Resume - Lindsay Stevens

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Contact Details

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

Skills

I have 8.5 years' experience in academic clinical trials and health research. I have developed strong skills in two main areas:

- Software application development
- Clinical trial data and project management

Software Application Development

An overview of my skills and experience in this area is below, followed by descriptions of some example projects (most of which are on GitHub):

- Programming languages:

- – Advanced: SQL, PL/PGSQL (PostgreSQL procedural language), Python, Visual Basic and XSLT
  - – Intermediate: JavaScript, PHP, Stata, SAS, Powershell/CMD and Java
- Environments:
  - – Advanced: Windows 7, Windows Server 2008, Android 4.4 to 6
  - – Intermediate: Ubuntu Server 14, Docker, Google Suite for Education
- Servers: PostgreSQL 8.4 to 9.6, Apache 2.4, Tomcat 6 to 7
- Development: Git, Intellij IDEA, Notepad++

Community DataMart

DataMart is a reporting tool implemented PostgreSQL using SQL, PL/PGSQL, and Python. Study definition metadata is read from an OpenClinica database and used to prepare tabulated data in a user-friendly format.

The deployment includes encrypted connections between servers and clients, strong access controls, and Windows domain integrated authentication. Client tools included for integration via ODBC with Stata, SAS and Microsoft Access.

This is used by many OpenClinica users as a key part of their data management processes, as well as integration with other data sources or reporting tools.

ODK Tools and Deployment

The ODK Tools application is a build tool implemented in Python. It provides a simple user interface for form designers to run scripts that convert Excel-based form definitions to XML, validate the XML, produce images for each form question in each specified language, and prepare a deployment package for each participating site.

This is used as part of a deployment of 83 (and growing) Android tablets for offline data collection at research study sites, including hospitals, clinics and prisons in Australia and internationally. I was reponsible for planning device configuration and management processes, and preparing training materials for end users.

Python Web Projects

A collection of smaller projects related to the web:

- Webservice clients OpenClinica's SOAP XML webservices, and LimeSurvey's REST JSON webservices
- Integration between LabKey's REST JSON webservice and OpenClinica to map and import daily hepatitis C test results
- A study promotional site using Django. Deployed on Windows as a service using CherryPy and pywin32, behind an Apache httpd reverse proxy
- A functional test suite for a custom, Bootstrap-themed LimeSurvey template using Selenium. Validated cross-browser behaviour of JavaScript shims and monkey-patches

Clinical Trial Data and Project Management

An overview of my skills and experience in this area is below. Project names and registry identifiers are detailed under the relevant role in the Employment section.

- Experience in building data systems with:

- OpenClinica: a web based tool for managing clinical trial data collection and cleaning
- ODK Collect: an Android app for data collection
- TeleForm: an Optical Character Recognition tool for digitising paper form data
- LimeSurvey: a web based questionnaire collection tool
- Coordination experience:
  - Compliance with ethics and regulatory requirements including the TGA guidance on ICH GCP, the NHMRC National Statement, and Australian Privacy Principles
  - Completion of standard forms including NEAF, SSA, CTN, and CIOMS SAE reports
  - Australia-wide and international clinical trials collaborating with hospitals, clinics, academic institutions, CROs, and pharmaceutical companies
  - Project management, staff training and collaboration with healthcare and research professionals

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Employment

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

Responsibilities:

- Implement data collection and validation systems for projects from the VHCRP
- Implement tools for reporting, systems preparation and asset management
- User management and system support

Achievements:

- Implemented OpenClinica systems for:
  - NCT02102451 (CEASE): surveillance of hepatitis C treatment
  - NCT02064049 (SToP-C): phase 4 hepatitis C
  - http://kirby.unsw.edu.au/projects/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: 1 year 1 month, 2012-05 to 2013-06

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: 1 year 10 months, 2010-07 to 2012-05

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: 2 years, 2008-07 to 2010-07

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:

- Data Management and Statistical Computing (Mark 90)
- Probability and Distribution Theory (Mark 75)
- Principles of Statistical Inference (Mark 62)
- Linear Models (Mark 86)

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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