Helen Phillips

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Who am I?

I am clinical trial professional with nearly 20 years of experience across clinical monitoring, clinical project management, clinical data management, and clinical database development in operational and line management roles both in the UK and Australia.

Over the last 9 years, I have developed more than 50 clinical study databases across a myriad of indications in a clinical programmer role. The study databases incorporated many different designs (SAD, MAD, Food Effect, Cross-Over, PK, Vaccines).

I am a certified designer in several EDC platforms including Rave EDC, Merative Zelta (formerly IBM Clinical Development), Viedoc and Medrio and I have conducted and supervised many mid-study updates/migrations and designed/implemented additional modules such as RTSM, Coder, ePRO. I have close links to the EDC vendors and have acted in an advisory role over the past few years offering product improvement suggestions and beta testing new features. I have also designed and maintained CDISC compliant CRF libraries across different EDC platforms.

As a Line Manager, I trained and managed a team of five clinical programmers including performance reviews, resourcing and utilization, ongoing training as well as contributing to departmental monthly project forecasting and financial performance.

What can I offer?

Undertaking	Overseeing
Certified designer in: Medidata Rave, Merative Zelta (formerly IBM CD), Medrio and Viedoc including RTSM, ePRO and E-Source modules.	General Data Management Consultation
Design / review / maintain CDASH compliant CRFs/Databases/E-Source templates	CDISC
Edit check programming	CRF and Database design advice
Mid-study migrations	Data Collection Methods
Database specifications/edit check specifications	Data Management / EDC Vendor Management
UAT and data cleaning	EDC platform options

Education & Qualifications

MSc in Social Science Research Methods, Cardiff University, UK (Sept 2003 – Sept 2004)

BSc (First Class Honors) in Applied Psychology, Sept 2001, Cardiff University, UK (Sept 1997 – July 2001)

Employment History

Owner & Principal Consultant *May 2022 – current*
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As a sole trader I am available as a "gun to hire". I have worked with small, medium and large CROs in Australia and New Zealand as well as the UK and USA. I have also worked directly with the small Australian Biotechs offering Data Management expertise. Contracts have included:

- Designing and building CDISC compliant libraries for Australian based CROs and Research Institutes– this offers them the chance of standardization and subsequent downstream efficiencies, reducing the overall build times (including edit checks)
- Designing and building therapeutic area specific CDISC compliant libraries (including edit checks) including oncology libraries (RECIST, Lugano, PCWG3, iRANO assessments)
- Acting as an Australian resource for R&D Tax sensitive clients (including DB build and general DM activities)
- SOP review and development for research institutes and CROs.
- SDTM conversion using SDTM conversion software
- Participate in Client meetings and Bid Defence meetings
- Vendor selection
- Developing general data management documentation (data management plans, lab data transfer agreements, eCRF guidelines)
- Protocol review from DM perspective
- Acting as therapeutic area SME

Data Team Manager *Nov 2020 – Feb 2022*
Avance Clinical Pty Ltd

Responsibilities as below but in the role of Data Team Manager I was also responsible for:

- Resourcing the Clinical Programming team
- Training new members of the Clinical Programming team on all aspects of the EDC platforms (ePRO, Randomisation and Trial Supply, E-source)
- Conducting CDISC training
- Writing and reviewing SOPs and re-designing the associated templates
- Providing justification to the SMT regarding resource expenditure
- Monitor projects against milestones and budget
- Conduct weekly meetings with the team and co-host larger departmental meetings
- Run induction sessions for new recruits
- Designed and facilitated the Junior Clinical Data Associate development program
- Participate in Client meetings and Audits
- Reviewing protocols for Medical Writing

Senior Clinical Programmer *May 2020 – Nov 2020*
Avance Clinical Pty Ltd

As below but this role included Medrio certification in EDC and the additional modules including Randomisation and ePRO. It also included a larger element of site and vendor training in those additional modules.
During this job I developed closer inks with IBM and along with an IBM Client Success Manager I helped put forward ideas for product improvement and feature requests.

Clinical Programmer / Senior Clinical Programmer *June 2016 – May 2020*
Clinical Network Services Pty Ltd/Novotech

- Designing and Maintaining Databases
- Designing eCRFs in Medidata Rave, IBM Clinical Development, Viedoc as per CDASH standards
- Programming edit checks into the system
- Conduct online Screen Review Meetings with clients, PMs, CRAs.
- Train DMs on eCRF /Database use and expectations
- Design eCRF specifications for other clinical programmers
- Follow company SOPs on database design, maintenance and close out
- Contribute to new company SOPs as per company need
- Act as database administrator for duration of study
- Conduct mid study updates/migrations as required
- Setting up additional modules as required (IWRS, Trial Supply Management, epRO, Coding, Smart Reports)

As a Senior Clinical Programmer I was involved with more training of junior clinical programmers and data managers. I also acted as the CDASH Subject Matter Expert. I designed and maintained CDASH compliant eCRF libraries in Medidata Rave, IBM and Viedoc.

Data Manager *August 2015– June 2016*
Clinical Network Services Pty Ltd

- Designing Databases with external vendors (Medidata Rave, Data Labs)
- Providing eCRF specifications to external vendors
- Training sites on crf completion
- Reviewing and cleaning data
- Handling external data (PK, PD, PCR, Safety data)
- Writing Lab Data Transfer Agreements
- Performing UAT
- Writing and testing edit checks
- Writing eCRF completion guidelines

CRA/*Senior CRA* *April 2010– August 2015*
Clinical Network Services Pty Ltd

Working as a CRA in a small, boutique CRO specializing in running early phase trials involves the following duties:

- Conducting site visits to assess for site capability (SSVs), to train site staff on protocol procedures (SIVs) and to assess protocol and regulatory compliance and manage required documentation (Monitoring visits) and closing out sites at trial completion (COVs)
- Ensuring the quality of data

- Maintain productive and collaborative relationships with both the client and the sites to ensure recruitment targets are met, data is clean and accurate and trial issues are resolved in a timely manner.
- Monitoring drug accountability
- Representing Clinical Network Services within the medical research community at conferences as well as at regular site visits.
- Coordinating site's HREC submissions and Amendments
- Writing and/or reviewing Patient Information Sheets
- Conducting in-house file reviews as well as reviewing site documentation
- Amending SOPs.
- Reporting SAEs and SUSARs according to TGA regulations

As a Senior CRA I also took on more of a leading role in trials and oversaw the duties of the more junior CRAs. I worked closely with Project Managers to discuss the CRAs current and predicted resourcing to help plan ahead.

Therapeutic Area Experience

Oncology: Solid tumours (including prostate, breast, colorectal, GBM, small cell lung cancer, non small cell lung cancer, melanoma, cancer pain, vulval intraepithelial neoplasia, lymphoma)
Dermatology: Psoriasis, Atopic dermatitis
CNS: Motor Neurone Disease, Parkinson's Disease, Huntingtons, Stroke
Endocrinology: Diabetes (Type I and II)
Infectious Diseases: Hepatitis C, malaria, RSV, influenza, COVID-19
Inflammation: Rheumatoid arthritis
Respiratory: COPD, pulmonary arterial hypertension, sinusitis
Opthalmology: Macular degeneration
Phase I Healthy volunteers/patient: FIH, PK, PD, SAD, MAD, Food Effect, bioavailability, bioequivalence, vaccine, slow-release, patient cohorts, DDI
Phases/stages: I,II, III, proof of concept
Patient populations: Adult, geriatric, ICU, neonatal

Certifications and Training

EDC Systems (Designer)

- Medidata (Rave EDC, RTSM, Coder, Configurator, Reporter)
- Merative Zelta (formeraly eClinical OS and IBM Clinical Development) (EDC, Coder, ePRO, Randomisation, Reporter) EDC1 and EDC2
- Medrio (EDC, Randomisation, ePRO, Reporter, Coder)
- Viedoc (EDC, Reporter, Coder, ePRO)

EDC Systems (Front end user)

- Medidata (Rave EDC, RTSM, Coder, Configurator, Reporter)
- IBM Clinical Development (EDC, Coder, ePRO, Randomisation, Reporter)
- Medrio (EDC, Randomisation, ePRO, Reporter, Coder)
- Viedoc (EDC, Reporter, Coder)
- Datalabs
- Oracle Clinical
- OpenClinica
- Castor
- RedCap
- Veeva

International Data Standards (FDA endorsed)

- CDISC Standards
- CDASH Implementation
- SDTM Theory and Application

Other

- ICH GCP