



Cancer Clinical Trials Resource Directory

**A comprehensive directory of resources
to support clinicians, trial coordinators,
and researchers across the cancer
clinical trials lifecycle**

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1. Introduction

Cancer clinical trials are essential to improving cancer prevention, diagnosis, treatment, and survivorship outcomes. They generate the evidence base that underpins best practice care and enable access to new and emerging treatments for patients.

In Australia, cancer clinical trials are conducted within a nationally coordinated regulatory, ethics and governance framework. Clinicians, researchers, consumers, and health services collaborate across the full research lifecycle to deliver high quality cancer clinical trials. Navigating this landscape can be complex and time-intensive. This directory provides a centralised, practical guide to clear and trusted resources that support scientifically rigorous, ethically sound and patient-centred research.

This directory brings together key cancer clinical trial resources available in Australia, with a focus on the New South Wales context. It is designed to support clinicians, trial coordinators and researchers planning, developing and conducting **Investigator-Initiated Trials (IITs)**, rather than industry-sponsored clinical trials.

It is structured to broadly mirror the real-world clinical trials lifecycle, while recognising that activities often overlap in practice, and occur across diverse settings and multidisciplinary teams. The content spans regulatory, ethics and governance requirements, through to the development of a robust and strategically aligned research question, trial design, protocol development, feasibility, budgeting, data management and safety oversight. It also incorporates consumer engagement, research impact planning and translation.

By mapping key national and NSW-specific guidance, templates, education programs and support services to each stage of trial development, the directory aims to improve efficiency in trial start-up, reduce duplication of effort and strengthen methodological quality, while supporting compliance with national and international standards, including Good Clinical Practice (GCP).

Ultimately, this directory serves as a practical planning and reference tool for NSW cancer investigators, supporting them to progress from concept to activation with greater clarity, confidence and coordination. It complements existing local policies, procedures or expert advice, to assist users identify relevant information, understand key requirements, and access further support as needed.

FURTHER RESOURCES

- [What is a clinical trial? \(Australian Clinical Trials\)](#)
- [Clinical Trial Life Cycle \(VCCC Alliance\)](#)

WHO IS THIS DIRECTORY FOR?

The information and tools contained in this directory relate to investigator-initiated clinical trials (IITs).

IITs are trials that are developed, led and managed by independent investigators such as clinicians or academic researchers working within Local Health Districts, universities and medical research institutes. Most IITs are designed to inform or improve clinical practice, evaluate models of care or compare the effectiveness of existing treatments).

In contrast, industry-sponsored or other commercially-led trials are typically driven by commercial goals and product development.

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The Regional Cancer Research Network NSW acknowledges the traditional custodians of the lands on which we work and live, and recognise their continuing connection to land, water and community. We pay our respect to Elders past and present.

FURTHER RESOURCES

- [Australian Clinical Trials website](#)
- [clinicaltrialsNSW website](#)
- [Clinical Trials Workforce Resources](#)
(Cancer Institute NSW)
- [Facilitating clinical trials in rural and regional NSW](#)
(NSW Regional Health Partners)
- [Clinical Trials Roadmap](#)
(NSW Regional Health Partners)
- [Rural, Regional and Remote Clinical Trial Enabling Program](#)
(NSW Government)
- [My Clinical Trial Planner](#)
(Clinical Trials Hub)
- [Investigator-Initiated Trials Toolkit](#)
(VCCC Alliance)
- [Templates](#) (Global Health Trials)

GLOSSARIES

- [Glossary](#) (Australian Cancer Trials)
- [Glossary terms](#)
(Therapeutic Goods Administration)
- [Clinical trials glossary of most used terms](#) (Cancer Institute NSW)
- [Glossary - Investigator Initiated Trials](#)
(VCCC Alliance)

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2. Understanding the Regulatory, Ethics and Governance Framework

Clinical trials in Australia operate within an interconnected national framework. A clear understanding of this regulatory, ethics and governance environment is essential when planning an Investigator-Initiated Trial (IIT).

Regulatory requirements primarily relate to the use of therapeutic goods including investigational medicines, biologicals and medical devices. This involves determining product classification, ensuring compliance with manufacturing standards where applicable, managing importation or supply arrangements, and meeting safety reporting obligations to the Therapeutic Goods Administration (TGA).

Ethical oversight is guided by the National Statement on Ethical Conduct in Human Research issued by the National Health and Medical Research Council (NHMRC). Trials involving therapeutic goods are regulated under the Therapeutic Goods Act and administered by the Therapeutic Goods Administration (TGA). In parallel, state-based research governance offices, such as those within NSW Health, assess institutional risk, contracts, indemnity, and local feasibility. These layers operate together but perform distinct functions. Ethics review evaluates scientific merit, participant protection and risk–benefit balance, whereas governance review assesses whether the institution is prepared and authorised to host the study.

Early attention to the regulatory and governance requirements reduces avoidable delays, prevents protocol redesign, and ensures participant safety and institutional protection are embedded from the outset.

FURTHER RESOURCES

- [Principles, regulations and governance of clinical trials \(ACT\)](#)
- [Regulations, ethics and governance in clinical trials \(Clinical Trials Hub\)](#)
- [National Standard Operating Procedures for Clinical Trials in Australia \(ACT\)](#)
- [National Statement on Ethical Conduct in Human Research \(NHMRC\)](#)
- [Ethics and governance policies and guidelines \(NSW OHMR\)](#)
- [Research Handbook \(NSW OHMR\)](#)

Regulatory Pathways (CTN vs CTA schemes)

Clinical trials involving unapproved therapeutic goods may be conducted in Australia under two schemes: Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) administered by the TGA.

Most IITs proceed under the CTN pathway, where a reviewing Human Research Ethics Committee (HREC) undertakes scientific and safety review and the TGA is formally notified before trial commencement. The CTA pathway, which involves direct TGA review, is typically used for higher-risk or novel products such as first-in-human studies and cell therapies. HREC review is still required, but after or alongside TGA review.

Determining the appropriate regulatory pathway is a critical early step and should be made before finalising the protocol, particularly where unapproved or repurposed products are involved. Early consultation with institutional clinical trial units can help in clarifying regulatory classification, manufacturing requirements, and import considerations if applicable.

FURTHER RESOURCES

- [Australian Clinical Trials Handbook \(TGA\)](#)
- [Clinical trials overview and approval pathways \(TGA\)](#)
- [CTN Form User Guide \(TGA\)](#)
- [CTA scheme forms \(TGA\)](#)

Ethics Review

Human Research Ethics Committee (HREC) review is a structured peer evaluation of the ethical and scientific integrity of the proposed study. It examines the research rationale, inclusion and exclusion criteria, safety monitoring plans, consent processes, privacy protections and data handling arrangements. Applications are commonly submitted through jurisdictional platforms such as the Research Ethics and Governance Information System (REGIS) in NSW.

Well-prepared submissions anticipate reviewer concerns and maintain consistency across all study documents. Discrepancies between the protocol, Participant Information and Consent Form (PICF), and recruitment materials are a frequent cause of delay. Internal peer review prior to submission, careful alignment of endpoints and procedures across all documents, and explicit justification of any higher-risk elements strengthen applications, reduce requests for clarification and mitigate delays.

Where studies involve concurrent preclinical or translational work in animal models, separate approval from an institutional Animal Ethics Committee (AEC) may also be required in accordance with the Australian Code for the Care and Use of Animals for Scientific Purposes.

FURTHER RESOURCES

- [National Statement on Ethical Conduct in Human Research \(NHMRC\)](#)
- [AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research \(AIATSIS\)](#)
- [Ethical guidelines for research involving Aboriginal and Torres Strait Islander Peoples \(NHMRC\)](#)
- [Ethical and scientific review \(NSW OHMR\)](#)
- [List of Australian Human Research Ethics Committees \(NHMRC\)](#)
- [NSW Ethics and Governance Contacts \(NSW OHMR\)](#)
- [NSW Population and Health Services Research Ethics Committee \(NSW OHMR\)](#)
- [NSW Health Early Phase Clinical Trials HRECs \(NSW OHMR\)](#)
- [NSW Health Research Ethics and Governance Information System \(REGIS\) \(NSW OHMR\)](#)

USEFUL TIPS

- ✓ **Conduct an internal peer review before submission.**
- ✓ **Ensure all study documents align exactly with the protocol.**
- ✓ **Clearly justify inclusion and exclusion criteria, especially for vulnerable populations.**
- ✓ **Anticipate reviewer concerns regarding data sharing and future use of biospecimens.**

Governance Approvals

Research governance review is distinct from HREC approval and is required before participant recruitment can begin. Governance offices confirm sponsorship arrangements, indemnity and insurance coverage, budget approval, contractual execution and site capability. Ethics approval alone does not authorise study commencement.

Site-Specific Assessment (SSA) ensures that each participating institution has the capacity, resources and local processes in place to safely and effectively conduct the study. This includes confirmation of feasibility, investigator suitability and alignment with local institutional requirements.

In multi-site IITs, governance approval timelines often exceed ethics review timelines, particularly where contract negotiation is complex. Initiating contract discussions in parallel with ethics submission can help mitigate delays. Delays commonly arise from incomplete or inconsistent regulatory documentation, unresolved contract negotiation or execution, misalignment with the HREC-approved protocol, and unclear sponsor responsibilities. Clarifying sponsor responsibilities in writing is particularly important in IITs, where sponsorship may rest with the institution or the principal investigator's organisation.

FURTHER RESOURCES

- [National Clinical Trials Governance Framework \(ACSQHC\)](#)
- [Good Practice Process for Site Assessment and Authorisation Phases of Clinical Trial Research Governance \(NHMRC\)](#)
- [NSW Governance Contacts \(NSW OHMR\)](#)
- [Authorisation to commence Human Research in NSW Public Health Organisations \(NSW Health\)](#)
- [Site authorisation and access request \(NSW OHMR\)](#)

Good Clinical Practice (GCP)

Compliance with Good Clinical Practice (GCP) is mandatory for investigators and key trial personnel. However, certification alone is insufficient. Principal investigators must demonstrate active oversight of trial conduct, including maintenance of delegation logs, documentation of safety review, and supervision of data integrity processes. Ensuring all staff complete GCP prior to commencing activities, and maintaining contemporaneous records of oversight, are critical safeguards against compliance risk.

What does Good Clinical Practice (GCP) training involve?

GCP training provides an understanding of the international ethical and scientific quality standards that govern clinical research. It ensures that research teams understand their responsibilities under International Council for Harmonisation-Good Clinical Practice (ICH-GCP) guidelines and Australian regulatory frameworks.

GCP training is mandatory for investigators and study staff prior to undertaking significant trial responsibilities, and many institutions require current certification prior to ethics submission or site activation. Refresher training is typically required every two to three years, depending on institutional policy.

Evidence of GCP compliance should be demonstrable through current training certification, documented training records, and audit ready systems.

Recognised Australian training providers offering online and face-to-face options include:

- [Association of Regulatory and Clinical Scientists \(Australia\)](#)
- [Australian Clinical Trials Education Centre](#)
- [Praxis Australia](#)
- [Genesis Research Services](#)

FURTHER RESOURCES

- [Handbook for Good Clinical Practice \(GCP\) – Guidance for Implementation \(WHO\)](#)
- [ICH Guideline for Good Clinical Practice \(TGA\)](#)
- [Good Clinical Practice training \(NSW OHMR\)](#)
- [Good Clinical Practice \(GCP\) for clinical trials in Australia \(ACT\)](#)
- [Good clinical practice \(GCP\) in clinical trials \(Clinical Trials Hub\)](#)
- [TransCelerate Mutual Recognition Program \(list of internationally recognised GCP providers\)](#)

Reporting Obligations

Regulatory obligations continue throughout the life of the trial. Investigators must submit annual progress reports, notify substantial amendments, report serious adverse events, safety events requiring expedited reporting, and serious breaches in accordance with regulatory timelines, and provide final study reports.

Failure to report serious breaches promptly to both HRECs and governance bodies exposes both investigators and institutions to regulatory consequences. Establishing a compliance calendar at trial activation, maintaining a version-controlled amendment log, and conducting periodic internal audits help support ongoing compliance to requirements.

The *National Clinical Trials Governance Framework* reinforces standards for quality and safety across Australian institutions. Audit readiness should be embedded into routine trial management rather than treated as a reactive exercise. Maintaining complete and up-to-date essential document files, implementing proportionate risk-based monitoring, and ensuring safety reporting pathways are clearly documented and understood by all team members strengthen preparedness.

For IITs specifically, regulatory planning should begin at the concept stage. These trials often operate with fewer dedicated regulatory staff than commercially sponsored studies, increasing the importance of early coordination.

Governance timelines should be incorporated into funding and milestone planning, and sponsor obligations must be clearly defined. A structured regulatory planning process prior to submission can prevent costly redesign, budget overruns and delayed activation.

FURTHER RESOURCES

- [National Clinical Trials Governance Framework \(ACSQHC\)](#)
- [National Standard Operating Procedures for Clinical Trials in Australia \(ACT\)](#)
- [Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centre research \(NHMRC\)](#)
- [Monitoring Trial Conduct \(VCCC Alliance\)](#)
- [Risk Management: Introduction to risk management principles and risk-based approach to managing quality in clinical trials \(VCCC Alliance\)](#)
- [National Clinical Trials Governance Framework – Audit Ready Resource Pack \(NSWRHP\)](#)

USEFUL TIPS

- ✓ Establish a compliance calendar at trial activation.
- ✓ Maintain a version-controlled amendment log.
- ✓ Conduct periodic internal audits before external inspection.
- ✓ Implement risk-based monitoring plans.
- ✓ Maintain complete and contemporaneous essential document files.
- ✓ Ensure safety reporting pathways are documented and understood by all staff.
- ✓ Maintain up-to-date delegation logs and training records for all trial personnel.

3. Planning a Clinical Trial

Designing and planning an IIT requires a structured and sequential approach that integrates scientific rigour, feasibility assessment, regulatory strategy and operational readiness from the outset. Progression from concept to activation should follow a clearly defined pathway: articulating a clinically meaningful research question; confirming evidence gaps and equipoise; engaging consumers and stakeholders; and undertaking early feasibility assessment.

Methodological design and biostatistical input must precede protocol finalisation to ensure appropriate endpoints, sample size and bias control strategies. In parallel, investigators should confirm the regulatory pathway, develop core documentation—including the Protocol, Statistical Analysis Plan and Data Management Plan—and initiate ethics and governance processes. Early clarification of the regulatory pathway (CTN or CTA) is essential as this influences documentation requirements, timelines and sponsor responsibilities. Budget finalisation, sponsor clarification, Good Clinical Practice compliance and trial registration are integral components of readiness. Data governance considerations, including privacy, data access and potential data linkage requirements, should also be addressed early to avoid delays during ethics and governance review.

A disciplined planning framework reduces avoidable redesign, strengthens funding competitiveness, and supports efficient activation.

For a general overview, visit [Setting Up a Clinical Trial](#), on the [Australia Cancer Trials](#) website.

Identifying the Research Question

The development of a clear and strategically aligned research question is the most consequential step in planning an IIT. Strong research questions address clinically meaningful or health system gaps and have the potential to generate impactful findings that inform practice, policy or service delivery. The objective is to define precisely what problem is being addressed and why it matters.

A well-constructed research question should:

- ✓ Address a clearly defined clinical or health system gap
- ✓ Be supported by systematic appraisal of existing evidence
- ✓ Align with funder, institutional and policy priorities
- ✓ Have clear potential for clinical, policy or health system impact

Investigators should undertake a formal literature review (e.g. using PubMed) and review of trial registries to confirm that the question has not already been answered, and to identify ongoing studies addressing the same or related questions. Trial registration databases and published study protocols often provide insight into how similar research questions have been operationalised, including common design approaches and implementation considerations.

FURTHER RESOURCES

- [Australian New Zealand Clinical Trials Registry \(ANZCTR\)](#)
- [ClinicalTrials.gov \(search database\)](#)
- [Australian Cancer Trials \(search database\)](#)
- [International Clinical Trials Registry Platform \(search platform\)](#)

How can I ensure that my clinical trial is aligned with current health system priorities?

To ensure alignment with health system priorities, Investigators should consider whether the proposed research addresses clearly identified real-world needs rather than solely investigator-driven interests. Structured priority setting helps determine whether a study responds to documented gaps in care, burden of disease, service delivery challenges, or areas highlighted in policy and funding agendas.

Investigators can consult strategic plans, government health priorities, clinical guidelines, and funding body statements to confirm alignment with unmet need and system direction. Engaging clinicians, health service leaders, policymakers and consumers during the concept development stage can further strengthen relevance. Demonstrating alignment with recognised priorities may improve the likelihood of meaningful implementation and enhance competitiveness in grant applications and funding rounds.

Examples:

- [NHMRC Research Priorities](#)
- [NHMRC Research Strategy 2026–2036](#)
- [MRFF Strategy and Priorities](#)
- [Australian Cancer Plan](#)
- [NSW Cancer Plan](#)
- [Future Health: Guiding the next decade of health care in NSW 2022–2032](#)
- [NSW Regional Health Strategic Plan 2022–2032](#)

Planning for Translation and Impact

The research question should anticipate downstream translation and real-world impact. Building on the identification of a high-value research question, Investigators should consider:

- ✓ If positive, how would this change clinical practice?
- ✓ What policy or guideline pathways exist?
- ✓ What barriers to implementation are foreseeable?
- ✓ Are cost-effectiveness or health service implications relevant?
- ✓ Which stakeholders will influence adoption and implementation?

Embedding impact thinking at the trial planning stage strengthens funding applications and supports later dissemination and implementation strategies.

Developing a written concept brief prior to protocol drafting is advisable. This document should summarise the question, rationale, proposed design, feasibility considerations and anticipated impact. Circulating this brief for early critique often identifies methodological or operational issues before substantial time is invested in full protocol development.

FURTHER RESOURCES

- [Assessing the impact of clinical trials: a scoping literature review \(ACTA\)](#)
- [A pilot study to prospectively estimate the health and economic return on research investment \(ACTA\)](#)

Consumer and Stakeholder Engagement

Meaningful involvement of consumers and relevant stakeholders improves the relevance, feasibility, and impact of a trial. Consumers (people with lived experience) and stakeholders (including health care professionals, service providers, policymakers and community representatives) contribute distinct but complementary perspectives to trial planning.

Engagement should begin at the trial planning stage rather than after the trial design is finalised. Early input helps ensure that research questions reflect lived experience and real-world clinical challenges, that the selected outcomes matter to patients and health services, and that study procedures are acceptable and practical. Consumers can contribute to refining research questions, selecting patient-reported and clinical outcomes, reviewing participant information and consent materials, advising on recruitment strategies, and highlighting trial participation barriers such as travel demands, appointment frequency and financial strain.

Stakeholders such as health service leaders and clinicians can provide insight into care pathways, workflow integration, site feasibility and implementation considerations. Including consumer representation within governance structures—such as trial steering committees or advisory boards—supports transparency and accountability throughout the study lifecycle.

Where feasible and appropriate, co-design approaches should be used to embed consumer input into trial planning. Efforts should be made to engage diverse and representative consumers to ensure the trial is relevant to those it intends to benefit.

How can I identify consumers who want to engage with clinical research?

Researchers can identify consumers through established networks and organisations that actively connect researchers with people affected by cancer. National and state-based consumer and advocacy organisations run structured consumer engagement programs and advisory panels that facilitate this involvement.

These include:

- [Cancer Voices NSW](#)
- [Health Consumers NSW](#)
- [Consumers Health Forum of Australia](#)

Engaging with these organisations early enables access to both experienced consumer representatives as well as individuals newly interested in contributing to research design, governance, and dissemination.

While consumer networks support lived-experience engagement, stakeholder involvement (e.g. clinicians and service leaders) is typically facilitated through professional networks, clinical services and institutional partnerships.

Investigators should allocate appropriate budget and time for engagement activities, including remuneration for consumer contributions, meeting attendance and training where required. Clear role descriptions, respectful communication, and feedback on how input has influenced decisions are essential to maintaining meaningful and ethical partnerships with both consumers and stakeholders, ensuring their input is appropriately recognised and integrated into decision-making.





Building capacity for consumer engagement

Structured training can help prepare consumers for meaningful engagement in health and medical research. Building research literacy enables consumers to contribute confidently, reduce the risk of tokenistic participation and strengthen the quality of input. Australian consumer training opportunities include:

- [Consumers in Research Training](#) (Cancer Council)
- [Joint training for researchers and consumers in health research](#) (Health Consumers NSW)
- [Consumer Research Training](#) (Cancer Voices NSW)

FURTHER RESOURCES

- [Statement on Consumer and Community Involvement in Health and Medical Research](#) (NHMRC)
- [Consumer Engagement Toolkit](#) (Cancer Australia)
- [Consumer Involvement and Engagement Toolkit](#) (ACTA)
- [Involving Consumers in Health and Medical Research: A practical handbook for organisational, researchers, consumers and funders](#) (AHRA)
- [Co-design toolkit](#) (ACI)
- [Consumer, carer and community member remuneration](#) (NSW Health)
- [All of Us: A guide to engaging consumers, carers and communities across NSW Health](#)
- [Consumer Engagement](#) (VCCC Alliance)
- [Consumer and Community Involvement](#) (Monash Partners)

Feasibility Assessment

Feasibility assessment at the planning stage is critical to determining whether a proposed clinical trial can be delivered safely, efficiently and within a reasonable timeframe.

Key considerations include estimated eligible patient numbers, the presence of competing trials in the same population, and the likely impact of the trial on clinical workflow and service delivery. Recruitment strategies should also be explicitly planned, including referral pathways, screening processes and clinician engagement, as overestimation of recruitment potential and underestimation of operational demands are common causes of trial delay or failure.

Investigators should also assess infrastructure availability, including pharmacy, imaging, pathology and data systems, as well as investigator and site capacity to manage recruitment, follow-up and reporting obligations. For multi-site trials, variability in site capacity, processes and patient flow should be evaluated early to minimise downstream delays.

Operational and regulatory requirements should be anticipated early, particularly where investigational products or complex interventions are involved. Data considerations – including data capture systems, interoperability and potential linkage – should also be addressed. Financial feasibility must also be reviewed, with a preliminary budget accounting for personnel, investigations, monitoring, data management and contingency costs.

Engaging clinical trial units or research support teams at this stage can prevent development of operationally unrealistic proposals. Input from consumers and stakeholders often identifies practical feasibility risks not apparent at protocol level.

Structured feasibility assessment strengthens funding applications, reduces downstream protocol amendments and increases the likelihood of timely, successful trial delivery.

FURTHER RESOURCES

- [**Trial Feasibility Assessment Tool**](#)
(Clinical Trials Hub)
- [**Protocol Feasibility Checklist.docx**](#)
(Global Health Trials)
- [**Research Feasibility**](#) (NSWRHP)
- [**Clinical trials best practice checklist: Guidance for Australian clinical research sites from CT:IQ**](#)
(Journal article)
- [**Conducting Feasibilities in Clinical Trials: An Investment to Ensure a Good Study**](#) (Journal article)
- [**What is Feasibility in Clinical Research?**](#)
(Video)

USEFUL TIPS

These steps are iterative and may occur in parallel rather than strictly sequential.

1. Define the clinical problem and develop a clear research question
2. Conduct targeted literature review and search of clinical trial registries
3. Align with strategic and funding priorities
4. Confirm clinical equipoise and ethical justification
5. Engage consumers and key stakeholders early
6. Conduct preliminary feasibility assessment
7. Seek early methodological and biostatistical input
8. Consider regulatory pathway, anticipated sponsor and funding strategy
9. Identify potential sites and collaborators
10. Draft a concise concept brief (1–2 pages) before progressing to full protocol

Concept briefs are typically reviewed by clinical trials units, research governance offices and collaborators prior to protocol development and funding submission. The following adaptable, ready-to-use templates may be helpful when drafting a clinical trial concept outline:

- [**Concept Proposal Template**](#)
(The Global Health Network)
- [**Clinical Trial Protocol Template**](#)
(Melanoma and Skin Cancer Trials Limited)
- [**Concept Proposal**](#) (Smartsheet)

4. Trial Design, Methodology and Statistical Planning

Robust trial design and methodology are critical to ensuring that clinical trials generate reliable, interpretable, and ethically sound evidence. Key decisions include the choice of design, comparator, sample size, trial duration, expected treatment effect, and the application of appropriate statistical methods.

Trial Design Options

Clinical trial designs range from traditional single-arm studies to modern adaptive trials. The choice of trial design should be driven by the research question, intervention type and feasibility considerations. Design selection should also consider the potential for bias and the level of evidence required to support clinical or policy impact.

Investigator-initiated trials (IITs) in Australia are typically academically-led, CTN-based studies focused on proof-of-concept or optimisation. This means that investigator-initiated cancer trials in Australia are most commonly single-arm phase II or early-phase studies. Designs such as large randomised controlled trials are less commonly used in IITs due to higher cost, operational complexity, and infrastructure requirements, despite being the gold standard for generating definitive, practice changing evidence. Use of biomarker-driven and adaptive platform designs are increasing as precision oncology evolves.

Key considerations

The selected trial design should:

- ✓ Be methodologically robust and capable of answering the research question
- ✓ Be ethically justified, including consideration of equipoise and accessibility
- ✓ Be feasible within available resources and timelines
- ✓ Align with regulatory and governance requirements

FURTHER RESOURCES

- [Clinical Trial Design \(NSWRHP\)](#)
- [Designing your research study \(NSW OHMR\)](#)
- [Intro to Clinical Trial Design video \(NIH\)](#)

Randomisation and Blinding

Randomisation methods, allocation concealment and blinding strategies should be clearly specified to minimise bias. Where blinding is not feasible, consider the use of objective outcome measures or blinded endpoint adjudication. Integrate data integrity and monitoring considerations into design decisions from the outset.

Endpoints and Outcomes

Endpoint selection is equally critical. Primary outcomes should be clinically meaningful, measurable, aligned with the hypothesis, and with careful consideration of accepted oncology endpoints such as overall survival, progression-free survival and response rates. Outcomes should be pre-specified and justified in accordance with established guidance (e.g. SPIRIT, CONSORT). Secondary and exploratory outcomes should be limited to those that are achievable within available resources to avoid unnecessary participant burden and data complexity. Where appropriate, incorporating valid and reliable patient-reported outcome measures can strengthen translational relevance and support health policy impact.



FURTHER RESOURCES

- [Response Evaluation Criteria in Solid Tumor \(RECIST\)](#)
- [Core Outcome Measures in Effectiveness Trials \(COMET\)](#)
- [Recommendations on the use of item libraries for PROMS in oncology trials \(The Lancet Oncology\)](#)

Statistical Considerations

Early consultation with biostatisticians is essential to ensure the proposed design is robust, feasible and aligned with the primary endpoint. Input should inform key decisions on study design, sample size, power, minimising bias, analysis planning, and endpoint validation prior to protocol development.

Sample size and power calculations should account for expected effect size, variability, dropout rates and recruitment feasibility. Underpowered trials risk producing inconclusive results, while overestimation of recruitment capacity can delay timelines and increase costs. Feasibility assessments should consider historical patient volumes, competing studies and site capacity, particularly across multi-site trials where recruitment may be improved but governance complexity increases.

Statistical approaches should be pre-specified to minimise bias and enhance validity of the findings. This includes clear definition of analysis populations (eg. intention-to-treat), handling missing data, adjusting for baseline imbalances, and controlling for multiplicity and interim analyses. Sensitivity analyses should be planned a-priori to assess robustness and support appropriate decision-making during the trial.

A detailed **Statistical Analysis Plan (SAP)** should be developed and finalised before recruitment or database lock. The SAP details the planned analytical methods including primary and secondary endpoints, analysis populations, handling of missing data, interim analyses, and reporting conventions. The SAP promotes transparency, reduces the risk of selective reporting, and strengthens the credibility and reproducibility of trial findings.

FURTHER RESOURCES

- [Statistical Analysis Plan \(SAP\) \(examples collated by ACTA\)](#)
- [Training modules \(A-CTEC\)](#)
- [ICH E9 statistical principles for clinical trials – Scientific guideline | European Medicines Agency \(EMA\)](#)



Are there professional services that can assist with clinical trial design, methodology and statistical planning?

Yes. A range of professional services in Australia can support clinical trial design, methodology selection, and biostatistics. Universities, medical research institutes, and major hospitals often host dedicated clinical trials units and biostatistics groups that provide input on study design, sample size calculation, endpoint selection, statistical analysis plans, and data management. Contact your Research Office to see if there are services available in your local area.

Engaging these services early—ideally at the concept and feasibility stage—helps ensure the study is methodologically robust, ethically sound, and appropriately powered before submission to ethics and governance review.

Investigators without access to local support can engage national networks such as:

- **Biostatistics Collaboration of Australia** – a national network of academic biostatisticians providing expertise, training and access to biostatistical support across institutions.

Protocol Development

Clinical trial protocol development produces a complete, compliant, and operational document that defines the scientific rationale, objectives, methodology, safety oversight, statistical framework and governance arrangements for the study. Protocols should follow established frameworks such as the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines to ensure completeness and transparency. The protocol serves as the primary reference for investigators, sponsors, ethics committees, and regulators, and must align with Good Clinical Practice and applicable regulatory requirements.

Core documentation developed at this stage includes the full trial protocol, Participant Information and Consent Form (PICF), Investigator Brochure (where relevant), and a detailed Statistical Analysis Plan. Use of nationally endorsed templates and targeted training in protocol development, compliance, and serious breach management supports consistency, regulatory alignment, and operational feasibility across trial sites.

FURTHER RESOURCES

- **Clinical trials toolkit (NSW OHMR)**
- **Preparing Trial Documents (VCCC Alliance)**
- **What is a clinical trial protocol? (Clinical Trials Hub)**
- **SPIRIT-CONSORT (website and SPIRIT protocol template)**
- **Clinical Trial Protocol (Clinical Trials Roadmap)**
- **Protocol Templates for Clinical Trials (NIH)**

5. Trial Start-up and Site Activation

Site feasibility, financial planning, and contractual arrangements are essential components of clinical trial start-up. In NSW public health organisations, these processes occur alongside ethics approval and research governance review (see Section 2), ensuring that the institution has the capacity, infrastructure, and financial arrangements required to safely conduct the study.

Feasibility assessments inform whether a site can meet the protocol requirements, while budgets and contracts formalise responsibilities, costs, indemnities, and timelines between the sponsor and the hosting institution. These activities are typically coordinated through the site's Clinical Trials Unit, and often involving consultation with a local Research Office and/or Research Governance Office.

FURTHER RESOURCES

- [NSW Health Clinical Trials Standard Operating Procedures \(NSW Health\)](#)

Site Feasibility and Selection

Assessment of site capacity is a fundamental component of trial feasibility and informs decisions about whether a health service can deliver the protocol safely and efficiently. Sponsors commonly request formal feasibility assessments prior to site selection, and these may be followed by site qualification visits to verify infrastructure, systems and staffing.

Within the NSW context, feasibility assessments consider:

- ✓ the expected availability of eligible participants,
- ✓ established referral pathways or recruitment networks,
- ✓ the presence of competing trials and service demands within the same clinical population,
- ✓ the experience of the proposed principal investigator and study team.

Equally important is access to an appropriately trained clinical trials workforce including research nurses, study coordinators, investigators, pharmacists, data managers, and regulatory staff who can support protocol delivery and compliance with Good Clinical Practice. Health services must also demonstrate that they have access to required supporting infrastructure such as investigational drug pharmacy services, pathology and imaging, specimen processing capabilities, secure investigational product storage, and appropriate data and IT systems.

Research governance offices review these elements via the Site-Specific Assessment to confirm that the institution has the operational capacity to undertake the trial prior to granting site authorisation.

FURTHER RESOURCES

- [Clinical Trial Site Recruitment Guide \(CTIQ\)](#)

Budget

Clinical trial budgets must clearly distinguish between routine clinical care and activities undertaken specifically for research. Standard of care costs refer to procedures, tests, or clinical services that participants would normally receive as part of usual clinical management even if they were not enrolled in a trial. These costs are typically covered through existing healthcare funding mechanisms such as hospital funding or Medicare.

In contrast, above standard of care costs relate to activities that are required solely for the purposes of conducting the trial. This distinction reflects commonly applied cost attribution principles used in Australian clinical trials. These may include additional laboratory investigations, protocol-specific imaging, data management activities, investigational product handling, monitoring visits, regulatory activities, and research staff time. Within the Australian clinical trials framework, these costs are generally recovered from the trial sponsor or funding body. Budgets may also include indirect costs or institutional overheads to support infrastructure, governance and administration services associated with trial delivery.

Clear identification of these cost categories is essential to ensure transparency, appropriate cost recovery for health services, and compliance with institutional financial governance requirements. Budget development is closely linked to feasibility assessment, ensuring that proposed costs align with the resources required to deliver the protocol. Final budgets are typically incorporated into the Clinical Trial Research Agreement (CTRA or CTA) and form the basis for invoicing and payment. Budgets are commonly structured around milestone- or activity-based payments, such as recruitment, study visits, and deliverables. Many health organisations in NSW use structured clinical trial budget templates to support consistent costing and negotiation with sponsors.

FURTHER RESOURCES

- [Clinical Trial Budget Costing Template \(NSW Health\)](#)

Contracts and Agreements

Formal agreements establish the legal and financial arrangements between the trial sponsor and the institution conducting the study.

In NSW public health organisations, these arrangements are typically documented in a **Clinical Trial Research Agreement (CTRA)**, which must be fully executed before any research activities begin. Execution of the CTRA is typically a prerequisite for site authorisation through the research governance process.

The agreement outlines the responsibilities of each party, including financial arrangements and payment schedules, intellectual property and publication rights, data ownership and confidentiality, and indemnity and insurance requirements associated with the trial.

To facilitate efficient contracting across Australia, nationally standardised CTRA templates have been developed through collaborative initiatives involving Medicines Australia, government agencies, and research organisations. These templates are widely used to streamline negotiation and promote consistency across institutions. Different templates are used depending on the study type and are widely adopted to streamline negotiation and promote consistency across institutions.

Despite the availability of standardised agreements, contract negotiation can still influence trial start-up timelines, particularly when protocols involve multiple sites, complex funding arrangements, or non-standard contractual terms. Early engagement between sponsors, investigators, and research governance offices can help minimise delays and support timely trial activation.

FURTHER RESOURCES

- [Clinical Trial Research Agreement \(CTRA\) Templates \(Medicines Australia\)](#)
- [Research Agreements in NSW Health Organisations](#)

Insurance and Indemnity

Clinical trials conducted within NSW public health organisations require appropriate insurance and indemnity arrangements before the study can commence. These ensure that the institution, investigators, and participants are protected against potential liabilities arising from the conduct of the trial.

For commercially sponsored studies, sponsors typically provide a contractual indemnity to the participating institution covering claims arising from the investigational product or protocol-related activities. Sponsors are also required to provide evidence of adequate clinical trial insurance.

This insurance is intended to address liabilities associated with the study, including participant injury and legal claims that may arise during trial participation.

Public health organisations typically maintain professional indemnity coverage for clinical activities undertaken by employees within the scope of their duties. Standard indemnity forms and compensation guidance are widely used across Australia and are incorporated into national Clinical Trial Research Agreement templates. Documentation relating to insurance and indemnity is reviewed by the relevant Research Governance Office as part of the site authorisation process.

FURTHER RESOURCES

- [Indemnity and Compensation Guidelines \(Medicines Australia\)](#)
- [Indemnity and Insurance Arrangements for Clinical Trials \(NHMRC\)](#)

Investigator Brochure

For trials involving investigational products, the Investigator Brochure summarises the clinical and non-clinical data relevant to the product. It provides investigators with essential safety, pharmacological, and efficacy information necessary to support participant safety, risk management and safety reporting obligations.

The Investigator Brochure is a core document under Good Clinical Practice and forms part of the essential documents required for trial conduct. Investigators use the document to understand the risk profile of the investigational product, support clinical decision-making, and guide safety monitoring throughout the trial.

The sponsor is responsible for preparing, maintaining, and updating the Investigator Brochure, which must remain current and consistent with regulatory submissions. The document is typically reviewed and updated periodically as new safety or efficacy information becomes available.

FURTHER RESOURCES

- [Investigator's brochures for medical device clinical trials \(TGA\)](#)
- [Clinical Trials Investigators Brochure \(SCHN\)](#)

Trial Registration

Prospective registration of clinical trials in a publicly accessible registry is a requirement for transparency, accountability, and research integrity. Registration ensures that key information about the study design, interventions, and outcomes is publicly available and supports the reporting and dissemination of trial results.

In Australia, clinical trials are typically registered on recognised international registries such as ClinicalTrials.gov or the Australian New Zealand Clinical Trials Registry (ANZCTR), both of which are part of the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP). Many funding bodies and journals require trials to be registered before any participants are enrolled as a condition of funding or publication.

Trial registration is generally undertaken by the sponsor or coordinating investigator. Registration details should be kept up to date throughout the study, including changes to status, recruitment, and outcomes.

FURTHER RESOURCES

- [Australian New Zealand Clinical Trials Registry \(ANZCTR\)](#)
- [ClinicalTrials.gov](#)

Site Initiation

Following completion of ethics and governance approvals, execution of contracts, and confirmation of resourcing, sites undergo a formal initiation process prior to commencing recruitment. This is typically conducted through a Site Initiation Visit (SIV), led by the sponsor or coordinating centre, to ensure that all study procedures, protocol requirements, safety reporting processes, and data capture systems are understood by the study team.

The initiation process confirms that all essential documents are in place, study staff are appropriately trained, and key systems (e.g. laboratory processes and data systems) are operational. Upon completion, the site is formally activated and may begin participant recruitment. The timing of site initiation and activation is a key determinant of overall trial start-up timelines.

6. Trial Conduct and Management



Participant Recruitment and Retention

Effective recruitment and retention of participants are critical to the successful conduct of clinical trials. Participants are typically identified through clinical services, referral networks, or database screening and assessed against protocol-specific inclusion and exclusion criteria. Recruitment must be conducted ethically, ensuring that participation is voluntary and free from coercion, and that potential participants are given adequate time and information to make an informed decision.

The **Participant Information and Consent Form (PICF)** is a key document in this process. It outlines the purpose of the study, procedures involved, potential risks and benefits, alternatives to participation, privacy protections, and withdrawal rights. The PICF must be written in clear, accessible language and reflect all protocol-specific requirements, supporting informed, voluntary participation in accordance with human research ethics standards.

Following consent, participants typically undergo screening and enrolment in accordance with the study protocol. Maintaining participant engagement and minimising loss to follow-up throughout the study is important for data quality, protocol adherence, and overall trial success.

FURTHER RESOURCES

- [Clinical Trial Site Recruitment Guide \(CTIQ\)](#)
- [Patient information and consent form \(NSW OHMRC\)](#)
- [CT:IQ InFORMed \(PICF template and supporting resources\)](#)
- [Integrated Consent User Guide and Template \(ACTA\)](#)

Data Management

Effective data management protects data quality, participant privacy, and the overall credibility of a clinical trial. A robust framework includes a comprehensive **Data Management Plan (DMP)** that outlines processes for data collection, storage, security, quality control, and archiving.

What is a Data Management Plan (DMP)?

A Data Management Plan (DMP) is a formal document describing how study data will be collected, managed, stored, protected, and ultimately archived. Its purpose is to ensure data integrity, participant confidentiality, regulatory compliance, and reproducibility of results.

In a clinical trial context, the DMP typically outlines the types of data to be collected (e.g., clinical outcomes, laboratory values, adverse events), the systems used to capture data (such as electronic case report forms within a secure database), and the standards applied for coding and formatting. It defines roles and responsibilities for data entry, review, and oversight, and describes procedures for data validation, query management, version control, audit trails and data corrections.

A DMP also addresses privacy and security requirements, including access controls, encryption, storage arrangements, and compliance with applicable legislation and Good Clinical Practice (GCP). Participant data should be coded and de-identified where possible, with access restricted to authorised study personnel.

Ethics committees, sponsors, and regulatory bodies expect a clear and proportionate DMP before recruitment begins. Developing it early helps to support data quality, minimises protocol deviations, and facilitates reliable analysis at study completion.

Investigators should select an appropriate database platform that supports secure data capture, validation rules, and audit trails. REDCap is one such platform; it is a research-focused online data capture platform used internationally and is available across many NSW health services and universities.

What is REDCap?

REDCap (Research Electronic Data Capture) is a free, secure, web-based platform developed to support data capture for clinical and translational research, including clinical trials. It is widely used across NSW particularly for IITs.

Alternative electronic data capture platforms include:

- [Castor EDC](#)
- [OpenClinica](#)
- [Qualtrics](#)
- [Medrio](#)

Researchers should finalise the DMP before recruitment commences, ensure that data collection is limited to information that is necessary to answer the research question, and test electronic case report forms (eCRFs) thoroughly before activating study sites. These measures support data quality, minimise errors, and support regulatory and ethical compliance.

FURTHER RESOURCES

- [Management of Data and Information in Research: A guide to supporting the Australian Code for the Responsible Conduct of Research \(NHMRC\)](#)
- [REDCap website](#)
- [NSW Health REDCap access](#)
- [NSW Health Clinical Trial Management System](#)

Safety Reporting

A safety reporting plan sets out how adverse events (AEs), including Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARs), are identified, assessed, documented, and reported. Adverse events include any untoward medical occurrence, while serious adverse events are those that result in death, are life-threatening, require hospitalisation, or result in significant disability.

Events must be assessed for seriousness, causality, and expectedness to determine appropriate reporting pathways. SAEs are typically required to be reported promptly (often within 24 hours) to the sponsor. Investigators are responsible for identifying and reporting events, while sponsors oversee ongoing safety evaluation and regulatory reporting, including communication with Human Research Ethics Committees and regulators.

The safety plan should define reporting timelines, roles and responsibilities of investigators and sponsors, escalation pathways, and communication requirements. Clearly specifying reporting pathways within the protocol is critical to timely and consistent safety management. Ongoing safety monitoring supports risk assessment throughout the trial and may inform protocol modifications or trial suspension if necessary.

FURTHER RESOURCES

- [Safety Monitoring \(VCCC Alliance\)](#)
- [Safety monitoring and reporting in clinical trials involving therapeutic goods \(NHMRC\)](#)
- [Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting \(TGA\)](#)

Monitoring and Quality Assurance

Clinical trial monitoring ensures that a study is conducted in accordance with the protocol, Good Clinical Practice, and applicable regulatory requirements. Monitoring is typically performed by the sponsor or their delegate and involves review of study conduct, verification of data against source documents, and confirmation that participant rights and safety are protected.

Monitoring activities may be conducted on-site, remotely, or through risk-based approaches, depending on the complexity and risk profile of the trial. Investigators and research teams are responsible for maintaining accurate, complete, and verifiable source documentation to support these activities.

Quality assurance provides additional oversight through structured processes designed to ensure compliance and consistency. This may include standard operating procedures, internal reviews, and independent audits. Audits may be conducted by sponsors or institutions, while regulatory inspections may be undertaken by authorities such as the Therapeutic Goods Administration (TGA).

For higher-risk trials, large multicentre studies, or those involving vulnerable populations, an independent Data and Safety Monitoring Board (DSMB) may be established. The DSMB reviews accumulating trial data to assess participant safety and, where relevant, efficacy outcomes. Effective DSMB oversight depends on clearly defined terms of reference, scheduled data reviews, and pre-specified decision-making criteria, including stopping or modification rules.

FURTHER RESOURCES

- [Data and Safety Monitoring Board \(DSMB\) \(Australian Cancer Trials\)](#)
- [Data Safety Monitoring Board \(DSMBs\) \(NHMRC\)](#)
- [Statistical requirements for a Data Safety Monitoring Board \(DSMB\) \(ACTA\)](#)

Audit Preparedness

Clinical trials may be subject to audit by sponsors, institutions, or regulators. Audit preparedness requires systematic record-keeping, clear documentation of investigator oversight and delegation, and demonstrable compliance with the approved protocol.

Maintaining up-to-date essential documents in accordance with Good Clinical Practice; ensuring study staff are familiar with the protocol, their delegated responsibilities and site processes; and conducting internal readiness reviews prior to external audits can help identify and address compliance gaps early. Self-audit or self-monitoring tools are provided by some research offices and the Office for Human Research Monitoring (OHRM).

FURTHER RESOURCES

- [Clinical Trials Audit Checklist](#)
(Sydney Partnership for Health, Education, Research and Enterprise)
- [National Clinical Trials Governance Framework – Audit Ready Resource Pack](#) (NSWRHP)



7. Dissemination, Translation and Impact

Planning for dissemination, translation and impact is an essential component of contemporary clinical trial design within the NSW health and medical research system. Beyond demonstrating scientific validity and regulatory compliance, clinical trials are expected to generate outcomes that can be translated into improvements in clinical practice, health policy, and patient outcomes.

In NSW, funding bodies and health agencies place strong emphasis on the importance of designing research with a clear pathway to implementation. Early planning enables investigators to align trial objectives with health system priorities, engage relevant stakeholders, and ensure that findings can inform clinical guidelines, policy development and models of care.

Reporting Results and Publication

Timely and transparent reporting of clinical trial results is a fundamental component of research integrity. Investigators should ensure that, regardless of study outcomes, trial findings are disseminated through appropriate channels, including clinical trial registries, peer-reviewed publications, and presentations at scientific meetings. Reporting should adhere to recognised standards and guidelines to ensure completeness, transparency, and reproducibility.

FURTHER RESOURCES

- [SPRIT Statement & Extensions](#)
- [CONSORT Statement & Extensions](#)
- [EQUATOR Network](#)
- [International Committee of Medical Journal Editors \(ICMJE\) Recommendations](#)
- [Results Reporting Requirements \(ANZCTR\)](#)



Dissemination and Knowledge Translation

Dissemination strategies should extend beyond academic publication to ensure that findings reach clinicians, policy makers, and healthcare organisations. This may include engagement with clinical networks, professional societies, guideline development bodies, and health service leadership groups.

Knowledge translation involves actively facilitating the movement of evidence from research into clinical practice, policy and decision-making. This may include developing implementation tools, clinical resources, or decision-support materials that facilitate adoption of new evidence in real-world settings.

Clear communication of results to participants, consumers, and the broader community is also an important component of dissemination and contributes to transparency and public trust in clinical research.

FURTHER RESOURCES

- ['What is research translation?' \(NHMRC\)](#)
- [What is translational research? \(NSW OHMR\)](#)

Implementation into Practice

Effective translation requires consideration of how trial findings will be incorporated into healthcare systems. Potential pathways include integration into clinical guidelines, regulatory approval processes, health technology assessments, and health service policy.

In NSW, organisations such as the Agency for Clinical Innovation and the Cancer Institute NSW play key roles in supporting implementation through development of models of care, clinical guidance, and statewide initiatives.

Consideration of implementation barriers—such as workforce capacity, resource constraints, and training requirements—is essential. Trials that generate evidence on feasibility, cost-effectiveness, and service delivery impact are more likely to support successful adoption into practice.

FURTHER RESOURCES

- [ACI-Implementation-Guide.pdf](#)
- ['Research translation' \(MRFF\)](#)
- ['Improving impact of clinical trials through implementability' \(ACTA\)](#)

Measuring Impact

Demonstrating the impact of clinical trials is an important component of accountability to funders, health services, and the community. Impact may be assessed across multiple domains, including improvements in patient outcomes, changes in clinical practice, health system efficiency, and policy influence.

Frameworks such as those developed by the NHMRC and the Medical Research Future Fund support structured evaluation of research impact and translation outcomes.

FURTHER RESOURCES

- [Research impact position statement \(NHMRC\)](#)
- [Guidelines for producing NHMRC Case Studies \(NHMRC\)](#)
- [Assessing the impact of clinical trials: a scoping literature review \(ACTA\)](#)

8. Consolidated Web Resource Directory

Introduction and General Clinical Trial Information

- [What is a clinical trial? – Australian Cancer Trials](#)
- [How clinical trials work – Australian Clinical Trials](#)
- [Cancer Clinical Trials Program – Cancer Institute NSW](#)
- [Clinical Trial Life Cycle Resources – VCCC Alliance](#)
- [Clinical Trials Roadmap – NSW Regional Health Partners](#)
- [My Clinical Trial Planner – Clinical Trials Hub](#)
- [Investigator-Initiated Trials Toolkit – VCCC Alliance](#)
- [Global Health Trials Tools and Templates](#)

Glossaries

- [Australian Cancer Trials](#)
- [Therapeutic Goods Administration](#)
- [Cancer Institute NSW](#)
- [VCCC Alliance](#)

Regulatory, Ethics and Governance Framework

- [Principles, regulations and governance of clinical trials – Australian Clinical Trials](#)
- [Regulations, ethics and governance of clinical trials – Clinical Trials Hub](#)
- [NSW Health Clinical Trials Toolkit – NSW Office for Health and Medical Research](#)
- [National Statement on Ethical Conduct in Human Research – NHMRC](#)
- [NSW Ethics and Governance Contacts – NSW Office for Health and Medical Research](#)

- [Research Handbook – NSW Office for Health and Medical Research](#)

Regulatory Pathways (CTN / CTA)

- [Australian Clinical Trial Handbook – Therapeutic Goods Administration \(TGA\)](#)
- [Clinical Trials Overview – Therapeutic Goods Administration](#)
- [Clinical Trial Notification \(CTN\) Scheme – TGA](#)
- [Clinical Trial Approval \(CTA\) Scheme – TGA](#)

Human Research Ethics Committees and Ethics Review

- [List of Australian Human Research Ethics Committees – NHMRC](#)
- [Research Ethics and Governance Information System \(REGIS\) – NSW Health](#)
- [NSW Ethics and Governance Contacts – NSW Office for Health and Medical Research](#)
- [Ethical Guidelines for Research Involving Aboriginal and Torres Strait Islander Peoples – NHMRC](#)
- [AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research](#)

Governance Approvals

- [National Clinical Trials Governance Framework – Australian Commission Safety and Quality in Health Care](#)
- [NSW Governance Contacts – NSW Office for Health and Medical Research](#)
- [Authorisation to Commence Human Research in NSW Public Health Organisations – NSW Health](#)

- [Site authorisation and access – NSW Office for Health and Medical Research](#)

- [Good Practice for Site Assessment and Authorisation Phases of Clinical Research Governance – NHMRC](#)

Good Clinical Practice (GCP)

- [ICH Guideline for Good Clinical Practice – TGA](#)
- [WHO Handbook for Good Clinical Practice](#)
- [Good Clinical Practice Training – NSW Office for Health and Medical Research](#)
- [Good Clinical Practice for clinical trials in Australia – Australian Cancer Trials](#)
- [Good Clinical Practice in clinical trials – Clinical Trials Hub](#)
- [TransCelerate Mutual Recognition Program for GCP Training](#)

Reporting Obligations

- [National Standard Operating Procedures for Clinical Trials in Australia – Australian Clinical Trials](#)
- [Framework for Monitoring: Guidance for the national approach to single ethical review of multi-centre research – NHMRC](#)
- [Monitoring Trial Conduct – VCCC Alliance](#)
- [Risk Management: Introduction to risk management principles and risk-based approach to managing quality in clinical trials – VCCC Alliance](#)

Clinical Trial Registries

- [Australian New Zealand Clinical Trials Registry](#)

- [Australian Cancer Trials Database](#)
- [Australian Clinical Trials Database](#)
- [ClinicalTrials.gov](#)
- [WHO International Clinical Trials Registry Platform](#)

Consumer and Stakeholder Engagement

- [Consumer Involvement and Engagement Toolkit – Australian Clinical Trials Alliance](#)
- [Consumer Engagement Toolkit – Cancer Australia](#)
- [Involving Consumers in Health and Medical Research – Australian Health Research Alliance](#)
- [Co-design toolkit – Agency for Clinical Innovation](#)
- [Consumer, carer and community member remuneration – NSW Health](#)
- [All of Us: A guide to engaging consumers, carers and communities across NSW Health – NSW Health](#)
- [Consumer Engagement – VCCC Alliance](#)
- [Consumer and Community Involvement – Monash Partners](#)
- [Statement on Consumer and Community Involvement in Health and Medical Research – NHMRC](#)
- [Cancer Voices NSW](#)
- [Health Consumers NSW](#)
- [Consumers Health Forum of Australia](#)

Trial Feasibility Assessment

- [Trial Feasibility Assessment Tool – Clinical Trials Hub](#)
- [Protocol Feasibility Checklist – The Global Health Network](#)
- [Research Feasibility – NSW Regional Health Partners](#)
- [Conducting feasibilities in clinical trials: An investment to ensure a good study – Journal article](#)
- [What is feasibility in clinical research? Video](#)

Trial Design and Methodology

- [Clinical Trial Design Resources – NSW Regional Health Partners](#)
- [Intro to Clinical Trial Design – VideoCast – National Institutes of Health](#)
- [Response Evaluation Criteria in Solid Tumor](#)

- [Core Outcome Measures in Effectiveness Trials – COMET Initiative](#)
- [Recommendations on the use of item libraries for PROMS in oncology trials – The Lancet Oncology](#)
- [Statistical Analysis Plan – Australian Clinical Trials Alliance](#)
- [ICH-9 statistical principles for clinical trials – Scientific guideline – European Medical Agency](#)

Protocol Development

- [Clinical Trial Protocol Template – National Institutes of Health](#)
- [Clinical Trial Protocol Guidance – Clinical Trials Hub](#)
- [Clinical Trial Protocol – Clinical Trials Roadmap](#)
- [Preparing Trial Documents – VCCC Alliance](#)
- [SPIRIT Clinical Trial Protocol Guidance](#)

Trial Start-up

- [Standard Operating Procedures – NSW Office for Health and Medical Research](#)
- [Clinical Trials Site Recruitment Guide – CT:IQ](#)
- [Clinical Trial Budget Costing Template – NSW Health](#)
- [Clinical Trial Research Agreement Templates – Medicines Australia](#)
- [Indemnity and Compensation Guidelines – Medicines Australia](#)
- [Indemnity and Insurance Arrangements for Clinical Trials – NHMRC](#)
- [Investigator's brochures for medical device clinical trials – TGA](#)

Participant Recruitment

- [Clinical Trials Site Recruitment Guide – CT:IQ](#)
- [Patient information and consent form – NSW Office for Health and Medical Research](#)
- [Patient Information and Consent Form Template – CT:IQ](#)
- [Integrated Consent User Guide and Template – Australian Clinical Trials Alliance](#)

Data Management

- [Management of Data and Information in Research – NHMRC](#)
- [Clinical Trial Management System – Office for Health and Medical Research](#)

- [REDCap Research Electronic Data Capture](#)

- [NSW Health REDCap](#)

Trial Safety and Monitoring

- [Safety Monitoring in Clinical Trials – VCCC Alliance](#)
- [Safety Monitoring and Reporting in Clinical Trials – NHMRC](#)
- [Risk-Based Monitoring Guidance – NHMRC](#)
- [Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Review – TGA](#)
- [Data and safety Monitoring Board – Australian Cancer Trials](#)
- [Data Safety Monitoring Board – NHMRC](#)
- [Statistical requirements for a Data safety Monitoring Board – Australian Clinical Trials Alliance](#)
- [Clinical Trials Audit Checklist – SPHERE Clinical Trials Platform](#)
- [National Clinical Trials Governance Framework – Audit Ready Resource Pack – NSW Regional Health Partners](#)

Dissemination, Translation and Impact

- [SPIRIT-CONSORT guidelines](#)
- [Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals – International Committee of Medical Journal Editors](#)
- [Research translation – NHMRC](#)
- [What is translational research? – NSW Office for Health and Medical Research](#)
- [Implementation Guide – NSW Agency for Clinical Innovation](#)
- [Research translation – MRFF](#)
- [Improving impact of clinical trials through implementability – Australian Clinical Trials Alliance](#)
- [Research Impact Position Statement – NHMRC](#)
- [Assessing the Impact of Clinical Trials – Australian Clinical Trials Alliance](#)



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