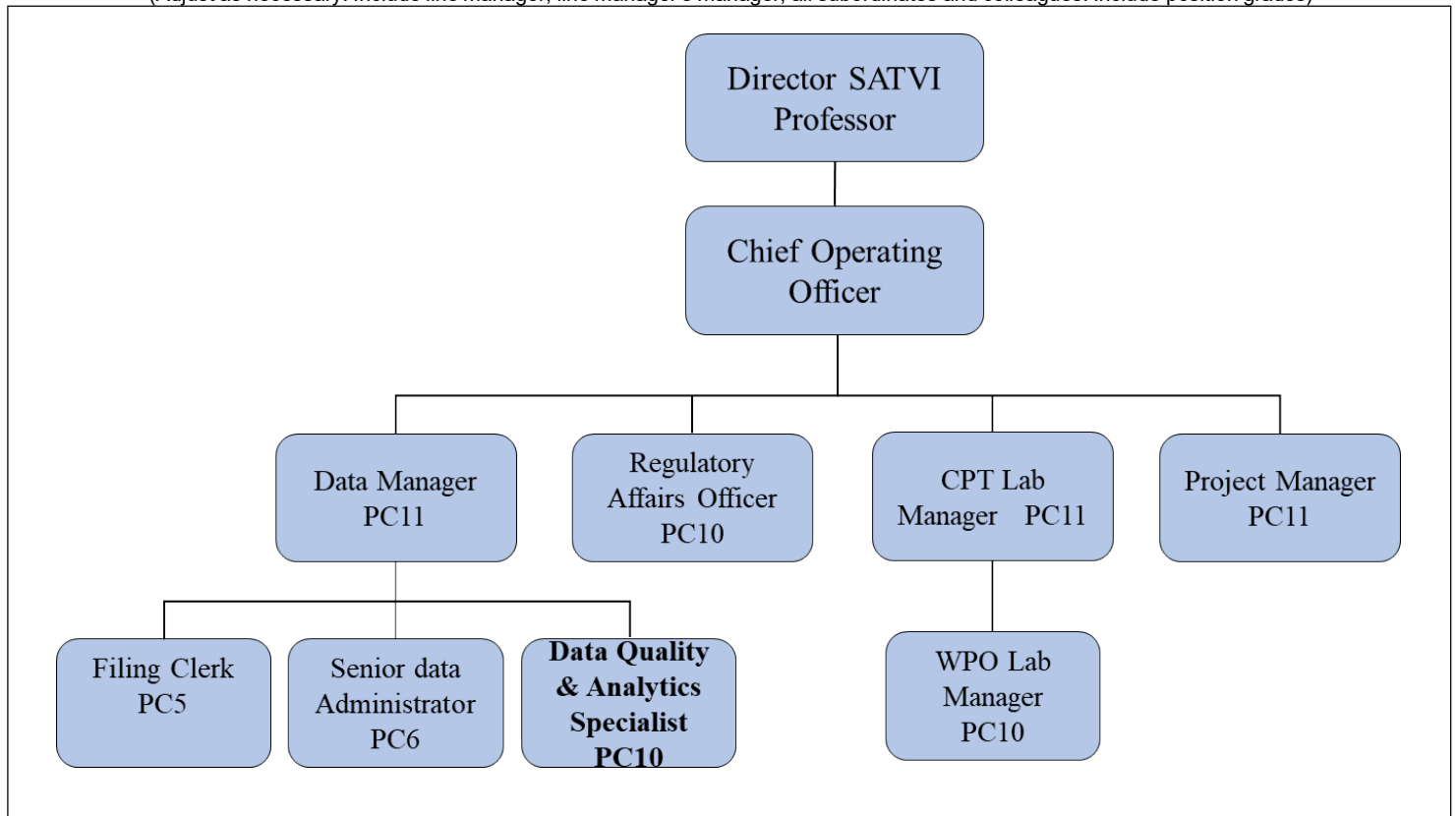
- Forms must be downloaded from the UCT website: <http://forms.uct.ac.za/forms.htm>
- This form serves as a template for the writing of position descriptions.
- A copy of this form is kept by the line manager and the position holder.

**POSITION DETAILS**

Position title	Data Quality & Analytics Specialist		
Job title (HR Practitioner to provide)			
Position grade (if known)	10	Date last graded (if known)	
Academic faculty / PASS department	Health Sciences		
Academic department / PASS unit	Pathology		
Division / section	SATVI		
Date of compilation	24-Apr-2024		

**ORGANOGRAM**

(Adjust as necessary. Include line manager, line manager's manager, all subordinates and colleagues. Include position grades)



**PURPOSE**

The main purpose of this position is the implementation and management of a clinical research data quality management system that functions to ensure high quality data for analysis. The Data Quality & Analytics Specialist will be responsible for coordinating and liaising with collaborating study sites to ensure that queries are resolved timeously to maintain accuracy, completeness, and reliability of the data. Further the Data Quality & Analytics Specialist is responsible for the design and implementation of an FDA 21 CFR Part 11 compliant research database, extraction and preliminary analysis of the data.

**CONTENT**

Key performance areas		% of time spent	Inputs (Responsibilities / activities / processes/ methods used)	Outputs (Expected results)
E.g.	General and office administration	25%	<p>Takes, types up and distributes minutes and agendas for monthly departmental meeting.</p> <p>Greets visitors, enquires as to the nature of their visit and directs them to the appropriate staff member.</p>	<p>All staff members receive an electronic copy of accurate minutes and agendas, in the departmental template/format, a week before the meeting.</p> <p>Visitors are directed to appropriate staff member in a professional and efficient manner.</p>
1	<b>Design of data infrastructure in line with research guidelines and regulations</b>	20%	<ul style="list-style-type: none"> <li>Gathers study requirements from investigators and uses protocol to create study case report forms (CRFs).</li> <li>Create a Data Dictionary document that defines the tables, variable names, types and format of data.</li> <li>Create an annotated CRF using data dictionary document and CRF</li> <li>Creates data structures in a relevant database management system and user interfaces using a relevant interface software.</li> <li>Implements security, access control, user identification, and audit trail to make it compliant with international standards.</li> <li>Installs and configures database for use within the study.</li> <li>Reads study protocol and then logically types up a data management plan</li> <li>Studies site norms and requirements to write SOP's for every aspect of data collection, capture, management and monitoring</li> </ul>	<ul style="list-style-type: none"> <li>Data Dictionary document created and distributed to sponsors or collaborators</li> <li>Databases developed and implemented according to protocol and standard guidelines and compliant with FDA 21 CFR Part 11 guidelines.</li> <li>SOP's written for every aspect of data collection, capture, management and monitoring.</li> </ul>
2	<b>Data Management and Quality Control</b>	45%	<ul style="list-style-type: none"> <li>Extracts data from databases and writes computer programs to compare the extracted data to enrolment logs to ensure all enrolments are entered timeously.</li> <li>Writes computer programs to check for overdue expected visits that are not yet entered on the database to ensure that all expected visits are accounted for.</li> <li>Writes computer programs to catch any non-conforming or missing data not identified by the database validation checks and produce a query list.</li> <li>Take databases and back them up to ensure safety in the event of data corruption or system failure.</li> <li>Take and compared 10% of the CRFs to the database entries to ensure that data entry personnel are entering the data correctly</li> </ul>	<ul style="list-style-type: none"> <li>All data entered timeously</li> <li>List of queries including expected overdue visits, incomplete entries, missing entries and invalid entries sent to data entry/clinical research personnel for resolution.</li> <li>Clean, (accurate, complete, and reliability) valid and verifiable data that is ready for analysis</li> </ul>

3	<b>Extraction and preliminary analysis of the data</b>	20%	<ul style="list-style-type: none"> <li>• Receive requests from Investigators and extract specified data</li> <li>• Receive requests from all SATVI students and post-docs and extract the requested data.</li> <li>• Collate and extract study data from a specific database in readiness for interim or final analysis</li> <li>• Write programs to analyze data in conjunction with project statistician</li> </ul>	<ul style="list-style-type: none"> <li>• Datasets that meet the specified criteria sent to investigators</li> <li>• Datasets that meet the specified criteria sent to students and post-docs</li> <li>• Exhaustive final dataset sent to statistician or investigator</li> <li>• Timely preliminary analysis when requested</li> </ul>
4	<b>Training of research teams both internal and external to UCT</b>	15%	<ul style="list-style-type: none"> <li>• Design and implement training for new staff (clinicians and their research teams).</li> <li>• Provide ongoing support and mentoring to new data staff at SATVI as well as collaborating sites.</li> </ul>	<ul style="list-style-type: none"> <li>• New staff trained.</li> <li>• Competent data staff</li> </ul>
5				

### MINIMUM REQUIREMENTS

Minimum qualifications	Basic degree/diploma in computer science/information technology/data science			
Minimum experience (type and years)	At least five years experience working in the health or biomedical or research sector At least five years' experience in data and data quality management At least five years' experience in database management systems At least two years experience and working knowledge of current enabling legislation as related to health and research At least two years experience and working knowledge of Good Clinical Practice and the Protection of Human Participants in Research Management/supervisory experience overseeing data entry staff.			
Skills	In-depth knowledge of database development using REDCap. Demonstrated skill set of any programming language/software for data cleaning. Database management systems – Microsoft SQL Server or Microsoft Access SOP and data management plans development Ability to oversee data collection, entry and cleaning at various levels to ensure accuracy Strong quantitative and analytical skills and ability to communicate technical information clearly and effectively.			
Knowledge	In-depth knowledge of REDCap is required Knowledge of Biostatistics will be advantageous Knowledge of Epidemiology will be advantageous			
Professional registration or license requirements	N/A			
Other requirements (If the position requires the handling of cash or finances, other requirements must include 'Honesty to handle cash or finances'.)	<ul style="list-style-type: none"> <li>• Teamwork and co-operation - The ability to work in a team, foster co-operation between team members and build team spirit. Ability to manage people and co-ordinate their involvement in projects</li> <li>• Innovation, initiative and problem solving – Ability to be innovative by questioning the way things are done and looking for better ways to do things without being asked. Also looking for creative solutions to difficult problems; seek and propose new opportunities to enhance effectiveness</li> <li>• Leadership ability – ability to collaborate with and lead a team, effect appropriate leadership in the attainment of goals and objectives. Ability to express opinions in a constructive and assertive way, but without dominating others. Ability to set goals, share information and encourage feedback</li> <li>• Organizational ability – ability to organize, plan and prioritize work</li> <li>• Decision making ability – ability to get things done, not procrastinate, but make decisions and be flexible</li> <li>• Negotiating ability – ability to influence, negotiate, persuade and motivate</li> <li>• Good interpersonal skills – ability to interact socially and professionally; also interact with people at all levels</li> <li>• Ability to network and form partnerships with various stakeholders</li> <li>• Analytical thinking - Ability to think analytically and independently and aggressively tackle new challenges. Break down complex tasks into manageable parts in a systematic way, ability to see the big picture and control important work through well-developed processes</li> <li>• Delegation – ability to recognize and use unique talents of each team member by delegating responsibility</li> <li>• Display appropriate degrees of autonomy, creativity and flexibility</li> <li>• Self-management – ability to plan and manage time effectively, take personal responsibility for all decisions and actions, maintain appropriate level of technical / professional knowledge and keep skills up to date</li> </ul>			
Competencies (Refer to <a href="#">UCT Competency Framework</a> )	Competence	Level	Competence	Level
	Analytical thinking / Problem solving	2	Decision making and judgement	2
	Individual leadership	2	Research support skills	2
	Professional knowledge and skill	2	Quality commitment/ work standard	2
	Teamwork / collaboration	2	People management	2

### SCOPE OF RESPONSIBILITY

Functions responsible for	Implementation and management of a clinical research data quality management system.
Amount and kind of supervision received	Functions independently with minimal supervision (general line management direction).

Amount and kind of supervision exercised	Direct responsibility for data quality management requirements including external liaison regarding data quality management.
Decisions which can be made	Decisions related to the optimal functioning of the data department regarding data quality.
Decisions which must be referred	Request for additional staffing, request for equipment.

**CONTACTS AND RELATIONSHIPS**

Internal to UCT	Investigators, students, clinical research teams and other data management personnel
External to UCT	External data management personnel, Sponsor data management personnel, Collaborating data management personnel for multi-site trials.