PANCREATIC CANCER ACTION NETWORK®

CLINICAL TRIALS

UNDERSTANDING HOW PANCREATIC CANCER CLINICAL TRIALS WORK

Pancreatic cancer patients who participate in clinical research have better outcomes. Every treatment available today was approved through a clinical trial. The Pancreatic Cancer Action Network strongly recommends clinical trials at diagnosis and during every treatment decision.

ABOUT THIS BOOKLET

The Pancreatic Cancer Action Network recommends that all patients consider clinical trials when exploring treatment options. In the fight against pancreatic cancer, clinical trials are the only way for researchers to develop new treatment options for pancreatic cancer patients, and they give patients early-access to cutting-edge treatments that may lead to better outcomes.

The Pancreatic Cancer Action Network created this booklet to educate patients about clinical trials and to guide discussions between patients and their doctors about whether participating in a clinical trial is their best choice. This booklet explains the clinical trial process and addresses common concerns regarding clinical trial participation. Some of the most common patient concerns include: receiving poor medical care, paying higher costs for care, receiving "sugar pills" or placebos, not being informed of all the potential risks involved and ability to stop trial participation.

The decision to participate in a clinical trial requires thoughtful consideration from potential participants, their families, caregivers and doctors. Questions at the end of this booklet can help guide these conversations.

If you would like further information about pancreatic cancer treatment options including clinical trials, contact Patient Central. Patient Central can perform personalized clinical trials searches based on each patient's specific diagnosis, treatment history and geographical location. You can also start your own search using our Clinical Trial Finder by visiting **clinicaltrials.pancan.org**.

Contact Patient Central toll-free at 877-2-PANCAN or by email at **patientcentral@pancan.org**. Patient Central is available Monday – Friday, 7 a.m. – 5 p.m. Pacific Time.

The glossary at the end of this booklet provides definitions for **bold** words in the booklet's text.

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UNDERSTANDING CLINICAL TRIALS

Treatment **clinical trials** are research studies that investigate new treatments or new combinations of treatments. Clinical trials play an important role in the development of new treatment options for pancreatic cancer and are necessary to determine whether new treatments developed in the laboratory are beneficial to people living with pancreatic cancer.

WHY ARE CLINICAL TRIALS IMPORTANT?

Clinical trials are the only way for researchers to make treatment progress and develop new treatment options for pancreatic cancer. In order for any pancreatic cancer therapy to be approved, it must pass through the clinical trial process to ensure that it is safe and effective for patients with pancreatic cancer. Therefore, clinical trials are an important step in the development of new treatment options. Clinical trials:

- Allow researchers to determine whether a new and potentially better treatment is safe and beneficial for patients.
- Provide patients the opportunity to receive a promising new drug or treatment.

HOW DO NEW TREATMENTS GAIN FDA APPROVAL?

The United States **Food and Drug Administration (FDA)** monitors all clinical trials to protect participants and the general public. The FDA reviews and analyzes data from successful clinical trials to determine whether an **experimental treatment** should be approved for a specific disease, such as pancreatic cancer.

Pancreatic cancer clinical trials may be carried out using either new experimental treatments or treatments already available for other conditions. Since all cancers are different, a drug that is approved by the FDA for the treatment of one type of cancer may not be approved to treat pancreatic cancer.

The drugs that are currently approved to treat pancreatic cancer were made available to patients after showing **efficacy** and safety in clinical trials.

When a drug or treatment enters the clinical trial process, it must pass through three phases of testing before becoming eligible for FDA approval. Only if the treatment proves to be safe and promising at each phase, is it allowed to proceed to the next phase of testing.

Phase I

Phase I clinical trials are the first step in testing a new treatment or combination of treatments. These trials often involve drugs that have not yet been given to humans, but have shown promise in the laboratory. Phase I trials enroll a small group of participants, typically 20 to 40 people. The goal of these trials is to determine safety, appropriate **dosage** and how the treatment is processed inside the body. Participants are closely monitored for **side effects** and doses are adjusted as needed. Often, **eligibility requirements** with regard to prior treatment are less strict in Phase I trials, allowing patients who have had multiple treatments to participate in these studies.

Phase I trials may be open to participants with any type of solid tumor, such as breast, lung and prostate tumors, rather than only to those with pancreatic tumors. Patients often choose to participate in Phase I trials when they are not eligible for later-phase trials and are not responding to **standard treatments**.

Phase II

Phase II clinical trials enroll a larger group of participants, typically 25 to 100 people. In these trials, participants generally have a specific type of disease, such as pancreatic cancer. The goal of a Phase II trial is to determine the new treatment's effect against pancreatic cancer, while further testing its safety. Some Phase II trials may be **randomized**, which means that patients are randomly assigned (by chance) to different treatment groups. These trials may involve randomization between standard treatments and the experimental treatment, or randomization between two experimental treatments.

Phase III

Phase III clinical trials test how the new treatment compares with the standard treatment. These trials enroll a large group of participants, typically 100 to 1000 or more. They are designed to determine if the new treatment is statistically more effective than the standard treatment in the group of people who participated in the study. Phase III trials are usually randomized. This means that patients are randomly assigned (by chance) to different treatment groups. Each group receives

a different treatment; some patients receive the new treatment, while others receive the standard treatment. In order to prevent bias, in some Phase III trials, neither the participant nor the doctor knows to which treatment group the participant has been assigned.

If the new treatment is found to be effective and meets safety requirements throughout all three phases, the sponsor of the trial may submit an application to the FDA asking for approval of the new treatment.

Phase IV

Phase IV trials take place after a therapy has been approved by the FDA. The treatment is observed in larger populations to determine long-term safety and cost effectiveness, and to improve the management of side effects.

THE DIFFERENCE BETWEEN PHASE AND STAGE

The phase of a clinical trial and the **stage** of cancer diagnosis both use a scale of I (one) to IV (four), creating potential confusion.

A phase is a step of clinical trial testing as described in the previous section. Stage is a measure of how far the cancer has grown in the body.

Each clinical trial has different requirements that patients must meet in order to participate, including the stage of cancer. However, the phases of clinical trials and stages of cancer are not correlated. For example, a phase II trial may be designed to accept patients with stage III or IV pancreatic cancer, or it may be designed to accept patients with stage I or II pancreatic cancer.

For more information about eligibility requirements, see the "Finding and Enrolling in a Clinical Trial" section on page 11. For more details on diagnosis and stages of pancreatic cancer, please refer to the educational booklet, *An Overview of Pancreatic Cancer*. To obtain any of the Pancreatic Cancer Action Network's complimentary educational materials, contact Patient Central toll-free at 877-2-PANCAN or email **patientcentral@pancan.org**.

TYPES OF CLINICAL TRIALS

Clinical trials can be classified as:

Treatment trials – test new treatments, new combinations of drugs or new approaches to surgery or radiation therapy. This is the most common type of clinical trial for pancreatic cancer.

Prevention trials – look for ways to prevent cancer in healthy people. These trials are not common in pancreatic cancer.

Maintenance trials – look for ways to prevent a cancer recurrence in patients who were successfully treated.

Diagnostic trials – look for better tests or procedures for diagnosing cancer.

Screening or surveillance trials – test for the best way to detect cancer in a large population.

Supportive care (quality of life) trials – look for different ways to improve comfort and quality of life for individuals with cancer.

CLINICAL TRIAL STUDY DESIGNS

In pancreatic cancer clinical trials, three main study designs are used:

Double-blind trials – neither the doctors nor the study participants know which treatment the patient is receiving. This helps to eliminate the bias doctors and patients may have toward a particular treatment.

Single-blind trials – only the doctors know which treatment the participant is receiving. This helps avoid patient bias toward a particular treatment, but allows the doctor to know which treatment is being administered.

Open-label trials – everyone involved knows which treatment is being administered.

PROTECTION AND RIGHTS OF CLINICAL TRIAL PARTICIPANTS

One of the most important goals of the researchers who conduct clinical trials is to protect the safety of clinical trial participants. To ensure participants' safety, there are several protective guidelines that researchers must follow when conducting clinical trials.

PROTOCOLS

Each clinical trial must have a unique action plan called a **protocol**. The clinical trial protocol is a study plan that contains complete details about the trial including the background and reasoning, objectives, design, methods and statistical considerations. The protocol describes what types of people may participate in the trial and details the schedule of tests, procedures, medications and dosages. Its purpose is to ensure that the study is justified, safe for participants and designed to allow the research questions to be answered. Due to the careful design of treatment protocols, clinical trials are the safest and quickest way to confirm whether new treatments are truly beneficial for patients.

INFORMED CONSENT

Part of the clinical trial protocol is a process required by the FDA called **informed consent**. Informed consent ensures that patients are given complete information about a clinical trial prior to their participation. In order to join any clinical trial, each participant must read and sign an informed consent form before any treatment or testing related to the clinical trial starts. This ensures that every participant understands his/her role and rights in the trial.

The informed consent form includes the following information:

- Trial approach (what will be done).
- Experimental nature of the trial (that the trial involves use of an unproven drug or device).
- Purpose of the trial.
- Procedures involved.
- Expected length of the trial.
- What happens during the trial and which parts of the trial are experimental.
- Possible benefits and risks of the trial.
- Other treatments that might be considered.
- Guarantee that identity will remain confidential.
- Guarantee that participants have the right to leave the trial at any time.
- Contact information in case patients have questions about the trial or patients experience side effects or other problems during the trial.

Though the FDA requires this form to be written in lay-level language, it can be difficult to understand, so it is important that the patient and his/her family members read it carefully to make sure the patient understands his/her rights before enrolling in a trial. The patient has the right to ask questions about any aspect of the clinical trial if he/she does not understand the information being presented.

INSTITUTIONAL REVIEW BOARD

An **Institutional Review Board (IRB)** is an independent committee made up of scientists, doctors, advocates and community members. The committee meets to review and monitor a hospital or research institution's clinical trials. These committees ensure that trial participants are exposed to the minimum possible risks and that the risks associated with the trial are reasonable in relation to the expected benefits. Any institution that conducts clinical trials is required to have the trials reviewed and approved by its IRB before participants can enroll. Always ask if the trial you are considering participating in is IRB-approved. The informed consent should have a date stamp on it that indicates the date of IRB approval and/or the date that this approval ends.

DATA SAFETY MONITORING BOARD

A **Data Safety Monitoring Board (DSMB)** is commonly used to further ensure the safety of participants. The DSMB is an impartial group that monitors the progress of clinical trials.

They ensure patient safety by checking for health-related problems called **adverse events** and by analyzing the safety and effectiveness of the experimental treatment before the trial is completed. If participants experience unexpected or severe side effects or if evidence shows that the risks to participants outweigh the benefits, the DSMB may stop the trial. In other cases, a trial might be stopped because trial data reveals significant benefit for patients. In these cases, the treatment that showed benefit may be made widely available to all appropriate participants through a larger trial, or the trial data will be given to the FDA for drug approval. The DSMB may be involved in all phases of trials.

PLACEBOS

In cancer treatment clinical trials, **placebos** ("sugar-pills" or inactive medication) are never used in place of the best-known standard treatment. In some randomized clinical trials, a placebo may be added to the standard treatment for comparison reasons. Participants are divided into two groups - the control group and the new treatment group. The control group would receive the standard treatment plus a placebo and the experimental group would receive the standard treatment plus the new drug. For example, in a Phase III trial, the control group might receive Gemzar® (gemcitabine) plus a placebo while the experimental group would receive gemcitabine plus a new drug. Before enrolling in a trial, participants are told whether there is a possibility of getting a placebo in addition to the standard active treatment.

FINDING AND ENROLLING IN A CLINICAL TRIAL

The Pancreatic Cancer Action Network recommends that all patients consider clinical trials when exploring treatment options. Only through clinical trials will researchers develop new and more effective treatment options for individuals diagnosed with pancreatic cancer. Since participating in a clinical trial is an important, personal decision, patients and their caregivers should work with their healthcare team to determine whether participating in a clinical trial is appropriate.

LOCATING CLINICAL TRIALS

The following resources are helpful in gathering information about ongoing trials and trial locations:

The Pancreatic Cancer Action Network

Patient Central maintains the most comprehensive and up-to-date database of IRB-approved pancreatic cancer clinical trials taking place throughout the United States. The Pancreatic Cancer Action Network has dedicated staff members who ensure that the information provided to patients is as accurate as possible. Information about these clinical trials is available to the public free-of-charge in two ways:

- Contact Patient Central for personalized clinical trials searches based on a patient's specific diagnosis including

type and stage of pancreatic cancer, treatment history and geographical location. Contact Patient Central by calling toll-free 877-2-PANCAN. Patient Central is available Monday – Friday, 7a.m. – 5p.m. Pacific Time.

- Use our Clinical Trial Finder at **clinicaltrials.pancan.org**. Through this tool, visitors can complete a series of questions about the patient's diagnosis to find available clinical trials for which the patient may qualify and to request more details about the trials they are interested in. Patient Central will send additional information about the requested trials for which the patient may qualify.

For more information on what to do after receiving a list of clinical trials, contact Patient Central and request the *Clinical Trials Next Steps* fact sheet.

Other Options

The U.S. National Institutes of Health (NIH) provides information about clinical trials at **clinicaltrials.gov**. Clinical trial listings are provided for all health conditions, not just cancer.

The National Cancer Institute (NCI), a division of the NIH, provides information specifically on cancer clinical trials by calling 1-800-4-CANCER or online at **cancer.gov/clinicaltrials**.

ELIGIBILITY

In order to participate in a clinical trial, patients must meet the clinical trial's enrollment guidelines or standard requirements. For cancer clinical trials, the standard requirements usually include:

- Type and stage of cancer
- Prior treatments received
- Age
- Medical history
- Current medical condition

Usually, all phases of clinical trials require an adequate level of physical functioning (known as **performance status**) and good major organ (liver, kidney, heart, etc.) function. In addition, some trials require that participants be off treatment for a specified length of time before participating in the trial. Other trials, like post-surgery trials, may require that patients enroll in the trial within a certain amount of time after surgery. For example, patients typically have to start treatment within two to three months after surgery.

Some clinical trials are specifically for patients who have a known **mutation** or biomarker in their tumor and/or blood. Some trials require prior molecular profiling to qualify, while others include it with participation.

Molecular profiling, also called precision medicine, can identify specific genetic mutations or biomarkers

(measurable substances that can be found in blood or tissue), which oncologists can use to determine if there are therapies to target that patient's tumor. Some patients undergo precision medicine as part of a clinical trial, through their institution or through a private company. Every pancreatic tumor is different. Patients who receive treatment based on their tumor's biological characteristics have better outcomes. The Pancreatic Cancer Action Network strongly recommends molecular profiling of your tumor to help determine the best treatment options.

Eligibility details for each trial are included in the trial protocol and are referred to as **inclusion** and **exclusion criteria**. The purpose of the eligibility criteria is to identify a patient population with enough in common to be able to determine whether or not the treatment helped.

If a patient meets the enrollment guidelines and wants to participate in a trial, he/she should contact the trial coordinator to get a full list of the eligibility criteria and to schedule a screening visit. During a screening visit, a member of the study, such as a trial nurse, will go over the full eligibility criteria and procedures, gather the patient's medical history, schedule any necessary tests and answer any questions.

LOCATIONS

Clinical trials are conducted by doctors and institutions (hospitals, academic medical centers, cancer centers, community hospitals) throughout the country. Depending on the trial, it may take place at only one institution or multiple institutions. The Pancreatic Cancer Action Network's Patient Central can help each patient locate the nearest suitable trial location.

CLINICAL TRIAL PARTICIPATION

When participating in a clinical trial, the patient works with a team of doctors, nurses, social workers, dietitians and other healthcare professionals. This team monitors the patient's health carefully, provides all necessary care and supplies specific instructions that patients must follow. Receiving treatment as part of a clinical trial may require more testing and doctor visits than receiving treatment outside of a clinical trial. Additionally, in many cases, the medical team members continue **follow-up** care with participants after the conclusion of the trial. In order for a clinical trial to produce valid results, it is essential for participants to follow the medical team's complete instructions, participate in all doctor visits and tests, take all medicines and therapies on time and complete all required logs or questionnaires.

BENEFITS AND RISKS OF CLINICAL TRIALS

Potential Benefits

- Possibility that the drugs or treatment program used in the trial will be better than currently approved treatment options.
- Care is provided by top doctors and researchers at leading healthcare facilities.
- Access to new treatments or treatment strategies that may not otherwise be available.
- Closer monitoring of the patient.
- Helping to advance treatment of the disease.

Potential Risks

- Possibility of unexpected or unpleasant side effects.
- Chance that the new drug or treatment may be ineffective or less effective than current options for pancreatic cancer.
- May require greater time commitment due to extra clinic visits for treatments or monitoring.
- Additional cost may be involved (i.e., housing and transportation, insurance payment for treatment outside covered network).

LENGTH OF CLINICAL TRIALS

All clinical trials are designed to enroll a defined number of participants in order to demonstrate **scientific validity**. The timeframe needed to enroll and then monitor participants' experiences varies for each trial. Additionally, the length of time each patient will actively receive treatment varies between trials.

DRUG DOSAGE

The dose (amount of drug given) depends on the clinical trial protocol. Fixed dose trials give all participants the same amount of drug. In other clinical trials, the dose may be determined based on the participant's total height and/or weight. Also, in some clinical trials, participants are assigned to different groups and each group receives a different dose. Additionally, Phase I trials, may use "dose escalation," which means that different participants may receive different doses to determine the highest safe dose.

SIDE EFFECTS

Side effects are unwanted effects that result from taking a drug. Common side effects of **chemotherapy** are nausea, fatigue, vomiting, constipation, diarrhea, decreased blood counts, mouth sores and hair loss. Lowered levels of certain blood cells may result in fatigue or a weakened immune system. The degree to which a patient experiences side effects can range from mild to severe. It is very important to discuss with the doctor any and all side effects that the patient experiences. In many cases, doctors can provide **supportive care** to manage any unpleasant effects of the treatment. The doctor can prescribe medications to help control side effects or can lower the dose of the treatment drug.

For more information about side effect management, contact Patient Central toll-free at 877-2-PANCAN or email **patientcentral@pancan.org** and request a copy of the Pancreatic Cancer Action Network's educational booklet, *Supportive (Palliative) Care: Quality of Life and Practical Care in Pancreatic Cancer*.

INEFFECTIVE TREATMENT AND CROSSOVER

Some trial protocols with more than one treatment group allow participants to switch to the other treatment in the trial, particularly if the first treatment does not work well. The process of switching to the other treatment is called crossover.

COSTS

There are two types of financial costs that participants may encounter when taking part in a clinical trial: research costs and routine medical care costs.

- **Research costs** include anything specifically performed for the purpose of the trial. This may include the treatment or procedure being studied and required tests. In most cases, these costs are covered by the clinical trial sponsor. The trials may be funded, or sponsored, through public institutions such as the National Cancer Institute, or privately through pharmaceutical companies, foundations or academic medical centers.
- **Routine medical care costs** include services and procedures that participants would typically receive whether or not they participate in a trial. Routine medical care may include diagnostic procedures, office visits, hospital admissions and standard treatments. The coverage for these costs varies according to state, person and health plan. Typically, the patient and/or his/her insurance plan is responsible for these costs. Starting in 2014, the Affordable Care Act (ACA) required all self-funded and fully insured health plans to provide coverage for routine medical costs for individuals who participate in an approved clinical trial. The requirement does not apply to grandfathered plans. Grandfathered plans are health plans that were in place when ACA was signed into law.

Financial costs should be discussed with the clinical trial coordinator and the patient's insurance company before enrolling in a clinical trial.

Patient Central has listings of financial, insurance and transportation resources which may help offset additional costs. To access these resources, call toll-free at 877-2-PANCAN or email **patientcentral@pancan.org**.

AFTER TREATMENT IS COMPLETED

COMPLETION OF TREATMENT AND FOLLOW-UP

After the treatment is completed, there is a period of follow-up when evaluation of effectiveness continues. Some clinical trials require testing during follow-up. The length of follow-up and the tests needed differ for each trial and are specified in both the trial protocol and the informed consent form. Patients are given a copy of the informed consent form before they agree to participate so they can refer to it at any point during their trial participation (see page 8).

EVALUATION OF TRIAL RESULTS

Before a clinical trial begins, researchers define **clinical endpoints** or specific measures of a trial's impact. Some clinical endpoints measured are efficacy, quality of life and **toxicity**.

- Efficacy – getting the desired positive result or benefit. Common efficacy endpoints include overall survival and disease-free survival. Overall survival measures whether a participant is still living at defined time periods during the clinical trial. Disease-free survival measures the length of time that the patient survives without any signs or symptoms of the cancer, after the primary treatment ends. Also, treatments can prove effective when participants have a complete or partial response. A complete response means there is no sign of the tumor on tests such as computed tomography (CT) scans or by measurement of tumor markers. A partial response usually means that the size of the tumor, or the extent of cancer in the body, decreased by a specified amount. Sometimes, a treatment is considered successful if the patient achieves stable disease, meaning that the tumor has neither grown, nor reduced in size. An unsuccessful treatment may result in progression or progressive cancer, meaning the tumor continues to grow.
- Quality of life – evaluation of the person's overall well-being. This evaluation can include the ability to live daily life as usual, symptoms such as pain, side effects of treatment, the ability to work, emotions and other factors. A participant's ability to carry out normal daily functions is called the **performance level** or performance status and is measured using various scales.
- Toxicity – measure of side effects of a drug or treatment. Doctors and researchers use a grading system to gather, record and understand information about side effects during a clinical trial. The scale runs from grade 1 to 4. Grade 1 indicates mild side effects and grade 4 indicates life-threatening side effects.

QUESTIONS TO ASK

Questions to ask when thinking about participating in a clinical trial:

- Are there pancreatic cancer specific clinical trials available at this hospital/institution?
- How can I find out more about these clinical trials?
- Do you know of any other trials that are available to me at other locations?

Questions to ask about the trial:

- What is the purpose of the trial?
- What are the eligibility criteria?
- What phase is the trial?

- Why do researchers believe the new treatment being studied may be effective?
- Has this treatment been studied before? What were the results of previous trials?
- Who is sponsoring the trial? Who has reviewed and approved it?
- How are the trial results and the participants' safety checked?
- How long will the trial last?
- What will I have to do if I participate?
- How many study arms does the trial have? What treatment does each arm receive?
- Will I know if I am taking the experimental treatment?

Questions to ask about possible risks and benefits:

- What are the expected short-term and long-term benefits of this treatment?
- What are the short-term and long-term risks, such as side effects?
- How can I best control side effects while I am participating in the trial?
- How do the benefits and risks of the trial compare with benefits and risks of other treatment options?

Questions to ask about medical care:

- What kinds of therapies, tests or procedures will I receive during the clinical trial?
- Will I be able to take my regular medications?
- Who will be in charge of my care? Will I be able to see my own doctor?
- Where will my treatment take place? Will I have to be in the hospital? If so, how often and for how long?
- How often will I need to come to the clinic for treatments or tests?
- How will I know if the treatment is working?
- How does the care compare with what I would receive outside the trial?
- Is there any pain or other side effect associated with the therapies, tests or procedures? If so, how severe, and how long will the pain or side effects last?
- How often and for how long will I receive the treatment?
- How long will I need to remain in the trial?
- Will there be follow-up after the trial? For how long and what will it consist of?
- Will I be expected to fill out any questionnaires (such as quality of life surveys)? If so, how much time will these questionnaires take and how often will I complete them?

QUESTIONS TO ASK YOURSELF

Personal issues:

- How will the trial affect my daily life?
- What treatment plan will I choose if I do not join a clinical trial?
- Is the time required to participate in a clinical trial reasonable for me and my family?
- What support services are available to me and to my family?

Cost issues:

- Will I have to pay for any part of the trial, such as tests or medication? If so, what will the cost be?
- What is my health insurance likely to cover or not cover?
- Who can answer questions from my insurance company or managed health care plan?
- Will my travel costs be covered?

GLOSSARY

Adverse event: A health-related problem that occurs during treatment that may or may not be related to the treatment. Adverse events may be mild, moderate or severe. All adverse events must be reported to the FDA.

Chemotherapy: A type of treatment that uses drugs to kill cancer cells.

Clinical endpoint: The specific medical measure(s) of a treatment's impact.

Clinical trial: A research study that involves human participants and is designed to answer scientific questions about treating and preventing a disorder or disease, such as pancreatic cancer.

Data Safety Monitoring Board (DSMB): An impartial group that oversees an ongoing clinical trial and reviews the results to determine if they are acceptable. This group determines if the trial should be modified or closed at any time during the trial.

Dosage: A determined amount of a prescribed drug.

Effectiveness/Efficacy: The ability of a treatment to produce the desired beneficial response. The efficacy of a treatment is evaluated during Phase II and Phase III clinical trials.

Eligibility requirements: A set of basic qualifying standards that participants must meet in order to participate in a clinical trial. Participants are selected by these inclusion and exclusion criteria.

Exclusion criteria: A set of standards used to determine participants who are not eligible to participate in a clinical trial.

Experimental treatment: A drug, medical device or combination of treatments being tested in humans for use in a specific disease or disorder. An experimental treatment for pancreatic cancer may or may not already have FDA approval to treat another disease or condition. Also called an investigational treatment/therapy.

Food and Drug Administration (FDA): A United States government agency that promotes and protects public health by ensuring the safety and effectiveness of medical treatments and devices.

Follow-up: The monitoring of a person's health over time after treatment has ended.

Inclusion criteria: A set of standards used to select participants who are eligible to participate in a clinical trial.

Informed consent: A process by which a person learns key facts about a clinical trial, including potential risks and benefits, before deciding whether or not to participate. The informed consent process continues throughout the trial.

Institutional Review Board (IRB): A group of scientists, doctors, clergy, advocates and consumers at each health care facility that protects the participants by reviewing and approving the action plan for every clinical trial. The IRB checks to see that the trial is well-designed and does not involve unreasonable risks.

Mutation: A change in the DNA of a cell. Certain mutations can lead to cancer. Mutations can be inherited or can occur over the course of a lifetime. Cancer cells also develop mutations over time, some of which may be able to be targeted by specific treatments.

Performance level/status: A measure of how well a participant is able to perform ordinary tasks and carry out daily activities.

Placebo: A substance containing no active medication that is used as a control in a clinical trial to determine the effectiveness of a drug. Placebos are generally not used alone in cancer clinical trials.

Protocol: An action plan that contains all the guidelines that must be followed within a particular clinical trial, including the number of participants, eligibility requirements, what treatments are provided and how often, and how and what information will be gathered. Clinical trial protocols are carefully designed to protect participants and answer specific research questions.

Randomize: The random or chance assignment of clinical trial participants into different treatment groups; neither the researchers nor the participants can choose which group individuals are placed in. Randomization ensures that groups will be statistically similar so the treatments delivered can be compared objectively and without bias.

Scientific validity: An objective index by which the accuracy of a test or procedure is measured.

Side effect: An undesired effect of a treatment. Problems occur when a treatment damages healthy cells and has a negative impact on the body.

Stage: A measure of how far the cancer has grown using size of the tumor, lymph node involvement and locations to which it has spread. Stages range from I to IV, with I describing the earliest form of cancer.

Standard treatment: The most widely used and accepted treatment in the medical community. This is the minimum treatment that healthcare providers are obligated to provide to patients.

Supportive care: A medical approach to care that serves to prevent, treat or eliminate symptoms and stress of serious illness, regardless of prognosis. This type of care may include surgery, chemotherapy or radiation therapy, if their intent is to alleviate pain and discomfort. Talk to the doctor to find out which treatments are most beneficial for each individual survivor.

Toxicity: Side effects of a drug or treatment.

The Pancreatic Cancer Action Network thanks the Patient Services Committee members of our

SCIENTIFIC AND MEDICAL ADVISORY BOARD

for providing their medical expertise in reviewing this booklet. These members are experts from such institutions as MD Anderson Cancer Center, Memorial Sloan-Kettering Cancer Center, Virginia Mason Medical Center, etc.

To see all of our Scientific and Medical Advisory Board members, visit pancan.org/SMAB.

Other booklets in the Pancreatic Cancer Action Network's educational library

Want to know more about any of the services we offer? Contact Patient Central, Monday through Friday, 7 a.m. to 5 p.m. Pacific Time.

Call toll-free **877-2-PANCAN**
Email **patientcentral@pancan.org**

Because of the philanthropy of generous friends, we are able to provide all of our resources and services to you, ***free of charge.***

The information and services provided by the Pancreatic Cancer Action Network, Inc., are for informational purposes only. The information and services are not intended to be substitutes for professional medical advice, diagnosis or treatment. If you are ill, or suspect that you are ill, see a doctor immediately. The Pancreatic Cancer Action Network does not recommend nor endorse any specific physicians, products or treatments even though they may be mentioned in this booklet. In addition, please note that any personal information you provide to the Pancreatic Cancer Action Network's Patient Central during telephone and/or email consultations may be stored in a secure database to assist the Pancreatic Cancer Action Network, Inc., in providing you with the best service possible. Portions of the constituent data stored in this database may be used to inform you about future programs and services of the Pancreatic Cancer Action Network, Inc., and may be provided in aggregate form to third parties to guide future pancreatic cancer research and treatment efforts. The Pancreatic Cancer Action Network, Inc., will not provide personal identifying information (such as your name or contact information) to third parties without your advanced written consent.

PS201 REV–10/18

Wage Hope is the rallying cry of the Pancreatic Cancer Action Network. It is our charge to accelerate progress in the fight against pancreatic cancer — no matter what it takes. We are here so no one has to face a pancreatic cancer diagnosis alone, and we will never surrender in our pursuit to change the course of this disease.

PATIENT SERVICES

We Wage Hope with free comprehensive services individualized for each pancreatic cancer patient. We connect each patient or family member to our Patient Central, which provides information about the disease, treatment options, clinical trials searches, diet and nutrition, Know Your Tumor® precision medicine service and much more.

SCIENTIFIC RESEARCH

We Wage Hope through research that has the greatest potential to achieve breakthroughs. We fund talented investigators conducting innovative research. We seek to grow the number of researchers dedicated to pancreatic cancer and foster collaboration across disciplines and institutions — with the goal of improving patient outcomes and extending survival.

GOVERNMENT ADVOCACY

We Wage Hope with a strong presence in Washington, D.C., and relentless grassroots advocacy. We advocate aggressively for more federal support for pancreatic cancer research by working year-round with elected officials. Our annual Advocacy Day efforts on Capitol Hill reinforces this urgent funding need.

COMMUNITY ENGAGEMENT

We Wage Hope by motivating a national network of volunteers. Through volunteer-led events like PurpleStride, our volunteers not only raise awareness for pancreatic cancer but also raise much-needed funds to support the mission of the organization. Throughout their communities, our volunteers also share information about our patient services, garner ongoing media attention and alert their elected officials about the urgent need to fund pancreatic cancer research.

ACTION FOR PATIENTS BEGINS HERE

Founded in 1999, the Pancreatic Cancer Action Network (PanCAN) is a nationwide network of people dedicated to working together to advance research, support patients and create hope for those affected by pancreatic cancer. We are determined to drive progress and improve patient outcomes.

In order to meet our ambitious goals, we aggressively advocate for more federal research funding of medical breakthroughs in prevention, diagnosis and treatment of pancreatic cancer; offer innovative patient services; and engage our grassroots army to raise awareness and drive fundraising nationally.

And through our Patient Central, we provide extensive individualized support and hope. Our Patient Central connects patients, their caregivers and family members to reliable information and resources. Our highly educated and expertly trained staff's passion is equaled only by their depth of knowledge about pancreatic cancer.

To learn more about our free, personalized resources and services, visit pancan.org or call 877–2–PANCAN.

PANCREATIC CANCER ACTION NETWORK®

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