This material was developed and funded by Pfizer Ltd and is intended for a UK public audience. This material is not a substitute for professional medical care. Readers are strongly advised to discuss the information provided and seek personalised advice from their doctor or care team.

Pfizer Ltd would like to offer their thanks to the patients who participated in the co-creation of this document.

Pfizer Medical Affairs

Cancer clinical trials

The role of clinical studies in cancer and the importance of ethnic diversity in treatment development

If you're thinking about taking part in a cancer clinical trial, it is likely that you will have questions for your healthcare team. This document answers some common questions about cancer clinical trials. It can also be used as a guide for questions to ask your healthcare team before you make a decision to join a trial.

Cancer clinical trials: The what and why?

What is a cancer clinical trial?

Cancer clinical trials test potential new treatments involving people living with cancer. They test whether different treatments are suitable and how well they work. Taking part in a trial may mean you get access to new treatments years before they are widely available.[1,2]

Why are clinical trials in cancer important?

All potential new treatments must be carefully and fully tested. This makes sure they are suitable and work better than treatments already used to treat cancer. By taking part in a cancer clinical trial you will be making a positive contribution to cancer research.[1–3]

Clinical trials can also be used to research other areas of cancer care, such as diagnosis, side effects and quality of life.[1–3]

Why is ethnic diversity in clinical trials important?

Ethnic diversity in cancer clinical trials means the inclusion of participants from diverse ethnic backgrounds and cultures. Race, ethnicity, age, and sex can all impact how different people respond to the same treatment. The more diverse a group of clinical trial participants is, the more we can learn about the safety and efficacy of a potential new treatment for people now and in the future.[4–6]

Trial organisers are changing to better serve diverse communities by following guidelines promoting race equality and prioritising access and knowledge of cancer clinical trials for minority populations.[4–6]

What are the stages of cancer clinical trials?

Before a trial can involve people, research into potential new treatments begins in the laboratory. Clinical trials then test how well these new potential treatments work in people and check their safety. Trials are divided into different stages, called phases. At each phase of a cancer clinical trial, researchers learn more about a potential new treatment.[1–3,7]

Phase 1	Phase 2	Phase 3	Phase 4
Continues to Phase 2	Continues to Phase 3	Continues to approval of treatment	
Tests a very low dose of the potential new treatment for the first time	Decides the best dose of the potential new treatment, and which cancer it works for	Compares the potential new treatment with existing treatments for cancer	Finds out even more about the new treatment once it's available to the general public

Adapted from: Macmillan Cancer Support[2] and Cancer Research UK.[7]

Joining a cancer clinical trial

Who can take part in a cancer clinical trial?

Your cancer care team will consider whether certain trials are suitable for you to take part in, and discuss these with you. All clinical trials have a list of entry conditions called 'inclusion and exclusion criteria'.[1,2]

What is informed consent during a cancer clinical trial?

A doctor, nurse or other researcher will always ask your permission to enter you into a clinical trial. They will give you the information you need to help you make a decision. You should feel free to ask any questions that will help you. Agreeing to enter a trial once you have been given this information is called giving informed consent.[1,2]

Your healthcare team will respect the decision you make and will not ask you to provide any explanation. You can leave a trial at any time without needing to give a reason.[1,2]

If English is not your first language, all information should be explained to you in a language you understand. The consent form to confirm your participation in any trial may be written in your preferred language, or translated by an interpreter.[1]

Who is involved in a cancer clinical trial?

Each trial has a main researcher and a surrounding medical team. These are usually medical doctors, nurses, pharmacists, research co-ordinators and other healthcare professionals who help to deliver treatment and monitor patient responses and side effects.[2]

Protocol and participation in cancer clinical trials

What is the trial protocol and design?

The plan for the trial is known as the protocol. This explains:[1,2]

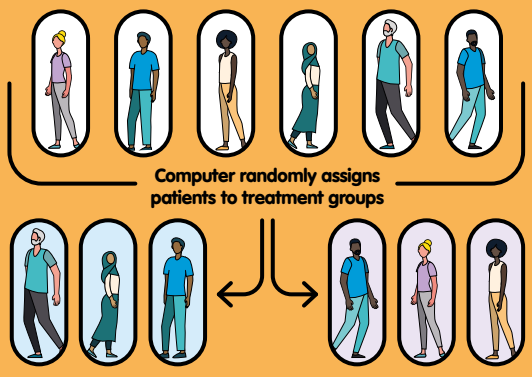
- The purpose of the trial
- How the trial is carried out
- What will happen during the trial
- Who can join the trial
- The trial design

The trial design describes the different ways that trials can be set up to learn as much as possible about the safety and effectiveness of a potential new treatment.[1,2]

It also describes what treatment participants will receive:[2]

Randomised trials:

Participants are randomly assigned to their treatment group. Each treatment group will have a specific ratio of trial participants.[2]



Controlled trials:

Compare a potential new treatment with an existing standard treatment.[2]

Placebo trials:

Only used when a potential new treatment is being tested as an addition to an existing standard treatment. Comparing the potential new treatment to the placebo can show if the treatment is really working.[2]

You may not know if you are receiving the potential new treatment or a placebo. **It is important to know that people who receive the placebo will also receive the standard treatment.**[2]

How are patients safeguarded during cancer clinical trials?

Every clinical trial protocol in the UK is reviewed by an ethics committee and a data monitoring committee that protect the rights and well-being of all people taking part in the trial. These committees can stop trials early if a potential new treatment is not working well, or there is evidence the treatment is causing harm.[1,2]

If you participate in a clinical trial, your General Practitioner (GP) will be informed so they can support your healthcare plan. Your medical records remain confidential to the trial research team and your healthcare team – nobody else can see the information gathered during the trial.[2]

What are the benefits or disadvantages to joining a cancer clinical trial?

Participating in a clinical trial comes with many potential benefits or disadvantages. Some to consider are listed below:

Potential benefits

- Could benefit from a new treatment that is only available through the trial[1,2]
- Improve treatment for other people with cancer[8]
- Learn more about your health[8]
- More monitoring by your healthcare team can feel reassuring[1,2,8]

Potential disadvantages

- There is always a risk that a potential new treatment may bring side effects. Your healthcare team will try to limit the risk of any side effects[1,2]
- The cost of more travel, hospital visits and time off work[1,2]

What happens after a cancer clinical trial has ended?

The research team will often want to continue checking in with you after the trial has ended to see how well you are doing after treatment. Results of trials are published to help decide the best treatments for people with cancer. The best way to find out about trial results is to ask your cancer specialist.[1,2]

Jargon buster: Common terms you may hear or see when learning about cancer clinical trials

Cancer specialist	Also known as an oncologist. This is a doctor who treats cancer and provides medical care for a person diagnosed with cancer[9]
Exclusion criteria	The reasons that a person is not allowed to participate in a clinical trial[10]
Inclusion criteria	The reasons that a person is allowed to participate in a clinical trial[10]
Placebo	A fake treatment that looks the same as, and is given in the same way as, a real treatment being studied[10]
Quality of life	How comfortable an individual is, and their ability to participate in or enjoy life events[2]
Side effects	An effect of a drug that is not intended to happen[10]
Standard treatment	The best available treatment for a particular type of cancer agreed by guidelines and widely used by healthcare professionals[2]

References

1. The UK Clinical Research Collaboration. Understanding clinical trials. Available at: https://www.ukcrc.org/wp-content/uploads/2014/03/iCT_Booklet.pdf. Accessed: August 2023; **2.** Macmillan Cancer Support. Understanding cancer research trials (clinical trials). https://be.macmillan.org.uk/downloads/bemacmillan%20pdfs/MAC11658_E13_N_Clinical_trials_lowres%20pdf_20200304_NO.pdf. Accessed: August 2023; **3.** Cancer Research UK. What are clinical trials? Available at: https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are. Accessed: August 2023; Cancer Research UK. Phases of clinical trials. Available at: https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are/phases-of-clinical-trials. Accessed: August 2023; **4.** NHS England. Increasing diversity in research participation: A good practice guide for engaging with underrepresented groups. Available at: https://www.england.nhs.uk/aac/publication/increasing-diversity-in-research-participation/. Accessed: August 2023; **5.** Symonds RP, et al. *Br J* 2012;107:1017–21; **6.** Pfizer Ltd. Diversity in our clinical trials. Available at: https://www.pfizer.com/science/clinical-trials/diversity. Accessed: August 2023; **7.** Cancer Research UK. Phases of clinical trials. Available at: https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are/phases-of-clinical-trials. Accessed: August 2023; **8.** National Institute for Health and Care Research. Patients, Carers and the public. Available at: https://www.nihr.ac.uk/patients-carers-and-the-public/i-want-to-take-part-in-a-study.htm. Accessed: August 2023; **9.** Cancer.Net. Types of oncologists. Available at: https://www.cancer.net/navigating-cancer-care/cancer-basics/cancer-care-team/types-oncologists. Accessed: August 2023; **10.** ClinicalTrials.gov. Glossary terms. Available at: https://clinicaltrials.gov/study-basics/glossary. Accessed: August 2023.

This material was developed and funded by Pfizer Ltd and is intended for a UK public audience. This material is not a substitute for professional medical care. Readers are strongly advised to discuss the information provided and seek personalised advice from their doctor or care team.

Pfizer Ltd would like to offer their thanks to the patients who participated in the co-creation of this document.

PP-UNP-GBR-6504 | September 2023