

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.

A trial may be run by researchers from universities, hospitals, or other organisations, or by a pharmaceutical company.

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 to make the trial as safe as possible. The criteria are set by the researchers. They are usually to do with your diagnosis, previous treatments and progress with ovarian cancer. Sometimes you might wish 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.

Before giving you treatment, the team will carry out specific tests required by the trial. So there is still a small chance that the team 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 several different designs of phase 1 studies.

The aim of the phase 1 trial is to look at what side effects a new drug has and to work out the correct dose. This means a phase 1 trial can recruit patients with different cancers. However, because the drug is so new, researchers cannot say whether you will benefit from taking part.



Taking part in a clinical trial  
can give access to new  
treatments that would not  
normally be available.

### 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.

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.

Some trials are called randomised phase 2 trials. This means if you take part a computer will allocate you to have the treatment being trialled or the standard treatment. This allows the researchers to see if the new treatment is better than the standard treatment.

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. Phase 2 trials may also involve giving some patients existing treatments only.

Placebos (dummy treatments) are rarely used in cancer medicine. They are only used where no standard treatment options exist. The patient information sheet about the clinical trial will say whether 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. 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 involve computers that randomly allocate patients to the standard treatment or the new treatment. This helps the trial to produce an unbiased result.

If the 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 the 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 trials progress to phase 4.

Development of a new treatment may be stopped at any point if it is found to be ineffective, if not enough people can be recruited to the trial, or if the risks of a new treatment outweigh the benefits to patients.



Development of a new treatment may be stopped at any point if it is found to be ineffective, if not enough people can be recruited to the trial, or if the risks of a new treatment outweigh the benefits to patients.



### Reasons to join a clinical trial

You might want to take part in a trial because your current treatment is no longer benefitting you. 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.

However, joining a trial can bring uncertainties and it is important that if you have any questions, you ask the researcher who is looking after you, or your oncologist.

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

### Finding a clinical 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 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)

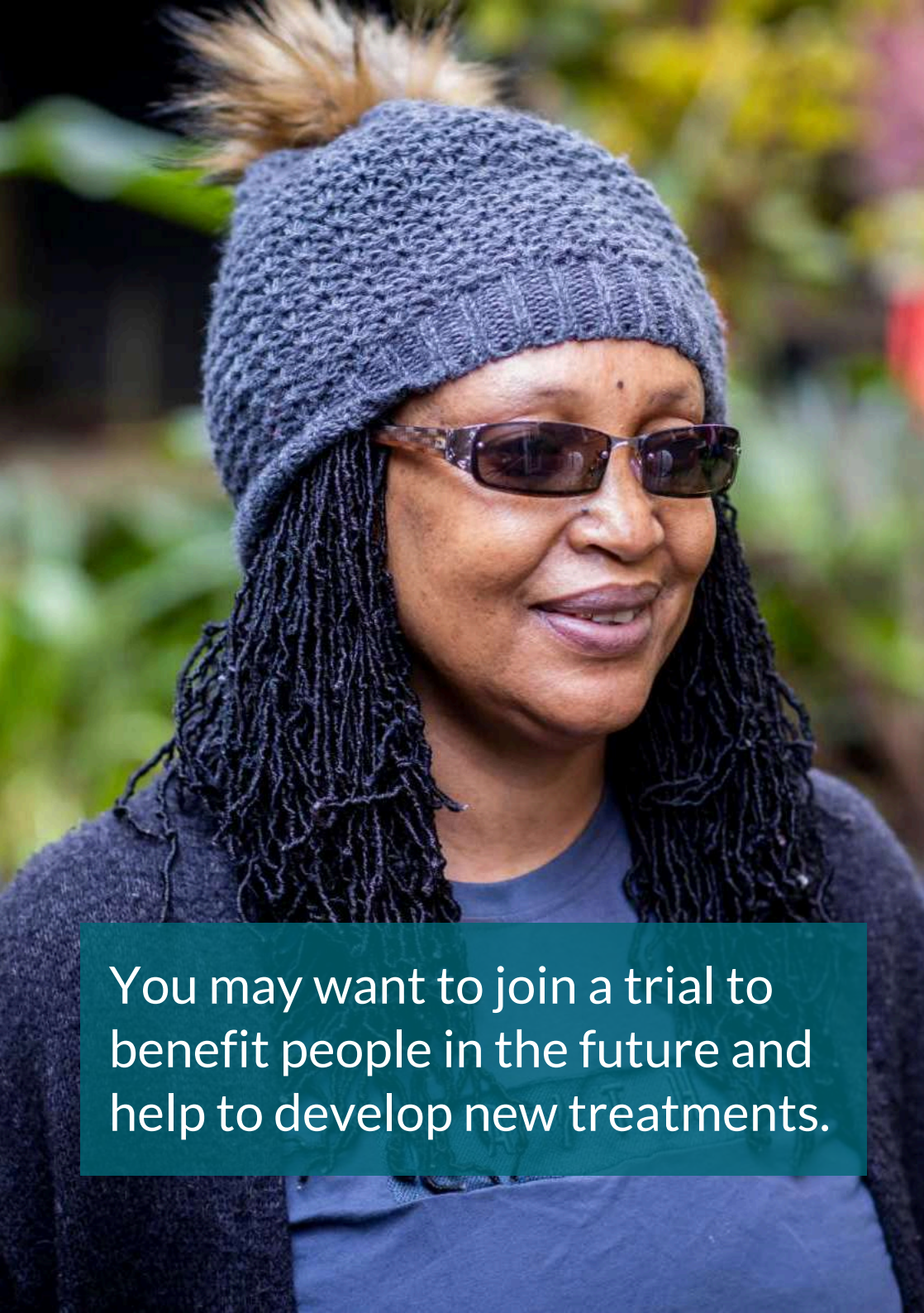
You can also try Clinical Trials.gov which is a database listing trials conducted around the world.

[clinicaltrials.gov](http://clinicaltrials.gov)

Once you have found a clinical trial and you meet the criteria to join, ask questions to make sure it is right for you.

### You may want to ask:

- Why is the trial being done?
- What are the possible risks and benefits for me taking part?
- Could you tell me what you know about the side effects of the new treatment?
- How long will the trial last and how long will I have treatment on the trial?
- How far and how often will I have to travel?
- Will I have to spend 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? Do you know 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

Ovacome booklets provide information and support. We make every effort to ensure the accuracy and reliability of the information at the time of publication. The information we give is not a substitute for professional medical care. If you suspect you have cancer, you should consult your doctor as quickly as possible. Ovacome cannot accept any liability for any inaccuracy in linked sources.

Version 2.4 | Date last updated February 2023 | Date for review February 2025



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)

Ovacome is a charity. We receive no government funding and most of our funding is provided by our community of supporters. We want to continue providing free support and information to people when they need it most. If you can, then please help us by making a donation. You can scan the QR code to the right or visit [www.ovacome.org.uk/donate](http://www.ovacome.org.uk/donate).



Registered with



Charity number 1159682