

Lilly Oncology

If additional treatment is needed

A guide to

Deciding your next steps



Lilly

Important Phone Numbers

Physician _____

Nurse _____

Care Partner _____

Pharmacy _____

Insurance _____

Other _____

The information presented in this booklet is not intended to replace discussions between you and your healthcare team, but to serve as a guide to making decisions about your cancer care and treatment—decisions that you can live with and feel good about.

Table of Contents

Your options	2
Types of cancer treatment	3
Your goals of therapy	4
Additional cancer therapy booklets	5
About ongoing therapy	6
Therapy given in a sequence	6
Therapy if the cancer returns	6
New treatment options	8
What you need to know about clinical trials	9
Additional information about clinical trials	13
Your therapy decision	15
Communication and agreement	17
Tips for communicating effectively	18
Cancer resources and support groups	19
Treatment comparison worksheets	22

Your options

Despite the best and most informed decisions you and your healthcare team make about your cancer treatment, you may later require additional or different therapy.

This does not mean that your original decision about treatment was incorrect. The need for additional treatment can be due to any of several reasons. Your particular tumor type may be best treated with sequential therapy; this means that one kind of treatment is followed by another kind to increase effectiveness. What also may be happening is that the therapy is not killing the tumor, or the therapy is causing side effects that are not tolerable.

The most important thing to remember is that, in any of these situations, *you have options to explore*. These options may include enrolling in a clinical trial, pursuing different types or combinations of treatment, or deciding whether you want to undergo further treatment.

Just as when you were first diagnosed, you are the one who, with the help of your medical team, can make the best decision for you. Even though your first treatment may not have been what you expected, you have the ability to decide what to do next. The best way to gain control over your situation is to learn as much as you can and discuss your options with your healthcare team.

Types of cancer treatment

Surgery—the most direct way to remove a visible tumor or cancer cells that have invaded a specific area.

Chemotherapy—treatment with medication, sometimes given orally, but more commonly by injection, into a vein or muscle to destroy cancer cells. It is a systemic treatment that reaches every organ of the body through the bloodstream.

Biotherapy—treatment to stimulate or restore the ability of the immune system to fight infection and disease. Also used to lessen side effects that may be caused by some cancer treatments. Also known as immunotherapy, biological therapy, or biological response modifier (BRM) therapy.

Radiation therapy—a treatment method that uses high-energy x-rays to destroy cancer cells.

Hormonal therapy—treatment or prevention of cancer by removing, blocking, or adding hormones that affect the growth of a tumor.

Your goals of therapy

Although you might be disappointed that your original treatment did not work as well as you would have hoped, it is likely that you still have several different options. More than ever, it is important that you have reliable information about these options so that you can have some control over your situation.

Your first step should be to talk with your medical team; be proactive, ask for information, and be organized. It is important to work with your healthcare team to make decisions that are the best for your particular situation. So, take some time to think about your options. Be patient with yourself.

You are your own best advocate, and it is important that you understand your feelings about further treatment and your goals of therapy. Only you can decide what your goals will be, based on what you and your healthcare team expect from your treatment. Your goals may involve treating your cancer as aggressively as possible or maintaining your normal daily activities for as long as possible. Your therapy goals will be determined in part by your lifestyle, including family and work obligations, how advanced your cancer is, and how well you can tolerate further treatment.

Additional cancer therapy booklets

In addition to this booklet, there is a range of other information to help you understand and talk with your healthcare professional about your goals of therapy before you make a treatment decision. These booklets can be obtained free of charge by calling 1-800-545-5979:

BEFORE YOU BEGIN THERAPY

A Guide to Researching the Best Therapy for Your Treatment Goals—
for anyone newly diagnosed with cancer to provide a road map of how to learn the basics of cancer care.

BEFORE YOU BEGIN CHEMOTHERAPY

A Guide to Some Things You Should Know About Side Effects—
for anyone considering chemotherapy. If your goal of therapy is to consider treatment side effects, you may want to read this booklet.

BEFORE YOU BEGIN THERAPY

A Guide to Making Decisions About Your Cancer Treatment—
for anyone newly diagnosed or newly rediagnosed with cancer to provide a road map of how to learn the basics of cancer care.

About ongoing therapy

Therapy given in a sequence

Because of advances in cancer care, people can live with and be treated for cancer for many years. There are different ways to give treatment. This is important to understand because it could affect the decision you make about your therapy. The first treatment a person receives after being diagnosed with cancer is called first-line therapy. This therapy can last from four to six months or longer, and can consist of multiple drugs. After first-line therapy is complete, your healthcare team may decide to move directly to a different type of treatment, even if the tumor has not started growing again (this is the original meaning of sequential therapy).

Therapy if the cancer returns

In other types of cancer, your healthcare team may wait until the tumor begins growing again before you are given more therapy. The beginning of additional therapy is called second-line therapy. If, after second-line therapy, the tumor continues to grow, the next therapy is called third-line therapy, and so on.

Many therapies have been tested and approved by the Food and Drug Administration (FDA) for a specific line of therapy. Keep in mind that if you receive a therapy in the first-line setting, you may not be able to receive that therapy in the second-line setting. If you receive that therapy in the second-line setting, you may not be able to receive it in the third-line setting. Discuss these situations with your healthcare team, so you can plan for multiple options, just in case you need them.



*The best advice I got about my cancer treatment?
Believe in the choices you make.
— Frank*

New treatment options

If you gathered information about your cancer treatment before deciding on your original therapy, you may already have a second or third treatment option in mind. Regardless, now is the time to review as much information as you can about your next steps.

Be sure to get help from someone you trust—a friend or family member who can be your “research partner”—to help gather and evaluate information. Information about cancer and cancer therapy is not difficult to find, but there is a lot of it! The job of reading and evaluating the information can be detailed and time-consuming—probably more than you should or would want to do alone.

Begin by finding the best sources of information about additional therapies for your type of cancer. The most obvious sources are your healthcare team and other members of your healthcare team. The research librarian at your local library can help you find a variety of information about cancer and cancer therapies. Additionally, a wide range of valuable information is available on the Internet. Internet sites include cancer research and support organizations, patient groups, pharmaceutical companies, and others. This booklet also provides many excellent sources of information for you to explore.

What you need to know about clinical trials

One of the first decisions you may want to make is whether to participate in a *clinical trial*. It is important to make this decision prior to starting any treatment because you may not qualify for certain clinical trials (also known as studies) if you have already received treatment for your cancer. If your doctor does not bring up this subject with you, you may want to ask him/her if participating in a clinical trial is an option for you.

If you take part in a clinical trial, you will receive treatment in your doctor's office, a clinic, or a hospital. As part of the study, your healthcare team will carefully monitor your progress. With clinical trials, you may be asked to fill out questionnaires in order to gather information about the way you feel while you are on treatment. It is important that you fill out these questionnaires if it is requested. These questionnaires provide valuable information to cancer researchers about how your cancer treatment is affecting your condition as well as your daily life.

Clinical trials are carried out following a plan of very strict, scientific guidelines, called a *protocol*. The protocol explains everything that will happen in the study. It must be approved by review boards composed of healthcare professionals and other qualified individuals before the study can enroll patients. Following preclinical or laboratory phases of studies, there are four possible phases of cancer clinical trials in humans, each addressing different questions about the treatment being studied.

Preclinical studies, which are conducted in a laboratory setting, help to assess whether an experimental drug is safe to test in humans. During this stage, the drug is usually studied in animals to answer questions about how a drug works, how it is eliminated, and how the drug might affect pregnancy and offspring.

In **phase I** clinical trials, doctors (also called investigators) study the safety of giving drugs to humans along with looking for the best way to give a medication (for example, as a pill, an injection, or an *infusion*). They will usually study how the drug is eliminated from the body in humans. In addition, doctors look to determine appropriate doses for further testing, and they carefully watch for any *side effects*. Phase I study drugs are usually given to small groups of humans. During this phase, for drugs used to treat cancer, doctors may be able to identify in which *tumors* a treatment might work.

In **phase II** clinical trials, the drug is studied in a larger group of humans. The focus is to study specific cancers to see how well the drug or treatment works. The doctor will watch closely for side effects and will also watch how the disease responds to the treatment.

In **phase III** clinical trials, a study drug or treatment is generally compared to a standard existing treatment. Patients are usually randomly assigned to receive either the standard treatment or the new treatment. During the trial, patients are not told which treatment they are receiving but are told what to expect and what to watch for. Also, sometimes the doctor will not be aware of which treatment each patient is receiving so that he/she can remain objective about how the disease is responding to the treatment and any side effects that patients may be experiencing.

In **phase IV** clinical trials, doctors study a drug that has already been approved by the Food and Drug Administration (FDA). Pharmaceutical companies often sponsor these trials to study expanded uses of drugs already available to treat other types of cancer.

Before patients enter a clinical trial, all of the procedures that are to be done in the trial will be explained, and patients will be asked to sign an *informed consent*. By signing the document, a patient is acknowledging that he/she understands the potential risks and benefits of the treatment they are to receive or of any tests that may be required. It is important to remember that patients may change their minds and withdraw from a clinical trial at any time. Non-English-speaking patients may ask for consent documents in their own language.

Some people have said that they chose to not participate in a clinical trial because they thought that their health insurance would not cover the cost of their treatment. There are a number of new laws and programs, which vary from state to state, that may help pay for all or part of the costs of treatment. It is important to have all of your questions answered by your insurance representative, your healthcare team, or one of the groups listed in the resource list at the back of this booklet before agreeing to participate in a clinical trial. To obtain additional information about clinical trials, contact the organizations listed in the following section. These Web sites are independent from Eli Lilly and Company, and Lilly does not control or endorse the content of these sites.



*I choose to look for the opportunities that come with the day-to-day struggles —
to look beyond the challenges.
— Lee*

Additional information about clinical trials

National Cancer Institute—clinical trial results

www.cancer.gov/clinicaltrials/results/

1.800.4CANCER (1-800-422-6237)

Centerwatch

www.centerwatch.com

National Institutes of Health

www.clinicaltrials.gov

Association of Cancer Online Resources

www.acor.org

Pharmaceutical company Web sites

Your decision to take part in a clinical trial is up to you, your family, and your healthcare team. There are potential risks and benefits associated with clinical trials that you will want to discuss with your doctor before deciding to participate in a clinical trial. A list of questions to guide your discussions with your doctor about clinical trials appears on the next page. If you choose to not participate in or do not qualify for a clinical trial, treatment options are still available for you.

Some questions to ask your healthcare team about clinical trials

1. Do you participate in clinical trials?
2. Do I qualify (meet the eligibility criteria) for any current clinical trials? If so, what is the purpose of these trials?
3. If I do qualify for a clinical trial, what is known about the effectiveness of the treatment being studied? What are the side effects?
4. How long does the clinical trial last? Can I stop participating in the clinical trial at any time I choose?
5. What costs am I responsible for if I participate in a clinical trial?
6. If I do not qualify for any current clinical trials, what are my options?
7. Will my privacy be protected?

Your therapy decision

As you explore the various options available to you, always consider them with your goal of therapy in mind.

Depending upon your options and the stage of your tumor, you may decide to:

- Undergo additional therapy, which could include surgery, chemotherapy, biotherapy, radiation therapy, or hormonal therapy—or a combination of therapies.
- Wait to see if your cancer progresses, and then decide what type of further treatment you need.
- Arrange for long-term care rather than undergo further therapy.

As you think about your next treatment options, the worksheets at the end of this booklet will help you organize and compare treatment options. This side-by-side comparison of key questions should help you narrow the options to two or three possible choices of treatment. If you plan to bring to your healthcare team's attention any information you found in books or articles, or on the Internet, be sure to highlight just the information that's especially important to you. This will help make discussions easier and more efficient.

Finally, schedule an appointment to talk with your healthcare team specifically about the results of your research, treatment options, and any questions you may have. Prepare carefully for your appointment: write down questions, information you've discovered, therapies that seem appropriate, and your feelings about your goal of therapy. If possible, take your research partner to the appointment with you—two heads are definitely better than one for remembering everything you will be talking about.



Nobody should face cancer alone. With my treatment team, I don't have to.
—David

Communication and agreement

During discussions with your healthcare team, use your notes to make sure you communicate your feelings, needs, and desires. It is very important that you tell your healthcare team what you are willing or not willing to do as a part of your continuing cancer treatment.

If your goal of therapy is to treat your cancer as aggressively as possible, you may be willing to tolerate more (such as a more demanding schedule or certain side effects) than if your goal of therapy is different. Regardless of your goal of therapy, there are options for you. The only way your healthcare team can advise you about what therapy is right for you is if you talk with him/her about what is important to you.

Do not be afraid to ask your healthcare team to clarify any information you do not understand. Ask questions until you are satisfied that you understand the information being discussed and how it relates to your therapy. This discussion should lead to an agreement between you and your healthcare team about whether you should proceed with additional therapy, and what that therapy should be.

Throughout this discussion with your healthcare team, remember that even though your cancer treatment may not have been what you expected, there are still options available to you. Be sure to consider all of them. You have the ability to decide your future course of action. These can be very difficult decisions. After all of your options have been identified, you may want to ask for the expert opinions of your healthcare team. Maintaining an open relationship with them and agreeing clearly on a course of treatment is an important part of your continuing cancer care.

Tips for communicating effectively

1. Prepare for your appointment. Write down questions when you think of them, and take them with you to discuss with your healthcare team.
2. Be as clear as you can when asking questions and communicating your needs.
3. If you bring books, articles, or information you have printed from the Internet to your appointment, highlight important information that you would like to discuss.
4. Listen carefully to what you are being told. Take notes or make an audiotape of your conversation.
5. Do not be afraid to ask for clarification if you do not understand some of the information that you receive. Ask questions until you are satisfied that you understand the information being provided to you.

Cancer resources and support groups

You are not alone in your efforts to manage your disease as well as you can. Many special organizations are dedicated to helping people who are living with cancer. A wealth of resources exists, and you probably will benefit from learning more about them.

Social support can be an important part of your medical treatment too. It is important that you discuss any information you are interested in with your healthcare team. If you do not have access to the Internet, contact your local library for help. You may also call these organizations at the following toll-free numbers.

The following resources are independent from Eli Lilly and Company, and Lilly does not control the content.

All Cancers

AMERICAN CANCER SOCIETY
1.800.ACS.2345 (1.800.227.2345)
www.cancer.org

CANCER CARE
1.800.813.HOPE (1.800.813.4673)
www.cancercare.org

CANCER RESEARCH
PREVENTION FOUNDATION
1.800.227.CRFA (1.800.227.2732)
www.preventcancer.org

fertileHOPE
1.888.994.HOPE (1.888.994.4673)
www.fertilehope.org

NATIONAL CANCER INSTITUTE
1.800.4.CANCER (1.800.422.6237)
www.cancer.gov

THE NATIONAL COALITION FOR
CANCER SURVIVORSHIP
1.877.NCCS.YES (1.877.622.7937)
www.canceradvocacy.org

PATIENT ADVOCATE
FOUNDATION
1.800.532.5274
www.patientadvocate.org

PEOPLE LIVING WITH CANCER
www.plwc.org

THE WELLNESS COMMUNITY,
NATIONAL HEADQUARTERS
1.888.793.WELL (1.888.793.9355)
www.thewellnesscommunity.org

VITAL OPTIONS INTERNATIONAL
1.818.508.5657
www.vitaloptions.org

Breast Cancer

NATIONAL BREAST CANCER
COALITION
1.800.622.2838
www.stopbreastcancer.org

SISTERS NETWORK INC.
1.866.781.1808
www.sistersnetworkinc.org

THE SUSAN G. KOMEN
BREAST CANCER FOUNDATION
1.800.I'M AWARE (1.800.462.9273)
www.komen.org

Y-ME NATIONAL BREAST
CANCER ORGANIZATION
1.800.221.2141
www.y-me.org

YOUNG SURVIVAL COALITION
1.212.206.6610
www.youngsurvival.org

Brain Cancer

NORTH AMERICAN
BRAIN TUMOR COALITION
www.nabraintumor.org

Colon Cancer

COLON CANCER ALLIANCE
1.877.422.2030
www.ccalliance.org

NATIONAL COLORECTAL
CANCER RESEARCH ALLIANCE
1.800.872.3000
www.nccra.org

Leukemia and Lymphoma

THE LEUKEMIA AND
LYMPHOMA SOCIETY
1.800.955.4572
www.leukemia-lymphoma.org

LYMPHOMA RESEARCH
FOUNDATION
1.800.235.6848 OR 1.800.500.9976
www.lymphoma.org

Lung Cancer

THE LUNG CANCER ALLIANCE
1.800.298.2436
www.lungcanceralliance.org

LUNG CANCER ONLINE
www.lungcanceronline.org

Ovarian Cancer

NATIONAL OVARIAN CANCER
COALITION
1.888.OVARIAN (1.888.682.7426)
www.ovarian.org

OVARIAN CANCER
NATIONAL ALLIANCE
1.202.331.1332
www.ovariancancer.org

Pancreatic Cancer

PANCREATIC CANCER
ACTION NETWORK
1.877.272.6226
www.pancan.org

Prostate Cancer

US TOO! INTERNATIONAL—
PROSTATE CANCER EDUCATION
AND SUPPORT NETWORK
1.800.808.7866
www.ustoo.com

As you think about your next option, the following worksheets will help you organize and compare treatment options.

Treatment Comparison Worksheet—Option 1

1. What were the response rates (percentage of patients whose cancer shrank or disappeared after treatment) shown by the therapy?

3. What was the time to tumor progression (the length of time after diagnosis or beginning of treatment until the treatment was no longer effective or the cancer returned)?

3. What were the survival statistics (the percentage of patients alive for a given time after treatment was started—typically a one-, two-, or five-year period)? Also, what was the median survival time (the average length of time the study group lived after receiving treatment)?

4. Did the therapy work as well or better than the therapy it was compared with? What were the possible grades 3/4 side effects (the most severe toxicities) from this therapy?

5. Were the side effects better, worse, or the same as the therapy it was compared with?

Treatment Comparison Worksheet—Option 2

1. What were the response rates (percentage of patients whose cancer shrank or disappeared after treatment) shown by the therapy?

3. What was the time to tumor progression (the length of time after diagnosis or beginning of treatment until the treatment was no longer effective or the cancer returned)?

3. What were the survival statistics (the percentage of patients alive for a given time after treatment was started—typically a one-, two-, or five-year period)? Also, what was the median survival time (the average length of time the study group lived after receiving treatment)?

4. Did the therapy work as well or better than the therapy it was compared with? What were the possible grades 3/4 side effects (the most severe toxicities) from this therapy?

5. Were the side effects better, worse, or the same as the therapy it was compared with?

Treatment Comparison Worksheet—Option 1

(continued)

6. How well do you think you will be able to tolerate the possible side effects, and how will they likely affect your life?

7. In how many phase III clinical trials has this therapy been tested?

8. Were results consistent in similar trials?

9. What is your goal of therapy? Is this therapy likely to meet that goal?

Treatment Comparison Worksheet—Option 2 (continued)

6. How well do you think you will be able to tolerate the possible side effects, and how will they likely affect your life?

7. In how many phase III clinical trials has this therapy been tested?

8. Were results consistent in similar trials?

9. What is your goal of therapy? Is this therapy likely to meet that goal?



The International Society of Nurses in Cancer Care (ISNCC) endorses this educational offering. The approval of ISNCC does not imply product endorsement.



This booklet meets Oncology Nursing Society (ONS) guidelines for quality educational content. ONS endorsement does not constitute medical advice. Healthcare providers should exercise their own independent medical judgment.

A Patient Education Service Provided by Lilly Oncology

www.LillyOncology.com