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Strategies for planning clinical
trials: Guidance for anaesthesia
investigators

August 2025

Purpose of document:

This guidance document serves as a practical resource for principal investigators, research co-ordinators, and sponsors involved in CTN-supported studies. It shares best practices and operational insights from landmark multi-centre and international trials, such as TRICS-IV, ROCKET, VAPOR-C, LOLIPOP, and CALIPSO, capturing the trial lifecycle from protocol design to global expansion and close-out.

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Strategies for planning clinical trials: Guidance for anaesthesia investigators

1. Introduction

The Australian and New Zealand College of Anaesthetists (ANZCA) Clinical Trials Network (CTN) supports the development, implementation, and dissemination of high-quality, collaborative clinical research in anaesthesia, perioperative and pain medicine. This guidance document aims to serve as a practical, dynamic resource for Principal Investigators (PIs), research co-ordinators, and trial sponsors engaged in CTN-supported studies. It captures best practices, operational guidance, and key learnings from multi-centre and international trials.

Drawing from the collective experience of landmark trials like TRICS-IV, ROCKet, VAPOR-C, LOLIPOP, and CALIPSO at the ANZCA CTN workshop 2023 by trial investigators and managers, this guidance document captures the trial lifecycle from protocol design and funding to global expansion, trial management, and final close-out.

2. Trial design and protocol development

- Focus on designing trials with pragmatic, patient-centred outcomes (e.g., days alive and at home).
- Align with national and international regulatory frameworks from the outset.
- Incorporate adaptive trial designs, such as those using pre-specified interim analyses and sub-studies, to increase value, efficiency, and ethical rigour. This could include Bayesian or frequentist approaches that allow for predefined modifications based on accumulating data, such as adjusting randomisation ratios, stopping for futility, or dropping ineffective interventions.
- Engage all relevant stakeholders early, including:
 - Multidisciplinary clinical teams (anaesthesia, surgery, Intensive Care Unit (ICU)).
 - Biostatisticians and health economists.
 - Consumer representatives.
 - Trial units and academic partners.
- Maximise feasibility across diverse sites (metropolitan, regional, public and private).

3. Site feasibility and selection

A structured site feasibility process ensures efficient site activation and sustainable recruitment. Consider:

- Patient population: volume and eligibility window.
- Staffing: dedicated research Full Time Equivalent (FTE), Principal Investigator (PI) engagement, clinical buy-in.
- Infrastructure: Electronic Medical Record (EMR) access, pharmacy, pathology, theatre, ICU/ward co-ordination.
- Trial burden: alignment with existing workflows and procedures.
- Competing studies: co-enrolment policies and trial fatigue.

Tip: Feasibility assessments should be completed collaboratively by the PI and research co-ordinator using the CTN guidance document on trial feasibility.

Tip: If possible once the feasibility assessment is completed, hold a feasibility call with the site to get a true feel for feasibility and commitment to recruitment.

4. Regulatory compliance and sponsorship

Sponsors play a central role in trial accountability. University-based sponsorship (e.g., Monash University) is typical. Considerations include:

- Ethics: [National Mutual Acceptance](#) (NMA)-supported Human Research Ethics Committees (HRECs) preferred (Australia); Site Specific Assessment (SSA) or governance submission and site authorisation. [Health and Disability Ethics Committee](#) (HDEC) approval is required in New Zealand. Note: Private Hospitals are not a party to the NMA and will require separate full ethics review.
- Legal agreements: [Medicines Australia Clinical Trial Research Agreement](#) (CTRA) or equivalent; New Zealand/European/United Kingdom variations.
- Insurance: local and international coverage, especially for paediatric or high-risk trials.
- Co-sponsorship models: useful for international studies or Investigational Medicinal Product (IMP) trials.

Tip: Use the [METIS Library](#) (Database of guidance to conduct clinical trials based at [Melbourne Children's Trial Centre](#) (MCTC)) to access standard operating procedures (SOPs) and regulatory templates.

5. Budget and funding strategies

- Plan in the protocol phase for diversified and staged funding for example:
 - [MRFF/NHMRC](#) (Australia)
 - [HRC](#) (New Zealand)
 - [NIHR](#) (United Kingdom)
 - [CIHR](#) (Canada)
 - [ANZCA Foundation grants](#)
 - Institutional support, philanthropy, or industry in-kind contributions.
- Budget categories should include:
 - Site start-up (including governance approvals) and per-patient payments.
 - Trial drug procurement, blinding, packaging, and shipping.
 - Clinical Trial Management System (CTMS) or trial database.
 - Equipment.
 - Staffing (central and site-level).
 - Monitoring, data management, and Good Clinical Practice (GCP) training.
 - Long-term follow-up and archiving.
 - Consumer engagement and dissemination.

Tip: Develop a clear invoicing and financial tracking process. This could be inbuilt in the CTMS

6. Trial operations

Efficient trial operations depend on trained teams, robust systems, and strong communication.

- Use secure electronic databases (e.g., REDCap, Medidata.)
- Define roles/responsibilities across operations, governance, and clinical teams.
- Implement detailed SOPs for:
 - Consent and eligibility confirmation.
 - Randomisation, allocation concealment, blinding.
 - Drug administration and accountability.
 - Case Record Form (CRF), data entry, adverse event and safety reporting, monitoring, endpoint reporting.
 - For large multi-centre trials, design the database and/or CTMS from the outset to draw together key information in downloadable committee-specific reports that allow timely trial steering by the operations committee, data quality committee and data safety and monitoring committee (open report only).

Train site staff in protocol-specific requirements and monitor for compliance.

7. International trials and global expansion

Global trials extend impact but require additional planning:

- Collaborator networks: Engage known leaders or CTN counterparts overseas.
- Local sponsors or legal representatives: Required in Europe/United Kingdom and other regions.
- Country-specific approvals: Health Canada, Medicines and Healthcare products Regulatory Agency (MHRA), EU Clinical Trials Regulation (CTR), etc.
- Protocol adaptations: Language translation, clinical practice variation.
- [General Data Protection Regulation](#) (GDPR) and data transfer: Data transfer agreements (DTAs) and anonymisation strategies.
- Coordinate with international trial offices and academic units for consistent delivery.

8. Recruitment and retention

Maximise recruitment and participant retention through:

- Clear, simple patient information and consent forms. If a long-term study, include generic statements that allow long-term outcome data to be collected from medical records without a separate consent.
- Obtain ethics approval for a one page invitation letter to accompany the Patient Information and Consent Form (PICF), both documents could ideally be emailed/mailed to the participant in advance of the initial consent conversation, allowing time for discussion with the family, General Practitioner (GP) etc.
- Option for electronic consent where ethically approved.
- Assess feasibility of early theatre list cases - obtain relevant pre-approval if required; avoid if likely to place undue pressure on the participant and/or interfere with theatre case flow.
- Ensuring clinical team buy-in and support.
- Incorporating patient-friendly follow-up (e.g., electronically collected Patient Reported Outcome Measures (PROMs), telehealth, SMS reminders).
- Regular engagement with sites through newsletters, training, and performance feedback.
- Celebrating site milestones and acknowledging contributions.

9. Monitoring and data management

Ensure high-quality data and GCP compliance throughout:

- Central monitoring and site audits (risk-based where appropriate).
- Data query systems and timelines for resolution.
- Version control of CRFs and participant materials.
- Secure, auditable data storage.
- Integration of data with EMR or institutional platforms.

Assign data custodianship clearly and maintain logs for database access.

10. Trial close-out and legacy

Refer to close out checklists. Activities include:

- Premature Termination/Suspension: Document rationale and regulatory notification.
- Data and Documentation:
 - All CRFs complete, queries resolved.
 - Final data lock and verification.
- Drug Accountability:
 - Final count and reconciliation.
 - Safe return or destruction of investigational product.
- Equipment:
 - Clean, store or return per agreement.

- Stakeholder communication:
 - Notify HRECs, RGOs, site teams, sponsors.
 - Communicate outcomes to participants and clinicians.
- Final signatures: Trial master file and logs signed.
- Financial Review:
 - Reconcile per-patient payments, monitor residuals.
- Archiving: Secure storage of essential documents (typically 15+ years in Australia).
- Data Custodianship: Assign responsibility for data sharing and re-use.
- Participant feedback: Share trial results with lay summaries and appreciation letters.

Tips: Refer to close out checklists.

11. Key lessons and emerging issues

- Early engagement with sponsors, PIs, and support departments is critical.
- Legal and regulatory timelines often exceed expectations—plan buffers.
- Shared authorship and transparent publication strategies enhance team cohesion.
- Data sovereignty and privacy laws require country-specific solutions.
- Centralised SOP libraries and templates save time and improve consistency.
- International collaboration is rewarding but requires strong communication and shared leadership.

12. Resources and templates

- [METIS Library](#): International SOPs, governance templates, budgeting tools.
- CTN tools: Site feasibility, monitoring plans, CRF templates.
- Ethics and governance: [NMA guidance](#), [HDEC](#), SSA checklists (check locally).
- Funding: MRFF/NHMRC guides, justification templates, budget calculators.
- GDPR and EU/UK trials: [EU Clinical Trials Regulation](#), [IRAS](#), [MHRA](#) portals.