

Clinical Trials for ALK-positive lung cancer - are they for me?

This document is an information sheet about clinical trials written by the ALK Positive Medical & Pharmaceutical Advocacy Committee. This document is not intended to substitute for medical advice.

Should I enroll in a clinical trial for ALK-positive lung cancer?

The decision to enroll in a clinical trial requires a real understanding of what is being studied and how you will participate in the study. It is important to remember that clinical trials have been instrumental in developing all treatments for ALK-positive lung cancer. Many of our longest survivors have participated in clinical trials of treatments that are now the standard of care.

Why should ALK-positive patients in particular enroll in clinical trials?

Treatment advances in ALK-positive lung cancer are occurring rapidly, and by joining a clinical trial you may have the opportunity to have the most effective treatment, even if it is not on the market yet. Since ALK-positive lung cancer is a rare disease, it takes a long time to recruit enough patients for a clinical trial. The longer it takes to complete a clinical trial, the longer it takes to find better treatments for the illness. If you join a clinical trial, you help speed recruitment, which then speeds results. Everyone with ALK NSCLC will benefit from your participation.

What are the types of clinical trials?

There are several types of clinical trials. This article is based on **interventional** clinical trials, which means that you will be given a new treatment either alone or in addition to a standard treatment. The new treatment could be a drug or other treatment that is not FDA approved yet, or it could be an approved treatment being used in a new way.

The other types of trials are **prevention, screening, monitoring, diagnostic, and supportive care**. These trials do not test a new treatment; instead they gather information about other aspects of the diagnostic and treatment process.

What are the “phases” of Clinical Trials?

Phase 1 Trial: This is a first in human study. A treatment has been tested in the lab and/or in animals, and it is now ready for use in humans. Phase I trials determine safety and correct dosing of a treatment, along with effectiveness. Phase 1 trial participants have often had progression on other treatments.

Phase 2 Trial: This is a study of a treatment that has been determined to be safe in phase 1 trials. These trials enroll more participants than phase 1 trials, with more standardized dosing.

Phase 3 Trial: This is a larger study of a treatment that has been shown to be effective in phase 2 trials. In these trials there is a comparison to the current standard treatment. Those in the trial are randomly divided into 2 groups. One group receives the new investigational treatment while the other receives the current standard treatment.

Am I eligible to enroll in a clinical trial?

Trial eligibility is different for every clinical study. There are a number of studies that are exclusively for ALK-positive lung cancer patients, and some that are for lung cancer in general but include ALK. To enter a trial, one usually has to be physically strong enough to manage the potential side effects of the new treatment.

Each clinical trial may have several locations, sometimes even in small cancer clinics. ALK-positive trials are located worldwide, and they are often conducted in academic cancer centers. Some people travel fairly long distances to participate in clinical trials that are right for them.

How can I find out about clinical trials?

Your doctor may refer you to a clinical trial, and this is ideal. But do not rely solely on your medical team to find the right clinical trial for you. There are many trials available, and it would be difficult for any oncologist to be aware of all current clinical trials. You are most invested in your care, and you can discover a clinical trial that meets your needs.

A great place to search is the <https://clinicaltrials.gov/> website. Although the site is managed in the USA, it lists trials that are recruiting all over the world. To find trials for ALK, go to the main page and under Find a Study check “recruiting and not yet recruiting”. Then enter “NSCLC” as the condition or disease, then put “ALK” in Other Terms.

There are also websites that can help you find a study, including lungcanceralliance.org, lungevity.org, and www.antidote.me.

Finally, our ALK Positive Facebook group can help you search for a study. Post to our closed Facebook group page that you are interested in available clinical trials. Our group will use our shared knowledge to help discover possible clinical trials for you.

What are the advantages of enrolling in a clinical trial?

- You may receive cutting edge treatment that could help you live longer
- The study treatment will be free of cost to you and your insurance company
- You will receive careful monitoring from an interested treatment team
- Your doctor will likely have more experience and expertise in ALK-positive lung cancer
- Your response to the new treatment will be recorded and will help determine treatment for ALK-positive patients in the future

What are the disadvantages of enrolling in a clinical trial?

- You may have to travel some distance to the clinical trial location
- The study may require more frequent appointments and tests, which is inconvenient and may result in more co-pays or medical expenses
- The new treatment may not be more effective than the standard care.
- There may be unexpected treatment results, side effects, or toxicity

When is the best time to enroll in a clinical trial?

Clinical trials are recruiting for all stages of disease, so you can enroll in clinical trials at many points in your treatment. The best times to enroll are: before any treatment at all, when you are not tolerating your current treatment, when you have had progression on your current treatment, or when you have exhausted all standard treatments.

Frequently Asked Questions about clinical trials:

- A. *Will I get a placebo?* Probably not. In the few trials with placebos, the placebo is added to standard treatment. If you are in the placebo group, it will be added to an effective treatment for your illness.
- B. *Can I quit the clinical trial at any time and choose to get standard treatment instead?* Yes. You will sign an informed consent form that explains your rights.
- C. *Can I contact the sponsor of a clinical trial on my own?* Yes. You can contact the study sponsors directly to find out more about the trial or your oncologist can contact them on your behalf.
- D. *Will I get paid for being in an interventional trial?* No. Treatment studies do not pay patients. But other types of studies can offer reimbursement for filling out questionnaires or other tasks.
- E. *What happens if I have progression on a trial?* This is different for every trial. Sometimes progression while in one trial makes you eligible for another study, and you can enroll in a different clinical trial. Other times if there is progression, you leave the trial and have standard treatment through your oncologist. If you are receiving the standard treatment on a Phase III trial and you have progression, you may be eligible to "cross over" to the investigational treatment.
- F. *The "standard treatment" that I could get in this trial is no longer up to date. Could I still be randomized to that outdated treatment?* Maybe. Make sure you understand what standard treatment you will get if you join a randomized phase 3 trial. It probably does not make sense to enroll in a clinical trial if you could be randomized to a treatment that is currently substandard.
- G. *What are the main reasons I would not be eligible for an ALK clinical trial?*
The main reasons for exclusion are: Leptomeningeal disease, interstitial lung disease, another active cancer, or another serious health problem that would put you at risk or confuse the results of the trial.
- H. *Where can I find out more about the design of clinical trials?*
Here is a good place: <https://clinicaltrials.gov/ct2/about-studies/learn>

In summary, almost anyone with ALK-positive lung cancer can be a good fit for a clinical trial. A clinical trial can give you access to cutting edge treatment, and the study treatment will be provided free of cost. Clinical trials are available at all stages of treatment. Although your oncologist can refer you to a clinical trial, you may need to do some research to find a trial on your own. ALK Positive members are working together to find new treatments for this disease. Participating in a clinical trial is a valuable way to advance treatment and eventually find a cure for ALK-positive lung cancer.