PASS IT ON

For Individuals and Families With a History of Cancer

Newsletter of the Cancer Genetic Counseling Service

THE LOWDOWN ON CLINICAL TRIALS

BY COURTNEY KOKENAKES, GENETIC COUNSELOR

Clinical trials are scientific studies designed to test new and improved ways to treat and manage cancer. In order to understand how clinical trials may benefit you, it is important to appreciate how they work.

The purpose of clinical trials is to develop improved treatments that cure or control cancer, while providing an improved quality of life. They are necessary to identify more effective interventions before they can be considered standard of care and offered to other patients. Standard of care is defined as the best treatment we have at this time, based on previous research. Clinical trials contribute to knowledge and progress towards treating cancer.

For many patients, clinical trials may be a potential option to access experimental and cutting edge therapy. If a new treatment proves effective in a study, it may become a new standard treatment that can help future patients. Because of progress made through clinical trials, many people treated for cancer are now living longer, and experience less side effects from their treatment. [continued on page 2]

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Most of the time when you take part in a clinical trial, you will only be enrolled in one phase of the study. Treatments move through the various phases, but patients do not. Each phase of a clinical trial is designed to study a different aspect of the new treatment. Learn more about each phase by reading the figure below!

PHASES OF CLINICAL TRIALS

Before considering whether a clinical trial may be right for you, it's important to have an understanding of the various clinical trial phases. There are typically three main phases. If a treatment is deemed safe or successful in one phase, it moves on to the next phase.

PHASE 1

- Relatively small, usually less than 30 individuals enrolled
- Designed to find a safe dose and best method for administering the new treatment (ex. oral pill vs. injection)
- Researchers also study how the treatment affects the body
- If a safe dose is identified, the treatment will move on to further studies in Phase 2

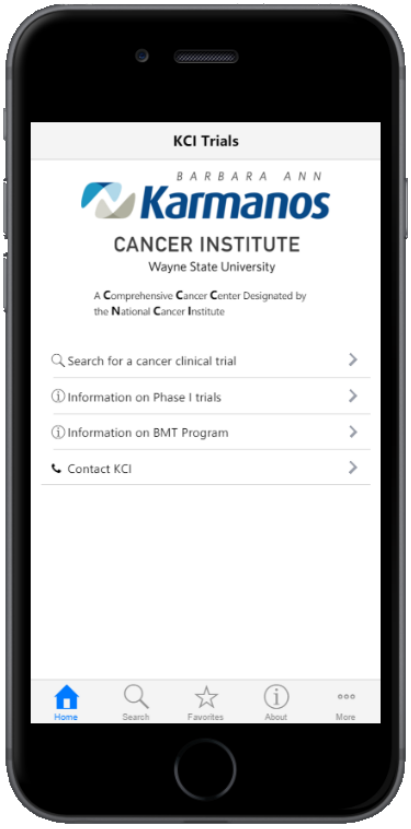
PHASE 2

- More patients are enrolled (usually 100 or less)
- Goal is to learn more about how this new treatment might affect the body and about any potential side effects
- More focus on how the treatment works for certain types of cancer
- If the treatment is found to have some benefit, it moves on to Phase 3

PHASE 3

- Usually much larger, enrolling between hundreds to thousands of patients
- Aim to compare the new treatment with the current treatment or standard of care
- Some studies include Phase 4 trials which aim to study long- term benefits and side effects after the treatment is FDA approved.

Did you know that The Barbara Ann Karmanos Cancer Institute has one of the largest clinical trials program in the United States? More than 100 promising new cancer therapies, which are not yet approved by the FDA, can be found at Karmanos through various clinical trials. Karmanos has patients actively participating in more than 800 clinical trials, which are developed and sponsored by our own physicians and researchers, major pharmaceutical companies or national cooperative group programs funded by the National Cancer Institute (NCI). You can learn more by asking your Karmanos healthcare provider or by visiting the Karmanos Clinical Trials website. The Barbara Ann Karmanos Cancer Institute also has a new app for the iPhone® and iPad®, giving you information about our cutting-edge, cancer clinical trials. The KCI Trials App is FREE and available on the App Store℠!



Importantly, there are many different types of clinical trials and not all of these studies are focused on cancer treatment. In fact, there are a number of clinical trials for both affected and unaffected individuals who may have tested positive for a genetic mutation or those that have a higher risk to develop cancer. Many of these studies focus on how to best screen and manage individuals with various hereditary cancer syndromes and/or family histories of cancer. **We encourage all of our patients who have tested positive for a genetic mutation to visit clinicaltrials.gov to see if there might be a study that could benefit you or your family.** By participating in a clinical trial, you may be contributing to research that might save lives in the future!

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GENE SPOTLIGHT: *CDH1*

WHAT IS HEREDITARY DIFFUSE CANCER SYNDROME?

Mutations in the *CDH1* gene are associated with a condition called Hereditary Diffuse Gastric Cancer syndrome. Individuals with this syndrome have a higher chance of developing certain cancers including diffuse gastric cancer, lobular breast cancer, and potentially colorectal cancer. An individual with a *CDH1* mutation will not necessarily develop cancer in his/her lifetime, but the risk for cancer is increased over the general population risk. If you have a *CDH1* mutation, there are steps you can take in hopes of preventing cancer or detecting it an earlier and more treatable stage.

CANCER RISKS FOR CDH1

GASTRIC	BREAST
MALES: 67–70%	FEMALES: 39–52%
FEMALES: 56–83%	

RECOMMENDATIONS FOR CDH1 MUTATIONS

Given the elevated risks for those with a *CDH1* mutation, specific recommendations for screening and reducing cancer risk are available. Diffuse gastric cancer is a type of adenocarcinoma that invades the stomach wall without forming a distinct tumor mass, which makes it difficult to detect with traditional screening methods such as upper endoscopy. Therefore the recommendation for *CDH1* mutation carriers is to have a preventative gastrectomy (surgical removal of the stomach) between ages 18-40. Women are recommended to initiate enhanced breast cancer screening at 30 years of age which includes an annual mammogram and a breast MRI, alternating every six months.

WHO ELSE IN MY FAMILY IS AT RISK FOR A CDH1 MUTATION?

CDH1 mutations are inherited in an autosomal dominant fashion meaning that both males and females have an equal chance to carry and transmit this mutation to their children. An individual who carries this mutation has a 50% chance of passing the mutation to each of his or her children. This same 50% risk also applies to siblings of someone with a *CDH1* mutation. The benefit of testing for the family is that those relatives who test negative for the mutation can be spared any unnecessary screening and/or surgery. For those that test positive for the familial mutation, he or she would follow the recommended guidelines mentioned above.

Infographic by Lauren DeMeyer

REMINDER: We offer annual genetic counseling appointments for any individual who has a positive genetic testing result. These appointments give us the chance to update you regarding any new information learned about that gene. Sometimes the screening recommendations or known cancer risks change over time. In addition, it gives us the opportunity to update your family history, review the importance of testing your relatives for your cancer gene mutation, and help facilitate such testing for your family members.

You can call us at 313-576-8748 to schedule your annual Genetics follow-up appointment!

COVID-19: To learn more about Karmanos Policies on COVID-19, please visit karmanos.org/karmanos/coronavirus-covid-19

The Cancer Genetic Counseling Service is still seeing patients during this time; however, all Genetics visits are being conducted over the telephone or via our video-chat platform. If you have questions about upcoming genetic counseling visits or scheduling, please email us at genetics@karmanos.org or call 313-576-8748.

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