ESGO
European Society of Gynaecological Oncology

ENGAGe
ESGO | European Network of Gynaecological Cancer Advocacy Groups

ENGOT
European Network of Gynaecological Oncological Trial groups

What is a clinical trial?

An introduction for patients and families

Introduction

Life expectancy in Europe in the first decade of this century has continued to rise. We owe this fortunate development to various factors, not least the enormous progress made in the field of medicine. Today, many diseases are either curable or can at least be treated to enable prolonged life expectancy. Clinical trials are pivotal in enabling this progress as they provide the scientific background for new medications, new treatment strategies and innovative diagnostic procedures.

Modern treatments are licensed by the European Medicines Agency (EMA) if they are proven to be more effective than the current standard of care and are monitored very closely in each country to ensure they are safe.

Before they can be used in clinical practice, they go through many years of development to ensure that they are safe and effective. On average it takes up to 10 years from the initial hypothesis to implementation in clinical practice.

This brochure is intended to give you comprehensive information about clinical trials in gynaecological cancers. It is designed to help you consider whether to participate in a clinical trial if you have been approached about taking part, and how you can find out more about participating in a trial.

Every person participating in a study does so on a completely voluntary basis and can also opt out of the study at any time without giving a reason.

Birthe Lemley,
Ovarian Cancer Patient, Denmark
EEG member of ENGAGe

Gynaecological cancer patients should be encouraged to enroll in clinical studies as they might get better quality of care than with standard treatment. They are monitored closely, and scans and blood test are done regularly according to the criteria in the study protocol. Follow-up monitoring is performed to evaluate safety and quality of life. Patients are usually randomized into different treatment arms. The new drug might be compared to standard of care or it might be compared to placebo (no treatment) if no standard treatment is available. Cancer patients will not get placebo in a trial if standard treatment is available. If the outcome of the study is successful, it might benefit the individual patient and future patients. Today there is much more potential for successful cancer treatment than just a few years ago, but new advances in research into new drugs is only possible if we as cancer patients are willing to enter into clinical trials. Trials offer hope for the individual patient and hope for better treatment in the future.

What is a clinical trial?

Clinical trials, sometimes called studies, are a form of research which involves people. They are the final step in a long process that begins with research in a laboratory, and there are typically three phases in every clinical trial:

Three phases of a clinical trial

1

In Phase I, the new treatment is usually given at very low doses in the first patients. Doses are then progressively increased in the subsequent patients, because the aim of this phase is primarily to examine how it affects the human body, to find a safe dose for Phase II and to determine how it should be delivered. A Phase I trial is usually fairly small, typically involving 15-30 patients.

2

In Phase II, the efficacy of the treatment is studied as well as its side effects. Phase II trials involve a larger number of patients than Phase I, but typically it will be less than 100.

In Phase III the safety and efficacy of the new treatment is usually tested against an existing optimum treatment or recognised standard of care.

3

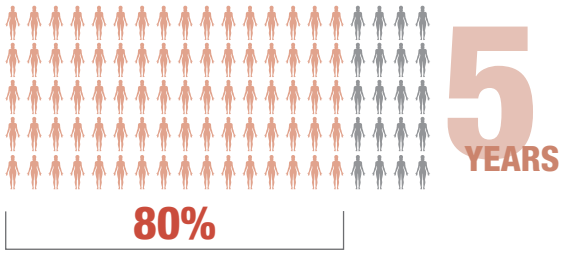
In Phase III trial, patients are randomly allocated to the various treatment arms, in a process similar to throwing a dice, known as "randomisation". The study group is given the new treatment or procedure to be tested; the control group is given an existing optimum treatment or recognized standard of care. It is important to understand that patients cannot choose which group they will be allocated to, and that they may not receive the experimental treatment in the trial. Some may receive an inactive drug called a placebo, and this will be explained to you in the information sheet.

A Phase III trial, which typically involves hundreds if not thousands of patients, is a prerequisite for official approval of a new treatment by EMA (the European Medicines Agency) in Europe as this is the only way to evaluate the efficacy of the new treatment compared to existing treatments.

It should be noted that randomisation, typically associated with Phase III trials, is also increasingly used in Phase II trials, to avoid the influence of factors other than treatment on the results.

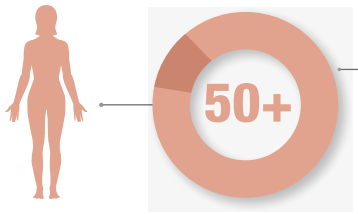
UTERINE CANCER IN NUMBERS:

On average, nearly **80%** are alive five years after their diagnosis.



More than one in **20** female cancers affects the endometrium, and rates are rising partly due to an aging population and obesity.

Over 90% of cases occur in women aged over 50 years.

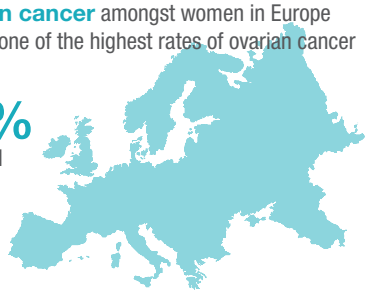


Over **90%** of cases occur in women aged over 50 years

OVARIAN CANCER IN NUMBERS:

6th most common cancer amongst women in Europe

Europe, in general, has one of the highest rates of ovarian cancer in the world



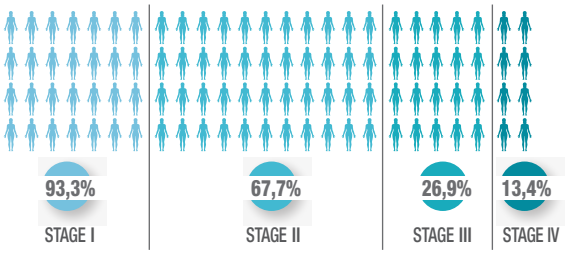
OVER 4%

of women in Europe will develop ovarian cancer

5-YEAR SURVIVAL

DECREASES SIGNIFICANTLY

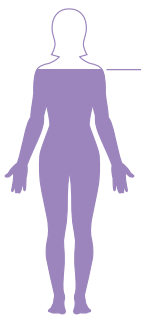
WITH STAGE OF DIAGNOSIS



VAGINAL/VULVAR CANCER IN NUMBERS:

95% of women are alive five years after their diagnosis if vaginal cancer is diagnosed in its early stages.

However, five-year survival is very poor for women with advanced disease.



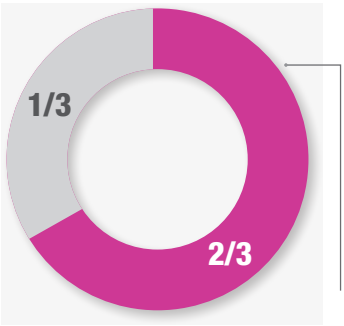
8 out of 10

with early vulval cancer will be alive five years after their diagnosis, but five-year survival in advanced disease is low at around

30%

Women aged **65+** are at highest risk of developing vulval cancer.

CERVICAL CANCER IN NUMBERS:



On Average

2/3

of women are alive five years after a diagnosis of cervical cancer

There are wide variations in risk: women in Romania are over ten times more likely than those in Finland to die of cervical cancer.

Who conducts clinical trials?

Researchers conduct clinical trials in different settings. Many clinical trials are done at cancer centers because the facilities available are usually the most advanced. Usually, cancer centers collaborate together within clinical networks, applying similar criteria of good quality of care, performing clinical studies and sharing results. The research team that conducts a clinical trial can include research scientists, doctors, nurses, social workers, dietitians, and other healthcare professionals.

How are clinical trials approved?

The prerequisite for conducting any clinical trial is a detailed study protocol, namely a predefined written description of the intention and purpose, possible side-effects and the precise course of the trial, rights and duties of patients and plans of the analysis to be done in order to find out the results. An Ethics Committee of independent experts and lay people examine the trial protocol and decide whether, on the basis of the latest medical knowledge, it is purposeful and ethically justifiable to conduct the study. The Ethics Committee also examine whether the doctors, and institutions, who conduct these studies have the necessary knowledge and structures to administer such treatment.

Any change in the protocol, no matter how small, must be discussed with the person holding overall responsibility for the study and submitted for ethical approval. This high standard ensures that the safety and confidentiality of patients participating in a trial to develop new treatments are always the guiding principles of the trial.

Every patient participating in a clinical trial must be given comprehensive oral and written information before entering the trial, and sufficient time to consider it.

Prof. Phillipe Maurice
ESGO President

> If we are talking about patients who enroll in clinical studies, they often get better medical care. Because treatment is given within a protocol according to criteria of good quality of care, follow up monitoring is performed to evaluate safety and there is the possibility of receiving a potentially more effective treatment.

Why enter a clinical trial?

The fundamental principle of any trial is the safety and well-being of the trial participants. This takes priority over the interests of scientific research.

There are numerous good reasons for participating in a clinical trial. For patients it is comforting to know that as trial participants they are acquiring access to new and possibly better treatment that might not otherwise be available to them. In addition, being able to actively contribute to the progress of medicine and improvement of knowledge that will benefit future patients is a positive motivation.

Benefits of participating in a clinical trial

Prof. Murat Gultekin, ENGAGe Co-Chair

> Clinical trials offer hope for many people and an opportunity to help researchers find better treatments for others in the future.

Another important advantage is the close monitoring of trial participants. Patients participating in clinical trials undergo particularly intense and careful medical examinations, and their treatment progress is precisely monitored, based on a schedule adapted to the study and to the treatment evaluated.

This patient monitoring not only brings important findings in terms of scientific work, but also helps your doctors notice any change in your condition so that the necessary steps can be taken quickly.

In most clinical studies the doctor responsible for the study and your care collects, analyses and checks not only the important health data obtained in the study, but also many other data. The advantage is that side-effects of treatment and changes in your health can be quickly recognised and treated.

Furthermore, a clinical trial involves medical specialists from a wide range of disciplines, who are specialised in the management of the particular disease. This ensures optimum treatment whichever arm of the trial the patient is on.

Anyone who is eligible to join a particular trial can be sure that they will not be forced to do anything against their will, and that they can withdraw from the trial at any time.

Participation in clinical trials is always voluntary and always requires your written consent. Patients should understand the objective of the trial, its special features, and what risks, if any, it entails. It should also be understood that new treatments that are being tested are not always better than, or even as good as, existing treatments and that they may have unexpected side effects.

Are you thinking about participating in a clinical trial?

Here are some of the questions you may wish to ask your oncologist or your health care team:

- Am I eligible for a clinical trial?
- What is the purpose of the trial?
- What are the benefits?
- What are the side effects and risks?
- How many people are being recruited to the trial?
- What will it involve and how long will it take?
- How often will I have to visit the clinic?
- Will I be informed of the results?
- How can I find out what clinical trials are being offered?
- What kind of therapies, procedures and/or tests will I have during the trial?
- How will the trial affect my current treatment plan and my daily life?
- Will I be taken off my current treatment or will I continue to take my regular medications while on the trial?
- If the person in charge of my medical care during the trial is different from the doctor that put me on my current care, what will be the communication/interaction between the two?
- Can I talk to other people in the study?
- What is the procedure for opting out of this study once I have started it?
- Will there be costs to me if I participate?
- Will my insurance cover the costs?
- What are my responsibilities if I participate?
- How long will I be in the study?
- Do I have more/other treatment options instead of clinical trial?

Prof. Antonio González, ENGOT Chair

"Gynaecological cancer patients should not hesitate to volunteer for clinical trials because they have led to numerous benefits for patients **all over the world and allowed access to the most innovative therapies**. However, we recommend that they speak with their treatment team so that they are fully informed before making a decision."

How to participate in a clinical trial?

Several ways are open to patients wishing to enquire about a clinical trial.

Some countries have national websites. The easiest way is to ask your oncologist. There is also information about clinical trials on the following sites:

European Union Clinical Trials Register: http://tinyurl.com/khewfg4
ENGOT: https://engot.esgo.org/discover/for-patients/
Target Ovarian Cancer: http://clinicaltrials.targetovariancancer.org.uk
NIH - database of privately and publicly funded clinical studies conducted around the world: clinicaltrials.gov

Icó Tóth, ENGAGe Co-Chair

Clinical trials are research studies designed to evaluate the safety and efficacy of new drugs or other types of therapies.

This brochure has been specifically written as an educational tool for patients and their families providing an insight into how clinical trials work. It is a resource for those who may consider volunteering to participate in a clinical trial on the recommendation of their doctor.

ENGAGe is working with health professionals, policy makers and patients themselves to better understand the role of patients in providing input into clinical trials design and to achieve a better understanding of current barriers to participation in research.

Patients have a unique knowledge about their disease, treatment and quality of life. These insights are of great value to researchers and policymakers when priorities need to be set.

The European Society of Gynaecological Oncology (ESGO) is a professional educational organisation and the principal European society of gynaecological oncology contributing to the study, prevention and treatment of gynaecological cancers. Today, ESGO has over 1800 members in over 40 countries in Europe and strives to improve the health and well-being of European women with gynaecological (genital and breast) cancer through prevention, excellence in care, high quality research and education.

The European Network of Gynaecological Oncological Trial groups (ENGOT) is a network of European study groups of ESGO and a platform that guarantees that the European spirit and culture are incorporated into medical progress, particularly in gynaecological cancer research, and that all European patients and countries can participate in an active way in clinical research and progress. It is the aim of ENGOT to bring the best treatment to all of Europe's gynaecological cancer patients and to enable every patient in every European country to access a clinical trial. The ENGOT network includes 21 trial groups from 25 European countries. These trial groups coordinate the development of new cancer treatments but also learn from basic research in the field of gynaecological cancer research.

Established by ESGO in 2012, the European Network of Gynaecological Cancer Advocacy Groups (ENGAGe) is a network of European patient advocacy groups representing all gynaecological cancers including ovarian, endometrial, cervical, vulvar and rarer gynaecological cancers under the umbrella of ESGO. There are wide variations in patient care across Europe, including patients not being adequately informed about gynaecological cancers and their management. There are also issues, in relation to psychosocial support throughout the patient's journey which may be less than ideal.

The objectives of ENGAGe are to:

- Facilitate the development of national gynaecological cancer patient groups in Europe and facilitate networking and collaboration between them.
- Disseminate information and share best practice to empower patient groups and improve the quality of care across Europe.
- To increase patient representation in ESGO activities by education on current research and health policy.
- To advocate patient care policies, practices and access to appropriate care at both national and European levels.
- To educate patient groups, health professionals, the public and health decision makers.

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