

CLINICAL TRIALS PLATFORM



A Resource Centre for Clinical Trial Excellence

Provides expertise, end-to-end support and services for clinical trials



CLINICAL TRIALS PLATFORM



Expertise in trial design, methodology and management



COMPLIANCE

Adhere to quality standards and regulatory requirements.



AVAILABLE TO

All academic, clinical, industry and government researchers.



CONTACT US

CTP@latrobe.edu.au
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TRIAL INITIATION

- Trial design and protocol development
- Grant development, budgeting
- Health economic impact analysis planning
- Trial set up, including facilitating agreement and registration
- Ethics and governance support, including advice on ethics submissions, indemnity and insurance
- Support with hybrid and adaptive trial design implementation



PROJECT MANAGEMENT

- Set up and review of Investigator Site File (ISF)
- Participant recruitment and selection
- Consumer advisory group engagement and management
- Safety and compliance monitoring and reporting
- Corrective and Preventive Actions (CAPA) implementation
- Preparation for audits and regulatory inspections
- Promoting trials, hosting events and study meetings
- Trial close-out and archiving of study documentation



DATA MANAGEMENT

- Database design and build
- Independent randomisation service
- Data extraction, linkage, sharing and database integration
- Data checking, cleaning and statistical analysis
- Advice on data management and storage
- Endpoint adjudication and independent safety monitoring



TRAINING AND RESOURCES

- Creation and delivery of investigator training packages
- Protocol tools and project templates, including ISF, CV, delegation and training log templates
- Training programs including Trials Methodology Seminar Series and Good Clinical Practice (GCP) training