

## PERSONAL DETAILS

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SURNAME : Crawford

NAME : Trisha

RESIDENTIAL AREA : Pretoria

CONTACT NUMBER : 082 875 7575

EMAIL ADDRESS : tcrawford@auruminstitute.org

NATIONALITY : South African

LANGUAGE PROFICIENCY : English & Afrikaans

DRIVERS' LICENCE : Code 08 – Own transport

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# EMPLOYMENT HISTORY

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NAME OF EMPLOYER : Aurum Institute for Health Research

POSITION HELD : Data Management Team Leader

## DUTIES

- Established a Data Management Team for the Thibela TB Project. (Thibela TB is a community wide isoniazid preventatitve therapy amongst South African gold miners. The plan was to recruit **70 000** participants where Aurum would be the site and the sponsor for the trial. Various data collection methods would be used from electronic CRF's to paper CRF's as well as collecting data electronically from external data sources).
- Assisted in designing CRF's.
- Phaseforwards Inform 4.5 Unplugged was chosen as the EDC tool and in collaboration with their Project Manager we developed, designed and implemented the eCRF's, on-line Data Edit checks and reports within our own hosting facilities.
- Developed a functional specification for the participant management system that would be used to operationally manage participants in a SQL database.
- Performed User Acceptance testing on **all** databases and developed user manuals.
- Developed a project plan for setting up and implementing the study centres. This included drawing up site plans, ordering IT equipment, setting up network infrastructure, installing software, testing and site support and maintenance.
- Developed SOP's and Guidelines for all Data Management activities.
- Performed quality control on data collected including processes and procedures for collecting data.
- Designed and implemented operational reports to manage participants throughout the study (38000 participants have to complete 9 months of INH).
- Designed and implemented monitoring reports to validate data and monitor safety requirements.
- Implemented procedures for identifying inconsistencies in data collected and implemented processes for handling them.
- Managed the data collection and entry of data from other sources e.g. Digital Chest X-rays, lab data, paper CRF's for sub studies.
- Set-up back-up and storage procedures for all sites data with our IT service provider.
- Set-up and managed an IT support and maintenance guideline.
- Implemented a training plan and developed all training material.
- Data Management spokesperson for Thibela which included giving presentations at various conferences and acting as references.
- Coordination of all 3<sup>rd</sup> Party Vendors.
- General Team Management: Reviewing workloads, timescales and practicalities, Training plans, Performance contracts and evaluations, Resource optimisation, Coaching and mentoring, Establishing Team objectives.

DATES OF EMPLOYMENT : 28 September 2005 – present

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NAME OF EMPLOYER : **AstraZeneca Pharmaceuticals – Clinical Research - SA**

POSITION HELD : Clinical Data Manager

DUTIES:

- Set up Data Management for a wide variety of Phase III Clinical Trials within various therapeutic areas including Speciality, Respiratory, Cardio-vascular, Central nervous systems and Gastro-intestinal.
- Established a Data Management Team in the Clinical Research department.
- Participated in International Data Management Meetings with the primary Research and Development sites based in Sweden and the UK.
- Set-up and implemented processes and procedures for the DM department based on the Global Standard Operating procedures.
- Presented on data management at National Investigator meetings, Internal meetings and training sessions and International Meetings.
- General Team Management (as above).
- Project planning to ensure that the DM team met incredibly stringent deadlines.
- Participation in Global Data Management Forum's for electronic data capture.
- Training:
  - Primary Trainer for all Data Management Tools for the Clinical Research Department.
  - Trained the Australian marketing company in Data Management Standard Operating Procedures and the MedDRA coding system.
- Managed data entry, verification, validation, reporting and quality control for all studies.

DATES OF EMPLOYMENT : 15 November 1999 – 15 December 2004

REASON FOR LEAVING : Maternity Leave

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NAME OF EMPLOYER : **AstraZeneca Pharmaceuticals – Clinical Research – UK**

POSITION HELD : Temporary Clinical Data Entry Associate

DUTIES

- All data entry work was on a wide variety of phase III studies from start-up to clean file within different therapeutic area's including respiratory, CNS, pain control, anaesthesia and gastro-intestinal.
- From the onset of the study, which included testing the database, editing data entry instructions, creating tracking sheets, reviewing and editing validation checks.
- Logging and tracking of CRF's, data-entry and proofreading, generating queries and running validation checks on the data.
- Maintaining and updating an in-house Clinical Trials Management System.
- Close liaison with CRA's, Clinical Trial Administrators and Data Management personnel both in the UK and Sweden.

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DATES OF EMPLOYMENT : 19 April 1999 – 23 October 1999

NAME OF EMPLOYER : **The South African Optometric Association**

POSITION HELD : Database Administrator

DUTIES :

- Creating and maintaining databases for over 2000 members of the Association.
- Producing all documentation to correspond with the database to ensure efficient and effective data input.
- Creating reports, mail shots and address lists.
- Corresponding with members was vital to ensure that all information on the database was correct.
- Responsible for co-ordinating a Continuing Education Course from Boston.
- General administration that included opening of post, general typing and creating newsletters for various branches.

DATES OF EMPLOYMENT : 1 April 1997 – 30 April 1998

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NAME OF EMPLOYER : **Firebrand CC**

POSITION HELD : Office Administrator

DUTIES :

- Office administration from basic bookkeeping such as salaries, creditors and debtor's payments and bank reconciliation's to general typing.
- Organising all company functions, dealing with all correspondence and banking.
- Dealing with high security projects that involved compiling tenders and drawing up contracts

DATES OF EMPLOYMENT : 1 March 1996 – 30 March 1997

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NAME OF EMPLOYER : **Kool Aluminium**

POSITION HELD : Commercial Sales Consultant

DATES OF EMPLOYMENT : 1 October 1994 – 31 August 1995

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# EDUCATION & QUALIFICATIONS

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## SECONDARY EDUCATION

NAME OF LAST SCHOOL : The Glen High School, Pretoria  
HIGHEST STANDARD ATTAINED : **Matric**  
YEAR : 1991

## TERTIARY EDUCATION

Name of Institution : Damelin College, Pretoria.  
Course : Public Relations and Business  
Communications Diploma  
Year : 1993

## IN-HOUSE TRAINING

- Querying SQL 2005
- Principles of Project Management
- Phaseforwards Inform 4.5 Train the Trainer and Reporting.
- Microsoft Word, Excel (Advanced), Access and PowerPoint.
- Microsoft Outlook
- Presentation skills course – Voice Clinic
- Global Effective *Train the Trainer* Course
- Pacific Institute – Investment in Excellence
- The Foundation for Professional Development – Tomorrow's leaders program
- MedDRA Train the Trainer
- Astrazeneca In-house data management system using Oracle and SAS.

## BUSINESS REFERENCES

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<b>PERSON</b>	<b>COMPANY</b>	<b>POSITION</b>	<b>TEL NO.</b>
Leonie Coetzee	Aurum Institute for Health Research	Program Director	(012) 643-1103
Raymond Scanlon	AstraZeneca Clinical Research Department	Clinical Operations Manager	(011) 797-6000
Adri van Eeden	South African Optometric	Clinical Operations Manager	(012) 322-1310