

OUTCOMES OF WORK SUPPORTED BY THE DATA MANAGEMENT UNIT

Our data management expertise has helped support researchers and other professionals in a wide variety of settings and study types including:

- Investigator initiated studies—e.g. SAFETY randomised controlled trial
- Pharmaceutical industry sponsored trials—e.g. VIPER-BP
- Data mining projects using large amounts of records—e.g. Pressure Points in Primary Care

This support has been integral to the publication of high profile papers in well respected academic journals.



Stewart S, Carrington MJ, Swemmer CH, et al. Effect of intensive structured care on individual blood pressure targets in primary care: multicentre randomised controlled trial. *BMJ* 2012; 345: e7156.

Stewart S, Ball J, Horowitz JD, et al. Standard versus atrial fibrillation-specific management strategy (SAFETY) to reduce recurrent admission and prolong survival: pragmatic, multicentre, randomised controlled trial. *Lancet* 2014. Carrington MJ, Jennings GL, Stewart S. Pressure points in primary care: blood pressure and management of hypertension in 532 050 patients from 2005 to 2010. *J Hypertens* 2013; 31(6): 1265-71.

DATA SECURITY AND CONFIDENTIALITY

You can be assured that the security and confidentiality for the access, retrieval and storage of your data and information will be maintained. All electronic files will be saved in a dedicated space on the network that is accessible only by authorised personnel. Paper documents and source records will be filed in a locked compactus within a secure area controlled by proxy access to authorised personnel.

Electronic data is in a secure server storage system housed at the University's Data Centre located off campus. All data is replicated in real time across the network to the University's Disaster Recovery Data Centre. All data is archived daily on to tape and stored off site at an accredited vault. "Snapshot" technology is used to minimise the accidental deletion of data via keeping multiple copies of data for one month, which are stored in situ on the University's Storage System.

The University's Data Centre is protected via a number of network firewalls which are supplemented by server based firewalls and access permissions. Server and desktop based anti-virus software is in place to minimise the corruption of data.

The University has a certified and accredited IT Security Manager who oversees all IT security for the University.

CONTACT US

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**Mary MacKillop Institute
for Health Research**



**DATA MANAGEMENT UNIT
LOCATED AT THE MARY MACKILLOP
INSTITUTE FOR HEALTH RESEARCH**

Providing professional assistance with the management of the data life cycle to develop databases and execute practices that effectively enhance the usefulness and quality of data and information.

The Data Management Unit will provide all your projects and initiatives with clean, high quality data. Good quality data is an essential characteristic that underlies the reliability of data for research and decision making.

We offer a personal, customised service to suit your requirements. We will discuss your project with you and provide expert advice and guidance with tailored solutions for all study design or activity needs.

Our support encompasses professional document development for effortless data capture and extends to building self-contained databases for users or more sophisticated ones operated by the Data Management Unit. Our higher level assistance includes an array of efficient data processing and verification, data review and correction cycles and data exports for analysis and reporting.

As your data is our highest priority, you will be provided with a Lead Data Manager who will be your point of contact to co-ordinate and oversee all aspects of your data management requirements from study start-up to database closure.

OUR DATA MANAGEMENT SERVICES

Data Governance

- Standard Operating Procedures outline our processes and methods to handle data

Data Document Design

- User friendly questionnaire or survey design in paper or electronic capture format
- Data dictionary compilation
- Periodic report production from subsets of data
- Data Management Plan creation

Database Development

- Database build in two formats:
 - ClinPlus®: administered by the specialist Data Management Unit
 - Microsoft Access: easy-to-use operation by user
- Randomisation schedules by telephone or computer assignment (blinded, stratified, single/multi-site or individual/clustered randomised controlled trials)
- Participant/patient follow up alerts and reminders
- Data processing with range checks on variables

Data Quality Management

- Quality assurance and data query generation to detect inconsistencies and anomalous data
- Data cleansing to correct inaccurate data
- Full audit trail to promote data integrity
- Double data entry to ensure low error rates

Data Programming and Intelligence

- Data mining to explore relationships between variables
- Data extraction and integration via SAS programming

Clinical Trials Data Management (Phase I - IV)

- Compliant with ICH GCP and industry standards
- Clinical signs, symptoms and drug coding (MedDRA, WHO Drug, ICD-10)
- Adverse Event and Serious Adverse Event reconciliation



OUR RESOURCES

Our staff have over 20 years experience gained from work in world-renowned research institutes and clinical trial organisations. They possess knowledge of standards for superior quality data management and have the skill to execute practices that consistently enhance data quality and information. Our high performing team are able to meet tight deadlines efficiently and within budget.

The Data Management Unit, led by the General Manager, includes professionals trained in research design and methodology, data programmers, database architects, clinical trial specialists and experienced data technicians.

All members of the team are trained in Good Clinical Practices and comply with the principles of this as well as other regulatory requirements and legislation.

We use ClinPlus® Data Management software to support projects across multiple fields of research and to collect quality data. This trusted and powerful system provides flexibility to build unique and complex databases as well as simple ones. ClinPlus® is a tool with the all-round functionality to capture, manage and report data and provide accurate information to investigators for further analyses.

