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Trial feasibility: Guidance for anaesthesia research departments

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Purpose of document:

This document provides structured guidance to support anaesthesia research departments in assessing the feasibility of clinical trial participation. It outlines key domains such as scientific rationale, staffing, infrastructure, governance, and financial viability, to help sites make informed, strategic decisions about trial readiness. Designed for investigators, research co-ordinators, and site managers, this resource promotes a comprehensive feasibility assessment to ensure clinical trials are conducted safely, efficiently, and sustainably within anaesthesia research departments.

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Trial feasibility: Guidance for anaesthesia research departments

Feasibility assessment is a foundational component of clinical trial planning. Before a site agrees to participate in a study or clinical trial, it must determine whether the trial can be conducted safely, ethically, and efficiently within its local context. This involves evaluating a broad range of factors - from patient population and staffing capacity to departmental resources, governance processes, and financial viability.

This guidance document compiles key considerations presented at the feasibility workshop during the ANZCA CTN 2024 Strategic Research Workshop, delivered by Ms Dhiraj Bhatia Dwivedi and Ms Tracy Hess. It provides a structured approach to feasibility assessment, tailored to the needs of research co-ordinators, investigators, and site managers working within anaesthesia, perioperative, and critical care research settings.

Each section addresses core feasibility domains, offering guiding questions and discussion points that help sites critically assess their readiness to undertake a new clinical trial. Whether responding to a sponsor issued questionnaire or conducting an internal review, this guide is designed to support robust decision making and successful study implementation at the site.

1. What does clinical trial feasibility mean for the site?

Clinical trial feasibility is the process of evaluating whether a particular clinical trial can be successfully and ethically conducted at a given site or in a specific region. It considers:

- Timelines: Can recruitment and study milestones be achieved on time?
- Targets: Can the site realistically meet enrolment and data collection targets?
- Cost: Is the trial financially viable with available or projected resources?

2. Site feasibility: purpose and benefits

Site feasibility is a structured assessment of whether your site has the capacity, resources, and systems to conduct a clinical trial safely, efficiently, and in accordance with protocol and regulatory standards. At its core, it helps answer the fundamental question:

"Can we deliver this trial successfully at our site?"

A robust feasibility assessment:

- Confirms alignment with the site's clinical priorities and strategic goals.
- Identifies potential operational or staffing challenges early.
- Enhances efficiency during trial startup and resourcing phases.
- Reduces the risk of poor recruitment, protocol deviation, or early study termination.
- Equips the site to make informed decisions about trial participation, ensuring sustainable and successful delivery.

Feasibility in practice

- Sponsors may issue a formal feasibility questionnaire to be completed by the site's Principal Investigator (PI) and research co-ordinator. Trial feasibility may be conducted by the site research co-ordinator or manager, with a PI identified later to lead the trial at the site.
- Regardless of sponsor request, conducting an internal feasibility review is considered best practice and can prevent costly issues downstream.
- Feasibility assessment is an essential investment for a site to make sure that the trial runs successfully at their site.

Timing of the assessment

Feasibility assessment should begin as soon as interest in a trial is expressed, whether by a sponsor, PI, research co-ordinator or department lead. It is not a one-off task but an ongoing process that evolves alongside trial planning and implementation.

- Early Stage: Initiated during preliminary discussions or upon receipt of a feasibility questionnaire.
- Mid Stage: Continues through protocol review, budget development, and contract negotiation to ensure realistic commitments and adequate resourcing.
- Later Stage: Revisited post-contract, especially if there are protocol amendments, shifts in patient availability, or changes in staffing or infrastructure.

A dynamic, staged approach to feasibility allows sites to adapt and remain aligned with trial requirements across the study lifecycle.

Parts of feasibility assessment:

This assessment covers several key areas:

1. Scientific consideration and relevance.
2. Eligibility and patient population.
3. Infrastructure, staffing and required resource assessment.
4. Documents, database review and regulatory processes .
5. Ethics and governance process and timeline.
6. Stakeholder involvement both internal and external.
7. Financial consideration.

3. Scientific consideration and relevance

The first step in feasibility evaluation is to assess whether the proposed trial is scientifically sound, clinically relevant, and aligned with site priorities. This involves more than technical review, it requires thoughtful engagement with the site's research culture, capacity, and core objectives.

Key questions

- What is the scientific or clinical rationale for the study?
- Will the study deliver high quality, evidence based care to your patient population?
- Does it address a common or burdensome condition?
- Will it help improve treatment options or symptom management?

Innovation and translation

- Does the study explore new ways to administer treatment (e.g. novel drug delivery or combinations)?
- Could the findings lead to improved clinical outcomes?
- Will the study inform or change local practice?
- Is it likely to be translatable across other hospitals or health services?
- Will the study provide your community with early access to cutting-edge or novel therapies?

Feasibility and acceptance

- Has a systematic review or meta-analysis of the existing evidence been conducted?
- Has a pilot study demonstrated safety and feasibility of the protocol?
- Has the study been endorsed by the ANZCA CTN and/or reviewed by other bodies?
- How likely are patients to trust or accept the intervention (especially if perceived as "experimental")?
- Will clinicians be comfortable offering the study intervention as an alternative to standard care?
- Does the intervention inhibit (or prohibit) certain care procedures? e.g. to withhold certain treatments for a specified period?

4. Eligibility and patient population

- Does your site have access to a suitable patient cohort?
- Discuss the inclusion and exclusion criteria with the site PI in detail.
- How specific or restrictive are the inclusion and exclusion criteria?
- Does your site have patients that would meet the eligibility criteria?
- Does the study include elective or emergency admissions?
- Is co-enrolment permitted with other trials running at your site?
- Are the recruitment targets realistic given your site's patient flow?
- Are the expectations placed on participants (e.g. follow-up visits, procedures) reasonable for your setting?
- Note existence of sub-studies and whether participation is mandatory or optional and the costs associated with these.

Timeline

- How long is the study timeline, including pre-screening, treatment, and follow-up phases?

Participant impact and burden

- Understand the direct impact of the study on participants, particularly the time, effort, and procedures required.
- Does the study require pre-operative assessments (e.g. blood tests, questionnaires)?
- When are the day-of-surgery assessments, in clinics or holding bays?
- Inpatient data collection (e.g. pain scores, Patient Reported Outcome Measures (PROMs))?
- Assess whether participants will realistically be able to complete required assessments, especially if they occur while recovering from anaesthesia, during periods of fatigue or discomfort, at off-peak times (e.g. early morning, after hours).

Follow-up requirements

- Review the schedule of assessments in the protocol and assess how many follow-up visits are required, what is the frequency and mode (in-person, phone, telehealth, electronic PROMS (ePROMS)), will participants be expected to complete multiple forms or assessments? Consider participant fatigue, especially for lengthy or repeated follow-ups.
- Ensure the timeline aligns with clinical workflows, staff availability for post-discharge follow-up, participant availability (e.g. remote location, work schedule).
- Logistics and Feasibility: Can tests or forms be completed during routine care (e.g. during clinic visits or while waiting for surgery), is remote or ePROMS follow-up feasible for your population? (e.g. phone reception, digital access), are there resources in place to support follow-up and reminder systems?

Competing trials

- What other clinical trials are currently active or planned in your department?
- Will participation in this new study affect recruitment or delivery of other current ongoing studies?
- Will this new study compete for the same pool of participants?
- Check with the sponsor if co-enrolment is permitted.

5. Infrastructure, staffing and required resource assessment

Evaluate the practical implications of the study on your site's clinical operations and research staff capacity. A single well resourced and high-quality study is better than spreading research staff too thinly across multiple trials.

Assessment for staffing required

- Estimate total co-ordinator hours per patient (screening, consent, data entry and queries, follow-up).
- Confirm database platform (e.g., REDCap, DataFax) and access/training needs.
- Review planned monitoring schedules and access to Electronic Medical Records (EMR).
- Evaluate technical requirements (e.g., software installations, apps).
- Assess availability of staff to manage trial across shifts, weekends, or leave periods.
- Assess if surgery for patient population is only on certain days of the week and if you have staff available on those days.
- Identify if new staff are required to be hired and the timeline of when they must commence.
- Plan for internal dry runs or simulations prior to trial go-live.
- Strategic decision-making: Consider whether it is more appropriate to decline a study if it would overstretch resources, may lead to under-recruitment or non-adherence to the protocol.

Study complexity and standard of care

- How does the study compare to routine care in terms of complexity?
- Can the intervention or study drug be integrated into standard workflows?
- Will additional staff, time, or procedures be required to implement the interventions?

Equipment requirements

- Does the study require specific equipment?
    - Is the equipment already available on site, or must it be purchased? Is it provided by the trial team?
    - Where will it be stored? Is it easily accessible for staff?
    - Are appropriate storage facilities available for supplies or devices?
- Will staff need specific training to use the equipment?
- Will the equipment need approval for use locally? How long will this approval take?

Clinical procedures and tests

- Are extra blood tests required? If so:
    - At what time points?
    - Who will be responsible for drawing the blood?
- Are additional observations or Electrocardiogram (ECGs) required?
    - Are they standard practice or additional tasks?
    - Do you have the necessary equipment?
    - Can you rely on clinical staff, or must research staff complete them?
    - Will any of these procedures need to occur after hours?
    - Will you be charged by the hospital for these extra tests?

Study drug administration and storage

- When is the study drug administered?
    - Can the co-ordinator hand it over to clinical staff, or must a member of the study team administer it directly?
    - Is staff training needed to ensure accurate administration?

- Where is the drug stored?
    - Does pharmacy need to store the study drug?
    - Is it secure but accessible during routine and after-hours times?
    - Will limited access affect recruitment?
- Who supplies the study drug?
    - Is it provided by the sponsor?
    - If special equipment is required for drug preparation or delivery, who provides or funds it?

Documentation and EMR Integration

- What level of documentation is required from clinical staff?
- Who is responsible for completing source documentation or study logs?
- Can the intervention or drug be recorded within the patient's medical record?
- If using an EMR system:
    - Is it feasible to create an alert for eligible patients?
    - Is it feasible to build a template or drug charting module into the system?
    - What administrative or Information Technology (IT) support will you need to implement this?

Staff training/Site Initiation Visit (SIV)

- Who provides the initial SIV?
- Who is required to attend the SIV?
- What training is required for each staff group involved in the trial?
- Who requires Good Clinical Practice (GCP) training?
- Is trial specific or protocol specific training required by the department?
- Who is responsible for delivering training to the department/collaborating teams/departments, and how frequently should it occur?

GCP and regulatory training

- Identify all staff who require current GCP certification (e.g. PI, associate investigators, research staff).
- Are all certificates up to date and compliant with sponsor and site requirements?

Protocol-specific and clinical training

- Does each department (e.g. pharmacy, imaging, nursing) require:
    - General trial awareness?
    - Protocol specific education?
    - Device or intervention specific clinical training (e.g. administering a study drug, using new equipment)?
- Training should align with:
    - Staff orientation.
    - Study start-up.
    - Major protocol amendments.
    - Staff turnover.

Training responsibilities

- Who delivers the training?
    - Trial manager and/or co-ordinating PI, sponsor, Clinical Research Associate (CRA), or site research staff?
- Who oversees the training plan and tracks completion?
- How will new staff be trained when the trial is underway?

6. Documents, database review and regulatory processes

Case Report Form (CRF) and data collection requirements

- How large and complex is the CRF?
- Estimate volume of data to be collected across screening, pre-operative, intra-operative, post-operative and follow-up phases.
- Identify how much of the required data is routinely collected.
- Determine who is responsible for intra-operative data capture - research staff or clinicians.
- Assess feasibility of retrospective data collection from EMR.
- Review clarity of data dictionary, CRF completion manual and tools. Tools are any study specific tools provided by the sponsor such as a flow chart that may help for screening of patients
- Check for special assessments requiring training (e.g. CAM-ICU for delirium studies).
- Do assessments need to be conducted out of hours or overnight by ward staff?

Database requirements and access

- What type of data capture system is used (e.g. paper-based CRF, electronic data capture (EDC), ePROMS)?
- What data platform is being used (e.g. REDCap, ResearchPath, Medidata, OpenClinica)?
    - Is this a familiar system or will staff require additional training?
    - Who needs access to the system (e.g. for randomisation, data entry, query resolution)?
    - Who will be responsible for data entry, query resolution, and database access? This needs to be noted on the delegation log.
- How will user accounts and permissions be managed?
- Are there IT requirements (e.g. firewalls, Virtual Private Network (VPN), approvals) to enable site access?
    - Engage your local IT department early to address any infrastructure or compliance needs.

Source documents

- Is it required to be recorded that the patient is participating in a research study? What standard documentation is required? E.g. EMR documentation (including clinical trial alert), anaesthetic chart, medication prescription (electronic or paper), notification to regular health carers, e.g., General Practitioner (GP)?
- Are paper source documents able to be appropriately stored in secure areas? E.g. patient specific information, consent forms, paper CRFs, laboratory or imaging results on paper.

Adverse events and safety reporting

- What is the process to report safety endpoints, Adverse Events (AEs) and Serious Adverse Events (SAEs)?
- Clarify AE and SAE definitions and reporting burden.
- What is the process for unblinding, particularly availability out of hours?

Consent process

- Determine how consent could be obtained, i.e. phoning the patient before attendance at clinic, pre-admission clinic.
- Determine who is allowed to obtain consent for the trial.
- Estimate time required for obtaining consent, particularly in pre-operative settings.
- Review options for substitute decision maker or delayed consent in emergency contexts if applicable.
- Ensure availability of translated documents or interpreter access for non-English speakers if applicable.
- Consider ethical implications for paediatric participants and consent from parents/guardians or assent directly from paediatric participants.

Regulatory documents

- Review Clinical Trial Research Agreements (CTRA) for template type (e.g., Medicines Australia).
- Are there any CTRA(d) clauses that need local review or modification?
- Send contracts to legal/governance for early review.
- Identify international sponsor involvement or special Schedule 4 conditions.
- Check indemnity and insurance requirements for your site.

7. Ethics and governance process and timelines

- Has the project already received pre-approval from a Human Research Ethics Committee (HREC) participating in the National Mutual Acceptance (NMA) scheme (Australia)? or Health and Disability Ethics Committee (HDEC) (New Zealand)?
- Will your site require a new ethics submission, or can you be added to an existing ethics application?
- Is a Site Specific Assessment (SSA) (Australia) or Locality Application (New Zealand) required for your site?
- Has the study already been approved or conducted at another site within your health service or network?

8. Stakeholder involvement - internal and external

Once preliminary scientific and clinical alignment has been established, the next phase of feasibility focuses on operational capability and interdepartmental readiness. Effective collaboration within and across departments ensures seamless trial delivery, resource availability, and staff engagement. It is essential to assess the organisational support, internal departmental support and support from the external departments in the hospital.

Organisational support

- What is the level of support for research from your site's leadership or executive?
- Would there be backing to help with study implementation and resourcing?

PI Engagement

- Do you have a committed, experienced, and enthusiastic PI? A supportive PI is a key enabler for the success of the trial delivery at the site.
- Assess their experience with clinical trials and their capacity to:
    - Oversee trial governance.
    - Supervise day-to-day trial activities.
    - Review and assess potential participants.
- Ensure their CV and GCP certificate are up to date.
- Support the PI in meeting pre-trial obligations and staying across all aspects of trial conduct throughout the study.

Early engagement with key departments

Engage relevant departments early to assess capacity, identify training needs, and secure support. Consider the following:

- Does the study intervention require support from departments beyond your primary research unit?
- What processes are in place to secure support from stakeholders such as Head of Departments (HODs), pharmacy, medical imaging, and pathology?
- Will these departments need additional training, infrastructure, or resources?

Some of the departments to consider are as follows

- Surgical and anaesthetic teams: Willingness to collaborate and integrate trial related procedures into clinical workflows.
- Pharmacy: Capacity to manage storage, drug preparation, blinding/unblinding, and after-hours access. (If applicable, sites may not need to use pharmacy for various reasons)
- Pathology: Ability to process, store, and ship protocol-specific samples; assess equipment availability and

whether sponsor-supplied items are needed.

- Medical Imaging: Confirm imaging availability, consent pathways, reporting timelines, and logistical feasibility.
- Infection Control: Ensure study materials and interventions meet safety and containment standards.
- Emergency Department (ED): Support for participant identification and consent during urgent presentations.
- Pre-admission clinics, Intensive Care Unit (ICU), and wards: Clarify touchpoints, potential complications, and protocol requirements.
- Nursing staff: How much would the nursing staff have to contribute for the trial? It is advisable to initiate the conversation with the nursing manager at an early stage to get the nursing support.

Letters of support and institutional approvals

- Does your site require a letter of support from HODs or clinical directors?
- Who needs to sign:
    - Clinical director or PI (what if they're the same person?)
    - Business or service manager.
    - Chief operating officer (COO).
    - Nursing director, particularly if the trial places a significant burden on nursing staff

Pharmacy

- Will the study drug require special handling, such as:
    - Storage conditions.
    - Accountability processes (manual or database-based).
    - Blinding/unblinding support?
- Confirm whether the pharmacy has capacity and whether additional support or training is needed.

Pathology

- Are protocol specific blood tests required?
    - Will your pathology provider need a contract?
    - Can they process, store, and ship samples per protocol?
- Determine:
    - Equipment availability (e.g., centrifuge, freezers).
    - Whether any new equipment will be sponsor supplied or must be purchased.

Medical imaging

- Ensure clear processes are in place to meet protocol specified imaging timelines.
- Confirm:
    - Booking pathways.
    - Consent processes.
    - Timeliness of access.

Nursing staff

- Will the protocol require non-standard care, procedures, or observations?
- Co-ordinate early with ward educators to plan and deliver tailored staff education.
- Confirm:
    - What support research co-ordinators can offer at the bedside.
    - Whether after hours contact will be needed.

Pre-admission clinics and other units

- Will pre-admission staff have a role in delivering or supporting trial activities?
    - If so, what training or procedural updates are needed?
- Are ICU or ED teams likely to encounter study participants during interventions or complications?
    - Engage early and clarify roles and response pathways.

Supporting trial success

- Consider department specific needs for:
    - Study protocol updates at unit meetings.
    - Drug administration support in Post Anaesthetic Care Unit (PACU)/theatre/inpatient wards.
    - Dedicated support and troubleshooting by research staff.
- Establish strong, early relationships with all supporting units to:
    - Streamline study delivery.
    - Embed a research positive culture into daily practice.
    - Reduce resistance and improve collaboration across departments.

9. Financial assessment

A thorough financial feasibility review ensures that trial participation is not only operationally viable but also financially sustainable. Key steps include:

- Comprehensive costing: Ensure that all resource intensive elements are captured in the budget, including staff time, pharmacy support, imaging, pathology, equipment use, and physical space requirements.
- Payment structure: Understand how the sponsor will pay, whether upfront, per participant, or by milestone and assess whether the timing aligns with internal cash flow needs.
- Check if there are any trial start up payments and payments for governance fees included. (Sometimes these can be negotiated).
- Revenue vs. costs: Compare projected sponsor payments to actual site costs to determine if the trial is sustainable without financial strain. Consider whether additional institutional support or goodwill is required to fill any funding gaps.
- Lead site responsibilities: If acting as a lead site, factor in the extra workload and costs associated with trial management, co-ordination, and governance reporting.
- Sponsor Terms and Systems:
    - Are per patient payments sufficient to cover study specific procedures and staffing?
    - Are startup and governance fees reimbursed or waived by the hospital?
    - Does the sponsor use a specific invoicing platform or payment portal?
    - Are all trial related assessments and procedures covered under the budget?
    - Who at the site receives the payments and manages reconciliation?

Early financial clarity prevents budget blowouts, strengthens internal planning, and supports transparent communication with hospital finance and executive teams.

Coverage and adequacy of per patient payments

- Do payments cover:
    - Research co-ordinator time?
    - Additional clinical care beyond standard practice?
    - Study intervention costs (e.g., pharmacy preparation, storage, equipment maintenance)?
    - Pathology or imaging charges. Do these require separate contracts or internal billing?
- Will your site incur any out-of-pocket costs, and if so, will these be reimbursed or absorbed?

Invoicing process

Understand per patient payment structures and when payments are triggered (e.g., recruitment, follow-up, when are payments not triggered).

- How frequently are payments made (monthly, quarterly, milestone based)?
- What is the invoicing process?
    - Is it manual or system based?
    - Are multiple platforms or portals used across different trials?
    - Will research staff need training to use a new invoicing system?
- Who is responsible for submitting and tracking invoices?

Budget management and reconciliation

- How are trial payments tracked against actual recruitment?
    - Who verifies participant numbers and matches them to received payments?
- Are incoming and outgoing costs monitored centrally?
    - Will there be any residual funds, and if so, how are they managed?

Other financial considerations

- Are archiving costs included in the budget?
    - Who covers onsite or offsite storage post study?
- Does the sponsor offer a start-up fee?
    - Does this cover your time for governance, SSA/Localities, and ethics submissions?

Feasibility documentation process

- Utilise standardised checklists to evaluate feasibility (e.g. Monash template, CTN questionnaires).
- Customise for your site's structure and departmental processes.
- Ensure documentation covers all of the topics mentioned above.
- Maintain version controlled records of feasibility findings and decisions for transparency.

10. Conclusion

Assessing clinical trial feasibility is a critical first step in ensuring the safe, efficient, and successful conduct of research at a site. This report outlines a comprehensive framework for feasibility evaluation, encompassing scientific rationale, operational readiness, departmental collaboration, resource capacity, and participant burden.

Feasibility assessment is both analytical and relational, it draws on objective data but also hinges on meaningful stakeholder engagement and honest forecasting. The most successful assessments are collaborative and iterative, involving early and sustained dialogue with PI's, clinical departments, pharmacy, governance, and administrative teams.

Effective feasibility planning not only determines whether a study can be conducted, but also how it can be embedded within routine clinical workflows without compromising care quality or research integrity. A thorough feasibility process saves time, builds trust, and positions sites for sustainable research delivery.

Ultimately, site feasibility is more than a checklist; it is a strategic, whole-of-site process that ensures the right trials are undertaken in the right settings, with the right support. By applying the structured considerations outlined in this document, sites can make informed decisions about trial participation, enhance internal research capacity, and contribute meaningfully to evidence-based healthcare delivery.

For access to feasibility assessment templates, contact the CTN office ctn@anzca.edu.au