Every GP can connect their community to clinical trials

A resource for GPs to understand their role in supporting patients to access clinical trials



This content is for Australian healthcare professionals only
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A clinical trial is a regulated research study that helps researchers determine whether a treatment:

- **Is safe and well tolerated**
- **Is effective compared with standard of care**
- **May benefit particular patient populations**
- **Improves patient quality of life**

Clinical trials in Australia are conducted under strict ethical and regulatory standards, with participant safety, informed consent, and clinical oversight central to every study.



Research site teams consist of doctors, nurses, pharmacists, and other healthcare professionals, led by a medically qualified Principal Investigator.

Research, participation and representation matter

- Clinical trials help research new treatments that **may improve and extend lives**
- **Participants** help researchers better understand new treatments
- Representation from all Australian communities—**rural, regional, and Culturally and Linguistically Diverse**—helps ensure new treatments are effective for everyone

Expand what's possible for your patients:

When to raise the conversation about clinical trials

Clinical trials may be considered throughout the patient journey—not only when standard treatment options have been exhausted.



Early in care journey

Clinical trials may be appropriate to consider alongside other treatment options and may offer another pathway before alternatives are exhausted.

Inadequate treatment response

Symptoms or disease remain difficult to manage despite standard treatment.

Limited available options

Clinical trials may offer access to investigational medicines where appropriate.

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Specialist referral appropriate

Patients may meet referral or study criteria.

Patient interest in new approaches

Patients express interest in research or emerging therapies.

You can help identify and connect patients to clinical trial opportunities. GPs remain a trusted point of care and communication, while research site teams manage trial-specific care.

Your role. Your patients.
Their access to clinical trials

You can support informed decision-making by connecting patients with trial centres while remaining involved in ongoing care throughout the clinical trial journey.



Identify appropriate patients

Recognise patients who may benefit from additional treatment options.



Initiate conversation

Discuss clinical trials as a potential option and address misconceptions and concerns.



Provide ongoing care

Continue routine care alongside the research site team, including management of general health needs and comorbidities.



Support patient experience

Provide reassurance and continuity of care throughout the clinical trial journey.



Connect and refer patients

Connect patients with trial centres and support informed decision-making.

Bench to bedside:

How new medicines progress from research to clinical care

Discovery

Laboratory testing

Preclinical testing

Clinical trials

Approval

Clinical trials are conducted in phases, with each phase designed to answer different questions about the safety and effectiveness of a study drug.









What is being studied

Phase 1 Small group	• Safety of the investigational study drug, which can be in healthy volunteers • Dosing levels and frequency of the study drug
Phase 2 Larger group	• Safety of the study drug in a larger group of patients (i.e. people with the disease) • Efficacy of the study drug and optimal dosing
Phase 3 Large-scale studies	• Efficacy and safety of the study drug in large groups of people representative of real-world patients • How the study drug compares with standard of care
Phase 4 Real world studies	• How the study drug works in the real world once it is approved • Frequency of side effects that may develop with long-term use in routine clinical practice

What happens during a clinical trial?

Most clinical trials follow a similar process that includes screening, study participation, and follow-up care.



1. Screening

The research site team assesses whether a patient may be eligible to participate. This may include:

- Review of medical history
- Physical examinations
- Blood test, scans, and/or other assessments



2. Study treatment

Participants may be assigned to receive either:

- The investigational medicine, or
- The control treatment (often the current standard of care or a placebo, depending on the study design).

Depending on the study design, your patient, you, and the research site team may or may not know which group your patient is assigned to.

During the study, participants may attend scheduled visits, complete health assessments, and report symptoms, side effects or other health changes.



3. Follow-up

After the treatment phase, additional follow-up visits or assessments may occur to monitor ongoing health and discuss next steps for care.

Participants are informed when study results become publicly available.

You can support patients throughout the clinical trial journey by:

- Providing ongoing routine care
- Managing general health and comorbidities
- Helping address patient questions or concerns
- Supporting continuity of care alongside the research site team

Understanding informed consent

The informed consent process helps your patient understand the clinical trial, ask questions, and make an informed decision about participation.

What the research site team will explain

- Purpose of the study
- Study duration and schedule of visits
- Required health checks, tests, and assessments
- Possible benefits and risks
- Healthcare professionals involved in their care
- Available practical support, including reimbursement for travel or meal expenses where applicable

Participation and patient rights

- Participation is voluntary, and participants may withdraw from a clinical trial at any time
- Informed consent is required in a clinical trial before any study procedures take place
- Adult participants provide consent by signing an informed consent form. For children, assent and caregiver consent are required
- Participants are encouraged to take their time asking questions and discussing participation with their support network
- Interpreters are available to support informed consent, ensuring Culturally and Linguistically Diverse communities are included and empowered
- Personal and health information collected during the study is handled confidentially in accordance with privacy requirements



You can support patients by helping them understand clinical trial information and discussing questions or concerns alongside the research site team.

Ethical and regulatory oversight of clinical trials

Clinical trials in Australia are conducted under strict ethical, scientific and regulatory standards designed to protect participants and support high-quality research.

Clinical trials in Australia are reviewed and monitored by Human Research Ethics Committees, research institutions, and the Therapeutic Goods Administration (TGA).

Key frameworks include:

National Statement on Ethical Conduct in Human Research
https://www.nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research

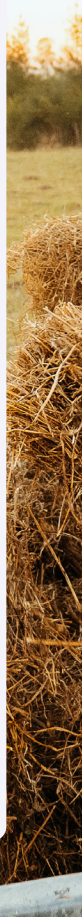
Australian clinical trial handbook
https://www.tga.gov.au/resources/guidance/australian-clinical-trial-handbook

International guidelines adopted by the TGA
https://www.tga.gov.au/resources/resource/international-scientific-guidelines

National Operating Procedures for Clinical Trials
https://www.australianclinicaltrials.gov.au/national-reforms/national-sops

These frameworks help ensure:

- Participant safety and wellbeing
- Informed consent and privacy protections
- Scientific and ethical oversight
- Ongoing safety monitoring and reporting
- There is additional ethical guidance to support culturally safe and appropriate research involving Aboriginal and Torres Strait Islander peoples and communities





Together, these frameworks help ensure clinical trials are conducted safely, ethically and responsibly.

- Ethics approved
- TGA regulated
- Participant safety monitored

Common myths vs facts about clinical trials

Many patients are interested in clinical trials but may still have concerns or misconceptions.



Clinical trials are a patient's 'last resort'

Participants are treated like 'guinea pigs'

Clinical trials are unsafe

Clinical trials are only available in major hospitals or cities

Patients cannot leave a clinical trial once they join

GPs are not involved once a patient joins a clinical trial

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- Clinical trials may be considered at different stages of care and may be an appropriate option for eligible patients
- Clinical trial participants are protected by strict ethical, safety, and informed consent processes
- Clinical trials in Australia are highly regulated and closely monitored to support participant safety
- Some clinical trials may be available through local hospitals, specialist centres, or community-based services
- Participation is voluntary, and participants may withdraw from a clinical trial at any time
- GPs often continue providing routine care alongside the research site team, supporting continuity of care throughout the study

Your role. Your patients.
Their access to clinical trials

Supporting informed patient conversations about clinical trial participation.

Potential benefits and considerations of clinical trial participation

- Access to additional treatment options under clinical supervision
- Close monitoring by the research site team
- Contributing to research that may inform future patient care

Challenges of clinical trial participation

- More frequent appointments, tests or assessments may be required
- Study drug may cause side effects or may not be effective
- Participation requirements may affect daily routines or travel

The importance of inclusive clinical trials

- Representation from all Australian communities—rural, regional, and Culturally and Linguistically Diverse—helps ensure new treatments are effective for everyone
- It is important that clinical trial populations reflect the real-world population that the new potential medicine will treat

! Remember: Participation is voluntary, and participants may withdraw from a clinical trial at any time.

Further information

Learn how to discuss clinical trial opportunities with your patients and support their clinical trial journey

Where to find clinical trials

Sanofi studies
https://www.sanofi.com/en/clinical-trials

ClinicalTrials.gov
https://clinicaltrials.gov

Other useful resources

Sanofi Campus
https://www.campus.sanofi/au/medical/clinical-trials

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