Bristol Myers Squibb™

Study participant's discussion guide to cancer clinical studies

Thank you for taking the time to think about joining a cancer clinical study. We understand that this may be a difficult and emotional time for you, filled with lots of information.

It is important to know that taking part in cancer clinical studies is always **completely voluntary.** You can also choose to leave the study at any time. Keep in mind that the choices you make will **not** affect your relationship with your healthcare team.

We created this discussion guide to help you navigate through the process of taking part in a cancer clinical study. This guide covers the following topics:

Clinical studies and why they are important

Clinical studies are **research studies that include human participants.** Clinical studies can explore how an **investigational drug** might act in the body and affect cancer.

An **investigational drug** is a drug that is still being researched. It is not yet approved for doctors to prescribe to the general public.

In clinical studies, an investigational drug is often compared to a **placebo**. A **placebo** is an inactive pill, liquid, or powder, that has no treatment value. In cancer clinical trials, instead of placebo, an investigational drug is often compared to the usual care provided for that particular type of cancer.

Clinical study research is carried out in a series of steps, known as phases, to study whether the investigational drug is safe and effective for people to use.

Overview of how a drug typically becomes available to the general public	
1. Researchers run lab and animal studies	This is the stage before an investigational drug is tested in humans.
2. Researchers run clinical studies (Phases 1, 2, and 3)	Researchers run clinical studies, and test the safety and effectiveness of an investigational drug in human participants.
3. Health Authority approves the drug	After the Health Authority approves the drug to help treat specific cancers, doctors are allowed to prescribe it to patients.
4. Researchers sometimes run more clinical studies (Phase 4)	The long-term effects of the approved drug are studied to improve the understanding of its safety and effectiveness.

Why do people take part in cancer clinical studies?

People take part in cancer clinical studies for a variety of reasons that are unique to them. For example, some people may decide to take part for the following reasons:

- to help researchers better understand a disease
- to help researchers find new treatments for people in the future

How can I get information about a specific clinical study?

Ask your doctor about whether there are clinical studies that may be right for you.

Read any documents that your doctor or your study team gives you, including the **Informed Consent Form (ICF).**

What is a clinical study Informed Consent Form (ICF)?

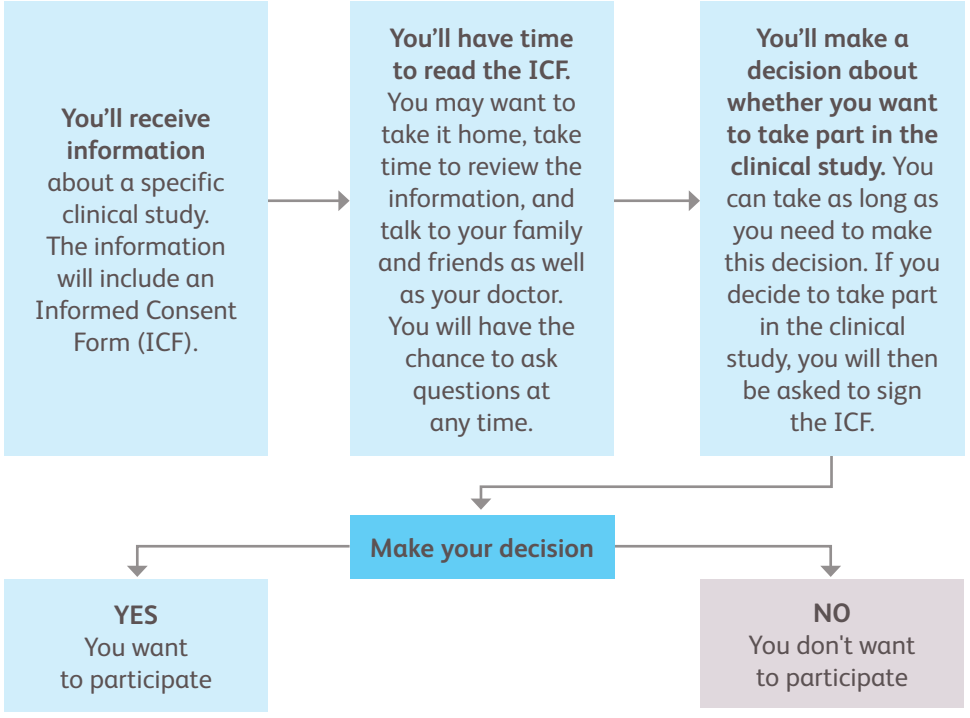
The ICF is a document that is made to help you understand a specific clinical study. This document guides you through what you can expect in the clinical study before you make your decision of whether to take part in it.

You can take as long as you need to read the ICF and make your decision. If you decide to take part in the clinical study, you will then be asked to sign the ICF to provide your informed consent.

An overview of your journey through a cancer clinical study

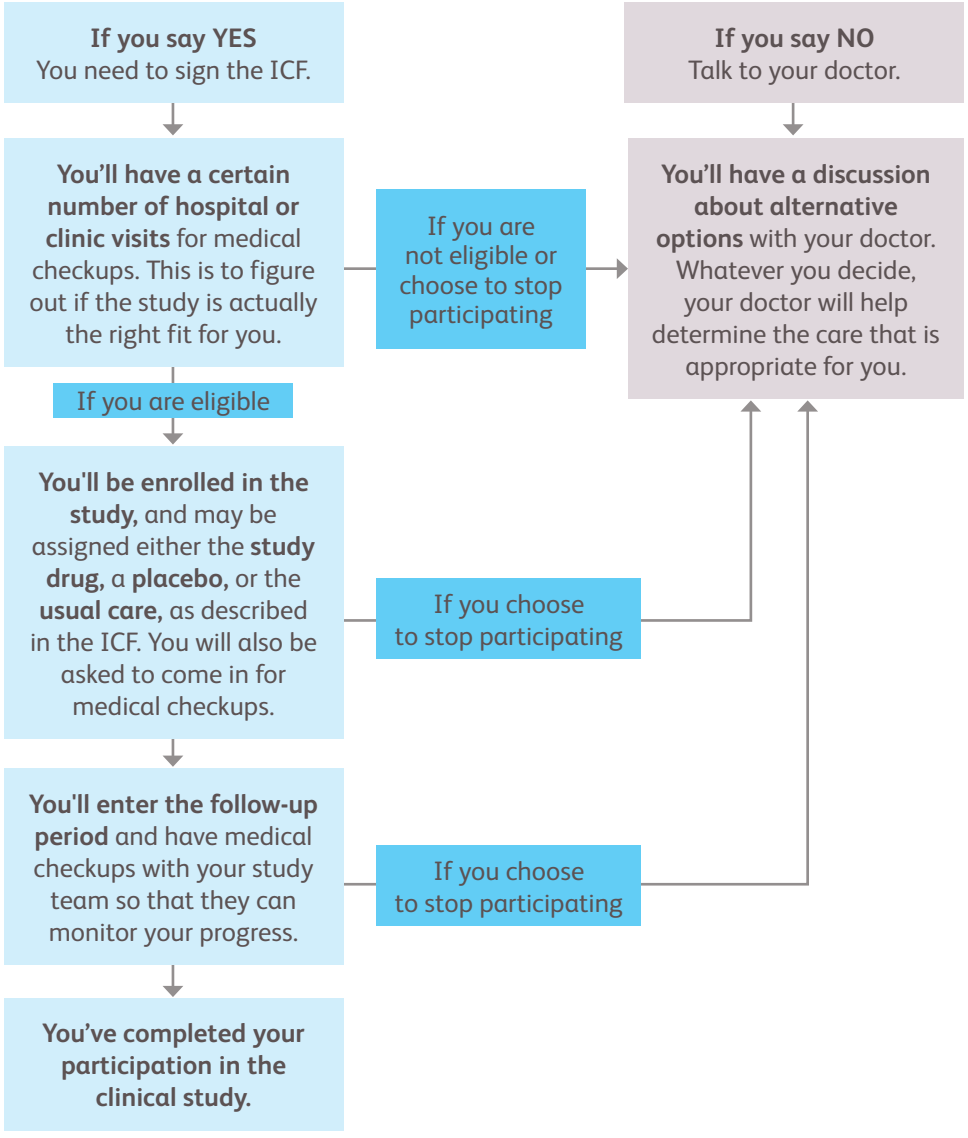
Keep in mind that everyone's journey through a clinical study is unique. You can always choose to stop taking part in the study at any time, and this will not affect your future medical care in any way.

BEFORE you make the decision about participating



(Continue reading on the next page to learn about what happens after you make your decision.)

AFTER you make the decision about participating



Preparing yourself to make the decision

It is important to understand what you will experience in a specific clinical study, before deciding to take part in it. You and your doctor will talk about clinical studies that may be right for you. You should only take part in a clinical study if:

you have read through the entire Informed Consent Form (ICF),
you understand the information in the ICF, and
you and your healthcare team think that it is a good option for you.

What factors are important for me to consider?

To help you get started, here's a list of factors that you may want to think about as you learn more about a specific clinical study:

- Will I have a convenient way of getting to the clinic?
- Do I have support or a caregiver to help me through this?
- If I choose to take part in this clinical study, will that affect my chances of taking part in other clinical studies later on?
- Will I be able to choose which study drug to receive?
- Will I have to take time off work?
- Will I still be able to take part in the activities that are important to me?
- If I move, can I continue the study at another hospital?
- Will I be allowed to get pregnant while on the study?

Consider using the space on the back note pages to add your own questions.

Questions that you might have for your study team

If you are ready to get into the details of the study, please refer to your Informed Consent Form (ICF). The ICF covers the following topics:


Key points about this study


Study flow and time commitment


Risks and benefits


Costs, reimbursements, and compensation for research-related injury


Rights, responsibilities, privacy, and data collection

To help you prepare for conversations with your study team, the **next 5 pages have some example questions** that you may want to ask at your next appointment.

There is empty space beside each question for you to jot down answers that you may receive from your study team.

1. Key points about this study

Example questions:

(Consider writing your answers in the available spaces)

Is it possible that I won't be eligible for the study?	
Have other people like me received this study drug?	
Will I get to choose which study drug I receive?	
Is there a chance that I might get a placebo?	
Other than this clinical study, what are my options?	

2. Study flow and time commitment

Example questions:

(Consider writing your answers in the available spaces)

What happens if I miss an appointment?	
Is there support available if I can't get to a certain location?	
How do I prepare for each visit?	
Where do I need to go for each procedure?	
How will I know if the study drug is working?	

How will I know if the study drug is working?

3. Risks and benefits

Keep in mind that each person's experience is unique. Some people may experience risks, while others may not. Examples of some of the risks you may face are:

Study drug risks, called side effects, may be caused by the study drug(s) themselves

Study procedure risks may be caused by doing procedures like x-rays, by dyes in CT scans, or by needle punctures from blood collection

Unknown risks are also possible because the study drug(s) are still being researched. These may include risks to reproduction, and risks to taking other drugs at the same time.

There may not be any benefit to you from taking part in a clinical study, and researchers are still trying to figure out if the study drug(s) will have any positive effect on you or your cancer.

Researchers hope that the information they collect from a clinical study will help them understand the study drug(s) better. The results of a clinical study can help researchers find benefits for people in the future.

Example questions:

(Consider writing your answers in the available spaces)

What kind of side effects might I experience?	
What can I do to manage my side effects?	
What are my options if I can't manage my side effects?	
Who should I talk to if I experience side effects?	
How will this study benefit me?	
What happens if my cancer gets worse while I am in the study?	

4. Costs, reimbursements, and compensation for research-related injury

Example questions:

(Consider writing your answers in the available spaces)

Will I need to pay for the study drugs that I receive?	
Who will cover the cost of the tests that I need to have?	
Will I get paid for taking part in the study?	
Will I be reimbursed for traveling to the hospital or clinic?	
How do I get reimbursed?	
Who should I talk to if I have questions about costs?	
If I get injured from taking the study drug, who will cover the cost?	
Who will take care of me if I get injured from being in this study (family doctor, study doctor, etc.)?	

5. Rights, responsibilities, privacy, and data collection

Example questions:

(Consider writing your answers in the available spaces)

What should I do if I don't want to participate anymore?	
Can my study doctor stop me from taking part in a clinical study?	
Can I take my scans and lab results home?	
What will happen to my samples? How will they be used?	
Who will have access to my medical and personal information?	
Will I eventually find out which study drug I received?	
Do I have to carry the Participant Alert Card everywhere with me?	

Your next steps and links to resources

Now that you have read through this document, here is a simple checklist that you can follow for your next steps:

- [ ] **1.** Read the Informed Consent Form (ICF). You should only sign the document if you:
  - Understand what is involved
  - Had a chance to ask questions
  - Have a member of your study team beside you as you sign the document
  - Want to take part in the clinical study
- [ ] **2.** Prepare for your next appointment with your study team and consider writing down any questions. There is space provided within this guide (pgs. 10–14) or within your copy of the ICF if you choose to write your questions in these documents.
- [ ] **3.** Review the ICF with your study team and ask any questions that you may have prepared.

Taking part in a clinical study is voluntary.
You may choose to leave the study at any time.

Notes/Questions

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Thank you

for considering a clinical study

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