

Early Phase Clinical Trials (EPCT)

Clinical Research Program



**PATIENT
EDUCATION**

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Early Phase Clinical Trial (EPCT) Research Program

Introduction

The Early Phase Clinical Trial (EPCT) Research Program at Roswell Park Comprehensive Cancer Center (RPCCC) offers patients an opportunity to participate in Early Phase clinical research studies.

The RPCCC team of health professionals who will be caring for you in this Program have created this guide to help answer your questions and prepare you for your visits. Knowing what to expect can help you feel more comfortable and less stressed.

Please ask questions and talk to the members of your RPCCC team about your treatment. We are here to help with any needs or concerns.

What is Clinical Research?

Clinical Research is full of words and processes that are new to many patients. Here are a few basics to help guide you. Remember, the RPCCC team will help answer any questions you may have.

- Clinical trial, clinical study, research study, clinical research study, and interventional study are all different names for the same thing. In this brochure, we will call it a clinical research study.
- The purpose of a clinical research study is to test how well new medical approaches work in people and help determine if it's safe.
- Each clinical research study answers specific scientific questions. At RPCCC, clinical research studies focus on preventing, treating, and curing cancer; reducing side effects and risks; and improving quality of life.
- Each clinical research study has a specific plan, called a study protocol, which outlines who is eligible to participate, how the interventions are used, the length of the study, and the safety measures taken to protect the patients participating in the study.
- All research studies in the U.S. are approved and monitored by an IRB (Institutional Review Board) to ensure that the benefits outweigh any potential risks.
- The interventions used in a research study may be medical products (drugs or devices), procedures, or behavior changes.
- Studies take place in phases - Phase I, II, III, or IV. Each phase tests a different aspect of the new intervention, such as safety, dose, and side effects. The Food and Drug Administration (FDA), usually considers granting approval after Phase III studies are completed.

What are the steps/phases for a clinical research study?

Most clinical research involves the testing of a new drug. The study progresses in an orderly series of steps, called phases. This allows researchers to ask and answer questions in a way that gives reliable results about the drug and protects the patients. Clinical trials are usually classified in three phases:

Phase I

Phase I trials are considered Early Phase trials and are the first step in testing a new approach in humans. In these studies, researchers evaluate what dose is safe, how a new agent should be given (by mouth, injected into a vein, or injected into the muscle), and how often. Researchers watch closely for any harmful side effects as the side effects may not be clearly understood. Phase I trials usually enroll a small number of patients and take place at only a few locations. The patients are divided into small groups, called cohorts. Each cohort is treated with an increased dose of the new treatment or technique. The highest dose with an acceptable level of side effects is determined to be appropriate for further testing.

Phase II

Phase II trials study the safety and effectiveness of an agent or intervention and evaluate how it affects the human body. Some phase II trials may also be considered early phase clinical trials as they continue to study drug safety. Phase II studies usually focus on a particular type of cancer, and include fewer than 100 patients.

Phase III

Phase III trials compare a new agent or intervention (or new use of a standard one) with the current standard therapy (a currently accepted and widely used treatment for a certain type of cancer, based on the results of past research). Participants are randomly assigned to the standard group or the new group, usually by a computer. This method, called randomization, helps to avoid bias and ensures that human choices or other factors do not affect the study's results. In most cases, studies move into phase III testing only after they have shown promise in phases I and II. Phase III trials may include hundreds of people across the country.

How do I enroll on an EPCT Clinical Research Study?

Patients come to the EPCT Program by referral from either their RPCCC oncologist or from their local oncologist. If you have questions about available clinical research studies, you can call 1-800-ROSWELL for more information.

Location

The EPCT Program clinic and treatment center operates out of the Clinical Research Center. The Clinical Research Center is located on the 5th floor of the RPCCC Scott Bieler Clinical Sciences Center (CSC) Building, Buffalo. The telephone number is **716-845-4720**.

Participating in a Clinical Research Study

Considering Participation

Talk to your physician about whether an Early Phase study would be an appropriate option for you. If so, he or she will refer you to the **Early Phase Clinical Trial (EPCT) Program**. All new patients entering the program will have an initial consultation with our EPCT Program Team.

The Initial Consultation Visit

The EPCT Program physician, Advanced Practice Provider (APP), and/or Clinical Research Coordinator (CRC) will:

- Talk with you and gather information.
- Review your medical history, including any treatments you may have had in the past.
- Compare the information collected with the study protocol for each study.
- Use this comparison to identify whether you may be eligible for any of the current studies, and if so, which one will be best for you.
- Explain what Phase I clinical research is and the process of participating in a study.
- Possibly give you study consent documents to take home and review. Please take them home and read them carefully.

We suggest you have a friend or family member with you, or that you take notes during your discussion with the EPCT Program Team. If you think of any questions after you get home, bring them with you to the next visit.

Please note: If you have been waiting for the CRC to contact you and are wondering how the process is moving along, please do not hesitate to contact the EPCT Program Clinical Research Administrator at **716-845-3165**.

Treatment Plan

Next, we will be contacting your insurance company to get verification and we will make sure we tell you the financial cost before you sign the consent document to participate in the clinical research study.

Continued on next page

Within Two Weeks

The CRC assigned to the recommended study or studies will contact you.

The CRC will:

- Answer any questions you may have about your treatment options.
- Answer any questions you may have about signing the consent document.
- Schedule another appointment with EPCT Program physician and/or APP.

Consent and Screen Visit

If you have decided to participate in a clinical research study an appointment will be arranged to review and sign the consent document. Once consent is signed tests will be scheduled to determine if you are eligible to participate in the study. This process is called “screening”. You must sign the informed consent document before we can begin the screening tests. The screening tests are defined in the consent and may include bloodwork, electrocardiogram (ECG), CT scan, echocardiogram (ECHO), biopsy, etc.

Determining Eligibility

After you have completed all of the screening tests, the EPCT Program Team will review the results and determine if you are eligible to participate in the clinical research study.

- If you are eligible, the CRC will set up future appointments to begin treatment.
- If you are not eligible for the identified study, you may get a call from the EPCT APP or physician to discuss another treatment option. He or she may schedule a follow up appointment so you can discuss other studies or standard treatments.

Starting Treatment

Initiating Treatment

Once you have enrolled in an EPCT clinical research study, all of your appointments will take place Monday - Friday in the Clinical Research Center on the 5th floor of the Scott Bieler Clinical Sciences Center (CSC) Building. The Center has three parts:

- **EPCT Clinic:** There are exam rooms where the physician or APP may examine you prior to your treatment.
- **Treatment Center:** These rooms are for patients receiving study treatment.
- **Investigational Drug Service Pharmacy (IDS):** IDS dispenses your study medications for administration by the clinical research nurse. In addition, IDS pharmacists are available for patient consultations or questions.

Day of Your Treatment

Blood tests: If you are scheduled for blood tests on the day of your visit, stop in phlebotomy, on the ground floor of the hospital, and get your blood drawn before you come up to the 5th floor CSC. Not every patient needs a blood test, so if a phlebotomy appointment is missing from your patient itinerary, ask your CRC what you need to do.

Ordering treatment medications after lab tests: Your EPCT program team will need the blood test results before they can decide about the medication(s) or dose you will receive. If you need blood tests, please note that it will take approximately 60 minutes (1 hour) for the results to be available for review, depending on the type of lab tests ordered. **Your physician must have the lab results before he or she can write the orders for your treatment medications.**

Preparing your medication(s): Your physician will send the orders for your medications to the IDS pharmacy, and a pharmacist will prepare all of your medications. For your safety, all medications and dosages are double-checked. **The pharmacists cannot prepare your medications until they receive the physician's orders AND you have checked into the Clinical Research Center.**

Wait Time

It is expected that you arrive at the Clinical Research Center at your scheduled appointment time. We schedule patients according to the amount of time the staff anticipates each patient will need.

- If you are too early, you may experience a longer wait time.
- If you arrive late, you may experience an extremely long wait time because other patients will be seen at their scheduled time.

Sometimes, it may seem that people who arrived after you are seen before you. Here are some reasons why this may occur:

- An unexpected medical emergency has occurred that requires the staff's immediate attention.
- A patient may have a timed blood draw. (The research study they are involved in requires that blood be drawn at very specific times during their treatment.)
- The exam rooms where physicians and nurse practitioners see patients are occupied, but treatment rooms are available.

We make every effort to keep your wait time short and apologize if you have a delay. We are always working on ways to improve your experience in the Clinical Research Center. If you have any questions or concerns, please ask your nurse or the nurse manager.

Your Appointment

The length of your appointment in the Clinical Research Center will include the blood tests and other processes we have described. The time it takes to get blood test results and for the IDS pharmacy to prepare your medication(s) needs to be taken into consideration for visit length. For example, if you have a 7 a.m. appointment, your treatment may not actually begin until about 9 a.m.

It is important that you are aware of this if you have to arrange for transportation or any other personal matter.

We want your appointment to go as safely and smoothly as possible and we want you to know what to expect, so you can plan accordingly.

As we strive to provide the best cancer treatments, nothing is more important to us than your safety and your comfort. We welcome your suggestions as to how we may make this experience better for you.

Treatment Plan

What is Investigational Therapy?

Investigational therapy is an agent/medication that is still being tested in research studies. The U.S. Food and Drug Administration (FDA) must approve it before doctors prescribe it to the public.

There are many types of anti-cancer investigational therapies including chemotherapy, biotherapy, and targeted agents.

- Chemotherapy, also called chemo, is the general term for any medication or combination of medication that kills, prevents growth of, or damages cancer cells.
- Biotherapy is a treatment that modifies your immune system to help fight the cancer cells. Cancer vaccines are one example of biotherapy.
- Targeted therapy is a treatment that may be so specific as to target a single receptor on the surface of tumor cells

How Will I Receive My Treatment?

Depending on the clinical research study, your medication may be a pill/oral liquid, injection, infusion, or topical (applied like a cream or lotion).

If you are receiving an injection, the name of the injection tells you where the medication/agent will be placed.

- intramuscular: into a muscle
- subcutaneous: just under the skin
- intraperitoneal (IP): into the abdominal cavity
- intravesical: into the bladder
- intratumoral: into the tumor

An infusion is usually done intravenously (IV), delivering medication directly into a vein on your hand or lower arm.

Let your nurse know if you should not have an IV inserted in a certain location. For example, if a physician you saw in the past said you should not have an IV in your left arm because of lymphedema.

Let the nurse know if you have any burning, redness, or swelling at the IV site during your treatment.

Central Lines, Catheters, and Pumps

Depending on the type of cancer you have, the medications you are receiving, and the length of your treatments, you may receive your treatment using one of these methods.

Central Lines: A central line is a soft, thin flexible tube (catheter) with one end of the catheter placed in one of the large veins near the heart. The central line remains in place between treatments and acts to avoid the need for repeated needle sticks into your veins. Central lines can be used to give fluids and medications and to draw blood for testing.

There are different types of central lines:

- **Chestports** (aka mediports) have two parts – the catheter that stays in the vein and a small, round disc that is stored in a pocket made under the skin (port reservoir). Once the area heals, it is very comfortable – though you will be able to see and feel a small bump underneath your skin. A special needle goes through the skin over the chestport, and into the port’s rubber membrane to administer medications or take blood. The rubber membrane seals itself after each stick. When you no longer need your chestport, usually when treatments have ended, it will be removed. This is the most common alternate used for IV administration.
- **Central venous catheters (CVC):** This catheter is inserted through the chest wall. A CVC may have multiple “ports” on the end that is outside of the body.
- **Peripherally inserted central catheter (PICC):** These catheters are longer because they are inserted through a vein in your arm and then guided into a large vein near the heart.

Catheters may be placed to deliver medication to specific locations:

- **Intrathecal catheters** deliver medications into the spinal fluid rather than into the blood system.
- **Intracavity catheters** deliver medication directly into a cavity (hollow space) such as the chest, belly, or pelvis. This exposes the tumor to the drug without having to use the bloodstream, avoiding the drug from coming into contact with all the tissues and cells of your body.

Pumps control how fast the medication(s) enters your system. External pumps are portable so you can move about during your treatment.

How long will a treatment take?

The length of your visit will vary depending on the clinical research study, the treatment you are receiving, and if the study requires any procedures to be done that day. The CRC will let you know if any procedures are scheduled and how long you should expect each visit to be.

Many of our studies require taking blood samples at specific times. These blood samples are called “PK” or pharmacokinetic blood samples. The samples let us know how much of the study drug is in your blood at different times during the day. Please ask your CRC if you will need to have these blood

tests, and if so, how often. Many patients need to come back 24 hours and 48 hours after treatment to have additional blood tests done.

An electrocardiogram (ECG or EKG) is a noninvasive, painless test that examines the electrical activity of the heart. Many of the clinical research studies require ECGs at specific times throughout the time of the treatment. The ECGs are a way to monitor you and see if the drug has any effect on your heart. Again, please ask your CRC if your treatment will require ECGs. The length of your visit will vary depending on the clinical research study, the treatment you are receiving, and if the study requires any procedures to be done that day. The CRC will let you know if any procedures are scheduled and how long you should expect each visit to be.

During Your Visit

There are both recliner chairs and stretcher beds available to you while you are receiving treatment. There are treatments that can take up most of the day, or that require a stretcher bed to give the treatment. We make every effort to accommodate requests for a stretcher bed depending on the availability. If a stretcher bed is not available at the time of your request, we will start your treatment in a recliner chair and move you to a room with a stretcher bed as soon as one becomes available.

Visitors: Due to limited space in rooms, please try to limit visitors to no more than 1 at a time.

Please note: All visitors must be age 18 or older.

Food: If your study does not have special requirements related to food, you may bring a snack with you or purchase something from the cafeteria to bring to the Clinical Research Center. Please avoid foods with a strong odor as they may cause nausea for others.

Dress: Dress warmly. The Center may feel cool, especially after you have received IV fluids. Blankets are available, so let your nurse know if you feel cold.

Television and Restroom: Each patient treatment area is equipped with a television. Restrooms are in various locations within close proximity to treatment areas.

How Will I Feel While I am Receiving My Treatment? Will it Be Painful?

Most people do not find getting these types of therapies to be a painful experience, but it affects people in different ways and those effects can vary widely. Factors that can influence how investigational treatment will affect you include:

- your previous health
- your type and stage of cancer
- the type and dose of treatment you are receiving
- any other current medical conditions you have

Physicians and nurses cannot know how you will feel during treatment. Please talk to your nurses about managing any side effects that you experience.

How Long Does Treatment Last?

Many anti-cancer treatments are given in a series of treatment sessions or cycles. Your RPCCC team will determine the number of sessions you need. A complete series of sessions is a *course*.

There are complications that can delay treatment. The most common physical cause of delay is a drop in your white blood count (WBC), also called neutropenia. Neutropenia puts you at high risk for infection.

Complications, such as a drop in WBCs, RBCs (red blood cells), or platelets, need to be addressed by your physician before you can have another treatment. Eat a balanced diet, get plenty of rest, and seek support.

Your Medications

Make a list of all the medications and the doses you are taking and bring the list with you to all of your appointments. Please keep the list current.

If another physician prescribes medication while you are receiving treatment in a study, make sure he or she knows the drugs you are receiving and when.

Before you begin taking any medications, vitamins, or supplements, always check with your doctor about what you may take while participating in the clinical research study. Some of these drugs/supplements may impact your treatment.

Nutrition

Eat a healthy diet to maintain your strength. Some clinical research studies have specific requirements regarding when you can eat and foods that you should avoid. The RPCCC team will advise you if any of these requirements apply to you. In addition, clinical dietitians are available to help you to make the best decisions about your diet. If you would like to speak with a dietitian, please ask for a referral from your nurse.

After Treatment

Precautions You Should Take

Avoid anyone who is sick, even if it is only a cold. The drugs used in cancer treatment need to be strong to kill the cancer cells. This can have an effect on your immune system and increase your risk of illness. You have the potential to become ill from germs that may only give everyone else a slight cold.

Taking Care of Yourself after Receiving Treatment

Get a lot of rest and avoid excessive activity.

Talk to your friends, family, or someone else about what you are feeling. Sometimes it is easier to talk to someone who is not a person who is close to you. There are support groups and online communities available where you can talk freely among those who share the same concerns as you. (See Resource section)

Keep your Roswell Park team informed. Let them know if you are not feeling well or if you are experiencing side effects. There are many options to help relieve nausea, diarrhea, pain, and other symptoms.

What You Can do to Prevent Mouth Problems

Here are some suggestions to help you prevent mouth discomfort and irritation.

If possible, have a dental checkup before starting treatment. Tooth decay, cavities, and other dental problems can increase your risk of infection.

- Keep your mouth moist and drink lots of water. Artificial saliva products are available if you need them.
- Keep your mouth clean: brush your teeth, gums, and tongue using a very soft toothbrush moistened with warm water. Use toothpaste that contains fluoride. If you use a water pick, use the weakest setting.
- Floss daily, but if you have areas of bleeding or ulcers, avoid these areas until they heal.
- Only use alcohol-free mouth products. Alcohol can cause mouth dryness and increase irritation. Biotene® is one example of a mouthwash that you can purchase without a prescription. Special toothpastes are also available. Use Biotene® toothpaste or one that is baking soda based. If you are not sure if a product contains alcohol, read the label or check with your pharmacist.

What Can You Do if You Wear Dentures or Removable Appliances?

- Make sure you clean them properly every day.
- Do not wear your dentures while you sleep at night.
- Keep your dentures fitting properly. Weight gain or loss can cause dentures to lose their “fit”. If this happens to you, ask your dentist to adjust your dentures to avoid injuring the tissue in your mouth.

What Can You Do if Your Mouth is Sore?

- Brush your teeth even if your mouth is sore. If a toothbrush causes too much discomfort, use an oral swab. An oral swab is similar to a Q-Tip, but it has a sponge on the end instead of cotton.
- Eat soft foods. Avoid hard, crunchy, and chewy foods.
- Soften your foods in a blender with some form of liquid such as gravy, juice, milk, or water, and drink them from a cup or through a straw.
- Ice chips may help with mouth pain and/or swelling.
- To lessen mouth pain, gargle with a 1/8 teaspoon of salt and ¼ teaspoon of baking soda mixed with 8 ounces of warm water. Swish it around in your mouth for a few minutes and then spit it out. Do not swallow it.
- To prevent making mouth ulcers worse, do not:
 - use any tobacco products (smoked or chewed)
 - use lemon and glycerin swabs
 - use any product containing alcohol
 - eat or drink citrus fruits or juices
 - eat condiments or foods made with vinegar
 - eat or drink any spicy, hot, or acidic foods and drinks (Cola, teas, and coffee are all acidic.)

It is always important to report any kind of side effect to your health care provider. Please consult with your RPCC team before taking any over the counter medications for mouth problems as these could interfere with your treatment.

Prescription Medications for Mouth Problems

If you need prescription medication, your Roswell Park team will discuss the options available for you. Nystatin comes as a mouth rinse and clotrimazole as a lozenge. Both medications prevent/treat fungal infections and sores in the mouth. In more severe cases, your physician may prescribe an antibiotic you can take by mouth.

BMX suspension is a special compound made in the pharmacy that reduces mouth pain and irritation. BMX is a combination of:

- Benadryl® (the antihistamine diphenhydramine)
- Maalox® (an antacid)
- lidocaine (a numbing agent like Novocain)

Nausea Vomiting and Diarrhea

Nausea, vomiting, and diarrhea are all common side effects of cancer treatment. Fortunately, we now have medications that can help prevent or stop these side effects. Please talk to your RPCI team if you are experiencing any of these side effects. He or she will be able to recommend the most appropriate treatment for your symptoms. Please note: Do NOT let these symptoms “run their course”, or you may become dehydrated. Not taking medication to prevent or treat these symptoms may result in serious problems.

When to Call Your Physician

In general, call your physician right away if you:

- have any sign of infection: **Fever of 100.4°F (38°C) or higher**; chills; cough; sore throat; pain or burning upon urination; or tenderness/ redness in any area with there is an IV, port, wound, or injury.
- have any itching or hives
- have unusual bruising or bleeding, blood in your urine or phlegm or mucus, unusually heavy menstrual bleeding, spontaneous bleeding from your gums or nose, or superficial bleeding into the skin that appears as a rash of pinpoint-sized reddish-purple spots (petechiae)
- have difficulty walking or bending; swelling and/or pain in your legs or arms; or numbness and/or tingling in your hands or feet
- have persistent and/or severe vomiting or diarrhea (loose, watery stools, more than 3 times in 1 day) that lasts more than 24 hours after your treatment and/or is not relieved with the medication your physician prescribed
- cannot keep down any food or liquid
- have problems with your eyesight, such as blurred or double vision
- have headaches and/or dizziness
- have a sore mouth or throat and/or white patches in your mouth or on your tongue
- are coughing up yellow, green, or rusty colored mucus
- are extremely weak, tired, or if you are sleeping most of the time

When to Call 911

Call **911** if you:

- are having chest pain or trouble breathing
- have any signs of a severe allergic reaction: swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing, dizziness, or palpitations
- have bleeding that lasts more than 10-15 minutes or that causes dizziness; black or bloody stools; vomit that is bloody or that looks like coffee grounds
- have a **sudden** onset of any of the following symptoms: Numbness or weakness of the face, arm, or leg - especially if it only happens one side of your body; confusion, trouble speaking or understanding; trouble seeing in one or both eyes; or severe headache

How to Contact your Roswell Park Team

You can always call when you have questions. We are here to help.

- For medical questions or concerns during office hours, please call the EPCT Clinic/Clinical Research Center at **716-845-4720**.
- For medical questions or concerns after hours, weekends, and holidays, please Roswell Park's main number, **716-845-2300** or toll free **1-800-ROSWELL (1-800-767-9355)** and our Call Center staff will assist you.
- If it is determined you need to be seen, we may ask you to come to our Assessment and Treatment Center (ATC), which is open 24/7. **You must be referred to the ATC by your provider (or the provider on call); it is not a walk in clinic.**

What Can I Do to Make my Treatment as Successful as Possible?

- Let your team know if you are taking any vitamins or herbal supplements or remedies, including garlic tablets.
- Tell your team whenever there are any changes in your prescription or over-the-counter medications/supplements.
- It is important to drink an extra quart or more of liquids every day to keep you hydrated. Water is particularly helpful.
- If you become constipated, you may take over-the-counter stool softeners.
- It is important to shower or bathe and to keep your skin hydrated.
- Your team will talk to you about the common side effects of your treatment. Talk to your physician and nurse if you have any unexpected side effect, or if any expected side effects become severe.

Preparing yourself is important. Your Roswell Park team is here to help.

What Happens if my Cancer Progresses While I am on a Phase I Study?

If your cancer progresses despite treatment, your physician and/or nurse practitioner will meet with you to discuss other available treatment options.

Summary

The EPCT Program at Roswell Park provides patients the opportunity to have access to novel cancer treatments through participation in clinical research studies. The EPCT Program team strives to have a broad variety of innovative studies open at all times, so that patients with all types of cancers have access to alternative treatments.

Please contact us with any questions or concerns you may have. The team would be happy to assist you in finding the best available cancer treatment.

Resources

Roswell Park

- **MyRoswell Patient Portal:** Access your medical information 24/7 and safely communicate with your care team. Go to <https://my.roswellpark.org/> to register.
- **Social Work Department:** Counseling and referrals for assistance with finances, disability, legal matters, intimacy, transportation, lodging, hospice, and foreign language(s). e. **716-845-8022**
<https://www.roswellpark.org/cancer-care/support/social-work>
- **Cancer Coach:** Matches patients to cancer survivors for support, comfort, and practical information – not medical advice. www.roswellpark.org/cancer-care/support/resource-center/cancer-coach
- **Roswell Park Online Community:** A supportive, private place for anyone whose life has been touched by cancer. Support and sharing among those who truly understand what you are going through. Go to: <https://community.roswellpark.org/>
- **The Resource Center for Patients & Families:** Located on the first floor of the hospital, the center offers cancer information, and other services. You can reach the resource center at **716-845-8659**. **Open Mon – Fri, 9 a.m. – 4 p.m.** <https://www.roswellpark.org/cancer-care/support/resource-center>
- **Elevate Salon:** Located on 1st floor of the Clinical Sciences Center near the Breast Center. People who have lost their hair due to cancer or treatment can have one free wig and head covering. The salon offers pretreatment haircuts, and wig styling. Hours: Mon.-Fri. 9a.m. – 4p.m. **716-845-8659**.
- **Roswell Park General Information: 1-800-ROSWELL (1-800-767-9355).** www.roswellpark.org
- **MedlinePlus®** <http://medlineplus.gov/> Drug and medical information from government agencies. Spanish available.
- **National Cancer Institute (NCI)** www.cancer.gov
- **NCI: Chemotherapy and You:** <http://www.cancer.gov/cancertopics/chemotherapy-and-you>