Clinical Trials at Mohawk Valley Health System

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Is a Clinical Trial Right for You?

In clinical trials, doctors test new medicines and treatments in people to find better ways to prevent, diagnose, and treat diseases. By joining a trial, you might access new treatment options and contribute to future medical advancements.

All participants in clinical trials are volunteers. You can choose to join or leave a trial at any time. Discuss with your care team to determine if a clinical trial is suitable for you.

Ways to find a clinical trial at Mohawk Valley Health System:

- Ask your doctor
- Visit our website at https://www.mvhealthsystem.org/research/
- Email, Clinical Trials Office at Research@mvhealthsystem.org or
- Call, 315-624-4842

Types of Clinical Trials

Medical research studies involving people are called clinical trials.

There are two main types of trials or studies - interventional and observational.

Interventional trials aim to find out more about a particular intervention, or treatment. A computer puts people taking part into different treatment groups. This is so that the research team can compare the results.

Observational studies aim to find out what happens to people in different situations. The research team observe the people taking part, but they don't influence what treatments people have. The people taking part aren't put into treatment groups.

There are different types of trials within these two groups.

Pilot studies and feasibility studies

Pilot studies and feasibility studies are small versions of studies which are sometimes done before a large trial takes place.

Feasibility studies are designed to see if it is possible to do the main study. They aim to find out things such as whether patients and doctors are happy to take part, and how long it might take to collect and analyze the information. They don't answer the main research question about how well a treatment works.

Pilot studies are small versions of the main study. Pilot studies help to test that all the main parts of the study work together. They may also help answer the research question. Sometimes the research team include the information collected during the pilot study in the results of the main study.

Prevention trials

Prevention trials look at whether a particular treatment can help prevent cancer. The people taking part don't have cancer.

These trials can be for the general population or for people who have a higher than normal risk of developing a certain cancer. For example, this could include people with a strong family history of cancer.

Screening trials

Screening tests people for the early signs of cancer before they have any symptoms. As with prevention trials, screening trials can be for the general population. Or they can be for a group of people who have a higher than normal risk of developing a certain cancer.

Researchers may plan screening trials to see if new tests are reliable enough to detect particular types of cancer. Or they may try to find out if there is an overall benefit in picking up the cancer early.

Treatment Options

Standard treatment is the treatment most often used for a specific condition, based on medical guidelines and FDA approval. Factors such as your health, disease stage, and family history determine the standard treatment for you.

Clinical trials may offer new or experimental treatments that aim to be more effective or have fewer side effects than the standard treatment. Clinical trials can be for any type of patient, involving different types and stages of diseases.

Types of treatments tested in clinical trials include:

- New medicines or treatments
- New combinations of existing treatments
- New approaches to surgery or therapy

People join clinical trials for different reasons. When thinking about your treatment options, gather as much information and ask as many questions as you need. Use the questions in this booklet as a guide for talking with your doctor.

What is the name of the condition that I have? How severe is my condition?

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What are the common treatment options for my condition?

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What trials on site could I participate?

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How You Are Protected in Clinical Trials

Finding new treatments is a long, careful process. Before a treatment is given to people, doctors know a great deal about it from other testing. For example, researchers may study cells in a lab and then study the treatment in animals. Only treatments that show promise during these first steps are studied in people through clinical trials. All treatments and procedures have some risk of harm. At MVHS, your safety is our top priority. Precautions and careful procedures are in place to make sure your risk is as low as possible. You will be informed of all potential benefits and risks before you agree to be part of a clinical trial

Study Protocols:
MVHS protects patients in clinical trials by following well planned protocols. A protocol is like a recipe for a research study. It lays out every step of the clinical trial process to make sure the research is carried out in a certain way. Trials must follow strict laws, regulations and safety procedures. A protocol explains:

- The goal of the trial
- Who is eligible to take part in the trial
- Details about the tests, procedures and treatment plan
- How long the trial may last
- How many patients may take part in the trial
- How patients are protected against possible risks

A committee called the Institutional Review Board (IRB) must approve clinical trials. You may only join a trial if the IRB has reviewed and approved it.

Institutional Review Board (IRB):

An IRB is a group of people who are responsible for protecting the rights and well-being of all volunteers in clinical trials. IRBs includes doctors, nurses, chaplains, social workers, lawyers, other healthcare professionals and patients.

To protect patients, the IRB at MVHS:

- Reviews a clinical trial's protocol and informed consent form
- Makes sure that the trial follows federal laws
- Makes sure that the risks in the trial, when compared to the possible benefits, are reasonable for patients
- Monitors the trial from start to end
- Provides contact information to patients. If you are in a clinical trial, you may contact the IRB with any questions or concerns. The FDA reviews and audits the IRB's files. FDA officials may visit MVHS at any time and review anything related to clinical trials

Informed Consent:
You join a trial as a volunteer. MVHS protects patients through a careful informed consent process to help you learn all that is involved in a trial before you join it. The research team explains the details of the trial to you, and you will receive an informed consent form that explains the details in writing. You may ask questions at any point in the trial.

Eligibility Criteria

Clinical trials must follow guidelines for who can qualify for the trial. These guidelines are called eligibility criteria. They describe conditions that must be shared by all patients in a trial. The conditions are different for each trial. Eligibility criteria often include age, gender, medical history and current health status.

Placebos and Cancer

A placebo is something that looks like the treatment being studied but has no physical effect. Some patients worry about receiving a placebo if they join a clinical trial. Placebos would never be used in a clinical trial if it would put participants at risk, which is why placebos are rarely used in cancer clinical trials.

Your doctor will always tell you if a clinical trial uses a placebo. In cancer, if a placebo is used, it is given together with the standard treatment. This means that you will still receive treatment for your condition. To test a new combination of treatments, a trial may give some patients standard treatment with a placebo and give other patients standard treatment with the new medicine. All patients receive at least the standard treatment for their cancer.

If there is no effective treatment for a cancer, standard treatment may mean that doctors normally care for the patient by treating symptoms and monitoring the cancer. To find a treatment that works for these cancers, a clinical trial may involve giving a placebo to some patients and a new treatment to others. This is not common in cancer trials.

How might standard treatment affect my outcomes?

How might the clinical trial affect my prognosis

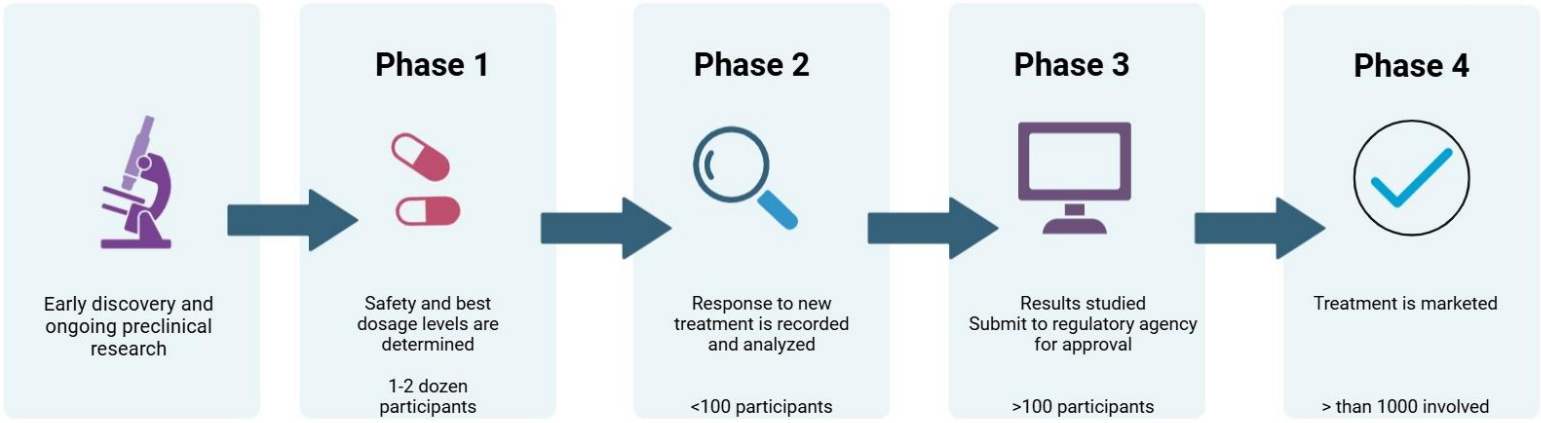
Phases of Clinical Trials

Trials are done in steps, called phases. Each clinical trial phase is designed to learn specific information about the new treatment. Knowing the phase or phases of a clinical trial may help you decide if the trial is right for you.

- The phases of clinical trials are done in order from 1 to 4.
- Successful treatments move through the phases.
- Doctors may stop a trial right away if they have concerns about the safety of the patients in the trial.

Each phase aims to find the answers to certain research questions and builds on knowledge gained in previous phases.

Many clinical trials only involve one phase of the research process. Some trials combine phases. For example, a trial may involve both phases 1 and 2.



What phase is this clinical trial?

What is the purpose of this clinical trial?

Phase 1 Trials

Phase 1 trials are the first step in testing a new treatment or combination of existing treatments in people. These trials often involve the greatest risk for patients. Most Phase 1 trials are small and involve fewer than 30 patients. In Phase 1 clinical trials, doctors:

- Test whether a new treatment is safe and look for the best dose of the treatment to use. (The dose is the amount of a medicine you receive)
- May look for the best way to give the treatment (such as through a pill or an injection)
- Watch for signs that the treatment is working

To test for the best dose of a treatment, patients are divided into small groups called cohorts. Patients in the first cohort get the first dose of the new medicine. If the first cohort does not have any severe side effects, then a new cohort gets a higher dose of the same medicine. The dose increases with each new cohort until doctors find the best dose. With each increasing dose, doctors also test to see if patients respond to the treatment.

If the doctors find that the treatment is safe, it moves to a Phase 2 trial for more testing

Phase 2 Trials

The goal of a Phase 2 clinical trial is to see if the new treatment has an effect on a cancer. Doctors study the treatment in one type of cancer. Most Phase 2 trials involve fewer than 100

patients. Even though the main goal is to see if the treatment works, doctors still closely watch for side effects. If the new treatment works, doctors may go on to study it in a Phase 3 trial.

Phase 3 Trials

Phase 3 trials may include hundreds to thousands of patients around the country or world. In this step of the research, doctors test if a new treatment is better than the standard treatment for a cancer. Safety is also closely monitored as the treatment is studied in more people.

In Phase 3 clinical trials, each patient in the trial will receive the standard treatment or the new treatment. Every patient in the trial has a chance to be put into one of 2 groups:

- The **control group** receives standard treatment.
- The **study group** receives the new treatment being tested

At this step of the research, doctors do not know if the new treatment is better than the standard treatment. They believe the new treatment is as good as, or even better, than the standard treatment.

Doctors do not decide how patients are grouped. Instead, they use a computer to randomly assign the groups. This process is called **randomization**

Randomization:

- Ensures all patients have equal chances of being in either group
- Allows doctors to compare outcomes between the study group and the control group
- Ensures if differences are found they are most likely due to the treatments and not other factors

After the computer assigns you to a group, you will not find out if you are in the study group or the control group. Your doctor may or may not know which group you are in. This depends on the design of the research study.

In single blind studies:

- The doctor knows the group the patient is in.
- The patients do not know which group they are in.

In double blind studies:

- The doctor does not know the group the patient is in.
- The patients do not know which group they are in.

In all studies, doctors can find this information in the case of an emergency.

A successful Phase 3 trial may lead to changes in the standard treatment for a condition. At this stage, the FDA reviews the study results to make sure the treatment is safe and effective. The FDA decides whether to approve the new treatment for patients who have that condition.

Phase 4 Trials

In Phase 4 trials, doctors study treatments that the FDA has already approved. The goal of these studies is to learn more about long-term side effects. Researchers may also look at how the treatment affects patients' quality of life and whether it is cost effective. Phase 4 trials often involve thousands of people.

Why do doctors believe this new treatment being tested might work for me?

Has the new treatment been tested before?

What has been written about this treatment (such as articles in medical journals that you may read)?

Benefits and Risks

Like all treatment options, clinical trials have possible benefits and risks. When thinking about joining a clinical trial, you may consider if the possible benefits are greater than the risks.

Possible benefits:

- The new treatment may work better than the standard treatment.
- The new treatment may only be available through the clinical trial.
- The results of the trial may advance research and help future patients.
- You receive close monitoring from an expert medical team.

Possible Risks:

- The new treatment may not be better than standard treatment.
- The new treatment may not work for you, even if it works for other patients
- There may be known and unknown side effects.

You can read about the possible benefits and risks of a specific clinical trial in the trial's informed consent form. The research team provides you with a copy of this form.

What are the possible short-term and long-term benefits of this clinical trial?

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What are the possible short-term and long-term risks of this clinical trial?

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How do the possible benefits and risks of this clinical trial compare with the standard of care treatment for my cancer?

Joining a Clinical Trial

Not all clinical trials are suitable for every patient. Each clinical trial is designed with strict guidelines about who is able to join. These guidelines are called eligibility criteria. To join a trial, you must meet all the eligibility criteria.

Eligibility criteria may include information about:

- You and your overall health
    - Age
    - Gender
    - Results of medical tests
    - Medicines that you are taking or have taken in the past
    - Any other health conditions you have
- Your disease/condition (for example in cancer);
    - Cancer type
    - Stage
    - Other treatments you may have had
    - How long it has been since you were last treated

If you find a clinical trial you would like to join, contact your doctor. You and your doctor can review the eligibility criteria to see if you qualify for the trial.

Informed Consent Process

Before you join a trial, take time to learn what you may expect during the trial. The research team will help you do this during a process called informed consent.

During informed consent, you will meet with the research team to talk about all that is involved in the trial. You will also receive a form that provides the details in writing. The research team reviews this informed consent form with you and answers any questions you may have.

Review the Details
Look for the following information on the informed consent form.

Treatment

- The reason for the clinical trial (what the doctors hope to learn)
- Who is eligible to take part in the clinical trial
- What is known about the treatment being studied
- Possible benefits and risks
- Other treatment options

Tests

- What tests are involved
- How often the tests are done

Study Visits

- What other visits with the research team are involved?
- How often you meet with the doctor
- How long you will be in the clinical trial

Costs

- Who pays for the clinical trial
- If the clinical trial causes you to need more medical care, who pays for those costs

Other

- Conflicts of interest (any direct financial benefit to MVHS or your doctor from the sponsor of the trial)
- How your privacy and information is protected
- What information about you is collected
- Who you may call if you have questions

The goal of informed consent is to make sure you know the details of a trial before you agree to join the trial. Take all the time you need to review the details and discuss them with your doctor and loved ones.

- Ask as many questions as you need.
- Bring a family member or friend to help you ask questions and write down answers.
- You may take the informed consent form home with you to review before signing it.

Signing the Informed Consent Form

If you choose to join the trial, you and the Principle Investigator (PI) will sign the informed consent form.

- You will receive a copy to keep for your records.
- Even after you sign the consent form, you can decide to stop and leave the clinical trial at any time.
- **You always have the right to leave a clinical trial.** Tell your team if you want to stop, and they will help you do so safely.

The informed consent process does not end once you sign the informed consent form. For example, your doctor must tell you if new risks or side effects of the treatment are found during the trial. You may ask questions at any time during the trial.

To join this trial, will I need to gather any medical or personal records?

Where will I receive treatment?

How often will I have to come to MVHS?

How does this compare to standard treatment?

How often will I have visits for the clinical trial?

How long will each visit last?

What practical details do I need to consider (such as childcare, transportation, travel, time away from work)?

How will this clinical trial affect my daily activities?

Can I talk with other people who are in this clinical trial?

Your Care Team

If you join a clinical trial your primary care team will still care for you.
You will also have a research care team. The people on your research care team include:

- **Principal investigator (PI):** The PI is usually a doctor. The PI runs the clinical trial and makes sure the research plan is followed. You can find the PI's phone number in the informed consent form. Your doctor and your PI will communicate together about your care.

- **Research nurse:** A research nurse works closely with the PI to monitor your treatment and will help teach you about each step of the clinical trial. Your research nurse is a good person to contact if you have questions.

- **Study coordinator:** Study coordinators help arrange your care and guide you through the clinical trial process.

After a trial, you may continue to see your research team for treatment and follow-up care along with your primary care team.

Paying for Clinical Trials

The services you receive in a clinical trial are either routine costs or research costs.

- **You and your insurance provider are billed for routine costs.** You are responsible for out-of-pocket costs such as co-pays, deductibles and co-insurance.
- **You do not pay for research costs.**

Routine Costs

A clinical trial may include services or procedures that are standard care to manage your cancer. You would receive these routine services even if you were not in the trial.

Research Costs

Unlike routine costs, research costs are for services and procedures provided only for the purpose of the clinical trial. Medicare If you have traditional Medicare, your Medicare insurance covers routine costs for clinical trials. If you have a Medicare Advantage plan, traditional Medicare also covers your routine costs. You may be responsible for out-of-pocket costs such as co-pays, deductibles and co-insurance. The routine and research costs of every trial are different.

Making the decision to join a clinical trial involves careful consideration. Reflect on what matters most to you and gather information to make an informed choice.

Does my insurance company provide coverage to participate in a clinical trial?

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What costs am I responsible for?

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Available Support

Clinical trials may involve more medical visits than standard treatment. These extra visits may mean you need to plan for more time, travel or other expenses such as childcare. Support may be available to help you with out-of-pocket costs related to clinical trial participation. Talk with the research team or ask your social work counselor about resources that may be available to you.

Are resources available to help me with trial expenses?

Leaving a Trial

All patients in clinical trials are volunteers. You can choose to leave a clinical trial at any time, but talk with your doctor first. Your doctor can tell you how leaving the trial might affect your health and if there are other treatment options. Your doctor can also tell you the safest way to stop taking any clinical trial medicines and collect any remaining research study medicine or empty bottles that you may have. Your relationship with your care team is not changed by your decision.

What happens if I decide to leave the trial?

Next Steps

If you are interested in joining a clinical trial, your next step is to discuss it with your doctor. Your doctor can help you find a trial and determine if you meet the eligibility criteria.

For more information, you can also:

- Visit our website at www.mvhealthsystem.org/research
- Call us at 315-624-4842
- Email research@mvhealthsystem.org

We are here to support you every step of the way. Thank you for considering a clinical trial at MVHS. Your participation can make a difference in breakthrough discoveries, the development of new medicines, treatments and diagnostics the improvement in life expectancy of and the fight against cancer and leading causes of death in Mohawk Valley.

https://www.cancerresearchuk.org/

https://www.nature.com/articles/s43856-022-00156-x

https://clinicaltrials.gov/

https://www.webmd.com/a-to-z-guides/clincial-trial-guide-patients

https://www.youtube.com/playlist?list=PLYKy4VbxNln61yshxvvGMNUXLTnDQ1VYG