Position Description

Position Title	Data Manager
Position Number	30006248
Division	Clinical Operations
Department	Clinical Trials
Enterprise Agreement	Allied Health Professionals (Victorian Public Sector) (Single Interest Employers) Enterprise Agreement 2021-2026
Classification Description	Health Information Manager
Classification Code	JA7-JB1
Reports to	Manager Cancer Research
Management Level	Non Management
Staff Capability Statement	Please click here for a link to staff capabilities statement
Mandatory Requirements	• National Police Record Check • Immunisation Requirements

Bendigo Health

Bendigo Health is a leading regional health service, learn more about us by visiting our website: Bendigo Health Website - About Bendigo Health

Our organisation is a child safe organisation, committed to the safety and wellbeing of all children and young people. All Aboriginal and Torres Strait Islander adults, children and families will be supported to express and be proud of their culture in an environment that is culturally safe and supported.

Our Vision

Excellent Care. Every Person. Every Time.

Our Values

CARING – We care for our community,

PASSIONATE – We are passionate about doing our best,

TRUSTWORTHY - We are open, honest and respectful

The Position

The Data Manager is responsible for the comprehensive data management of investigator-initiated trials led by Bendigo Health Cancer Centre, ensuring the integrity, quality, and compliance of all clinical research data. The role also includes responsibility for reporting clinical trial metrics to support operational decision-making and performance monitoring.

Responsibilities and Accountabilities

Key Responsibilities

Data Management

- Compile clinical trial performance metrics for both internal and external stakeholders
- Prepare Bendigo Health clinical data for routine external audits
- Ensure patient confidentiality is maintained at all times
- Collection of patient data from medical, departmental and electronic records and other
- primary source documents for clinical trials and registry trials
- Entry of data into Case Report Forms (both paper and electronic) utilising source
- documents

Support the development and conduct of investigator-initiated trial

- Development of the Data Management Plan and any other SOPs or guidelines to ensure data management activities are in accordance with Good Clinical Practice (GCP) and any other applicable regulations or local requirements
- Coordinate the design, build, test and validation of the Case Report Form (CRF) or clinical database
- Coordinate process for integrating other systems for Electronic Data Capture (EDC)
- Develop CRF Completion Guidelines for participating sites
- Assign database user permissions in accordance with PI approval
- Enter data from paper CRFs into database
- Perform data cleaning, resolve data queries
- Generate datasets for interim analysis (if applicable) or reporting and final analysis (after database lock)
- Archive trial data at end of trial

Clinical Trials Coordination

Trial coordination of assigned research projects, and may coordinate more than one trial contemporaneously

- Ensures the conduct of the research study is in accordance with TGA ICH GCP, the NHMRC National Statement on Ethical Conduct in Research Involving Humans; state and federal regulations; Ethics Committee approval and Bendigo Health Governance approval; and hospital policy. Assists with screening and recruiting of clinical trial participants into clinical trials
- Assists with recruitment strategies within the team to optimise recruitment
- Organises relevant outpatient clinic appointments and completes all protocol dictated patient assessments as per the clinical trial protocol
- Coordinates the delivery of direct and indirect clinical-trial-related care of patients
- Obtains and documents all required clinical trial data information into required data collection systems (paper /electronic / online web-based databases) with high attention to detail
- Timely maintenance (resolution of data queries etc) of relevant clinical trial electronic databases
- Performs safe handling, storage, processing and postage of Clinical trial protocol required blood / body samples, in accordance with relevant Hospital and relevant research project guidelines
- Maintains current knowledge of clinical practice and research in oncology
- Performs their research-related duties in accordance with Good Clinical Practice (GCP).
- Establishes a positive and constructive working relationship both internally and externally within the work environment
- Develops and maintain relationships with external sponsors and vendors.

Undertaking work activities relevant to the role's key accountabilities as approved by the Clinical Program Lead and commensurate to the role's classification level (e.g., site closure activities). Any other duties as required in accordance with the classification of the position.

Key Selection Criteria

Essential

1. Relevant tertiary qualification with substantial relevant professional experience
2. Experience in clinical trial coordination and data management
3. Experience in the use of Electronic Data Capture Software such as REDCap, including data validation and cleaning, building databases and data extractions (reports/queries)
4. Highly developed organisational skills and proven ability to establish priorities, manage tasks, exercise sound judgement and work to multiple, tight and conflicting deadlines
5. Knowledge of Good Clinical Practice (GCP) guidelines and regulatory requirements
6. Excellent verbal communication skills, including the ability to explain technical concepts
7. Demonstrated ability to meet deadlines without compromising close attention to detail and accuracy

Generic Responsibilities

All Bendigo Health staff are required to:

- Adhere to the **Victorian Government's Code of Conduct**
- Uphold **Occupational Health and Safety** responsibilities, including self-care, safeguarding others, and participating in safety initiatives and reporting.
- Comply with all **Bendigo Health policies and procedures**, including those related to clinical, managerial, and standard work practices.
- Follow **Infection Control** procedures to prevent cross-contamination and ensure the health and safety of all.
- Maintain **strict confidentiality** regarding all organisational, patient, and staff information.
- Engage in **continuous quality improvement** activities aligned with the National Safety and Quality Health Service Standards (NSQHSS).
- Recognise and respect **diversity**, fostering inclusive practices in the workplace and service delivery.
- Staff must carry out all lawful and reasonable directions and comply with relevant professional standards and ethical codes.
- Safeguard children and young people in our care, by ensuring that your interactions are positive and safe, and report any suspicions or concerns of abuse by any person internal or external to Bendigo Health.
- Maintain ability to perform the inherent requirements of this role. Inherent requirements are the essential tasks necessary to perform this role, including reasonable adjustments. Bendigo Health is committed to a safe workplace that supports all employees. The role may require specific physical and cognitive abilities, which can be discussed with the manager during recruitment or at any time. We understand that personal circumstances can change and impact your ability to meet these requirements; additional policies are available to guide you through this process. Please request the relevant procedures for more information.

All Bendigo Health sites, workplaces and vehicles are smoke free.

This position description is intended to describe the general nature and level of work that is to be performed by the person appointed to the role. It is not intended to be an exhaustive list of all responsibilities, duties and skills required. Any elements of this document may be changed at Bendigo Health's discretion and activities may be added, removed or amended at any time.