

Your Cancer Journey *at* Mary Crowley Cancer Research

Where Compassion Meets Science

Our mission is to expand treatment options for all cancer patients through investigational vaccine, gene and cellular therapies.

www.marycrowley.org

Welcome to Mary Crowley

Welcome to Mary Crowley. You have most likely started your cancer journey before coming or being referred to Mary Crowley Cancer Research. We are privileged to be able to join you as you continue your journey.

Mary Crowley is committed to changing the way cancer patients are treated. We understand that no two people are the same, and cancer does not react the same way in different people.

We are all individuals, therefore Mary Crowley seeks individual solutions. We are inspired by our patients, driven by science and focused on our mission.

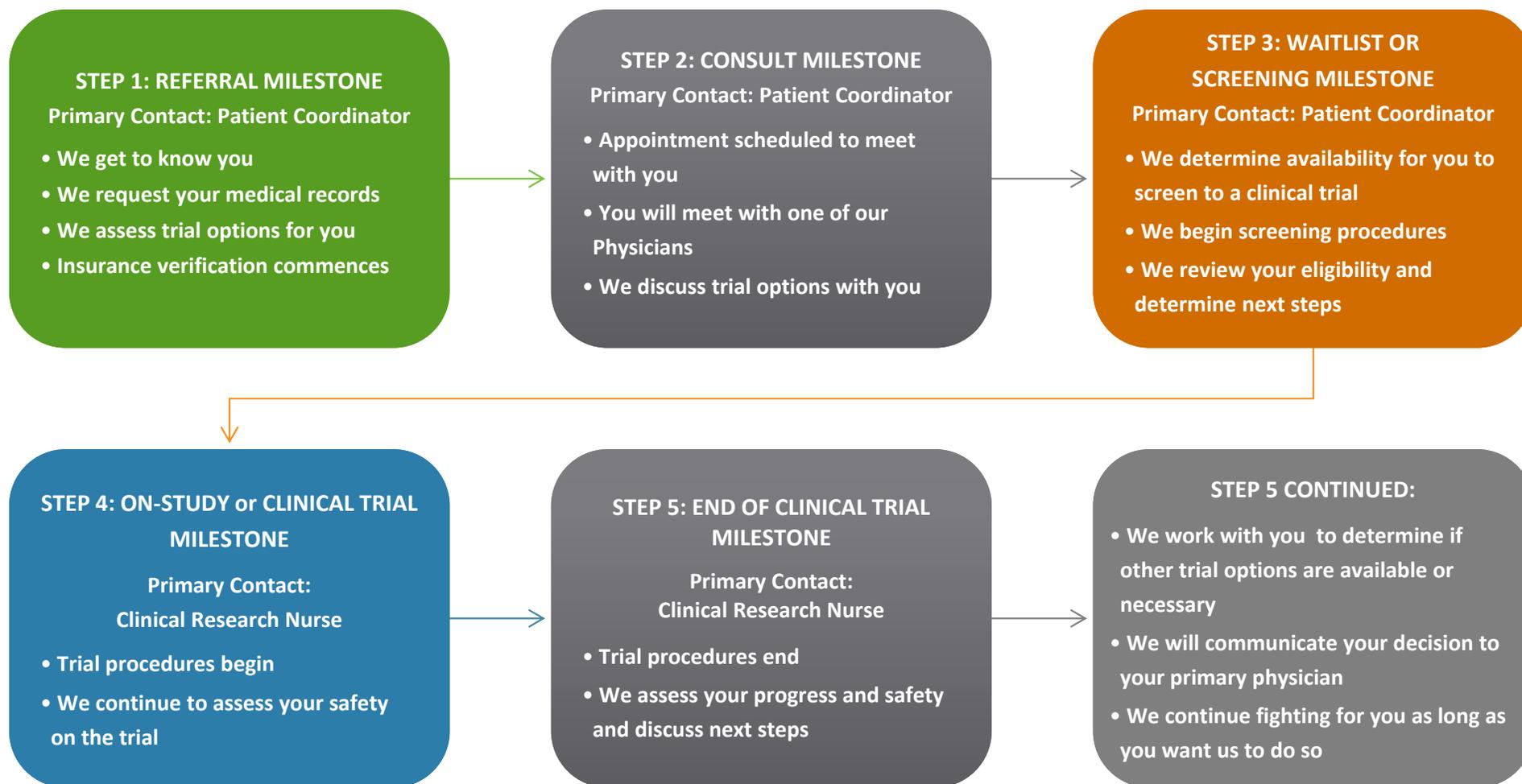
The best way to learn more about Mary Crowley is to contact us so we can discuss options for your cancer. You can also learn more about us, our physicians, research, clinical trials and other information by visiting our website at www.marycrowley.org.

During each step of your journey we will partner you with a primary contact at Mary Crowley. The goal is to ensure you are supported, informed and comfortable.



Your Cancer Journey: What Can You Expect?

We have identified five key milestones which will guide you through your cancer journey at Mary Crowley. This brief document explains what to expect during each milestone and who will be your Primary Contact. We are with you every step of the way.



STEP 1: REFERRAL MILESTONE

WELCOME TO THE REFERRAL MILESTONE

Primary Guide: Patient Coordinator

You have most likely started your cancer journey before coming or being referred to Mary Crowley Cancer Research. We are privileged to be able to join you as you continue your journey. Because we are informal, we call ourselves Mary Crowley, and we invite you to do the same.

I was referred to Mary Crowley, what does that mean?

A referral usually means that one of your physicians contacted us because they believe that Mary Crowley may offer new options for your cancer. Sometimes, a friend or a Mary Crowley patient may also suggest that you explore options at our center. This recommendation or referral is your first step towards participating in a clinical trial at Mary Crowley.

What happens during the referral process?

A member of the **Patient Coordination Team** will reach out to you. They will provide you with their name and phone number so you may contact them with questions about Mary Crowley, or obtain updates on the status of your referral.

Your **Patient Coordinator** will work with you to obtain some basic information:

- Demographic details about you: name, address, contact information and date of birth
- Information about your physicians
- A brief cancer history
- Your insurance details



STEP 1: REFERRAL MILESTONE

If the Mary Crowley **Physician** determines a potential clinical trial may be available for you, they will request additional medical information from you or your referring physician which may include records related to any or all of the following:

- Pathology Report
- Comprehensive and recent physician notes
- Medication lists
- Recent lab tests
- CT scans and results
- Treatment records (for radiation, chemotherapy, surgery)

Once all the records are received, the medical team will review them to determine whether you may qualify for any clinical trials. It is possible that you may have a medical issue that needs to be resolved before we can qualify you for a trial. If so, this information will be communicated to you and your Primary Physician or Oncologist so they may assist in resolving the issue. For example, they may have to treat you for a bladder infection or require you to have a blood transfusion for a low blood count or anemia.

If you have no underlying medical issues that need to be resolved, the **Patient Coordinator** will call you to discuss next steps. It may take up to 14 days from the time you contacted us to determine whether you may qualify for a clinical trial.

At the same time, our **Financial Counselor** will verify your insurance information. Should you have any issues with insurance, the **Patient Coordinator** will work closely with you and your insurance provider in an attempt to clarify your medical needs. This process could delay the timing of your first visit to Mary Crowley. Each insurance company has different requirements.

If you are potentially eligible for a clinical trial, you will be scheduled for an initial consultation visit, the Consult Milestone of your journey. If there are no clinical trials currently available for you, you will be informed and will be asked if you would like us to contact you from time to time for medical updates and to discuss new options that may become available.



STEP 1: REFERRAL MILESTONE

Remember! Please continue to see your regular physicians.

Please maintain your relationship with all of your Primary Physicians or Oncologists while you are considering participation on a clinical trial and even after you are enrolled on a clinical trial. This will ensure that your physicians are available to provide you any necessary medical care *during* or *after* participation on a Mary Crowley clinical trial. We require this for your own safety and to ensure that you receive the best overall care possible.

If you are seeing any other physician to manage non-cancer related health problems, you should continue regular visits, just as you did before you began considering clinical trials. Always tell your physicians that you are considering or participating in a clinical trial.

How does Mary Crowley work with your Primary Oncologist?

Mary Crowley values the relationship you have with your Primary Oncologist. With your permission, we will notify your Primary Oncologist (and anyone else you indicate) of updates to your referral status.

Mary Crowley will oversee the portion of your care that relates to the clinical trial and its related questions or side effects. If it becomes necessary for you to be admitted to the hospital for any reason, we may ask that your Primary Oncologist be available to admit you.

If these roles need clarification, our **Patient Coordinator** will provide examples of how we work closely with your Primary Oncologist to ensure you receive the care that you need and deserve.

Wherever your journey takes you, we will provide information during each step of the way and will be available to answer your questions.

Welcome to Mary Crowley.



STEP 2: CONSULT MILESTONE

WELCOME TO THE CONSULT MILESTONE

Primary Guide: Patient Coordinator

*The Consult Milestone is achieved when you are first scheduled to consult with one of our physicians. Our physicians are often referred to as **Investigators**. They are all oncologists, but we call them **Investigators** because part of their role, along with protecting your rights, safety, and welfare, is to uncover facts or information about experimental therapies. Additionally, you will meet several other staff members who will serve you during your journey at Mary Crowley, such as Physician Assistants.*

What to expect at your consultation visit?

When you first walk in to Mary Crowley, you will be greeted by our **Front Desk** team member(s) who will collect some of your personal information and any required insurance co-pay that may be due. A **Financial Counselor** will also be available to answer questions or concerns about which costs are covered in your insurance plan.

Secondly, one of our **Nurses or Medical Assistants** will check your height, weight, and vital signs (temperature, how fast you breathe and your heart rate) before introducing you to one of our **Physician Investigators**. Your physical condition will be further assessed during a complete examination by the **Physician Investigator**. After the exam and review of your medical and cancer history, they will explain which clinical trials are best suited for you and answer any of your questions.



STEP 2: CONSULT MILESTONE

During the Consult Milestone, you will also meet one of our **Patient Coordinators** who will provide you with printed information about any discussed clinical trials, review logistics and time commitment of participating in a clinical trial, provide a timeline of when you may be able to start the trial, and possibly schedule your next visit to Mary Crowley. The **Patient Coordinator** will be your primary point of contact during this milestone. They will provide you their contact information so you may reach them for any continuing questions.

Remember! Please continue to see your regular physicians.

Please maintain your relationship with all of your Primary Physicians or Oncologists while you are considering participation on a clinical trial and even after you are enrolled. This will ensure that your physicians are available to provide you any necessary medical care *during* or *after* participation on a Mary Crowley clinical trial. We require this for your own safety and to ensure that you receive the best overall care possible.

If you are seeing any other physician to manage non-cancer related health problems, you should continue regular visits. Always tell your physicians that you are considering or participating in a clinical trial.

How does Mary Crowley work with your Primary Oncologist?

Mary Crowley values the relationship you have with your Primary Oncologist. With your permission, we will notify your Primary Oncologist (and anyone else you indicate) of your progress while on a clinical trial.

Mary Crowley will oversee the portion of your care that relates to the clinical trial and its related questions or side effects. If it becomes necessary for you to be admitted to the hospital for any reason, we may ask that your Primary Oncologist be available to admit you.



STEP 2: CONSULT MILESTONE

If these roles need clarification, our **Patient Coordinator** will provide examples of how we work closely with your Primary Oncologist to ensure you receive the care that you need and deserve.

What to expect after your consultation visit?

At the end of the consultation visit, you will know which clinical trial option(s) are best suited for you. You will be provided with copies of the Informed Consent Forms that you can take home to review and discuss with your physicians, family and/or friends.

If you decide to participate in the clinical trial and the clinical trial is still enrolling patients, you will be scheduled for a **Screening** appointment; this is where the **Screening Milestone** of your journey begins.

Screening is what helps the **Physician Investigators** determine whether you are eligible to participate in a specific clinical trial. There may be instances where you may not be able to immediately screen onto the clinical trial. In these cases, if you would like to continue to have Mary Crowley involved in your journey, you will be placed on our waitlist and notified when you can be rescheduled for screening.

Wherever your journey takes you, we will provide information during each step of the way and will be available to answer your questions.

Welcome to Mary Crowley.



STEP 3a: WAITLIST MILESTONE

THE WAITLIST MILESTONE

Primary Guide: Patient Coordinator and Social Worker

Sometimes, you may encounter a delay in your journey and go on a waitlist before you can be screened to a clinical trial. This happens because many of the clinical trials conducted at Mary Crowley are designed to have a limited number of enrollees. This is to ensure patient safety, as the potential side effects are unknown in early phase clinical trials. It is safer to enroll a few patients at a time so that any problems can be detected early in a smaller group of patients and reported to the Food and Drug Administration (FDA).

Every effort is made by Mary Crowley staff members to reduce your time on the waitlist. Even so, you may still have to wait from several weeks to several months. In cases such as these, we work with your Primary Oncologist to find other options for you during this time.

What to expect when you are placed on the waitlist?

The **Patient Coordinator** will inform you if you have been added to a waitlist. This will occur within a week of your consultation visit. You will be provided with the **Patient Coordinator's** and **Social Worker's** contact information. These two individuals will be your primary point of contact while you are on the waitlist and remain available to answer your questions.

You will be contacted approximately every three to four weeks with an update on the status of the clinical trial. When space becomes available, you will be contacted to come to the Mary Crowley for a screening appointment.

If, at any time, you no longer wish to be on the waitlist, you may notify us.



STEP 3a: WAITLIST MILESTONE

Remember! Please continue to see your regular physicians.

Please maintain your relationship with all of your Primary Physicians or Oncologists while you are on the waitlist for a clinical trial and even after you are enrolled. This will ensure that your physicians are available to provide you any necessary medical care *during* or *after* participation on a clinical trial. We require this for your own safety and to ensure that you receive the best overall care possible.

If you are seeing any other physician to manage non-cancer related health problems, you should continue regular visits just as you did before you began considering clinical trials. Always tell your physicians that you are considering or participating in clinical trials.

How does Mary Crowley work with your Primary Oncologist?

Mary Crowley values the relationship you have with your Primary Oncologist. With your permission, we will notify your Primary Oncologist (and anyone else you indicate) of any updates while you are on the waitlist.

If it becomes necessary for you to be admitted to the hospital for any reason, we may ask that your Primary Oncologist be available to admit you.

If these roles need clarification, our **Patient Coordinator** will provide you more examples of how we work closely with your Primary Oncologist to ensure you receive the care that you need and deserve.



STEP 3a: WAITLIST MILESTONE

What to expect after your time on the waitlist ends?

You will remain on the waitlist until the **Patient Coordinator** is able to secure a spot for you on the clinical trial, until a better option becomes available or until you determine you no longer want to be on the waitlist.

If a spot is secured or another clinical trial becomes available, and you agree to participate, we will schedule you to come in for a screening visit.

If you no longer want to be on the waitlist, you may call us at any time and we will stop contacting you.

Wherever your journey takes you, we will provide information during each step of the way and will be available to answer your questions.

Welcome to Mary Crowley.



STEP 3b: SCREENING MILESTONE

THE SCREENING MILESTONE

Primary Guide: Patient Coordinator

*The Screening Milestone is achieved when you are scheduled to meet or screen with one of our **Physician Investigators**. Once it is determined that you are a candidate to screen for a clinical trial and a space is available, we will contact you to schedule a screening appointment. A screening appointment is an educational meeting when you learn about every detail of the clinical trial and when certain procedures are initiated to determine your eligibility to participate in the clinical trial.*

What to expect at your screening appointment?

First, you will be asked to sign in at the front desk. Second, one of our **Nurses** or **Medical Assistants** will check your height, weight and vital signs (temperature, blood pressure, how fast you breathe and your heart rate). Next, you will be escorted to one of our private exam rooms where you will meet with one of our **Physician Investigators** or your **Patient Coordinator**.

This person will discuss all the clinical trial details with you as part of the Informed Consent process. They will review each page of the consent document. It is very important that you understand and are informed of every aspect of the clinical trial. This process may take some time. You will be given ample time to ask questions. Once you are comfortable with proceeding, we will ask you to sign the Informed Consent Form, and you will be provided with a copy. Next, the **Physician Investigator** will:

- Perform a detailed review of your medical history
- Complete a physical exam
- Review your current medications
- Review any current problems you are experiencing
- Review the science behind the research drug and answer any additional questions



STEP 3b: SCREENING MILESTONE

During the Screening visit, a **Financial Counselor** will review your insurance coverage as it applies to the screening of your specific clinical trial. You will be provided with an estimate of any out-of-pocket expenses.

You may be asked to have lab work, EKG, scans, breathing tests, eye exams, tumor biopsies or cardiology evaluations; all of these tests will be dependent on your health and the screening requirements of your specific clinic trial. Some of these procedures may be performed in our center, and others may be scheduled at other facilities, either on the same day as your appointment, or on a different day.

You will meet your assigned **Clinical Research Nurse**, who will provide you with their contact information and be available to answer scheduling questions and address any other issues, including any potential side effects that may occur during your clinical trial.

Lastly, you will re-visit the **Patient Coordinator** so that they can review any remaining screening tests or procedures that require scheduling and answer any remaining questions.

Remember! Please continue to see your regular physicians.

Please maintain your relationship with all of your Primary Physicians or Oncologists while you are considering participation on a clinical trial and even after you are enrolled. This will ensure that your physicians are available to provide you any necessary medical care *during or after* participation on a Mary Crowley clinical trial. We require this for your own safety and to ensure that you receive the best overall care possible.

If you are seeing any other physician to manage non-cancer related health problems, you should continue regular visits just as you did before you began considering clinical trial. Always tell your physicians that you are considering or participating in clinical trials.



STEP 3b: SCREENING MILESTONE

How does Mary Crowley work with your Primary Oncologist?

Mary Crowley values the relationship you have with your Primary Oncologist. With your permission, we will notify your Primary Oncologist (and anyone else you indicate) of your progress while you are on a clinical trial.

Mary Crowley will oversee the portion of your care that relates to the clinical trial and its related questions or side effects. If it becomes necessary for you to be admitted to the hospital for any reason, we may ask that your Primary Oncologist be available to admit you.

If these roles need clarification, our **Patient Coordinator** will provide examples of how we work closely with your Primary Oncologist to ensure you receive the care that you need and deserve.

What to expect after your screening visit?

It usually takes between one and four weeks to complete all of the screening examinations and for our staff to collect all of the results. During this time period, the **Patient Coordinator** will be in contact with you as they are your main point of contact during the screening phase. Once you have completed the screening requirements and it is determined that you are eligible, you will be enrolled onto the clinical trial and can expect to start receiving your investigational therapy within one to three days.

If your eligibility or screening requirements cannot be met on this or other trials, our staff will work diligently with your Primary Oncologist to find other options for your cancer.

Wherever your journey takes you, we will provide information during each step of the way and will be available to answer your questions.

Welcome to Mary Crowley.



STEP 4: ON-STUDY or CLINICAL TRIAL MILESTONE

WELCOME TO THE ON-STUDY or CLINICAL TRIAL MILESTONE

Primary Guide: Clinical Research Nurse

The On-Study or Clinical Trial Milestone is achieved when the screening procedures are completed and indicate that you are eligible to participate in a clinical trial. Once it is determined that you will be enrolled on a clinical trial, you will receive a calendar that details all of the clinical trial related tests or procedures necessary during a given month. Each clinical trial may have different requirements for each visit. Participating in a clinical trial will require that you receive the clinical trial therapy, labs, scans and other procedures at very specific time points.

*You will meet with your specific **Clinical Research Nurse** who you will see at each visit. They will answer your questions about schedules and address any other issues, including any side effects you may be experiencing. This nurse will be the link between you and the pharmaceutical company that is sponsoring the clinical trial.*

*They will keep the **Physician Investigator** and the pharmaceutical company informed of your progress, and likewise inform you of any changes the company may make to the clinical trial.*

What to expect at On-Study/Clinical Trial appointments?

Initially, you will be asked to sign in at the front desk. The **Front Desk** team member may ask you to provide your insurance card. A co-pay may be collected at some visits based on your specific insurance coverage.

To help prepare you for any future payments, your **Clinical Research Nurse** will review your calendar and procedures. Additionally, the **Financial Counselor** is available to meet with you at any time to help explain your insurance coverage and any out-of-pocket expenses.



STEP 4: ON-STUDY or CLINICAL TRIAL MILESTONE

One of our **Nurses** or **Medical Assistants** will greet you and escort you to the examination area where we will obtain your weight and vital signs (temperature, blood pressure, how fast you breathe and your heart rate). Some visits require an evaluation of your lab work prior to you receiving the study drug or agent. We may perform these lab tests at Mary Crowley, or if it is more convenient for you, some trials allow these lab tests to be obtained at outside laboratories prior to your visit. Your **Clinical Research Nurse** can tell you if this is an option for you.

To monitor your progress on the clinical trial and for your safety, you will meet with one of our **Physician Investigators** during many of your visits.

- Some visits require a physical examination which will be performed by a **Physician Investigator**
- At some of your visits, you will be seen by a **Physician Assistant**
- The **Physician Investigator** will see you at all major decision points, such as when your scans are reviewed and a decision must be made concerning continued participation on the clinical trial

You are your best advocate, so it is very important that you discuss questions, problems or concerns with any of our **Physician Investigators** or your **Clinical Research Nurse**. Keep them informed of any new medications you begin taking. Your calendar will include information for your key contacts while you are participating in the clinical trial.

After meeting with the **Physician Investigator**, you will be escorted to our open infusion area to receive your study or clinical trial agent. In this area, you will be able to meet other patients and our team of **Nurses** and **Medical Assistants**.

The **Pharmacy Team Member(s)** will prepare your study agent and any other medications you may need to receive and are available to answer medication-specific questions. One of our **Infusion Nurses** will administer the study or clinical trial agent. They may also provide additional educational material related to your care.

Your **Clinical Research Nurse** will review your future appointments, evaluate any side effects you may be experiencing and review your current medication list.



STEP 4: ON CLINICAL TRIAL MILESTONE

At any time, you may request to meet with our **Social Worker** who will assist with travel, lodging, financial assistance or social support.

Please check out at the **Front Desk** when your appointment is completed to confirm your next visit. It is important to keep your contact information current so that reminder calls and general updates may be communicated as needed.

Remember! Please continue to see your regular physicians.

Please maintain your relationship with all of your Primary Physicians or Oncologists while you are participating in the clinical trial. This will ensure that your physicians are available to provide you any necessary medical care *during or after* participation in a Mary Crowley clinical trial. We require this for your own safety and to ensure that you receive the best overall care possible.

How does Mary Crowley work with your Primary Oncologist?

Mary Crowley values the relationship you have with your Primary Oncologist. With your permission, we will notify your Primary Oncologist (and anyone else you indicate) of your clinical progress. Mary Crowley will oversee the portion of your care that relates to the clinical trial and its related questions or side effects. If it becomes necessary for you to be admitted to the hospital for any reason, we may ask that your Primary Oncologist be available to admit you.

If these roles need clarification, our **Clinical Research Nurse** will provide examples of how we work closely with your Primary Oncologist to ensure you receive the care that you need and deserve.

Wherever your journey takes you, we will provide information during each step of the way and will be available to answer your questions.

Thank you for choosing Mary Crowley.



STEP 5: END OF CLINICAL TRIAL MILESTONE

Once you have completed your clinical trial with the investigational therapy, your clinical trial has come to an end. Generally, unless the pharmaceutical company has determined to discontinue the clinical trial, the reason your participation ends is unique to your situation. Based on the discussion with the **Physician Investigator** today, you are ending your clinical trial because:

You have several options available to you. The **Physician Investigator** recommends the following:

We encourage you to discuss these options with your Primary Oncologist prior to making your final decision.

Additional follow up may still be required even after you no longer receive the investigational therapy. The follow up visits and procedures are discussed in the Informed Consent Form.

These visit(s) are intended to ensure your safety and are very important to complete.

We understand you may have questions, therefore your contact moving forward is:

Remember! Please continue to see your regular physicians.

Please maintain your relationship with your Primary Physicians or Oncologists after you come off-study. This will ensure that they will be available to provide you any necessary medical care after your Mary Crowley clinical trial. We ask this for your own safety and to ensure that you receive the best overall care possible.

How does Mary Crowley work with your Primary Oncologist?

Mary Crowley values the relationship you have with your Primary Oncologist. We will notify them when you are no longer on a clinical trial so that they may assist you in the evaluation of other options.



STEP 5: END OF CLINICAL TRIAL MILESTONE

In Summary:

- We work with you to determine whether you would like to evaluate other clinical trial options.
- We will communicate your decision to your primary physician or oncologist.
- We will continue fighting your cancer as long as you want us to do so.

