Ninth Edition
UNDERSTANDING
CLINICAL TRIALS

SHATTERING
THE MYTHS

› KNOW THE FACTS – finding the true and false of clinical trials

See page 2
Luminosity Study: A study in patients with previously treated locally advanced or metastatic c-Met+ Non-Small Cell Lung Cancer

Non-Small Cell Lung Cancer Research Study

Do you or someone you know have Non-Small Cell Lung Cancer? Consider the Luminosity Study.

This research study is evaluating the safety and effectiveness of an investigational study medication, called telisotuzumab vedotin (ABBV-399), in Non-Small Cell Lung Cancer patients (NSCLC).

Patient Population
Subjects with locally advanced or metastatic c-Met+ NSCLC, who have progressed on systemic cytotoxic therapy (or are ineligible) and an immune checkpoint inhibitor (as monotherapy or in combination with systemic cytotoxic chemotherapy, or ineligible), and prior anti-cancer therapies targeting driver gene alterations (if applicable).

Patients Must Meet the Following Criteria
• 18 years of age or older
• Diagnosed with locally advanced or metastatic non-small cell lung cancer
• Has histologically documented non-squamous cell NSCLC or histologically documented squamous cell NSCLC
• Completed one or two rounds of chemotherapy and the cancer has gotten worse during or after treatment
• Test positive for c-Met protein expression
• Does not have adenosquamous histology
• Has not received prior c-MET-targeted antibody-based therapies
• Other criteria apply*

*The study doctor will tell you about additional requirements to be able to participate in this study.

For more information, ask your doctor about the Luminosity Study or visit https://ClinicalTrials.gov (NCT03539536) to learn more about this study.

ABBV-399 is an investigational drug that is not approved by the FDA or other global health authorities. Safety and efficacy have not been established.
IN THIS GUIDE

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I am wide open to considering another trial in the future. Today I feel like I don’t even have cancer. I’m thrilled to continue doing what I love to do.

— Davi D’Agostino, pancreatic cancer survivor, page 7

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Graphic Designer
Todd Smith
Sonia Wilson

Medical Illustrator
Amy Galey
Kathy Hungerford

Circulation & Production Manager
Billy Dunbar
8455 Lenexa Drive
Overland Park, KS 66214

For Additional Information
prp@patientresource.com
Visit our website at PatientResource.com to read bios of our Medical and Patient Advisory Board.

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The true and false of clinical trials

The myths surrounding clinical trials can make this valuable treatment option seem too scary or far too risky to consider. Some people hesitate simply because they aren’t familiar enough with clinical trials. Others dismiss them outright because of misconceptions based on inaccurate information. As a result, many patients miss an opportunity for access to what may be the most effective treatment for their unique cancer diagnosis.

The truth is, a clinical trial may be the best treatment option when an individual’s cancer has become resistant to the current treatment; when curative therapies are not yet available for that cancer type, subtype or stage; or the cancer is rare and has few, if any, approved treatments. Even with such promise, it is often challenging for researchers to recruit enough adult participants.

Cancer patients who are well-informed about clinical trials have been found to be much more likely to participate, particularly when they are eligible for studies being conducted where they are receiving treatment.

CLINICAL TRIALS: KNOW THE BASICS

Most cancer treatments used today were once research therapies or procedures that were developed, tested and evaluated through the clinical trials process to gain approval from the U.S. Food and Drug Administration. Clinical trials may be conducted to evaluate new methods for improving different areas of cancer care, including disease prevention, patient screening, diagnostic tools and procedures, genetic risk factors, and lifestyle or behavioral changes that may improve health and/or quality of life. This includes testing drugs, biologics and other non-medication therapies such as radiation therapy and surgery, medical devices, screening approaches and other interventions. Trials may also evaluate patient-reported outcomes, which are important to improving the quality of patient care.

This guide focuses on treatment trials. These studies evaluate whether a new treatment, such as a drug or vaccine, drug combination, surgical procedure, type of radiation therapy or a combination of therapies, is more effective or better in some way than the current standard of care.

Clinical trials are carefully planned and structured and highly regulated for the safety of all participants (see Safety Measures, page 6). They often take into consideration the individual’s genetic characteristics and other factors unique to his or her diagnosis. The following are among new types of clinical trials designed for this purpose.

• Basket trials test the effectiveness of a drug on a single gene mutation/variant simultaneously across tumor types throughout the body. For example, trial participants will all have tumors with the same gene mutation, but the tumors may be in the breast, colon, lung, bladder or other locations.

• Umbrella trials are designed with multiple treatment arms within the same study. Participants are grouped into a specific arm based on the type of cancer they have and its molecular profile. You will need to undergo genetic testing before joining one of these trials.

INFORMED CONSENT PUTS YOU IN CONTROL

Once you express interest in a clinical trial, you will receive comprehensive information in a document known as an Informed Consent form. It details the purpose of the research, including your role in the trial, the treatment to be studied, how the trial will work, risks and benefits. The form also explains how you will be monitored, potential side effects of the treatment, the current standard of care for your type and stage of cancer, the safeguards in place to protect you, how to withdraw from the trial, and a detailed list of the costs the trial sponsor will cover (see Financial Considerations, page 8).

The trial’s medical team or administrator will go through the information with you. It’s very important to get clear answers to all your questions. Signing the

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Myth-busters

I can’t join a clinical trial unless there are no other options.

A very common misconception is that clinical trials are the last resort. Joining a research study is the first choice of many patients today, as it may offer access to a promising new therapy not available otherwise. In some situations, a trial may be the best option.

Trials offered outside my cancer center won’t be open to me.

Sites for clinical trials range from nationally known cancer centers to community hospitals and oncologist’s offices. Some people join clinical trials through their treatment centers, while others travel to participate. Before you rule out a trial because it will require you to travel, check out potential resources for assistance (flip over this guide to see Transportation & Travel Resources, page 83).

Drug therapies that aren’t yet approved aren’t safe.

Most cancer treatments used today were once researched, developed, evaluated and approved through clinical trials. Participating cancer research facilities, from university medical centers to pharmaceutical company research laboratories, are subject to strict safety standards established by the FDA.
Informed Consent form does not lock you in to the trial or to continue your participation. If you decide you no longer want to be involved, you may withdraw at any time and return to the standard of care.

Signing the form also does not guarantee you a spot in the clinical trial. Each research study has its own unique eligibility criteria, such as cancer type, subtype, stage, biomarker or treatment history. Your age, gender and any additional health conditions may also be factors.

**PARTICIPATING OFFERS POTENTIAL BENEFITS**
Receiving your cancer treatment through a clinical trial may offer you the following:

- Access to state-of-the-art cancer treatment that is not available outside clinical trials.
- A higher level of care from being monitored by the clinical trial’s medical team in addition to by your regular oncologist.
- Early intervention in treating side effects or addressing any complications, due to extra medical attention.
- A role in advancing cancer research by helping to improve treatment options for future patients.

As with any cancer treatment, a clinical trial presents potential risks and side effects. It may require more medical appointments and/or tests than you would ordinarily have scheduled. Ask in advance to make sure you’ll be able to rearrange your schedules for work, school, family commitments and other obligations to accommodate the appointments required to meet the trial’s protocol.

**IS A CLINICAL TRIAL RIGHT FOR YOU?**
Deciding whether to pursue a clinical trial as a treatment choice is not easy, and the element of uncertainty can cause some anxiety. Ask questions, consult with your doctor and consider getting a second opinion. You can also reach out to current or former clinical trial participants through local or online cancer support groups, as well as conduct your own online research (see Online Searches, page 4).

The trial coordinator will know all aspects of the study and can help address any concerns. For example, you can ask the coordinator to provide additional information or printed materials, such as results from previous phases of the trial and the trial sponsor’s track record on cancer drug development. Find out if the investigational drug will be available to you post-trial (and at what cost) if you’re responding to it and how your care will be transitioned back to your current doctor.

This is a deeply personal decision only you can make. But now that you’ve found the true and false of clinical trials, you have the knowledge you need to give this treatment option the consideration it deserves.

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**Learn more to see if a clinical trial is right for you.**
Once you separate the truth from the misinformation, you’ll gain the insight needed to discuss with your medical team.

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**I can’t afford to be in a clinical trial because the treatments are so expensive.**

Many people mistakenly assume their health insurance provider will deny coverage for their cancer care if they’re in a clinical trial because the treatment is experimental. First, keep in mind that most cancer treatments have associated costs that depend on the type and length of therapy, the treatment facility and other factors. Second, the trial sponsor typically covers research-related expenses, but talk with the trial coordinator to find out. Lastly, your insurance provider may pay for costs normally covered as part of standard care. Contact them early to find what your policy will and won’t cover so you’ll know what costs will be your responsibility to pay.

**If this was my best option for treatment, I’d already know about it.**

Thousands of cancer research trials are being conducted worldwide. With new studies continually opening, it’s difficult for doctors to know about them all. Be sure to let your doctor or nurse navigator know you’re open to considering a clinical trial. Online resources now make it possible for you to search on your own (see Online Searches, page 4).

**Only people with advanced cancer are eligible.**

Clinical studies are being conducted for patients at every stage of cancer. Depending on your diagnosis, a clinical trial may be considered your best first treatment.
As you and your doctor discuss the potential treatment option of a clinical trial, keep in mind that so many trials take place at the same time that it is difficult for your doctor to know about all of them. It takes research, and that's where you come in. While your health care team is exploring potential trials, you can, too. However, navigating some sites can be overwhelming. To help you get started, step through these instructions.

Before you begin, have your exact diagnosis, pathology report and details of previous cancer treatments on hand to help determine if you meet the basic eligibility criteria. Consider asking friends or family members to help search as well.

Know where to look. Clinical trials search sites are hosted by the government, the National Cancer Institute, cancer advocacy groups, pharmaceutical companies and industry trade organizations, academic medical centers and major hospitals. Flip over this guide and get started with listings in Clinical Trials, page 65. No single list contains every open clinical trial. New trials are continually being added, so check back often.

Once you and your doctor find a clinical trial, it's important to know what happens next. Although every trial is different, most follow a general process. Your eligibility will be assessed when you and/or your doctor first contact the clinical trial coordinator to learn more details. If you are a likely candidate, you'll meet with the principal researchers to further determine your eligibility and answer your questions about the study. You may meet the clinical trial team, which may include doctors, nurses, specialists, your trial coordinator, social workers or other health care professionals.

Before entering the trial, you will be given an Informed Consent form that provides detailed information about it. Review the document carefully. Consider sharing it with loved ones and discuss anything you don't understand with your doctor, especially any medical terms. Before you sign the Informed Consent form, it's a good idea to contact your insurance provider to find out which procedures, tests, follow-ups, etc., are covered and which you may be required to pay out of pocket.

Continue to be your own advocate. After you begin a clinical trial, keep asking questions and alert your health care and trial teams about new symptoms and side effects. And remember, you may choose to leave the trial at any time, for any reason, and return to standard of care.

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**GETTING STARTED ON YOUR OWN**

- Be an active participant in your own care by looking online for available trials. You may also choose to move ahead with your treatment plan and still continue to search. These instructions will help guide you through the process.

**[STEP 1] FILL IN YOUR INFORMATION**

**Your Diagnosis**
For example, enter “pancreatic cancer.” To create more options, you can also search for “advanced pancreatic cancer” and compare results.

**Desired Location**
If you prefer a clinical trial close to home, enter your address. Enter additional locations if you’re willing and able to travel for treatment.

**[STEP 2] READ YOUR SEARCH RESULTS**

**Recruitment Status**
This indicates whether the trial is actively seeking patients, not yet recruiting or otherwise inactive. The status will change, so check for updates.

**Summary of Study**
Here you’ll find details about the purpose of the clinical trial and the treatment being studied. This section is usually written for health care providers, so it may be difficult to understand. If so, print out the information to discuss with your doctor.

**Eligibility Criteria**
This outlines the criteria you must meet to be eligible for the trial, such as previous treatments, age and overall health requirements.

**[STEP 3] FIND A CLINICAL TRIAL**

**Search Clinical Trials**
Enter Medical Condition
Enter Location

**Other Terms**
You can refine your search by adding a treatment type such as immunotherapy or targeted therapy, a specific drug or National Clinical Trial (NCT) identifier. Identifiers begin with the letters “NCT” followed by eight numbers.

**Contacts and Locations**
This may contain contact information for the clinical trial investigators, staff and sponsors, as they may be able to provide more details about the study. Trial locations may also be listed.

**Sponsor**
The organization responsible for the clinical trial is listed here. It may be a pharmaceutical or biotechnology company, a university or the National Cancer Institute or others.
From the Expert

Darlene Timmerman, MSN, RN, OCN, is the Oncology Clinical Research Nurse at the Olathe Health Cancer Center. Impressed by the clinical trial process, she works closely with patients to educate them about clinical trials as they consider their treatment options.

What has made you so passionate about clinical trials?
I’ve been an oncology nurse for most of my career. Over the years, I’ve seen the emergence of many new drugs and techniques. These new developments have always intrigued me and made me think, “If this is true, then how do we apply it to that?”

Not long ago, I left the hospital administration world to get back to the science of cancer by working with clinical trials and educating our patients about these innovative research studies.

Do you look for clinical trials for every patient?
Whether an oncologist requests a particular clinical trial or it’s the result of my daily review of the oncology schedule, I’m always looking for trials that may be appropriate for our patients.

First, I look at those that are taking place at our cancer center. We are affiliated with a group of cancer programs in both Kansas and Missouri that is an outreach arm of the National Cancer Institute (NCI). To determine if a clinical trial may be a good fit, I conduct an informal pre-screening to see if the patient meets the unique qualifications for that specific trial. That may include reviewing the results of their genetic and genomic testing and looking for the presence of certain mutations. If none are a potential match, I look at those in the region. NCI-designated trials across the country are another option if a patient is willing and able to travel.

Occasionally, patients will request a clinical trial at a cancer center out of state if they have family near the facility, for example, and will therefore have a built-in support system. In those cases, I coordinate with that facility. Patients appreciate that we can assist with the process. And they may end up returning to us in the future, so it’s nice to keep up the relationship.

When the medical team feels a trial is a valid treatment option, the oncologist introduces the topic during the appointment. When patients express interest, I explain clinical trials in more detail.

Do you find that many people are familiar with clinical trials?
More people are coming to the clinic with at least basic cancer treatment knowledge. Some even request specific clinical trials. Other people may never have heard of them. Regardless of their level of knowledge, my goal is to educate, and I do that with open and honest communication.

I begin by explaining the basics of clinical trials, emphasizing that their involvement is 100 percent voluntary. I give patients who are interested an Informed Consent form. It details the purpose of the research, including the patient’s role, treatment to be studied, how the trial will work and risks and benefits. The form also explains how the patient is monitored, potential side effects of the treatment, the current standard of care for that type and stage of cancer, and the safeguards in place to protect participants and more. We review the form together, and I answer their questions. Sometimes, once they realize they can help others simply by participating, they are on board and sign the Informed Consent form right away; others take more time to review it.

What are some of the most common questions or concerns you hear?
I’m often asked about side effects. I let patients know that not every person is affected by every side effect. And, for every one that does happen, we have options to manage it.

Nausea and vomiting are common concerns. We have made such progress in limiting these side effects and can prescribe many medications to prevent and lessen them. We are dedicated to making patients as comfortable as possible and adjust those medications as needed.

How do you respond to someone who is unsure about committing to a clinical trial?
Sometimes, the patient or a family member has doubts. They may have heard something negative about someone else’s experience with a clinical trial. I answer their questions and suggest more information and up-to-date resources they can trust, and I always encourage them to ask enough questions to ensure they understand.

What happens once a patient decides to move forward?
Once the patient signs the Informed Consent form, a full screening is set up to determine eligibility for the trial.

As a whole, our patients have really embraced the clinical trials program. They are pleased to have access to so many clinical trials. It allows them to stay under the care of their oncologist and to include these innovative treatments in their care plans without having to travel. They really value the familiarity of staying with their medical team in their own clinic or hospital where they’ve already built those levels of trust and confidence. Staying close to home is comforting.

Do patients worry their health care team will be disappointed in them if they choose not to participate?
I assure them that will never be the case. We will always support our patients. Patients who decline to do a clinical trial will meet again with their oncologist to further discuss their treatment plan.

What advice do you have for patients about clinical trials?
Consider clinical trials as a treatment option right along with drug therapies, radiation therapy and surgery.

Ask all your questions, and then ask more! Don’t be shy. Our goal is for you to be comfortable with your treatment plan.
Multiple safeguards are in place for protection

Strict regulations and rigorous guidelines are among the many levels of safeguards that protect people who take part in clinical trials. Clinical researchers rely on these volunteers, and their safety throughout the entire clinical trials process is the number one priority. Protecting patient rights and well-being is crucial.

Another safeguard is a set of rules called a protocol. It defines a clinical trial’s eligibility criteria, specifies the tests and procedures, describes the medications and dosages, and establishes the duration of the study. Before the study begins, a scientific review panel evaluates the protocol carefully to make sure the trial is based on sound science. Regardless of their size or location, all clinics, hospitals, universities, cancer centers and medical offices that conduct clinical trials must follow the same protocol.

GROUPS PROVIDE OVERSIGHT

These safeguards and protections are overseen by three main groups, and each is responsible for different aspects of the trials.

The U.S. Food and Drug Administration (FDA) is responsible for the safety, efficacy and security of drugs and has regulated them since the 1970s. It monitors several steps in the drug development process, which requires extensive research and numerous applications before and after clinical testing. The FDA also works closely with pharmaceutical companies to ensure the integrity of the new treatments and medications.

Institutional Review Boards (IRBs) review each clinical trial’s protocols before the study begins and monitor the trial’s ongoing progress from beginning to end. Members are in charge of reducing the risk of harm when compared with possible benefits to participants. An IRB may consist of scientists, doctors, nurses, social workers, chaplains, patient advocates and other health care or community professionals.

Data and Safety Monitoring Boards (DSMBs) review the progress of a clinical trial while monitoring the participants. They also review data on the effectiveness of the trial interventions. Each trial has only one DSMB, and it is usually composed of doctors, statisticians and others who are independent of the people, organizations and institutions that are sponsoring, organizing and conducting the clinical trial. Members are experts in clinical research and clinical trials, and they can stop a trial early if safety concerns develop.

In addition to safety oversight from these groups, the government passed the National Research Act in 1974, which ultimately led to the creation of three basic ethical guidelines for clinical trials.

ADDITIONAL SAFETY GUIDELINES

To ensure compliance with all scientific and ethical guidelines, all studies are directly supervised by physicians and research experts. These regulatory requirements for drug studies address safety and efficacy issues unique to the use of drugs in clinical research and are designed to guarantee the safety of all participants in a clinical trial.

Failure to meet the FDA’s regulations can have legal and financial consequences for those conducting the research as well as for the institutions associated with the research activities.

All drugs must pass a series of tests and undergo a rigorous evaluation process by the FDA’s Center for Drug Evaluation and Research (CDER) to ensure they are safe and effective before they’re made available to the public. A team of CDER doctors, chemists, pharmacologists and other scientists analyze the medications at various stages during the approval process.

Another safeguard is the Informed Consent process, which protects participants throughout the clinical trial (see Overview, page 2). This process requires the research team to explain all the details about the trial, including the purpose, tests and treatment involved and the possible risks and benefits so people can make an informed decision about volunteering for a trial.

Understanding the four phases of clinical trials

Traditionally, clinical trials have been designed in four phases, and each phase adds another building block to the study’s foundation of knowledge. This approach allows researchers to ask and answer questions in a way that produces the most reliable information and provides the greatest protection of trial participants. The process also ensures that only treatments that have been rigorously studied are approved for the public.

1 Phase I evaluates a new drug (or other type of treatment) to see if it is safe for use in people. The goal is to determine how the drug should be given, how often and at what dosage to be most effective for killing diseased cells while causing the fewest side effects.

2 Phase II determines how well a treatment works and how safe it is in a greater number of patients.

3 Phase III compares the new treatment with the current standard of care to see if it is more effective or has fewer side effects.

4 Phase IV tests a drug that has already been FDA approved to gather more information about its effect in different populations and learn about long-term side effects.

The time it takes for the FDA to approve new therapies has been shortened considerably. Previously, approvals took about 10 years. Recently, based on successes of other trials, researchers have begun investigating and conducting seamless trials that begin in earlier phases (see Overview, page 2). Today, the FDA considers approvals at any phase of research, including as early as Phase I trials, and frequently approves therapies before many other countries’ organizations. These advances give patients access to lifesaving treatments sooner.

KEY TAKEAWAYS

- The number one priority of clinical trials is the safety of participants.
- Many levels of safeguards are in place to protect participants’ rights, safety and well-being.

PatientResource.com
Survivor beats prognosis through clinical trial

After being completely surprised by a Stage IV pancreatic cancer diagnosis, Davi D’Agostino found a specialist with expertise in aggressively treating this challenging cancer. With the help of her doctor and the Pancreatic Cancer Action Network (PANCAN), she found a clinical trial to join. She’s been in the trial ever since and feels like she doesn’t even have cancer. She’s enjoying life with friends, painting and spending time in her vacation home in France.

It was a total fluke that I was diagnosed with pancreatic cancer. In the fall of 2017, I grew concerned about a gynecological issue, so I found a well-known oncological surgeon. During our first meeting, he quoted survival statistics for ovarian cancer and recommended removing both ovaries even before performing an exam or tests. I argued to keep the unaffected ovary and he agreed to just remove one.

For some unknown reason, the surgeon included a CA 19-9 blood test with my pre-op tests, which is a biomarker for pancreatic cancer. So when I received the lab results in January 2018, I was alarmed that my score was 948, far above the normal range of 0 to 35. I called the doctor’s office, and when the doctor called a week later, he recommended a total hysterectomy. Frustrated, I refused and went back to my primary care doctor who immediately sent me for a CT, which revealed a growth on my pancreas, not my ovary.

I’m grateful the doctor ordered the CA 19-9 blood test. Without it, I would have never known. Pancreatic cancer often doesn’t have symptoms, and I didn’t have any.

Determined to find a pancreatic cancer specialist, I tapped into my 30 years of research experience as an auditor to drill down to the best treatment centers. I found one with experience diagnosing 800 cases per year. A wonderful nurse navigator arranged for me to come by train for a scan and biopsy. She made it incredibly easy. The scans showed (with more than 90 percent confidence) that I had adenocarcinoma of the pancreas that had spread to my liver.

Two days later, a liver biopsy confirmed Stage IV pancreatic cancer. The center also performed molecular profiling on my biopsied tissue and germline testing of my blood. Results revealed no germline (inherited) characteristics for pancreatic cancer. But months later, I received a report saying my tumor had, among others, a BRCA2 mutation. The doctor explained mine was a “somatic,” or acquired, mutation rather than genetically inherited, which was unusual. Most people with BRCA mutations inherit them.

The doctor said I was not a candidate for Whipple surgery. He recommended chemotherapy with the possibility of a clinical trial. He also suggested seeing a local oncologist. I did, and within five minutes the doctor was already talking about clinical trials. He acknowledged this was a very challenging and smart cancer, and he wanted me to beat it. He recommended a couple of different trials to consider after completing chemotherapy. I was open to the idea but was only prepared to think about starting chemotherapy at the time.

The chemotherapy was particularly nasty. I struggled with a lot of diarrhea, nonstop nausea, vomiting, constant fatigue and weight loss, even though my appetite was good. I made it through nine rounds, and the side effects gradually tapered off.

Although my doctor gave me information about a couple of trials, being the independent-minded person I am, I wanted to research clinical trials on my own. There were hundreds. I contacted the Pancreatic Cancer Action Network (PANCAN) for help, and they were wonderful. PANCAN personnel analyzed all of the trials I was eligible for and provided me with brief summaries for 22 trials, which was tremendously helpful. My doctor helped me narrow the choices to two that were perfect for me. Fortunately, having a BRCA2 mutation helped me qualify for a trial testing a targeted therapy, specifically a PARP inhibitor. I joined it and was the only one with a somatic BRCA2 mutation.

Although the trial is now closed, I remain in it with good results. In the meantime, I get a CT every other month. Although my doctor is concerned the treatment will stop working, I am wide open to considering another trial in the future.

Today I feel like I don’t even have cancer. I’m thrilled to continue doing what I love to do. I have a lot of living left to do, including spending time in France. I didn’t want to have any regrets, so I bought a home there and will visit several times a year.

Fill up all the time in between treatments with things you love to do. Plan things to look forward to. Focus on living. It’ll help your attitude and health.

Find the best expertise you can near you. Be willing to travel for excellent care. Don’t settle for less, especially if you have pancreatic cancer. Keep getting second opinions and even third opinions. If you have pancreatic cancer, clinical trials may be the only hope you have. Being in a clinical trial also helps other patients, so everyone benefits.
Many clinical trial-related costs may be covered

Many patients assume new treatments studied in clinical trials will be too expensive for them to participate. Frequently, this is not the case. Although there are costs associated with receiving clinical trial therapies, costs are associated with receiving any cancer treatment. Before you dismiss this valuable treatment option, make sure you understand how all the components will be paid for. Then you can make a more informed decision.

When you receive the Informed Consent form for the trial, look it over carefully. A detailed list of the costs covered by the trial and those you or your insurer are responsible for will be included. Before you sign the form, it is extremely important to address all your concerns about cost and payment. The clinical trial administrators understand this and will expect you to have questions.

Costs are typically separated into routine patient care and research. Routine patient care usually includes expenses related to doctor visits, hospital stays and some testing procedures. They are part of standard care, which would be included in any type of treatment. In a clinical trial, these are usually covered by your health insurance. Research costs, which are directly related to the clinical trial and include drugs and procedures, are typically covered by the trial sponsor.

If you are unsure if your insurance covers the expenses of a clinical trial, review your policy and contact your insurance company. Also, verify if the costs not covered through the clinical trial will be covered by your health insurance plan, or if they will be your responsibility.

Even if you don’t have insurance or are underinsured, assistance may be available. Ask the clinical trial administrators about patient assistance programs, and explore the resources in this guide (flip over this guide to see Assistance & Support, page 64). Many patient advocacy organizations may help offset the costs and navigate the often confusing financial part of cancer treatment.

Fran Castellow, MSED, Patient Advocate Foundation, believes no patient should have to struggle with financial obstacles alone. According to Fran, “Our expert case managers work alongside the patient or caregiver to identify solutions to problems surrounding insurance, medical debt and many other challenges, as well as helping them better afford their out-of-pocket costs.”

Also, learn about federal and state requirements associated with clinical trials. Some government programs may offer assistance:

- **Medicare** covers portions of clinical research studies, such as trials designed to evaluate a cancer drug’s effectiveness. Medicare Part A and/or Part B may cover some things, such as office visits and tests, in certain qualifying clinical research studies. Talk with your clinical trial administrators before proceeding to ensure you understand their recommendations, the costs and the covered expenses.

- **TRICARE** is the Department of Defense’s health care program. In partnership with the National Cancer Institute (NCI), the Department of Defense now covers participation in Phase I, II and III NCI-sponsored cancer clinical trials as a TRICARE benefit.

- The U.S. Department of Veterans Affairs (VA) allows eligible veterans to participate in NCI-sponsored clinical trials at VA medical centers.

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**Glossary**

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<tr>
<td>Case manager</td>
<td>A personal advocate who collaborates with healthcare professionals and nonmedical personnel to help patients overcome various financial, logistical and other common barriers to care.</td>
</tr>
<tr>
<td>Claim</td>
<td>A request for payment you make to your insurance provider based on the terms of your policy.</td>
</tr>
<tr>
<td>Coinsurance</td>
<td>The percentage of medical care expenses you are responsible for paying after meeting the deductible.</td>
</tr>
<tr>
<td>Copay</td>
<td>The fixed amount, according to your insurance plan, that you must pay for specific types of medical care, usually at time of service.</td>
</tr>
<tr>
<td>Deductible</td>
<td>The amount that you must pay for medical expenses before your insurance begins paying.</td>
</tr>
<tr>
<td>Eligibility criteria</td>
<td>The guidelines defining who can participate in the clinical trial based on several factors, which may include age, type and stage of cancer and treatment history.</td>
</tr>
<tr>
<td>Explanation of benefits (EOB)</td>
<td>A statement your health insurance company provides to explain which medical treatments and/or services were paid on your behalf.</td>
</tr>
<tr>
<td>Financial counselor/investigator</td>
<td>A person who works with patients and their families to reduce stress or hardships related to treatment costs. This may include setting up payment plans, finding cost-saving methods and improving access to services.</td>
</tr>
<tr>
<td>HIPAA</td>
<td>The Health Insurance Portability and Accountability Act, a law that protects the privacy of your personal medical information.</td>
</tr>
<tr>
<td>In-network</td>
<td>Health care providers or facilities associated with your health insurance plan. Their fees are typically less than out-of-network provider fees.</td>
</tr>
<tr>
<td>Informed Consent form</td>
<td>A document that contains information about the clinical trial, including the potential benefits, risks and the alternatives to the research being conducted. You are required to review the document and sign the form to enroll in a trial.</td>
</tr>
<tr>
<td>Intervention</td>
<td>A process or action that is the focus of a clinical trial. Interventions include drugs (alone or in combination), medical devices, procedures, vaccines and other products that are either investigational or already available.</td>
</tr>
<tr>
<td>Investigator</td>
<td>A person involved in a clinical trial or research study who may help prepare and carry out the protocol (plan for the study), monitor safety, collect and analyze the data and report the results.</td>
</tr>
<tr>
<td>Out-of-network</td>
<td>Health care providers or facilities not associated with your insurance plan. Their fees are typically more than in-network fees.</td>
</tr>
<tr>
<td>Out-of-pocket costs</td>
<td>Medical expenses you are responsible for paying. This may include deductibles, coinsurances and copayments for covered services, plus all costs for services not covered by your insurance plan or other entities.</td>
</tr>
<tr>
<td>Precertification</td>
<td>The process of getting approved by your insurance company for specific services, procedures or treatments before you have them.</td>
</tr>
<tr>
<td>Premium</td>
<td>The amount you pay monthly for health insurance.</td>
</tr>
<tr>
<td>Principal investigator</td>
<td>The person(s) in charge of a clinical trial who prepares and carries out the protocol (plan for the study) or research, analyzes the data and reports the results.</td>
</tr>
<tr>
<td>Protocol</td>
<td>A detailed plan of how a clinical trial will be conducted. It includes the drug or intervention the study is testing and why, who is eligible, the information that will be collected and any required testing.</td>
</tr>
<tr>
<td>Recruitment status</td>
<td>Indicates whether a clinical study is currently open (accepting participants).</td>
</tr>
<tr>
<td>Sponsor</td>
<td>The organization, institution or person (also called the trial sponsor or sponsor-investigator) who initiates and oversees the clinical trial and is responsible for analyzing the study data.</td>
</tr>
</tbody>
</table>

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Some definitions courtesy of the National Cancer Institute website (www.cancer.gov)
Many clinical trial-related costs may be covered. For more information, ask your doctor about the AbbVie M16-109 Study, or visit ClinicalTrials.gov and search “NCT03222609.”

Navitoclax is an investigational drug that is not approved by the FDA or other global health authorities. Safety and efficacy have not been established.