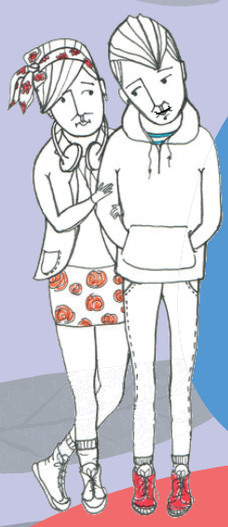
A TEEN'S GUIDE TO CLINICAL TRIALS



WHAT IS A CANCER CLINICAL TRIAL?

When someone has cancer, the doctors and nurses will try to give them the best treatment possible to make them feel better. Sometimes, new ways of treating cancer are discovered, and doctors want to test if these new treatments are better than the ones they are already using.

A cancer clinical trial is a research study that tests new treatments or procedures for people who have cancer. Clinical trials are conducted to find out if the new treatment is safe and effective, and if it should become part of the standard of treatment for that type of cancer.

Clinical trials may involve testing new drugs, radiation therapy, or surgery techniques, or combinations of these treatments. Anyone taking part is closely monitored by healthcare professionals to ensure their safety and to evaluate the effectiveness of the new treatment.

IF SOMEONE IS ALREADY BEING TREATED FOR CANCER, HOW WILL IT BE DIFFERENT ON A CLINICAL TRIAL?

A treatment in a clinical trial might be different from the standard treatment because the trial is designed to test a new approach to treating cancer. The new treatment might involve a new drug, a new combination of drugs, or a new way of using existing drugs.

Patients taking part in a clinical trial may have more tests and scans than other patients, this is to check how well the drug is working, and how the patient is feeling. They may also be given a placebo.

WHAT IS A PLACEBO AND WHY DO WE NEED THEM?

A placebo is an inactive substance that looks like the new treatment but does not contain any active ingredients. In a clinical trial, participants who receive the placebo are part of a "control group," which means they serve as a comparison group to the participants who receive the new treatment. By comparing the results of the two groups, researchers can determine whether the new treatment is effective or not.

While it might seem unfair to some participants to receive a placebo instead of the new treatment, it is important to use placebos to ensure that the trial is as accurate as possible.

Not all cancer trials use placebos especially where a delay in treatment could be harmful to the participant.

HOW SAFE IS A CLINICAL TRIAL?

Clinical trials are conducted under strict guidelines and monitored very closely by healthcare professionals to ensure the safety of the patients.

WHAT DO PHASE 1,2,3 AND 4 TRIALS MEAN?

Phase I clinical trials are the earliest stage of testing in humans. These trials are done to test a new treatment and find out how much of it is safe to give people.

Phase II clinical trials are the next stage of testing in humans. These trials are done to see if the treatment works for a specific type of cancer.

Phase III clinical trials are the final stage of testing in humans. These trials are done to compare the new treatment with the standard treatment that is already being used for that type of cancer.

Phase IV clinical trials are done after the treatment has been approved by the government agency that regulates medicines. These trials are done to learn more about the treatment's long-term effects, how it works in different groups of people, and how it works in combination with other treatments.

DOES MY PARENT HAVE TO PARTICIPATE IN A CLINICAL TRIAL?

No, a patient has the right to decide whether to take part in the study. Before giving their consent, the patient will be given all information about the trial and has the right to withdraw from the trial at any time without consequences. Consent is a fundamental principle of ethical research and ensures that the patient's rights and well-being are protected throughout the study.

WHO DESIGNS CLINICAL TRIALS?

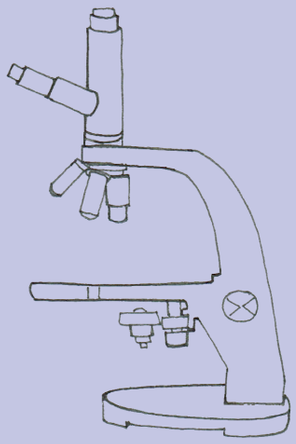
The design of clinical trials is usually done by a team of researchers, including doctors, scientists, and other healthcare professionals, as well as patients who will have experienced the condition being researched. The design of a clinical trial is very important because it determines how the study will be carried out, how the data will be analysed, and ultimately, how the results will be interpreted. The design is carefully reviewed and approved by ethical committees before the trial can begin.

WHY DO PEOPLE GO INTO CLINICAL TRIALS?

People take part in clinical trials for many reasons. Some people may want to try a new treatment because they have exhausted all other options and hope that the trial might help them. Others may take part because they want to contribute to the development of new treatments for their own condition or to help other patients in the future.

WHO LOOKS AFTER THEM?

Patients are looked after by a team of healthcare professionals who work on the study. This team includes doctors, nurses, and other medical staff who specialise in the condition being studied.

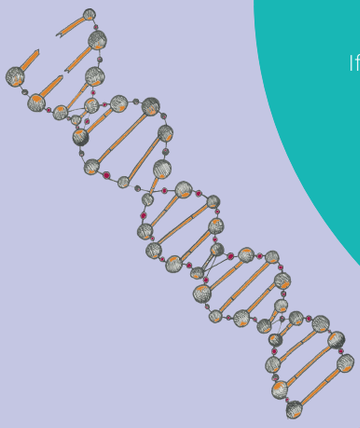


WHAT HAPPENS TO A PERSON WHO STARTS A CLINICAL TRIAL?

They will first meet with the study team to learn more about the trial, including the purpose, potential risks and benefits, and what their participation will involve. After signing a consent form, they will have checks such as physical exams, blood tests, and other tests to make sure that they are suitable for the trial.

If they are suitable, they will be randomly assigned to a study group, which could be the treatment group or the control group.

Throughout the trial, patients will need to follow the study's plan, which could include taking the treatment as directed, attending regular appointments, and completing follow-up assessments.



WHAT DO YOU HAVE TO DO WHEN YOU TAKE PART IN A CLINICAL TRIAL?

When you take part in a clinical trial, there are several things you may be asked to do, depending on the study's requirements. Here are some common tasks that participants may be asked to do:

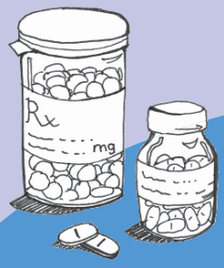
1.Attend regular appointments: You may need to attend regular appointments with the study team to monitor your health and progress.

2.Follow the study plan: This could involve taking the treatment as directed, following a specific diet or exercise plan, or completing regular assessments.

3. Keep a diary: You may be asked to keep a diary or record of your symptoms, medication use, and any other information related to the study.

4. Allow the study team to collect data: The study team may need to collect data from you, such as blood or urine samples, to monitor your health and progress.

5. Report any side effects or adverse reactions.



HOW DO THEY KNOW IF A DRUG IS WORKING?

During a clinical trial, researchers use various methods to evaluate if a drug is working.

One way to measure the drug's effectiveness is to look at measurable outcomes, such as changes in tumour size or levels of certain biomarkers in the blood. For example, in a cancer clinical trial, the researchers may measure the size of the tumour before and after treatment to see if the drug has shrunk the tumour. If the tumour has decreased in size, it suggests that the drug is working.

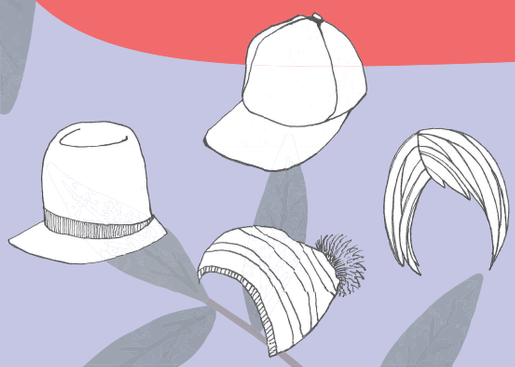
Another way to measure effectiveness is to look at subjective outcomes, such as improvements in quality of life or symptoms. For example, the researchers may ask the participants to rate their mood and feelings of well-being before, during and after treatment.

The data collected during the trial is then analysed statistically to determine if the drug has a significant effect compared to the control group. If the results show that the drug is safe and effective, the drug may be approved by regulatory agencies for use in the general population.

WILL THERE BE SIDE EFFECTS?

People may experience side effects when they take part in a cancer clinical trial. This is because cancer treatments, such as chemotherapy, radiation therapy, and immunotherapy, can cause side effects. In addition, some clinical trials involve new treatments that have not been fully tested in humans, so researchers may not know all of the potential side effects.

Patients will be closely monitored throughout the trial to manage any side effects and to ensure their safety.



WHAT HAPPENS AT THE END OF A CLINICAL TRIAL?

At the end of a clinical trial, the researchers will analyse all the data they have collected during the study to see if the treatment being tested is safe and effective. If yes, the treatment may become available to the general public; if no, the researchers may use the information to design new studies.

People who took part in the trial will be informed of the results of the study and may be given the option to continue receiving the treatment if it is approved for use. The researchers may also follow up with participants to monitor their health and any long-term effects of the treatment.