Resume - Lindsay Stevens

2017-06-05

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Contact Details

- Name: Lindsay Stevens
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- GitHub: https://github.com/lindsay-stevens

Summary

I am a clinical trials data management (CTDM) specialist. I have 9 years' experience, spanning the trial data lifecycle:

- developing CTDM plans, policies and systems that comply with regulatory requirements and guidelines

- building and maintaining CTDM systems to collect, collate, manage, and clean study data
- extraction, linkage, reporting, analysis, and governance of clinical and operational study data

In addition, I have a strong technical skills with applications programming, analytics and visualisation tools, IT system administration, and security standards. This experience spans a range of modern computing environments, including cloud / virtual servers, desktop PCs, and mobile tablets and phones.

I aim to promote adoption of best practice CTDM through the delivery of pragmatic, high quality, and compliant solutions that enable users to efficiently meet their objectives. My broad range of experience facilitates effective engagement with diverse stakeholders to ensure that both the technical and functional aspects of these solutions are optimised.

Skills

Clinical Trials Data Management

I am familiar with the following compliance aspects of trials:

- Ethics and regulatory requirements including the TGA guidance on ICH GCP, the NHMRC National Statement, and Australian Privacy Principles
- Standard regulatory forms including NEAF, SSA, CTN, and CIOMS SAE reports
- Essential documents preparation from start-up to close-out in Australian and international trials in collaboration with hospitals, academic institutions, CROs, and pharmaceutical companies
- Project management, site initiations, and delivering training for protocols and data systems
- Design and implementation of data management plans, validation rules, interim analysis cleaning and centralised monitoring of key source documents
- Development of documentation, procedures and operational frameworks for data systems development, data management workflows and data governance

I am familiar with the following off-the-shelf data systems useful for trials:

- Systems collecting and managing clinical trial data: OpenClinica, InForm, RedCap, ClinTrial
- Survey tools: ODK Collect, Enketo, LimeSurvey, SurveyMonkey
- Others:
  - TeleForm: an Optical Character Recognition tool for digitising paper form data
  - LabKey: a system for laboratory sample management and annotation

Technical

I am familiar with the following technologies.

- Programming languages:
  - Advanced: SQL, PL/PGSQL, Python, Stata, VBA/VBScript, and XSLT
  - Intermediate: PHP, JavaScript, SAS, Powershell/CMD, R, Java, and C#
- Environments:
  - Advanced: Windows, Windows Server, Android 4.4 and up

  - Intermediate: Ubuntu, Docker, Google Suite for Education
- Other (Advanced): Microsoft Access, Microsoft Excel
- Servers:
  - Advanced: PostgreSQL 8.4 and up
  - Intermediate: Microsoft SQL Server 2012, Apache 2.4, Tomcat 6 and up, Nginx, CherryPy
- Development tools: Git, Intellij IDEA, Notepad++, Trello, TFS, SSMS, RStudio

My GitHub profile (see Contact Details) contains examples of projects where permission was given to share the code.

Projects

The following are projects where the above skills were employed.

Mobile Data Collection

I designed and implemented a mobile data collection framework that improved quality and completeness of participant questionnaire data for 5 projects conducted by the VHCRP team at the Kirby Institute.

The framework covered all aspects - policies for device procurement, configuration, management, account management and security; tools for form design, validation, multi-language capable presentation customisation; procedures for data collection, submission, and storage; tools for ETL of collected data for analysis in Stata.

The deployment included 83 Android tablets for offline data collection at study sites, including hospitals, clinics and prisons in Australia and internationally, with thousands of responses from hundreds of participants had been collected and processed. At the centre of the framework was ODK Collect, an Android app for processing XML-based form definitions. Design and data processing tools included custom distributable desktop apps written in Python.

OpenClinica Community DataMart

I designed and implemented an ETL and reporting system that streamlined reporting and analysis workflows for 13 projects conducted by the VHCRP team at the Kirby Institute.

This system replaced a time-intensive process with numerous manual steps, with a robust, automated process that integrated with existing reporting and analysis tools while maintaining a high level of security and ease of use.

This system was implemented with PostgreSQL using SQL, PL/PGSQL, and Python. The ETL system involved transforming a column-based data storage format into user-friendly tables corresponding to the original form design templates uploaded to OpenClinica.

The deployment included encrypted connections between database servers and with client machines, data access controls mirroring those in OpenClinica, and integrated Windows domain authentication. Client tools were also developed to integrate via ODBC with Stata, SAS and Microsoft Access; as well as automated VBScript tools to simplify setup for new users. The preparation of detailed documentation and delivery of targeted training encouraged adoption of the system across the team.

System Integrations

I designed and implemented the following system integrations for the VHCRP team at the Kirby Institute:

- An automated daily transfer of hepatitis C test results from a LabKey sample management database to the clinical database in OpenClinica. Written in Python, and included development of a re-usable library for interacting with OpenClinica's SOAP XML webservices.
- A promotional website for a study with a custom styled LimeSurvey instance for web-based data collection from study participants. Written in Python and JavaScript and included development of a re-usable library for interacting with LimeSurvey's REST JSON webservices.
- An automated integration test suite for the above custom LimeSurvey template to ensure that these elements worked as expected across common browsers. Written in Python using Selenium WebDrivers for Firefox, Chrome and Internet Explorer.

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Employment

Cancer Institute NSW: Systems Analyst / Architect

- Department: Strategic Research and Investment (SRI) Division, Data Intelligence Team
- Reporting to: Data Intelligence Manager
- Duration: 2017-03 to present (3 months)

Key Responsibilities

- System support and vendor management for SRI data systems, including the Clinical Trials portal and Grants Management System
- Identify and oversee or implement system enhancements, changes or upgrades to SRI data systems
- Implement tools and processes for reporting to meet diverse stakeholder requirements, leveraging appropriate tools such as SQL, R, Qlik, or Business Objects

OpenClinica LLC: Solutions Engineer

- Department: Product and Service Development / Customer Support
- Reporting to: OpenClinica CEO
- Duration: 2017-01 to 2017-03 (3 months)

Key Responsibilities

- Prototype an new, enhanced ETL and self-serve capable reporting and analytics solution

UNSW Australia: Clinical Trials Database Developer

- Department: Kirby Institute, Viral Hepatitis C Research Program (VHCRP)
- Reporting To: VHCRP Clinical Trials Manager
- Duration: 2013-06 to 2016-12 (3 years 6 months)

Key Responsibilities

- System support for VHCRP data systems, including OpenClinica and mobile data collection
- Implement data collection and validation systems for projects from the VHCRP
- Implement tools and processes for reporting, mobile device preparation and management

Achievements

- Major projects described above at Skills > Projects
- Implemented OpenClinica systems for:
  - NCT02102451 (CEASE): surveillance of hepatitis C treatment
  - NCT02064049 (SToP-C): phase 4 hepatitis C
  - Healthy Liver Campaign (LiverLife): Liver health promotion among injecting drug users
  - NCT01364090 (ACTIVATE): phase 4 hepatitis C
  - NCT01336010 (ATAHC II): phase 4 hepatitis C
  - NCT01743521 (DARE-C): phase 4 hepatitis C
  - NCT02156570 (DARE-C II): phase 4 hepatitis C
- Implemented ODK Collect systems for:
  - LiverLife (as above)
  - SToP-C (as above)
  - NCT02336139 (SIMPLIFY): phase 2 hepatitis C
- Implemented a LimeSurvey survey for CEASE (as above)

University of Sydney: Clinical Data Coordinator

- Department: NHMRC Clinical Trials Centre (CTC), Data Management
- Reporting To: Head of Data Management
- Duration: 2012-05 to 2013-06 (1 year 1 month)

Key Responsibilities

- Implement data collection and validation systems for projects from the CTC
- Train project staff in data management with OpenClinica and TeleForm
- User management and system support

Achievements

- Implemented OpenClinica systems for:
  - ACTRN12611000378921 (SEED): quality of life study for brain cancer
  - ACTRN12610000796088 (PARAGON): phase 2, gynaecological cancer
- Implemented TeleForm Optical Character Recognition systems for:
  - ACTRN12610000796088 (PARAGON): phase 2, gynaecological cancer
  - ACTRN12605000055606 (BOOST II): phase 3, neonatal health

University of Sydney: Trial Coordinator / Data Manager

- Department: NHMRC Clinical Trials Centre (CTC), Oncology Trials Program
- Reporting To: Associate Oncology Program Manager
- Duration: 2010-07 to 2012-05 (1 year 10 months)

Key Responsibilities

- Study start-up phase: conduct feasibility surveys, vendor selection, write study documentation, ethics and regulatory applications, data systems specifications;
- Study conduct phase: collect, distribute and track GCP Essential Documents; data collection, entry, and validation; safety and project progress reporting; coordinate pathology sample collection;
- Study closure phase: finalise GCP Essential Documents, data cleaning, and distribute final reports;

Achievements

- Worked on:
  - ACTRN12611000245998 (TACTIC): phase 2, biliary tract cancer
  - ACTRN12609000158268 (LAP07): phase 3, pancreatic cancer
  - ACTRN12609000109202 (ATTAX3): phase 2, oesophago-gastric cancer
  - ACTRN12605000361606 (ESPAC-3): phase 3, pancreatic cancer
  - ACTRN12608000382370 (DECO): phase 2 oesophageal cancer
- Prepared specifications for a clinical trials management system for the centre

University of Sydney: Clinical Trials Assistant / Data Manager

- Department: NHMRC Clinical Trials Centre, Oncology Trials Program
- Reporting To: Associate Oncology Program Manager
- Duration: 2008-07 to 2010-07 (2 years)

Key Responsibilities

- Obtain, file and track GCP Essential Documents
- Quality of Life questionnaire data entry
- Assist the study coordination team

Achievements

- Worked on:
  - ACTRN12605000025639 (MAX): phase 2/3, colorectal cancer
  - ACTRN12605000359639 (DaVINCI): phase 2, colorectal cancer
  - ACTRN12607000294459 (Accelerated BEP): phase 1/2, germ cell cancer
  - ACTRN12608000254392 (Aprepitant): phase 2, germ cell cancer
  - ACTRN12609000545268 (Chemo and Cog): quality of life study for testicular cancer

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Education

Master of Biostatistics

- Institution: Macquarie University
- Graduation: 2020 (Planned)
- Grade: TBA

Subjects

- 2014 Data Management and Statistical Computing (Mark 90)
- 2015 Probability and Distribution Theory (Mark 75)
- 2015 Principles of Statistical Inference (Mark 62)
- 2016 Linear Models (Mark 86)
- 2017 Survival Analysis (Mark TBA)

Bachelor of Science

- Institution: Macquarie University
- Graduation: 2010
- Grade: GPA 3.5/4.0

Subjects

- Anatomy (Clinical Anatomy and Introductory Histology)
- Physiology (Physiology, Introductory Pathology)
- Basic Sciences (Introductory Chemistry, Physics and Math)
- Public Health (Introductory Statistics, Epidemiology and Research Methods)

Short Courses

- 2014 (MedDRA MSSO): MedDRA Safety Data Analysis and SMQs
- 2011 (Sydney Learning): Communication, Negotiation and Team Skills
- 2010 (University of Sydney): Controlled Clinical Trials - PUBH5206

Presentations

- OpenClinica Conference, Boston US: 2016-10
  - Community DataMart ETL project
  - Tablet Data Collection: deploying Android tablets and ODK Collect
- Sydney Python User Group Meetup: 2015-09
  - PostgreSQL query optimisation and PL/Python
- OpenClinica Conference, Amsterdam NL: 2015-06
  - Community DataMart ETL project
  - Interactive demonstration session of data management tools and scripting

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