

Clinical trials are very important for doctors and scientists to understand how new treatments, therapies and medicines can be used to help people overcome serious illnesses like bowel cancer. If you are invited to take part in a clinical trial, it is important that you have access to all the information you need to help you and your family decide whether or not you wish to take part.

## What is a clinical trial?

Clinical trials are carefully controlled research studies designed to look at very specific aspects of a single treatment, or to compare the effectiveness of several different treatments, to establish what is effective in treating a particular disease. They might be testing new medicines or treatment, or they might be looking at new ways of using current or older treatments to make them work better, or for different types of problems. They are not a guarantee of any better treatment, or a way of accessing new medicines not currently in use within the NHS in the UK.

Approximately 18 cancer patients in every 100 take part in a clinical trial to help doctors and scientists to find more effective ways to prevent and treat the disease and improve the quality of life for people affected by it.

*“Clinical trials are a vital step in developing new, more effective treatments and assessing side-effects and tolerability. Improved outcomes should not be at the detriment of quality of life and clinical trials also assess this important aspect of care.”*

**Katharine Williams, Senior Research Sister  
Academic Unit of Clinical Oncology  
Weston Park Hospital, Sheffield**

## Are there different types of trials?

**Diagnosing trials** look at new technologies or ways of improving the way diseases are diagnosed in humans.

**Prevention trials** ask questions about how disease and illness can be prevented, and invite participants to do something that will prove or disprove the question being asked. For example, it might be an ‘action’ study – *“Does exercising three times a week reduce your risk of cancer?”* Or it might ask a question about how effective an agent is – *“Does taking a certain vitamin reduce your risk of cancer?”*

**Quality of life trials** can measure an individual’s sense of well-being and how your quality of life is affected by any given treatment.

**Screening trials** test new methods of screening for cancer which may lead to more cases being diagnosed at an earlier stage.

**Treatment trials** look at new ways of treating a specific illness or symptom more effectively.

## Why are clinical trials needed in cancer?

Clinical trials help to provide the proof that the medicines or therapies being used to treat patients are effective and safe.

As well as testing new medicines, new ways of taking existing medicines or even different combinations of treatment, trials can also look at the consequences of treatments for people. They can assess and reduce the risk of unwanted side-effects of treatment by changing dosages or timing of the treatments.



## Beating Bowel Cancer

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Clinical trials will also consider the direct patient benefit, which arm of the trial (see below) showed the most benefit and also how the treatments affected quality of life both in a positive and negative way.

### What are the different phases of treatment trials?

Treatment trials go through a series of phases to test whether they are safe and if they work. All new cancer drugs are tested in the laboratory before they are given to people.

**Phase 1** trials involve a very small number of people in a specialist research unit. They aim to discover what the most appropriate human dose might be, and what the side-effects are. If the drug is effective and a safe dose is found after a number of phase 1 trials, it will progress to phase 2.

**Phase 2** trials, still involving a small number of patients, aim to discover which types of cancer the treatment is going to be most effective for. They may also check the best way of giving the treatment, the optimum dose for effective treatment, and the side-effects and consequences of this pattern of treatment.

**Phase 3** trials compare the effectiveness of the new treatment with current, standard treatment. This phase often involves much bigger groups of patients from many different hospitals, often in different countries.

They can gather much more information on the effectiveness and side-effects of new treatments, and often last a year or more. They always involve 'randomisation'.

**Phase 4** trials are carried out after a drug has been given a licence which proves it to be safe and effective for patients. These studies usually investigate the long term risks / side-effects of treatment in standard use. Phase 4 studies are not required for every medicine.

### What is randomisation?

Randomisation is a way of allocating people to a certain treatment pathway (arm) within the trial – including the new treatment, or the standard 'best currently available' treatment. Occasionally, if there is no current treatment, a new treatment may need to be compared with a placebo (dummy treatment).

Randomisation is done by a computer in order to avoid bias. Treatment arms are allocated according to various criteria ie gender, age, stage of disease to ensure that the different arms of the trial are as similar as possible.

Each patient has an equal chance of being given the new treatment; it does mean you may not get access to the treatment being tested.

### Should you take part in a clinical trial?

There are a number of reasons why you may wish to take part in a clinical trial. They offer you the chance to:

- Access new treatments before they become widely available
- Contribute to current medical knowledge and cancer research
- Receive healthcare provided by leading clinicians in the field of cancer research
- Have your health closely monitored during the trial.

If you are considering entering a trial, you should discuss it not only with your doctors and nurses, but with your family and friends. They may also have worries and concerns and it is helpful to have a different point of view when you are making such a big decision. You can leave the trial at any time, without giving a reason, if you change your mind. However, if you have been receiving a new treatment it is unlikely that you would be able to continue with this. It is essential that you discuss this with your doctor before making a final decision.



If you have any questions or comments about this publication, or would like information on the evidence used to produce it, please write to us or email [info@beatingbowelcancer.org](mailto:info@beatingbowelcancer.org).



It is important to be aware that if you enter a clinical trial you may be allocated to any of the arms. You therefore need to feel comfortable about receiving any of the treatments offered within the trial ie the standard treatment or the new treatment.

### What is informed consent?

Informed consent means being given all the information you need about the trial and the treatments being offered, before you decide whether or not to take part. This is usually done by the dedicated research nurse or consultant who will be looking after you during the whole of the trial period.

They will tell you about different aspects of the trial, including:

- Why the trial is taking place
- Why the trial may be suitable for you
- What will happen to you during the trial
- Whether or not it is a randomised trial and that you may or may not get the new drug or treatment being tested
- The standard treatment available if you do not want to enter the trial
- Information on other treatment options available
- The possible risks, side-effects and benefits of the treatment will be described to you and the research nurse will also describe to you how your progress will be monitored, whatever you decide

Participation in research and clinical trials is entirely voluntary and you will be advised that you can withdraw at any time.

You will be asked to complete and sign a consent form for the trial after you have had time to read the patient information sheet and ask questions.

You may also be asked to agree to additional tests being carried out on existing tissue samples that have

been stored in the lab since they were taken during your original operation or biopsy.

These samples will help scientists to better understand cancer and develop new treatments. In future, this will help to develop more successful and personalised treatments for bowel cancer patients.

You should only agree to take part in a trial if you are completely happy with what you are being asked to do. Your medical care / treatment will not be jeopardised in any way should you decide not to take part in a trial.

### Placebo controlled trials

A trial may use a placebo (dummy treatment) if it is trying to establish how effective a new treatment is when there is *no comparative treatment* available for any particular disease or symptom.

If you were taking part in a trial using a placebo, you would have an equal chance of being randomised between the new treatment arm and the placebo, which will look like the treatment being tested, but will not contain any active medicines. This is done on a 'blind' protocol - no-one in your specialist team will know which treatment you are having, so that they cannot unintentionally influence you or how you are feeling in any way.

These kinds of trials could be looking to see if a particular treatment helps to prevent cancer coming back, for example.

Occasionally, a trial which is randomised to the standard treatment plus a new treatment may also use a placebo, where it is ethical to do so. An example might be a study to find out if some of the symptoms or complications of treatment could be prevented or treated more effectively by adding in a new medicine. In this case, you could be randomised to the standard treatment as a minimum, PLUS the new drug or the placebo.



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Placebo controlled trials attempt to further remove any bias within the trial, to prove - or disprove - that there is a benefit, or any other difference, between the two types of treatment by comparing the results from both. By doing this with lots of different people, it may be possible to conclude that this difference is due to the new drug rather than other factors such as the power of positive thinking etc.

### Are there any risks in taking part?

Clinical trials involve a long and careful research process, but they do still carry potential risks, including:

- Side-effects or risks that have not been noticed previously
- The treatment may be less effective than standard treatment
- The new treatment may not work for you.

### Your responsibilities if taking part in a clinical trial

If you are asked to fill in any questionnaires asking about how the treatment is affecting your quality of life, it is very important that you are able to do this.

Your answers to the questions will help the researchers to understand if there are side-effects associated with the treatment which need to be considered when decisions are made about making the treatment more widely available.

### Follow up

Taking part in a clinical trial is not only about having the active treatment, but also to find out what happens to you in the months and years after the treatment has been completed. For this reason, it is likely that you will be asked to attend the hospital at more regular intervals. It is also possible that your tumour or biopsy samples may be used for some additional tests and investigations that you might not

otherwise have had, or you may continue to have follow up appointments and assessments of your symptoms and quality of life for a much longer period of time than for a standard treatment pathway.

### How do you get involved in a clinical trial?

Some people are invited to take part in a clinical trial by the medical team treating them. Other people actively seek to enter a clinical trial to potentially get access to treatment that is not currently available on the NHS. If you want to find out more, speak to your Clinical Nurse Specialist or your consultant.

For more information on treatment options please refer to our booklets:

**'Treating Bowel Cancer - Your Pathway'**

**'Advanced Bowel Cancer - Treating Metastases'**

For more information about current trials in the UK:

**Cancer Research UK**  
[www.cancerresearchuk.org/cancer-help/trials/](http://www.cancerresearchuk.org/cancer-help/trials/)

**UK Clinical Trials Gateway**  
[www.ukctg.nihr.ac.uk](http://www.ukctg.nihr.ac.uk)

Although these websites are updated regularly, there may also be local trials which your hospital team will be aware of.



If you have any questions or comments about this publication, or would like information on the evidence used to produce it, please write to us or email [info@beatingbowelcancer.org](mailto:info@beatingbowelcancer.org).

