

Clinical Trials

A DISCUSSION GUIDE FOR PATIENTS AND FAMILIES

WHAT IS A CLINICAL TRIAL?

A clinical trial is a research study that helps researchers learn whether a new treatment, medicine, medical device, or way of providing care is safe and effective. Depending on the study, participants may be healthy volunteers or people living with a particular health condition.

Clinical trials are an essential step in developing better healthcare and improving treatment options for current and future patients.

*Taking part
in a clinical
trial is always
your choice*



**UNDERSTANDING WHAT PARTICIPATION INVOLVES
CAN HELP YOU DECIDE WHETHER IT IS THE RIGHT
OPTION FOR YOU**

YOU CAN CHOOSE TO LEAVE THE STUDY AT ANY TIME

WHY MIGHT YOUR DOCTOR SUGGEST A CLINICAL TRIAL?

Your healthcare provider might recommend you join a specific clinical trial study when the standard treatment is not working for you, or when a treatment for your specific condition does not exist.

A clinical trial may give you access to new medicines or approaches that are not yet widely available, as well as additional monitoring and follow-up, while contributing to future patient care.

PHASES OF CLINICAL TRIALS

Before a new medicine or treatment becomes widely available, it goes through several phases, each answering different questions about its safety and effectiveness.

- 1 PHASE I – IS IT SAFE?**
The new treatment is given to a small group of volunteers to see how it affects the body, find possible side effects, and work out the safest dose.
- 2 PHASE II – DOES IT WORK?**
The new treatment is given to a larger group of people who have the condition it is designed to treat. Researchers check how well it works, look for side effects, and find the right dose.
- 3 PHASE III – HOW DOES IT COMPARE WITH CURRENT TREATMENT?**
The new treatment is given to a much larger group of patients. Researchers compare it with current standard treatments to see how well it works, how safe it is, and whether it should be approved for use.
- 4 PHASE IV – WHAT HAPPENS AFTER APPROVAL?**
Researchers continue to collect information about the treatment in everyday clinical practice; this helps identify rare side effects and understand the treatment's long term impact.

Important to know: Not every clinical trial is testing a brand-new treatment. Some studies compare existing treatments, evaluate different ways of using a treatment, or look at ways to improve quality of life or healthcare delivery.

UNDERSTANDING THE ADVANTAGES AND DISADVANTAGES

POSSIBLE ADVANTAGES:



ACCESS
TO NEW
THERAPIES



CLOSER
MEDICAL
MONITORING



HELPING
ADVANCE
RESEARCH



COSTS OF
STUDY-RELATED
TREATMENTS
COVERED BY
THE TRIAL

POSSIBLE DISADVANTAGES:



RISK OF
SIDE EFFECTS



RISK OF
TREATMENT
NOT WORKING



EXTRA
VISITS
OR TESTS



TIME AND
TRAVEL
COMMITMENTS

YOUR RIGHTS AS A PATIENT IN EUROPE

Patients will not be treated as test subjects. They are protected by the Good Clinical Practice (GCP) standard that must be followed during clinical trials in Europe. It is made to ensure your rights, safety and wellbeing when participating in trials.

If you are considering taking part in a clinical trial, it is important to know that your rights, safety, and wellbeing are protected throughout the study.

♥ YOU HAVE THE RIGHT TO MAKE YOUR OWN DECISION:

Taking part in a clinical trial is always **voluntary**. No one should pressure you to participate, and you can decide whether a clinical trial is right for you.

♥ YOU HAVE THE RIGHT TO CLEAR INFORMATION:

Before you decide, the research team should explain the study in language you can understand. You should have plenty of time to think about the information, ask questions, and discuss your decision with your family, caregiver, or healthcare professionals if you wish.

♥ YOU HAVE THE RIGHT TO GIVE INFORMED CONSENT:

If you choose to participate, you will be asked to sign an informed consent form. This confirms that you understand the study and agree to take part.

Giving informed consent is an ongoing process—not just signing a form.

♥ YOU HAVE THE RIGHT TO CHANGE YOUR MIND:

You can decide not to participate or withdraw from a clinical trial at any time, without giving a reason.

♥ YOU HAVE THE RIGHT TO BE INFORMED THROUGHOUT THE STUDY:

If researchers learn new information that could affect your decision to continue in the trial—such as new benefits, risks, or side effects—they must share this with you so that you can make an informed choice about continuing.

♥ YOU HAVE THE RIGHT TO PRIVACY:

Your personal and medical information must be kept secure and handled according to data protection laws, including the GDPR. The research team should explain how your data will be used and protected. Wherever possible, identifying details will be replaced by a code.

♥ YOU HAVE THE RIGHT TO APPROPRIATE FOLLOW-UP:

At the end of the study, the research team will explain what happens next, including any follow-up care that may be needed. In some situations, participants may be able to continue receiving a treatment that has been shown to be beneficial, depending on the study and local regulations.

FINDING RELIABLE INFORMATION

Find reliable information in the below sources:

- ♥ HEALTHCARE PROFESSIONALS
- ♥ PATIENT ORGANISATIONS
- ♥ NATIONAL HEALTH AUTHORITIES
- ♥ EU CLINICAL TRIALS INFORMATION SYSTEM (CTIS)

PARTICIPATING IN A CLINICAL TRIAL IS A
personal decision
THAT SHOULD ONLY BE MADE WITH CLEAR
INFORMATION AND SUPPORT AVAILABLE



INFORMED CONSENT: WHAT DOES IT REALLY MEAN?

CONSENT MUST BE

voluntary, informed, and documented

PREFERABLY WRITTEN, WITH THE RIGHT TO WITHDRAW AT ANY TIME

INFORMATION SHOULD BE TAILORED TO INDIVIDUAL NEEDS AND
PROVIDED BY QUALIFIED PERSONNEL, WITH VERIFICATION OF

patient understanding



PATIENTS MUST RECEIVE COMPREHENSIVE, CLEAR, AND
UNDERSTANDABLE INFORMATION ABOUT THE TRIAL, INCLUDING ITS:

*nature, risks, benefits, alternatives,
and follow up measures*

Patients must be informed

ABOUT COMPENSATION SYSTEMS, TRIAL REGISTRATION NUMBERS, AND RESULT AVAILABILITY



Informed consent should not be treated as just a formality or a signature on a document.

QUESTIONS TO ASK YOUR DOCTOR AND RESEARCH TEAM

- ✓ Why is this trial being offered to me?
- ✓ What are my other treatment options?
- ✓ What are the possible benefits and risks?
- ✓ How often are visits required?
- ✓ Will I have extra costs?
- ✓ What happens if I decide to stop?
- ✓ What will happen to my personal and health information if I decide to leave the clinical trial?
- ✓ Who can I contact with questions?



Mended Hearts
Europe

WWW.MENDEDHEARTSEUROPE.ORG

✉ MHEUROPE@MENDEDHEARTS.ORG    

SUPPORTED BY

AstraZeneca 