Talk Lung Cancer...

A guide to clinical trials for people with lung cancer

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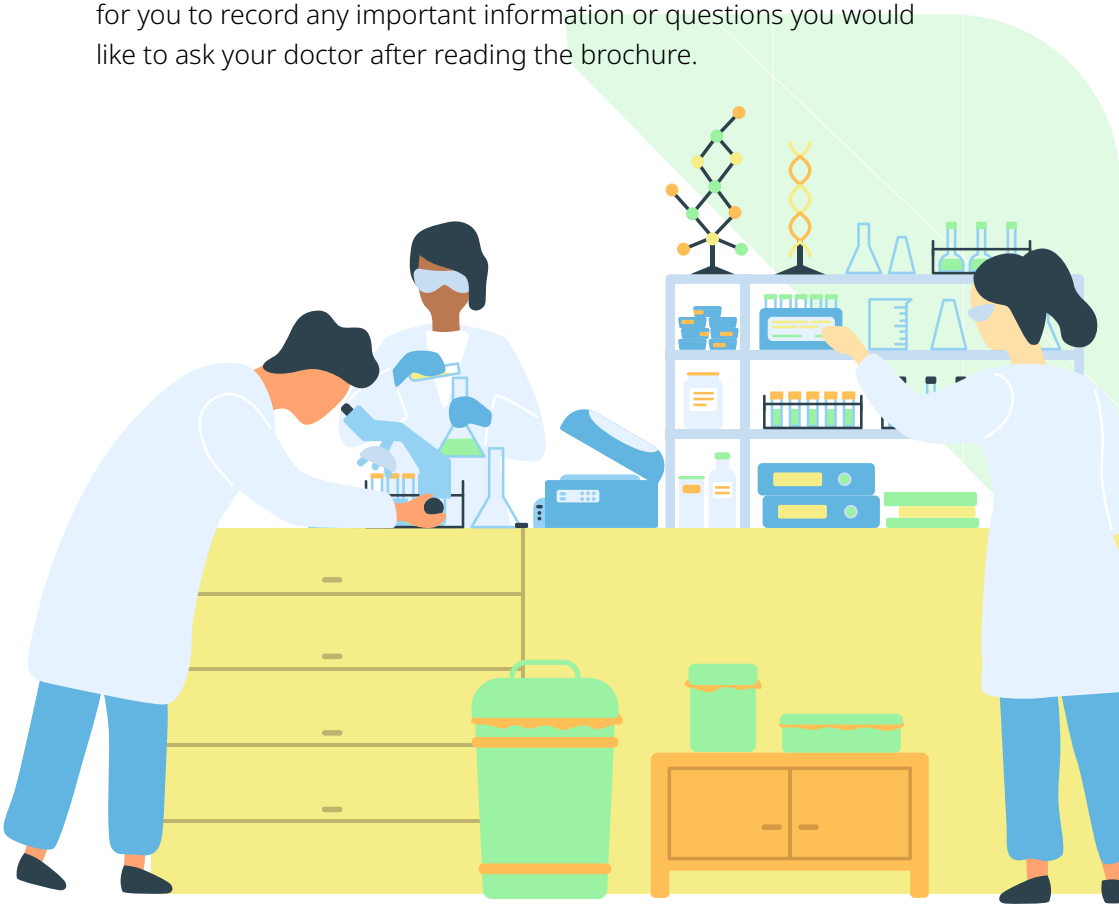
Janssen Oncology
PHARMACEUTICAL COMPANIES OF Johnson&Johnson

Overview and aim

This brochure helps to summarise relevant information on clinical trials in lung cancer. This includes:

- What they are
- How to take part in one
- How they can help people with lung cancer

You will also find a notes section at the end of the brochure. This is for you to record any important information or questions you would like to ask your doctor after reading the brochure.



Introducing Clinical Trials

What are clinical trials?

What?
A clinical trial is the main way in which researchers investigate and evaluate a new treatment.[1]

How?
The information gained from a clinical trial is then used to determine if a treatment's benefits outweigh its risks,[2] and whether it can be made available for anyone who needs it.

Why?
The goal of a clinical trial is simply to find a treatment that is potentially more effective, or less harmful, than existing treatment options.[1,3] Within this, the safety of every participant in a lung cancer clinical trial is always the number one priority,[4] even if outcomes can vary between different patients.[5]

What is meant by 'phases' of clinical trials?

When you sign up for a lung cancer clinical trial, you may notice that it is in a certain phase.

Clinical trials for lung cancer are generally within three main phases:

- **Phase 1** – Aims to find the best dose of treatment, what the side effects are and what happens to the treatment in the body.[6]
- **Phase 2** – Checks the best dose of treatment, finding out more about side effects and looking at how well the treatment works.[6]
- **Phase 3** – Compares the new treatment to the standard treatment. [6]

The information gathered from these three phases is then used to determine if a new treatment is safe and effective by regulatory bodies, like the European Medicines Agency (EMA),[7] so that it can be approved for use for people with lung cancer.

After a treatment has been approved for use by regulatory bodies, further studies may be conducted:

- **Phase 4** – Explores the long-term benefits and side effects of the new treatment.[6]

Why are clinical trials important?

Clinical trials help us understand more about health and disease.[1] By providing important clinical evidence, they are vital to ensure new and effective treatments are formally assessed and, where appropriate, approved so that they can be made more widely available.[1]

Why is diversity important in clinical trials?

Clinical trials should represent a broad spectrum of people from different backgrounds, age groups and ethnicities.[8] Gathering evidence across different groups in society is important, as it ensures new lung cancer treatments are tested for everyone, and therefore can be checked to see whether they are effective for the majority of people with the condition.[9,10]

Every clinical trial will have eligibility criteria which are a set of characteristics that have to be met by anyone that wants to participate, like 'entry requirements.[11] Examples of characteristics are someone's age, general health status, stage of lung cancer or treatment history.[12]

What happens when clinical trial results are known?

Following availability of clinical trial results, when the formal period of testing in people ends there can be an additional **follow-up period.**[13]

During this time, you will be regularly monitored to assess various aspects of your health. This takes place across follow-up appointments in which members of staff working on the clinical trial will track the progress of participants.[14]

The follow-up period can range from a few months to more than 10 years, depending on the type of lung cancer treatment the clinical trial focuses on and the people involved.[13,15] Later phase clinical trials, which test whether cancer returns after treatment, are also followed up over a period of several years to get accurate results.[15]

The process

Taking part in a clinical trial

Before deciding whether you want to take part in a clinical trial or not, there are a number of aspects you may want to consider first:

What 'eligibility criteria' may be put in place for a clinical trial?

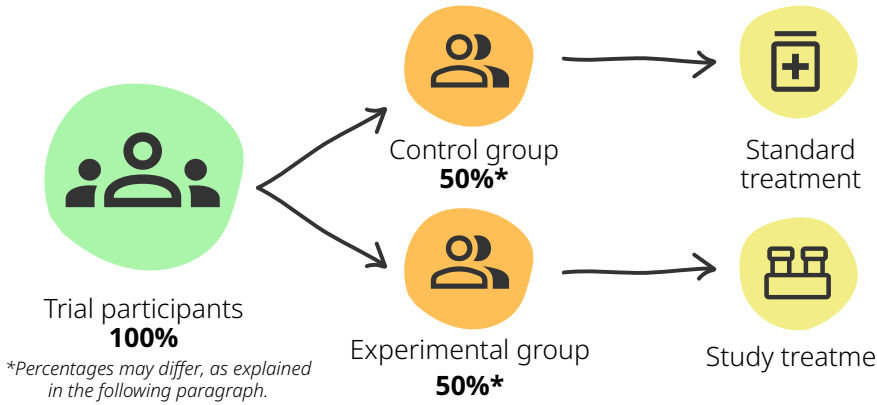
Researchers call the 'entry requirements' of a clinical trial 'eligibility criteria', which are put in place to ensure those people participating are as similar as possible and have appropriate characteristics to take part.[12]

What is informed consent?

Before starting a clinical trial, you must choose if you wish to provide your 'informed consent'.[16] This process is designed to ensure that everyone who participates in a clinical trial has all the necessary information presented to them first. Once you have read and understood this information, you will be able to give your informed consent and proceed with the lung cancer clinical trial, knowing exactly what it will entail.[16,17]

What is meant by a 'randomised' clinical trial?

Most clinical trials aim to determine the effectiveness and safety of a lung cancer treatment using the following method:[18]



What are the 'control' and 'experimental' groups?

In a lung cancer clinical trial, the 'control' group are the participants who receive existing (standard) treatment that is already approved for use.[18] The 'experimental' group, or groups (as there may be more than one), receive the study treatment.[18] Depending on the study, the number of people in the experimental and control group are not always equal in number.

Why is it important to have a control group?

The control group serves as a marker which can be compared to the study treatment. By comparing data from the experimental group with the control group, the clinical trial researchers can minimise any external factors that may be affecting the overall condition of the participants.[19,20]

As a result, the researchers will have a clearer idea of how effective the new treatment is and a better understanding of its safety profile for people with lung cancer. These findings can help determine whether the treatment should be approved.[19]

If I am placed in the 'control' group, does that mean I am not receiving treatment?

Sometimes a study is 'blinded', meaning that you are not told which group you are in, and in certain trials the researchers will not know either until after the trial. This is to prevent accidental bias, however it is possible to find out which group you are in if medically necessary.[2] Lung cancer clinical trials will typically provide treatment which has already been approved for use to the control group, known as standard treatment.[2] Therefore, you will always be receiving treatment for your lung cancer, regardless of whether you are put into the control group or the experimental group.[18]

What is an 'ethics committee' and why is it important each clinical trial is reviewed by one?

Before you enter into a lung cancer clinical trial, the trial protocol (the agreed plan outlining the process, aims and objectives of a clinical trial) will be reviewed by a Research Ethics Committee.[21]

Each of these committees has up to 15 members who are not involved with the trial in any way. One in three of these people will be members of the public, who are not researchers or healthcare professionals.[21]

This committee looks into each aspect of the clinical trial to ensure that your rights, safety, dignity and welfare are prioritised throughout the trial process, should you choose to participate. This ensures that your needs will always be put first before, during and after the trial.[21]

Deciding whether to take part in a clinical trial

Why should I take part in a lung cancer clinical trial?

For some people with lung cancer, a clinical trial may provide an opportunity to use a new treatment which is only available within a research setting. This new treatment may have the potential to be more effective or have less side effects than an alternative treatment. A clinical trial will help test this.

What are the pros and cons of participating in a clinical trial?[22]

Potential benefits	Considerations
The study treatment may help to shrink, reduce or make your lung cancer more manageable.	When testing new lung cancer treatments, there is always the possibility of the treatment being less effective than expected and having unanticipated side effects.
You are more likely to have regular, thorough consultations with healthcare professionals that will check how you are responding to the study treatment, in addition to regular blood tests and scans.	The clinical trial process may be time consuming, depending on what is required of participants. You may have to attend more appointments than usual, which may require more frequent travel.
By participating in a clinical trial, you will be contributing to advancements in lung cancer research, which has the potential to improve the lives of people with the condition.	Participating in a clinical trial can be time consuming so that sufficient results can be collected, and so you may have to consider how participating impacts your work schedule and personal time.

It's important to remember that all treatments used in clinical trials have been extensively researched in laboratories before being used in humans. While their safety is not guaranteed, a lung cancer clinical trial will not go ahead without positive findings from this prior research.[18]

Finding a trial

If you're interested in joining a clinical trial, your first point of contact should always be your healthcare team. Your doctor can tell you if they know of any trials that would be suitable for you. National or European patient organisations will also able to provide you with useful resources.

It may be that you have found a clinical trial online that you feel is suitable. Always speak to your doctor first to find out if your participation is appropriate.

You can find ongoing or proposed trials through Clinical Trials.gov or the EU Clinical Trials Register.

What if I can't find a clinical trial that's right for me?

The treatment landscape for lung cancer is constantly changing[23,25] and so even if there are no clinical trials available to you currently, there may be in the future. Consult with your healthcare team to see if there's a lung cancer clinical trial that's right for you.

Taking part in a clinical trial

There are a number of considerations you need to make when participating in a trial. Participating in a clinical trial is voluntary. You will always have the option to opt out of the trial without your care provision being affected. Here are some of our top tips for clinical study participation:

T

Track your progress

Before and during a clinical trial, you will be asked many questions about how you are feeling, whether you have encountered any symptoms or what your thoughts are about each step of the process. It can be difficult to remember each and every detail, so keeping a diary and journal to chart your progress and log anything that would be useful to share with the clinical trial team is advisable.

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Read the paperwork

A lot of important information will be given to you before you start the trial. This can be digested at your own pace at home. As you go through it, jot down any points you don't understand so you can clarify them later with your healthcare team.

I

Include friends, family or loved ones

Being part of a clinical trial can be a complex and sometimes worrying experience, but it doesn't need to be one that you undertake alone.

A

Ask questions

You should never be afraid to ask questions and get the clarification you need, to ensure you are always kept in the loop. Your clinical trial team are there to help you. If you'd like to talk about any part of the process, or have any concerns you would like to share, don't be deterred from starting the conversation yourself.

L

Live your life

Taking part in a clinical trial is a big decision and should be given plenty of consideration. When weighing up your options, it's important to prioritise your life outside the trial as well as your participation.

Support for clinical trials

What support is available to me as a clinical trial participant?

Support will be provided through a dedicated clinical trial team, who will be on hand to respond to any questions you may have.

Healthcare providers, charities and foundations also provide lung cancer support groups, where you can discuss how you are feeling with fellow patients.

During a clinical trial, you can also rely on the support of your friends, family or loved ones. You will not be asked to keep anything from your primary support network.

Questions for your clinical trials team

- Who is my point of contact for all my questions throughout the clinical trial?
- What treatments will I have as part of this clinical trial?
- Is the study blinded and will I know if I am getting the study treatment?
- What phase is the trial in? (e.g., Phase 1, 2, 3 or 4?)
- What are the expected side effects of the study treatment?
- What benefit might I get from participating in this clinical trial?
- What additional tests will I need to have and how often will I need to have them?
- Can I stop participating in the clinical trial at any time?
- What happens if my health gets worse during the clinical trial?
- How will the clinical trial affect my everyday life?
- What costs will my health insurance cover?
- What costs will I have?
- Can I continue taking other treatments?
- Who will be in charge of my care while I am in the study?
- What is the role of my primary doctor?
- What happens once the clinical trial ends?

Answers

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Notes / questions for your doctor

Talk Lung Cancer has been developed by Janssen Pharmaceutica NV, with input from the following Patient Advocacy Groups and healthcare professionals.

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