

Increasing access to clinical research by offering flexibility



Purpose

This document discusses options for how people might participate in a clinical trial. For example, this might mean participants completing some or all trial activities closer to home, rather than coming into a central research location. Building these options into a trial before it starts can be good for both researchers and participants. We want people planning a clinical trial to think about all the options that could be offered to participants. Deciding which options are possible will depend on:

- what type of treatment or health service the trial is testing, and
- the health or vulnerability of people taking part.

It may be difficult to think of all the possible options for participants—and how to make them work—if you haven't done this before. This document will be useful for researchers, reviewers and consumer advocates when they are planning a trial.

Defining Flexible Trial Delivery

People who take part in a clinical trial often must go to a hospital or a research centre many times during the trial. This can be difficult for some people for a whole range of reasons. To make participation easier, there are a growing number of options for how people can complete clinical trial tasks.

For this project, we have called these options “flexible trial delivery” to think as broadly as possible about how trials can be designed and run. Other terms you may have heard of are “decentralised clinical trials” (used internationally) or “teletrials” (used in Australia). See the “more information” section to learn more about these terms.



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Flexibility is good for participants

There are many reasons why people might want different options to take part in a clinical trial. This could be because of their:

- current health
- home address
- gender or sexuality
- age
- education
- income
- caring duties
- culture
- mobility
- access to the internet



Having a range of options for how to undertake trial activities removes barriers for a wider range of people to take part. In turn, this helps researchers see how well a new product or health service works for people in many different situations and locations.

There are many ways that trials can be flexible

Options for how to take part in a clinical trial could use new technologies or use existing technologies with simple changes. Examples are trials where:

- the participant uses apps or online surveys to record their symptoms or behaviours.
- the participant wears a device (e.g. a smart watch or a patch) that tracks their health or behaviour.
- the participant visits a local hospital or doctor for their tests. The local staff then use tele-health technology to talk to a larger clinical trial team somewhere else.
- the participant visits a local health service to check on their health. This could be their usual doctor, pharmacist, or medical testing centre.
- there are home visits. This is where a nurse from the research team can visit people in their homes or another trusted place. The nurse could give the participant their medicine or check on their progress.



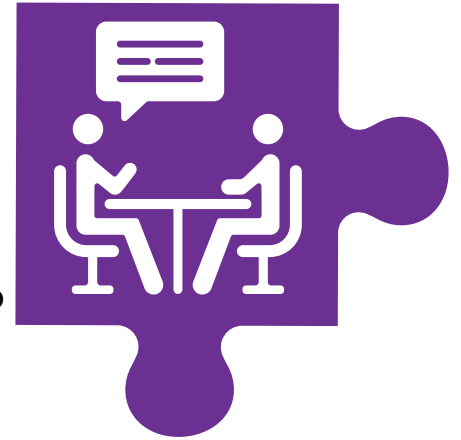
Researchers should only offer options that are appropriate for the risks of their clinical trial. They also need to think about how easy the options will be for the participants to complete. Some trials will be better suited to having more options than others, and some sites will be able to support more options.



Designing flexibility into a clinical trial

By creating a toolbox of options that will work, researchers can make it easier for people to take part in that clinical trial. The participant can then decide what options will work for them. To design these options, researchers should think about the people who are likely to take part in the trial:

- Can they travel to the trial site? This could be hard because of where they live, their mobility, or caring for others.
- Where and with whom do they live? This might make home visits or storage of medicine difficult.
- Are there parts of the trial that may be culturally sensitive?
- Are they likely to have people they trust to support them to travel or who can report their symptoms or behaviours?
- Are they likely to have additional information needs? For example, difficulty seeing or hearing, or if English is their second language.



When we understand the needs of people who may participate, we can make better decisions about how to run the trial. Having a toolbox of options as part of the trial design means that researchers can respond to the needs of each participant once the trial has started. This is much easier than trying to create solutions for participants after they have started taking part in the trial.



More information about flexible trial delivery in Australia



There are several groups working to make clinical trials more flexible in Australia. Talk to others who are already working this way to find out what might work for your clinical trials. Here are some useful resources:

- CT:IQ:
 - [Flexible Trial Delivery Methods](#) project includes a Design Checklist and other tools for designing and delivery trials flexibly
 - The [InFORMed PICF template](#): layered information in consent forms
 - The [Beyond the Form Toolkit](#): building flexible communication plans
- Australian Teletrials Program (ATP):
 - Resources for clinicians, sponsors and patients, including a [definition guide](#).
- NSW Regional Health Partners: [Doing Research Together](#)
 - Resources for co-designing and co-delivering medical research



Options for Flexibility for Participants in Clinical Trials

Activity	Standard	Possible flexible options
Invitation to take part in clinical trial	Targeted through direct advertising or through specialists/GPs	Potential participants targeted through: • Community groups or consumer partnerships • Healthcare provider networks - pathology, pharmacy etc • Data registries, with participant entered data or entered by health service • Social media
Consent - providing an informed decision and permission to take part	Consent discussion in person at trial site	Consent conducted using: • An app without direct in-person interaction supported by a help line • A telehealth link to a trial doctor or allied healthcare professional from home or another location
Trial Visits	Visits at trial site	Visit activities done: • Online using telehealth or through wearable devices • With trial staff at participants home or another place of their choice • With trial staff at a location near the participant - mobile bio-bus, community hall etc
Trial activities and assessments	All activities and assessments done at the trial site - e.g. blood draws, imaging, physical check-up	Activities and assessments done by: • Participant at home or another place of choice using a DIY collection kit • Trial staff or local nurse, who comes to the participant to do the tests in person, either at their home or a convenient location • Trial staff doing tests remotely using telehealth • Local healthcare providers - pathology, medical imaging, GP etc • Automatically using wearable devices
Investigational product (e.g. new drugs)	Investigational product provided at the research site	Investigational products are: • Posted to home address • Picked up at local pharmacy or another clinical facility • Given by research staff at another convenient location
Information collection	Information collected using paper or electronic forms completed and returned to the site	Information collected using a device that: • Automatically records information enters it into the online record. This could be owned by the participant or supplied by the sponsor, like a phone or smart watch • Sends information into the online record only when it is used, like smart scales or pill bottles