

ovacome..  
ovarian cancer

## Clinical trials



**Ovacome is a national charity providing support and information to anyone affected by ovarian cancer.**

**We run a free telephone and email support line and work to raise awareness and give a voice to all those affected by ovarian cancer.**

**This booklet is part of a series giving clinical information about ovarian cancer.**

It describes how clinical trials are conducted and gives information about taking part in trials that test new treatments for ovarian cancer.



# Taking part in clinical trials

Many people with ovarian cancer want to join a clinical trial. Taking part in a trial can give you access to new treatments that would not normally be available. This booklet tells you how to find out about trials which you could discuss further with your team.

## What is a clinical trial?

A clinical trial is medical research that uses people - usually patients - to try out new treatments. Some clinical trials investigate standard treatments, how they work, why they don't work or the effects that the standard treatments have on the cancer. A trial may be run by researchers from universities, hospitals, or other organisations, or by a pharmaceutical company. All trials are governed by rules that include ethical review of the work.

To take part in a clinical trial you will need to meet requirements, which are called eligibility criteria. These can be strict, but they are included to make the trial as safe as possible.

The criteria are set by researchers. They are usually to do with your diagnosis, previous treatments and progress with ovarian cancer. Sometimes you might want to take part in a clinical trial but can't because an unexpected test result excludes you.

If you can take part in a clinical trial the research team will ask you to sign a consent form. Often you will have to commit to a series of clinic visits and monitoring which is likely to be more than you would have with standard treatments.

After you sign the consent form, the research team will carry out specific tests required by the trial before giving you treatment. So, there is still a small chance that they will not be able to treat you on the trial once these results return. If this happens you will usually be offered the standard treatment instead.

### **Are there different types of clinical trial?**

Clinical trials are carried out in a series of stages called phases.

#### **Phase 1**

When a brand-new treatment is first given to people, doctors do not know the best dose of the drug, how often to give it or the side effects of the drug.

A phase 1 trial is designed to work out the best dose, frequency and side effects. There are different designs of phase 1 trials. They can recruit patients with different cancers. However, because the drug is so new, researchers cannot say whether you will benefit from taking part.

#### **Phase 2**

If the phase 1 trial shows that the dose and side effects of the new treatment are acceptable, the drug may be tested in a phase 2 trial. In these trials patients with a particular type of cancer, such as ovarian cancer, will be asked to take part.



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The aim of the phase 2 trial is to see if the drug stops ovarian cancer getting worse or even shrinks it down. These trials usually ask 30 to 50 patients to participate.

A similar design is used if researchers want to develop new tests that see how standard treatments stop cancers growing. Or if they want to develop tests that help us understand why resistance to standard treatments happens. These trials aim to develop new tests, called cancer markers (sometimes called biomarkers), which help guide cancer doctors to recommend the best treatments for patients.

Some trials are called randomised phase 2 trials. This means a computer will randomly place you either in a group that receives the new treatment or in a group that receives the standard treatment. This allows researchers to see if the new treatment is better than the standard treatment.

Rarely, randomised phase 2 trials may involve giving placebos to some patients taking part. These are substances that look like the treatment being tested but which have no effect on the body. Placebos (dummy treatments) are rarely used in cancer medicine. They are only used in trials where no standard treatment options exist. The patient information sheet about the clinical trial will clearly say if a placebo is being used. If you have any questions about this, you can ask the researchers.

If the trial suggests the new treatment is as good or better than existing treatments it will go on to a phase 3 trial.

### Phase 3

These trials are usually much larger than phase 1 or phase 2 trials. They compare the new treatment with standard treatments. Some phase 3 trials have thousands of patients taking part across many hospitals and sometimes in many different countries.


Phase 3 trials use computers to randomly allocate patients to the standard treatment or the new treatment. This helps the trial to produce an unbiased result.

If the new drug or treatment passes the phase 3 trial, it may go on to the licensing process and become available for use in the health service.

### Phase 4

Once a treatment has been licensed it can be further examined in a phase 4 trial. This is to find out more about its safety, side effects, risks and benefits, and to see how it works when it is widely used. Not all treatments progress to phase 4.

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### Reasons to join a clinical trial - or not

You might want to take part in a trial because your current treatment is no longer benefitting you. Or you may be looking for a new treatment because there are limited choices for you. You may want to take part to benefit people in the future and help to develop new treatments.

Joining a trial can give you access to new treatments that would not otherwise be available. You will be closely monitored during the trial, which can be reassuring but it can also involve more visits to hospital. Joining a trial can also bring uncertainties and it is important that if you have any questions, you ask the researcher who is looking after you, or your oncologist.

People wanting to take part in clinical trials are invited to do so when they are relatively well. This is because if you become unwell during the trial, the researchers are more likely to know if it is the treatment being tested or an existing illness that is causing the problem. So, the best time to look for a trial is when you are feeling well, and your consultant thinks a trial might be a good option.

Your decision to take part needs to be weighed against the effectiveness of standard treatments. If an effective treatment option exists, it might not be the right time to look for an alternative.

You can leave a trial at any time, and you do not have to give a reason.

### How to find a trial

The easiest way to find a trial that may be suitable for you is to ask your consultant. You will have to meet the trial entry conditions set by the researchers and your consultant will be able to advise on this.

You can find out about ovarian cancer treatment trials yourself by calling the Ovacome free support line on 0800 008 7054. We can give you details of current trials, the main requirements to take part, where they are running and questions to think about and to discuss further with your consultant.

Cancer Research UK has a lot of detailed information about clinical trials on its website including a database of current UK trials at [www.cancerresearchuk.org/about-cancer/find-a-clinical-trial](http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial) You can also try [www.clinicaltrials.gov](http://www.clinicaltrials.gov) which is a database listing trials conducted around the world. Once you have found a clinical trial that interests you, ask questions to make sure it is right for you.

### You can ask

- Why is the trial being done?
- What are the possible risks and benefits for me taking part?
- What are the side effects of the new treatment?
- How long will the trial last and how long will I have treatment?
- How far and how often will I have to travel?
- Will I need more time in hospital having scans and tests?
- What information will be kept about me and who will see it?
- How likely am I to benefit from taking part in the trial?
- How much benefit I will gain?
- How will I find out the results of the trial?
- Can I claim expenses?
- If anything goes wrong, will I be covered by insurance?



You may want to join a trial to benefit people in the future and help to develop new treatments.

We welcome your feedback on this booklet. Please email [ovacome@ovacome.org.uk](mailto:ovacome@ovacome.org.uk) or call 0800 008 7054. If you would like to discuss anything about ovarian cancer, please phone our support line on 0800 008 7054 Monday to Friday between 10am and 5pm. You can also visit our website at [www.ovacome.org.uk](http://www.ovacome.org.uk). This is one of a series of information booklets produced by Ovacome. You can see them here: [ovacome.org.uk/information](http://ovacome.org.uk/information)

**Reviewed by: Gordon Jayson PhD FRCP Professor of Medical Oncology, Christie Hospital and University of Manchester**

### Disclaimer

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Support line: 0800 008 7054  
Office phone: 0207 299 6654  
Website: [www.ovacome.org.uk](http://www.ovacome.org.uk)  
Email: [ovacome@ovacome.org.uk](mailto:ovacome@ovacome.org.uk)

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