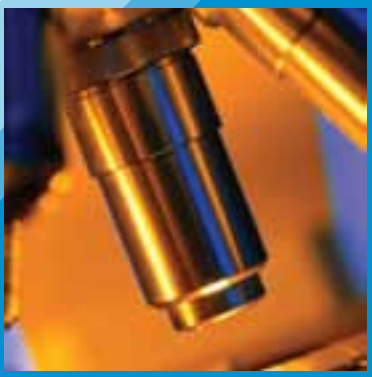
Mesothelioma Applied Research Foundation

Mesothelioma Applied® Research Foundation
research - education - support - advocacy

# MESOTHELIOMA CLINICAL TRIALS

## INFORMATION FOR PATIENTS AND FAMILIES

**IDENTIFYING AND EVALUATING EXPERIMENTAL TREATMENTS**



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## PHASES OF A CLINICAL TRIAL

**NOTE:** A clinical trial can be entered during any of its three phases, provided the patient meets eligibility criteria.

| **PHASE 1** |
|---|
| To determine the maximum dose tolerated with acceptable side effects |
| To test a new intervention (e.g.; surgical trial) |
| To determine the effect of this drug on cancer and the human body |
| Observing patient response to the drug |
| **PHASE 2** |
| Builds upon what is learned during the Phase 1 trial |
| Focus is on response to this therapy with a particular cancer |
| Side effects continue to be monitored |
| **PHASE 3** |
| To determine if the new treatment or intervention is better than the standard of care |
| If successful this may result in an FDA approval |



## MESOTHELIOMA AND CLINICAL TRIALS

Mesothelioma is a rare cancer diagnosed each year in approximately 3,500 people in the United States. To date, there is only one FDA-approved treatment for patients with mesothelioma.

In 2004, the combination of pemetrexed (best known as Alimta) and cisplatin was approved for the treatment of mesothelioma following the completion of a randomized controlled phase III clinical trial. The trial, which enrolled 456 participants, reported a 40% response rate, and showed increased survival as compared to cisplatin alone. This breakthrough advance was met with wide-spread excitement, because prior to the introduction of this combination of agents, mesothelioma was thought to be resistant to chemotherapy. The Alimta trial demonstrated that patients with mesothelioma can and do respond to treatment.

We now refer to this regimen as first-line therapy and, in the last decade, thousands of mesothelioma patients have benefited from this development.

The participation of patients who volunteered for the various phases of the Alimta clinical trial was essential in bringing this drug to market and making it available to future generations. Although, currently there is no FDA-approved treatment option following this first-line therapy, clinical trials offer patients the opportunity to try new therapies, while helping develop potential breakthroughs in the treatment of mesothelioma.

# IS A CLINICAL TRIAL THE RIGHT CHOICE FOR ME?

While there is no question that without mesothelioma clinical trials the development of new procedures and medicines would come to a virtual standstill, this may not be of much concern to a newly diagnosed mesothelioma patient facing a prognosis of a short median survival time.

It is true that clinical trials are somewhat altruistic, because they benefit future patients, but this shouldn't be the primary motivation for participating in trials. With only one, non-curative FDA-approved treatment for mesothelioma in the medical kit bag, mesothelioma clinical trials are often the most effective and, sometimes, the only way a patient can access innovative treatment options.

When deciding whether a clinical trial is the right choice for you, it is wise to ask questions and to fully understand the risks and expected benefits before signing the informed consent form.

| ✓ | Questions to ask include: |
|---|---|
| | What is the purpose of the trial? |
| | What tests and treatments will be used? |
| | What is the track record, if any, of the experimental treatment? |
| | What are the benefits, risks and side-effects in contrast to other treatment choices? |
| | What steps will be taken to monitor safety and who will be responsible for actions in the event of a problem? |
| | How long will the trial take and how long will I need to participate? |
| | Can I opt out of the trial and under what conditions? |
| | Who will conduct the trial and what are their credentials? |
| | What portion of the trial is subsidized and by whom? |
| | What drugs will be used during the clinical trial? Are these covered by the study? |
| | What portion of my treatment will my insurance cover and how much will I be responsible for? |



> "mesothelioma clinical trials are often the most effective and, sometimes, the only way a patient can access innovative treatment options"

If you are a surgical patient, some additional questions to ask might include:

- How do your stage and histology (epithelial, biphasic or sarcomatoid) impact upon the expected results?
- Is there an opportunity to try an intervention or drug under investigation at the time of surgery that might have a positive impact on my survival?
- Is there an experimental intervention that might lessen some of the expected side effects?

If you are not a candidate for surgery you will want to learn about:

- Pemetrexed and cisplatin and what you can expect to gain from this combination of drugs alone
- Consider a trial that delivers a new drug in addition to, or following standard treatment with pemetrexed and cisplatin.

In either instance, due to varied guidelines, clinical trial eligibility largely depends on the patient's previously administered treatments. To maximize the availability of treatment options, ***it is crucial for you to know about all treatments available prior to beginning any treatment regimen***, experimental or not.

## WEIGHING THE RISKS VS. BENEFITS

The primary risk of a clinical trial is that it may not work and the patient may continue to get worse. Since one of the primary objectives of a clinical trial is to establish the safety of the treatment, some participants may experience side-effects that could range from being uncomfortable to being life-threatening.

When researching and preparing for a clinical trial, some points you may want to consider include:

- How is the clinical trial treatment different than the standard treatment?
- Are there any side-effects that are specifically associated to the treatment?

Despite the experimental nature of clinical trials, the institutions that offer them are committed to minimizing the above risks as much as possible. The goal, after all, is to find a treatment that will help the patients, not harm them. This process is aided by the requirement that clinical trials be approved by two boards, one being the Institutional Review Board (IRB), prior to opening for enrollment.

Clinical trials must adhere to the same legal and ethical standards that apply to general medical practices and most American clinical trials are registered with, and regulated by, the United States government to ensure consistency and enforcement of standards.

> “Clinical trials must adhere to the same legal and ethical standards that apply to general medical practices”



## YOU DECIDED TO ENROLL IN A CLINICAL TRIAL: NOW WHAT?

Following your decision to enroll in a clinical trial, there are a few more considerations to keep in mind:

- Keep the lines of communication open between you and the doctor who has been overseeing your care to this point. Keep them informed of your progress, side-effects, and results.
- The great news is that you will receive regular and careful medical attention from the research team working on your clinical trial. That will include doctors, nurses, and other health professionals. You will be followed very closely by the research team.
- You also have the support of the Mesothelioma Applied Research Foundation. Our nurse practitioner can assist you in identifying clinical trials that might be appropriate based upon your personal health history, as well as guide you though all stages of your disease. Your well-being and support of you and your loved ones remains our top priority.
- Always remember that you are not only getting the latest in available treatments, but are also furthering the field of mesothelioma research for generations to come.

# ABOUT THE MESOTHELIOMA APPLIED RESEARCH FOUNDATION

The Mesothelioma Applied Research Foundation is the only 501(c)3 non-profit organization dedicated to eradicating mesothelioma and easing the suffering it causes by:

- funding the highest quality and most promising research projects from around the world through our rigorous peer-reviewed process;
- helping patients connect with national mesothelioma experts and obtain the most up-to-date information on treatment options;
- advocating in Washington D.C. for federal mesothelioma research funding to stop this national tragedy.

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