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What is a Clinical Trial?

Clinical trials are carefully controlled research studies that are done with patients. These studies test whether a new treatment is safe and how well it works in patients, or they may test new ways to diagnose or prevent a disease. The investigational drug may be compared with a placebo (a substance not expected to have any real therapeutic effect) or a different treatment. Clinical trials have led to many advances in colorectal cancer prevention, diagnosis, and treatment.

A clinical trial is performed only when there is good reason to believe that the treatment, test, or procedure being studied may be better than the one currently used. Treatments used in clinical trials are often found to have real benefits and may go on to become tomorrow's standard treatment.

Clinical trials involving investigational drugs provide information regarding:

- Whether the drug has the effect it is supposed to have
- How much of the drug to give to a patient (also called the treatment dose) and how often (also called the treatment regimen)
- What side effects are associated with the drug, and how they can best be managed
- How a drug is broken down in the body, and how long it stays in the body
- Which foods, drinks, or other drugs can be used at the same time, or should be avoided

It is important to remember that all new cancer drugs that are currently available for the treatment of colorectal cancer, were once only available in clinical trials. In Canada, all new cancer treatment products must proceed through an orderly clinical trials evaluation process to ensure that they have an acceptable level of safety and demonstrate benefit to patients with a specific cancer before they become commercially available to other patients.

When clinical trials show that a new treatment is better than older standard of care, and these results are verified by objective third parties, the treatment that was used in the clinical trial becomes the new standard of care. Run in the clinic on patients, the word "clinical" distinguishes these trials from tests done on tumor samples or on animals. Clinical trials are not started on humans until a substance has shown promise when tested first on human tumor samples, and then on animals, usually mice. There are many kinds of clinical trials, whose content is discussed below, but the ones that usually interest most colorectal cancer patients, are the ones that focus on treatment, but trials also exist to improve cancer support, detection, and prevention as previously mentioned. Clinical trials are designed and structured such that the results can withstand the minute and critical scientific scrutiny necessary to determine if a new treatment is effective. Three study designs that aid in ensuring that the results of treatment are attributable to the new agent and not to chance or confounding factors are:

- Randomization: a randomized trial is one in which a large number of patients with the same disease are assigned via computer to receive either the new treatment or existing, standard treatment. This means that a patient might not receive the new substance at all.

Randomization is used to demonstrate as clearly as possible that a group of similar patients did either better or worse, and that only the treatment given explains the difference in outcome.

- Blinded Trial: In a blinded trial, not only are patients randomized, they also are unaware of which treatment they are being given. This is considered necessary to rule out the placebo effect, defined as the ability of the human body to respond differently to treatment in measurable, physical ways, based on complex psychological and motivational factors experienced by the patient. Some patients might respond better to a treatment, for example, simply if they know they're getting a new treatment as opposed to an older one.

- Double-blinded Trial: A double-blinded trial is one in which the patients and some of the medical staff are unaware which substance is being given to whom. For example, the patient, the nurse who measures vital signs, and the pathologist who examines tissue samples might be unaware of which substance is being given. The doctor writing orders as outlined by the trial's protocol is aware, though, as he or she must be prepared to deal with side effects that arise. Double-blinding is used to eliminate the possibility that subtle factors, such as motivation and mood on the part of the nursing staff, might be sensed by the patient.

BENEFITS AND POTENTIAL RISKS OF PARTICIPATING IN A CLINICAL TRIAL	
BENEFITS	**POTENTIAL RISK**
May gain access to promising new therapy not available outside of clinical trial setting	The investigational therapy may not be better than the standard of care to which is being compared.
Access to more effective therapy	You may experience side effects that doctors could not anticipate or that are worse than those resulting from standard of care
Getting actively involved in your health care	In randomized trials, you will not be able to choose the approach you receive because patients in phase III clinical trials are assigned at random to either the experimental or control group – a process that makes some people uncomfortable
May receive regular and careful medical attention from a research team consisting of expert doctors, nurses, and other health professionals for colorectal cancer	You may be required to make more visits to the doctor than you would if you were not in a clinical trial, be subjected to additional tests, get more follow up complex dosage requirements

Participants receive correct dosages as a result of carefully designed regimens and strict protocol, and correct dosage often contributes to the effectiveness of a cancer treatment regimen.	
Thanks to “stopping rules”, which are included in all cancer research protocols, clinical trials are stopped when one cancer treatment is proven to be superior so that no patient is intentionally given an inferior treatment.	
Medical community gains knowledge about the treatment of colorectal cancer that can be used to treat other colorectal cancer patients and to develop newer colorectal cnacer treatments	
You will have the satisfaction of knowing that results from the study may help others in the future	

Phases of Clinical Trials

Clinical trials are conducted in distinct phases. Each phase is designed to answer specific questions. Knowing the phase of the clinical trial is important because it may give you some idea about how much is known about the treatment being studied. Each phase is designed to determine specific information about the potential new treatment such as its risks, safety, and effectiveness compared to standard therapy.

Phase I Clinical Trial: Is the Treatment Safe?

Phase I clinical studies are, perhaps, the most important step in the development of a new drug or therapy. These studies are usually the first trials to involve people. Although the treatment has been tested in lab and animal studies, the side effects in people can't always be predicted. For this reason, these studies usually include a small number of people (15 to 50) and may be reserved for those who do not have other good treatment options. Often, people with different types of cancer are eligible for the same study. These studies are usually done in major cancer centers. The main reasons for doing phase I studies are to find out the highest dose of the new treatment that can be given safely (without serious side effects) and to decide on the best way to give the new treatment. The first few people in

the study often get a low dose of the treatment and are watched very closely. If there are only minor side effects, the next few patients may get a higher dose. This process continues until doctors find the dose that is most likely to work while having an acceptable level of side effects. Safety is the main concern at this point because this is usually the first time the treatment has been used in people. Doctors keep a close eye on how the people in the study are responding. They watch for any common but serious side effects. Special tests, such as blood tests to measure levels of the drug in the body at certain time points, are often a part of these clinical trials.

Some studies may require time in a hospital. Placebos (sham or inactive treatments) are not part of phase I trials. These studies are not designed to find out if the new treatment works against cancer. Overall, these trials are the ones with the most potential risk. Phase I studies do help some patients. For those with life-threatening illnesses, weighing the potential risks and benefits carefully is key. In summary, the primary goals of this phase are to determine safety issues, which include:

- The maximum tolerated dose of the treatment
- The manner in which the drug works in the body
- The toxic side effects related to different doses, and
- Whether toxic side effects are reversible

Advantages of a Phase I Trial:

- **You may receive a treatment that is better than anything else currently approved years before it becomes available to the general public**
- **If this drug is already in use for other illnesses, its toxic effects might not be completely unknown**
- **Candidate agents for cancer treatment are not approved for phase I trials unless the substance has shown reasonably acceptable toxicity, and activity against cancer, in cultured tumor cell lines and in animal studies. Of every 5,000 substances tested in animals, only 5 enter phase I trials.**

Disadvantages of a Phase I Trial:

- For every 100 drugs tested in phase I trials, only 70 will prove successful or safe enough to carry forward into phase II trials.
- Because phase I trials are chiefly concerned with discovering dose-limiting toxicity, they are brief compared to phase II and III trials. You may receive too few doses of the test substance to destroy all of your cancerous cells.
- Phase I trials usually test one substance alone, yet experience has shown that, at least for the chemotherapeutic agents commonly used today, combined drug regimens are more effective

against most cancers than single-drug regimens.

- The substance, although it may be an approved drug for other illnesses or even for other cancers, most likely has never before been used in humans for your illness. Although it has been tested in cultured tumor cell lines, and in animals implanted with tumors, it may not be effective against your tumor, or it may be better than existing treatments.
- The substance, although it may be an approved drug for other illnesses or even for other cancers, may be administered to you at a much higher, more toxic dose.
- The dosage will be varied among those enrolled, thus its effects on your tumor may not be directly comparable to the effects on the tumors of others enrolled in the trial ... and patients do talk among themselves.
- The use of patients with different tumor types makes it difficult for you to compare your progress to that of other patients.
- Toxicity may cause substantial discomfort, illness, or permanent damage, in spite of the safeguards designed to prevent damage.
- Often phase I trials are run by one principal investigator at one institution. You may be required to travel to participate in a phase I trial.

Phase II Clinical Trial: Does the Therapy Work?

Phase II trials are designed to determine the effectiveness of the treatment in a specific patient population. If a new treatment is found to be reasonably safe in phase I clinical trials, the treatment can then be tested in a phase II clinical trial to see if it works the way researchers think it will. Usually, a group of 25 to 100 patients with the same type of cancer gets the new treatment in a phase II study. They are treated using the dose and method found to be most safe and effective in phase I studies. In a typical phase II clinical trial, all the volunteers usually gain access to the same dose, and no placebo is used. But some phase II studies do randomly assign participants to 1 of 2 treatment groups, much like what is done in phase III trials (see below). These groups may get different doses or get the treatment in different ways to see which provides the best balance of safety and effectiveness. Phase II studies are often done at major cancer centers. Doctors look for some evidence that the treatment works. The type of benefit or response they look for depends on the goals of the clinical trial. This may mean the tumor shrinks or disappears. Or it might mean there is an extended period of time where the tumor does not get any bigger, or there is a longer time before a cancer returns. In some studies the benefit may be an improved quality of life. Many studies look to see if people getting the new treatment live longer than they would have been expected to without the treatment. If a certain percentage of the patients benefit from the treatment, and the side effects aren't severe, the treatment is allowed to go on to a phase III clinical trial. Along with watching for responses, the research team keeps looking for any side effects. Larger numbers of patients get the treatment in phase II studies, so there is a better chance that less common side effects may be seen.

Advantages of a Phase II Clinical Trial:

- Candidate substances for cancer treatment are not approved for phase II trials unless phase I trials have shown that the substance is safe at a given dose and, in some trials, that the substance has some activity against cancer in humans.
- You'll be receiving a treatment that may be better than anything else currently approved by Health Canada or the FDA several years before it becomes available to the general public.
- Only doses of acceptable toxicity, determined during phase I testing, are utilized.
- Randomizing and blinding usually are not used in phase II trials. Therefore, you are assured of receiving the experimental treatment.

The disadvantages of a Phase II Clinical Trial are:

- More than half of the drugs used in phase II trials will be found ineffective against cancer or too problematic for use. Of the original 100 drugs that entered phase I trials, of which 70 survived to pass to phase II, only 33 will survive phase II testing.
- The substance, although it may be an approved drug for other illnesses or even for other cancers, may not prove to be better than existing treatments for your illness.
- Although its toxicity was determined in the phase I trial of this substance, the substance is still an evolving treatment with the potential for unexpected side effects.
- More of your time will be needed for a phase II trial than for a phase I trial.
- You may have to travel to participate in a phase II trial.

Phase III Clinical Trial: Is the Therapy Better Than What is Currently Available?

Treatments that have been shown to work in phase II studies usually must go through one more stage of testing before they are approved for general use. Phase III clinical trials compare the safety and effectiveness of the new treatment against the current standard treatment. Phase III clinical trials usually have a large number of patients, at least several hundreds. These studies are often done in many places across the country (or even around the world) at the same time. Because doctors do not yet know which treatment is better, patients are often chosen at random, (called *randomized*) to get either the standard treatment or the new treatment. When possible, neither the doctor nor the patient knows which of the treatments the patient is getting. This type of study is called a *double-blind study*. Randomization and blinding are discussed in more detail later on. As with other studies, patients in phase III clinical trials are watched closely for side effects, and treatment is stopped if they are too severe. Placebos may be used in some phase III studies, but they are never used alone if there is already a treatment available that may work.

The advantages of a phase III trial are:

- A substance that has survived the scrutiny of phases I and II is very likely to be better than current treatments: either more efficacious, or equally effective but less toxic.
- You'll be receiving a treatment that may be better than anything else currently approved by Health Canada or the FDA a year or two before it becomes available to the general public.
- If, during the trial, a new treatment shows itself to be profoundly superior to existing treatment, those receiving the existing treatment are switched to the arm of the study utilizing the new substance.
- If a new treatment shows itself to be clearly or dangerously inferior to existing treatment, those receiving the new treatment are switched to the standard treatment regimen.

The disadvantages of a phase III trial are:

- Of the 33 drugs that survived phase II testing, only about 25 will be found effective in phase III trials.
- Randomizing and blinding may not appeal to those who are determined to receive only the new treatment, not the contrasting current treatment.
- The new substance may prove to be just as effective as, but no better than, the existing treatment.

Phase IV Clinical Trial: What Else Do We Need to Know?

Even after testing a new medicine on thousands of people, the full effects of the treatment may not be known, and some questions may still need to be answered. For example, a drug may obtain approval based on the fact that it was shown to reduce the risk of cancer recurrence. But does this mean that those who get it are more likely to live longer? Are there rare side effects that haven't been seen yet, or side effects that only show up after the drug is used for a long time? These types of questions may take many years to answer fully, and may not be critical for getting a medicine to market. They are often addressed in what are known as phase IV clinical trials. Phase IV studies look at drugs that have already been approved by the nation's regulatory agency (in Canada it is Health Canada). They are already available for doctors to give to patients, but these studies are still needed to answer important questions. When thinking about taking part in a phase IV trial, you should know that the drug has already been approved for use on the federal level but may not be funded by the respective province's government. Enrollment in the study Is not required to gain access to the drug. At the same time, the care you would get in these types of studies often is very much like what you could expect if you were to get the treatment outside of a clinical trial. You should be reassured that in taking part you would be getting a form of treatment that has already been studied a great deal and that you would be doing a service to future patients.

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Frequently Asked Questions & Answers

Choosing to participate in a clinical trial is an important personal decision. The following frequently asked questions provide detailed information about clinical trials.

What is a clinical trial?

Clinical trials are research studies aimed at making cancer treatments better so people can live longer or live with less negative side effects. To achieve this, researchers test new drugs, medical protocols, treatments, medical devices and other cancer-fighting tools to learn innovative ways to tackle a disease. Researchers and doctors involved in clinical trials follow strict guidelines and steps to protect participants and their information while studying the effectiveness and safety of new treatments and medical devices. (https://fightcolorectalcancer.org/research/clinical-trials/)

Why participate in a clinical trial?

Participants in clinical trials can play a more active role in their own health care, gain access to new research treatments before they are widely available, and help others by contributing to medical research.

Who can participate in a clinical trial?

All clinical trials have guidelines about who can participate. Using inclusion/exclusion criteria is an important principle of medical research that helps to produce reliable results. The factors that allow someone to participate in a clinical trial are called "inclusion criteria" and those that disallow someone from participating are called "exclusion criteria". These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. Before joining a clinical trial, a participant must qualify for the study. Some research studies seek participants with illnesses or conditions to be studied in the clinical trial, while others need healthy participants. It is important to note that inclusion and exclusion criteria are not used to reject people personally. Instead, the criteria are used to identify appropriate participants and keep them safe. The criteria help ensure that researchers will be able to answer the questions they plan to study.

What happens during a clinical trial?

The clinical trial process depends on the kind of trial being conducted. The clinical trial team includes doctors and nurses as well as social workers and other health care professionals. They check the health of the participant at the beginning of the trial, give specific instructions for participating in the trial,

monitor the participant carefully during the trial, and stay in touch after the trial is completed. Some clinical trials involve more tests and doctor visits than the participant would normally have for an illness or condition. For all types of trials, the participant works with a research team. Clinical trial participation is most successful when the protocol is carefully followed and there is frequent contact with the research staff.

What is informed consent?

Informed consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate. It is also a continuing process throughout the study to provide information for participants. To help someone decide whether or not to participate, the doctors and nurses involved in the trial explain the details of the study. If the participant's native language is not English, translation assistance can be provided. Then the research team provides an informed consent document that includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document. The participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.

What are the benefits and risks of participating in a clinical trial?

Benefits

Clinical trials that are well-designed and well-executed are the best approach for eligible participants to:

- Play an active role in their own health care.
- Gain access to new research treatments before they are widely available.
- Obtain expert medical care at leading health care facilities during the trial.
- Help others by contributing to medical research.

Risks

There are risks to clinical trials.

- There may be unpleasant, serious or even life-threatening side effects to experimental treatment.
- The experimental treatment may not be effective for the participant.
- The protocol may require more of their time and attention than would a non-protocol treatment, including trips to the study site, more treatments, hospital stays or complex dosage requirements.

What are side effects and adverse reactions?

Side effects are any undesired actions or effects of the experimental drug or treatment. Negative or adverse effects may include headache, nausea, hair loss, skin irritation, or other physical problems. Experimental treatments must be evaluated for both immediate and long-term side effects.

How is the safety of the participant protected?

The ethical and legal codes that govern medical practice also apply to clinical trials. In addition, most clinical research is federally regulated with built in safeguards to protect the participants. The trial follows a carefully controlled protocol, a study plan which details what researchers will do in the study. As a clinical trial progresses, researchers report the results of the trial at scientific meetings, to medical journals, and to various government agencies. Individual participants' names will remain secret and will not be mentioned in these reports.

What should people consider before participating in a trial?

People should know as much as possible about the clinical trial and feel comfortable asking the members of the health care team questions about it, the care expected while in a trial, and the cost of the trial if any. The following questions might be helpful for the participant to discuss with the health care team. Some of the answers to these questions are found in the informed consent document.

- What is the purpose of the study?
- Who is going to be in the study?
- Why do researchers believe the experimental treatment being tested may be effective? Has it been tested before?
- What kinds of tests and experimental treatments are involved?
- How do the possible risks, side effects, and benefits in the study compare with my current treatment?
- How might this trial affect my daily life?
- How long will the trial last?
- Will hospitalization be required?
- Who will pay for the experimental treatment?
- What type of long-term follow up care is part of this study?
- How will I know that the experimental treatment is working? Will results of the trials be provided to me?
- Who will be in charge of my care?

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What kind of preparation should a potential participant make for the meeting with the research coordinator or doctor?

- Plan ahead and write down possible questions to ask.
- Ask a friend or relative to come along for support and to hear the responses to the questions.
- Bring a tape recorder to record the discussion to replay later.

Does a participant continue to work with a primary health care provider while in a trial?

Yes. Most clinical trials provide short-term treatments related to a designated illness or condition, but do not provide extended or complete primary health care. In addition, by having the health care provider work with the research team, the participant can ensure that other medications or treatments will not conflict with the protocol.

Can a participant leave a clinical trial after it has begun?

Yes. A participant can leave a clinical trial, at any time. When withdrawing from the trial, the participant should let the research team know about it, and the reasons for leaving the study.

Where do the ideas for trials come from?

Ideas for clinical trials usually come from researchers. After researchers test new therapies or procedures in the laboratory and in animal studies, the experimental treatments with the most promising laboratory results are moved into clinical trials. During a trial, more and more information is gained about an experimental treatment, its risks and how well it may or may not work.

Who sponsors clinical trials?

Clinical trials are sponsored or funded by a variety of organizations or individuals such as physicians, medical institutions, foundations, voluntary groups, and pharmaceutical companies, in addition to federal agencies such as the National Institutes of Health (NIH), the Department of Defense (DOD), and the Department of Veteran's Affairs (VA). Trials can take place in a variety of locations, such as hospitals, universities, or community clinics.

What is a protocol?

A protocol is a study plan on which all clinical trials are based. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment.

What is a placebo?

A placebo is an inactive pill, liquid, or powder that has no treatment value. In clinical trials, experimental treatments are often compared with placebos to assess the experimental treatment's effectiveness. In some studies, the participants in the control group will receive a placebo instead of an active drug or experimental treatment.

What is a control or control group?

A control is the standard by which experimental observations are evaluated. In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo.

What are the different types of clinical trials?

Treatment trials test experimental treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

Prevention trials look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vaccines, vitamins, minerals, or lifestyle changes.

Diagnostic trials are conducted to find better tests or procedures for diagnosing a particular disease or condition.

Screening trials test the best way to detect certain diseases or health conditions.

Quality of Life trials (or Supportive Care trials) explore ways to improve comfort and the quality of life for individuals with a chronic illness.

What are the phases of clinical trials?

Clinical trials are conducted in phases. The trials at each phase have a different purpose and help

scientists answer different questions:

In Phase I trials, researchers test an experimental drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

In Phase II trials, the experimental study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.

In Phase III trials, the experimental study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.

In Phase IV trials, post marketing studies delineate additional information including the drug's risks, benefits, and optimal use.

What is an "expanded access" protocol?

Most human use of investigational new drugs takes place in controlled, clinical trials conducted to assess safety and efficacy of new drugs. Data from the trials can serve as the basis for the drug marketing application. Sometimes, patients do not qualify for these carefully-controlled trials because of other health problems, age, or other factors. For patients who may benefit from the drug use but don't qualify for the trials, federal regulations enable manufacturers of investigational new drugs to provide for "expanded access" use of the drug. For example, a treatment IND (Investigational New Drug application) or treatment protocol is a relatively unrestricted study. The primary intent of a treatment IND/protocol is to provide for access to the new drug for people with a life-threatening or serious disease for which there is no good alternative treatment. A secondary purpose for a treatment IND/protocol is to generate additional information about the drug, especially its safety. Expanded access protocols can be undertaken only if clinical investigators are actively studying the experimental treatment in well-controlled studies, or all studies have been completed. There must be evidence that the drug may be an effective treatment in patients like those to be treated under the protocol. The drug cannot expose patients to unreasonable risks given the severity of the disease to be treated.

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What is Compassionate Use?

Being part of a clinical trial is the most common way that patients receive investigational drugs (drugs that have not yet been approved by Health Canada or the FDA). The term "compassionate use" or "special access" refers to a patient being allowed access to a drug even though they do not meet the eligibility criteria of a clinical trial in which a drug is being studied. The decision to provide a drug in this manner is made on a case by case basis and there must be a reasonable expectation the drug will prolong life or improve a patient's quality of life. In addition, the sponsor of the clinical trial must agree to make the drug available and, the drug being studied must also meet the following criteria:

- There must be substantial clinical evidence that the drug may benefit patients with a particular type of cancer
- The drug must be able to be given safely outside a clinical trial
- The drug must be in sufficient supply for ongoing and planned clinical trials

Since these investigational drugs have not yet been approved by Health Canada or the FDA as safe and effective, they may or may not be effective in the treatment of a cancer. They also may have unexpected serious side effects. Hence, the possible risks must be considered when seeking access to an investigational drug.

Who Qualifies for Compassionate Use

In order for a patient to gain access to an investigational drug outside of a clinical trial, the patient must have a serious or immediately life-threatening disease or condition and no comparable or satisfactory therapeutic alternatives. Additionally, the drug manufacturer and the patient's doctor must make special arrangements to obtain the drug for the patient. These arrangements must be authorized by Health Canada and in the US, the FDA. Manufacturers may not always be willing or able to provide access to a drug outside of their clinical trials. Physicians may not always be able to seek compassionate use for patients, depending on a patient's medical history and the risks associated with taking an investigational drug. The physician must determine that the probable risk from the drug is not greater than the probable risk from the disease. Not all physicians are willing to manage the use of an investigational drug for patients in their care. Also, companies are not required to make their drug available through compassionate use, or to make more of a drug for that purpose.

Costs

Investigational drugs are expensive to manufacture. Some companies provide the drug for free to patients. Other companies charge patients costs associated with the manufacture of the drug. Most insurance companies will not pay for access to an investigational drug. In addition, there may be additional costs associated with administration and monitoring of the investigational drug by

healthcare professionals.

Accessing Investigational Drugs

Some companies have established expanded access programs. ClincialTrials.gov has compiled a list of expanded access studies on the web, or patients may search for specific compassionate use programs. The option of calling a drug company directly to inquire about their policies is always available to the patient and their healthcare provider. The following link provides instructions for accessing non-marketed drugs through the Special Access Program in Canada https://www.canada.ca/en/health-canada/services/drugs-health-products/special-access/drugs.html . It contains background information as well as the Special Access Request Form.

Questions to Ask Your Research Team

Appearing below are some questions you may wish to ask the clinical trials coordinator or principal investigator of the clinical trial you are considering:

- What is the purpose of the study?
- What kinds of tests and treatments does the study involve and how often?
- What does this treatment do? Has it been used before?
- Will I know which treatment I receive?
- What is likely to happen in my case with, or without, this new treatment?
- What are my other choices and their pros and cons?
- What side effects can I expect from the study? Can the side effects be controlled? If so, how?
- Will I have to stay in the hospital? If so, how often and for how long?
- Will the study cost me anything?
- If I am harmed as a result of the research, what treatment would I be entitled to?
- What type of long-term follow-up care is part of the study?
- Has the therapy been used to treat other types of cancers?
- Will I get a placebo?
- Will my information be kept confidential?
- Do I have any other options (standard treatments, other studies)? What are their pros and cons?
- How much experience do you have with this particular treatment? With clinical trials in general?
- What were the results in previous studies of this treatment? How likely are they to apply to me?
- Will this require an extra time or travel commitment on my part?

- How could the study affect my daily life?
- Will I still be seeing my regular doctor?
- How long will I remain in the study?
- Are there reasons I would be removed from the study? Are there reasons the study might be stopped early?
- If the treatment is working for me, can I choose to continue getting it even after the study ends?
- Are there others already taking part in the study whom I could speak to?
- Will I be able to find out about the results of the study once completed?

Sources:

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