



**CT:IQ**  
Clinical Trials:  
Thinking Smarter



# A Site Guide to Flexible Trial Participation



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CT:IQ acknowledges Aboriginal and Torres Strait Islander peoples as the traditional custodians of the land on which we meet, work and learn. We pay our respects to Elders past and present.

CT:IQ would like to thank the members of the participant subcommittee whose lived experience informed the design of this guide.

# Flexible Trial Delivery

Clinical trials are often set up with rigid requirements for participants. This may mean participants need to go to a hospital or a research centre many times during the trial or need to use unfamiliar technology to complete trial activities.

The Flexible Trial Delivery project is about giving participants options rather than dictating a set mode of participation, either in-person or through technology. There are many reasons why people might value being offered flexibility, and broadening the options for how a person can experience a trial will make it easier for people with diverse backgrounds and needs to take part. This is key to the success of any clinical trial. Including participants from a wider range of backgrounds and life circumstances also helps researchers better understand how an intervention will work in the real world.

This guide gives site staff tools to assess what flexible trial delivery methods can be offered for clinical trials, and to discuss these options with trial participants to decide which of the options available will work best for them.

This document is part of the Flexible Trial Delivery project. Other resources include:

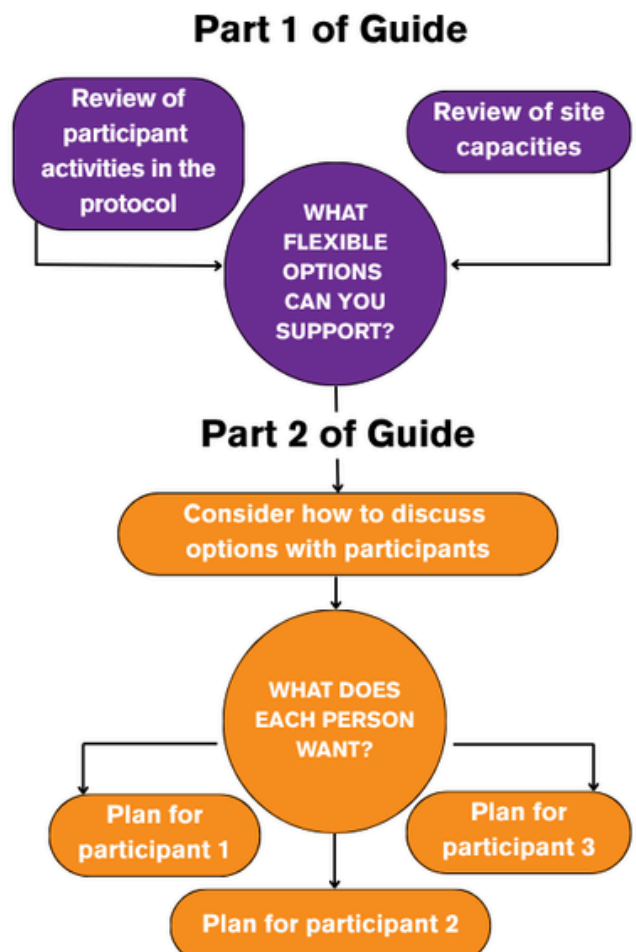
- [A plain language introduction to the value and options for conducting trials flexibly.](#)
- [A checklist of high level considerations to make sure trials delivered flexibly comply with Australian and international regulations and standards.](#)
- [A library of case studies illustrating how others have delivered trials flexibly.](#)

## How to use this guide

This guide is divided into two parts:

- Part 1 discusses how site staff can review protocols and their site capacity to be clear on what types of flexibility are suited to how the trial can run at their site. This will guide what types of flexibility site staff can discuss with participants.
- Part 2 examines why conversations with participants are important and why participants may have different preferences for how they complete trial activities. It also provides guidance for how to talk about these options with participants.

The guide provides high-level guidance rather than fine detail, as there is significant variation in how trials are delivered both between institutions and clinical trial types. The guide is focused on situations where the protocol has been developed by others. If you are involved in developing protocols, we suggest you first look at the FTD Design Checklist and Case Studies.



# Part 1: Assessing the feasibility of flexible trial delivery



Site feasibility assessments are a standard part of determining if and how a trial will run at your site. This is a great time to think about how you can support options for how participants complete study activities (see Part 2 for why this is important).

For general guidance on conducting feasibility assessments, see Part 1 of CT:IQ's [Clinical Trial Site Recruitment Guide](#).

To assess which methods you can use to be more flexible in how you deliver a trial at your site, review the protocol, your institutional policies and staff knowledge to assess:

- What is in the protocol?**
- a. Are there aspects of trial delivery that are core to the protocol, especially if the trial is testing a new delivery mechanism? These aspects will need to be delivered as described.
  - b. What are the remaining aspects of the protocol where flexible trial delivery is possible?
  - c. What supports for flexibility has the sponsor already set up? This could include online resources (e.g. apps or websites) or third-party providers (e.g. home nursing or delivery of medications or supplies directly to participants). Which flexible trial delivery methods would you like to explore at your site?

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- What will work at your site?**
- a. What has worked well for your participants in other similar trials or similar locations?
  - b. Are you able to access any supports set up by the sponsor? You may need to check your institutional policies.
  - c. If sponsor-contracted third-party providers are not available or won't work for you, do you have local healthcare providers who you could contract to deliver trial activities?
  - d. If you are a healthcare provider, what systems do you have in place for facilitating flexibility within standard care (e.g. home visit or community outreach protocols)? Could these systems be used for this trial?

Once you have this information, you can consider what options can be offered to participants. This will make sure that you are only offering options that can be fully supported (either by your site, a third party, or directly by the sponsor).

**The Flexible Trial Delivery project has developed the following case studies that may provide inspiration:**

- **Strategies for palliative and chronic care research:**  
A suite of strategies for building flexibility into timing of trial activities.
- **Investigative product access at sites without clinical trial pharmacists:**  
Establishing a remote pharmacist model to facilitate access to a trial in remote Northern Territory communities.
- **International participant travel:**  
Setting up systems to maintain investigational product dosing when a participant travels internationally.
- **Virtual and direct-to-participant elements in an irritable bowel syndrome supplement trial:**  
Using virtual and direct to participant elements to delivery and receive testing kits.
- **Remote prescribing processes:**  
Procedures for the remote prescription of trial medications to enable home delivery of the investigative product.
- **Regional satellite site:**  
Processes for establishing a regional Western Australia site for a dialysis trial.

## **ACCESS CASE STUDIES HERE**

The final preparation step before discussing options with participants (see Part 2) is to develop a set of key questions to help participants articulate their preferences. This should be co-designed with consumer representatives.



## Part 2: Conversations with participants

### Why participant conversations are important

It's important to note that how flexibility is introduced into a trial often involves technology solutions, such as apps or telehealth. While these may be beneficial for many participants, others may prioritise in-person interactions with study staff. Additionally, participants may struggle to use apps or devices if they have limited access to internet, data or technology, or a lack of confidence with using technology.



Wherever possible, avoid assumptions and ask participants about their needs and preferences. You may find that:

- participants who live close to a research site may struggle to attend, for example because of mobility, work or caring considerations, or travel expenses.
- participants who live a long way from a research site may prefer to travel into the site, for example due to privacy concerns or to combine travel with personal business.
- participants of any age may embrace or lack confidence with technology.
- participants may or may not have a smartphone or computer, or sufficient download capacity or internet access to use digital resources.

To help potential participants make informed choices, they need to understand the trade-offs of different options. By talking through what each option might mean for them, you can help participants determine what options for participation might suit them best and any supports they may need. As highlighted in Part 1, early planning for what you can feasibly offer is essential.

### Developing key questions for participants

When you are recruiting people to a trial which uses flexible delivery methods, it's important to think through how and when you will talk to them about their options. Asking lots of questions about their life may be overwhelming. Depending on how the trial will be run at your site, you might focus on the fact that there are options initially, with a deeper discussion about their participation after they have consented.

A set of “key questions” is a useful prompt for participants to consider how they can participate, and to reflect on their preferences. Wherever possible, these questions should be co-designed with consumer partners. The questions should cover the available options but stay short enough to avoid overwhelming participants.

What the key questions are will depend on the nature of the trial and who your participants are likely to be. For instance, the following questions may be relevant:

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### **For telehealth visits:**

*You could do some of the visits by phone or in an online meeting. Do you have a private space at home where you can comfortably speak with the study team?*

### **In a culturally diverse community:**

*Are there any cultural or religious practices, sensitivities, or preferences you would like our staff to be aware of to help you feel more comfortable and respected during visits?*

### **For digital elements:**

*There are some aspects of the trial that use the internet. Do you have reliable and consistent access to the internet or Wi-Fi? Do you need to travel or get help from others to access this?*

### **For home sampling:**

*We could provide you with a home sampling kit. Do you have concerns such as children or pets accessing stored samples or the sampling devices?*

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Transcelerate's [Patient Protocol Engagement Toolkit](#) (P-PET) includes a Decentralised Clinical Trial (DCT) Considerations Addendum with a comprehensive Question Bank that may be useful in developing your questions.

## **Participant letter**

Once you have determined your question set, include them in a short letter for participants. This gives participants the opportunity to consider how they wish to participate and any additional supports or adjustments they may need to take part in the trial. As this is a participant facing document, it is likely to need ethical and governance approval.

You may find Appendix 1: Participant Letter Guide helpful, or you could develop your own study template.

## **Talking to the participant: What do they want?**

You are now ready to talk with participants about the best way for them to take part in the trial. This conversation should be guided by, but not limited to, the question set provided in the participant letter. The question set should not be treated as a checklist; instead, it is there to frame the conversation.



During the conversation:

- ✓ be mindful that the participant may already be feeling overwhelmed by their health status or the trial requirements.
- ✓ attempt to build rapport with the participant as this is likely to assist them in voicing their needs.
- ✓ record the options that the participant has chosen and talk through the specifics of the next steps for the participant.
- ✓ remind the participant that they can contact you if they need to change how they participate during the trial, and that you will check in with them.

## Examples of participants' preferences

To illustrate how a participant's circumstances can impact how they would like to take part in trial activities, consider the following scenarios. What flexibility could you offer to these people at your site?

1

Alex is a student who lives in share housing, doesn't have a lot of privacy at home, and works variable hours. They would prefer to attend a local clinic for physical assessments but would need to be able to vary the timing from visit-to-visit to fit with their work schedule.

2

Basma lives regionally and has patchy internet reception. She would prefer to talk to a person by telephone or at a clinic rather than use apps but would need financial support (e.g. taxi vouchers) to travel to appointments.

3

Carol has young children at home, which makes it hard to travel to appointments. She would prefer if trial activities could be done as part of her regular GP appointments or if someone could come to her house.

4

David has a vision disability and needs any apps or documents to be compatible with his screen readers. He would prefer to come into a site, but would need help navigating the first visit.

## Additional resources

Participants may also appreciate resources to help them navigate the logistics of flexibly delivered trials, such as flyers, maps and/or short videos. For example, these could:

- show how to get from parking facilities to the clinic and what the clinic and waiting rooms look like,
- give an introduction to any third-party providers (e.g. local testing or imaging services, or at-home nursing) and describe how the participant might interact with them.

If your trial involves activities that your participants will need to learn how to complete (e.g. at-home testing or receiving and storing medications shipped to their home), this should be provided separately by either the site staff or the sponsor. Make sure that materials provided by the sponsor are suitable for your site and participants.

People may also have general questions about clinical trials. Some people may find it helpful to be directed to external resources explaining common concepts around clinical trials, e.g.:

- [What are clinical trials?](#) ACTA and CT:IQ
- [What is randomisation?](#) ACTA and CT:IQ



# Appendix 1: Participant Letter Guide

The text below illustrates what you might include in a letter to participants. The [blue] text is included as examples that can be adapted to your situation, while the <orange> text would be specific to each participant's letter.

We know that your life may be very busy. We want to work with you to decide which ways of taking part in this trial will suit you best. To help us have a conversation about what will work for you, think about the questions below.

[A list of example questions is provided below. Remember that there are many additional ways that your site may be able to support participant flexibility. Make sure that all questions are phrased simply and that the question set is kept as short as possible.]

- **Participant diaries:**

You will need to keep a record of how you are going during the trial.

- Would you rather do this on paper, or on your phone or computer?
- Do you have any concerns about using these devices or accessing the internet?

- **Where tests (and/or imaging) are done:**

You will need do some [blood tests] as part of this trial.

- Would you rather do these at: a testing centre near your home, at the main study site, or have someone visit your home? [offer only options that your site can support.]

- **Telehealth visits:**

- Do you have a private space at home where you can speak to the study team?
- Are you concerned about anyone at home knowing about your medical condition or that you are taking part in a trial?

- **Receiving trial medications:**

- We need to send you medication as part of the trial. Would you rather these were mailed to your home, or to your usual pharmacy or GP?
- Do you have a regular mail service, and either a secure mailbox or times when someone could accept a delivery?
- Will you be able to securely store the medication in a fridge?

- **Where physical exams are done:**

- We need a doctor or nurse to check your [list relevant body part or function] during the trial. Would you rather this was done in your home, at your usual doctor's office, or at the main study site?]

When we see you at your <next appointment/consent discussion> we will talk through these questions and the options together. You can contact us on <main study contact> if you have questions before then.