

One of the goals for The Cancer Team at Bellin Health is allowing patients access to the latest therapies closer to home by promoting the availability of clinical trials to oncologists in the community setting. The Cancer Team is committed to utilizing an integrated approach to cancer care for each cancer patient. The patient's cancer-care team — medical oncologist, radiation oncologist, and surgeon will collaborate to ensure delivery of the highest quality and most advanced care to our patients.

Bellin Health and The Cancer Team know that patients respond best to treatment when they receive integrated care close to home, where they enjoy the support of family and friends and keep their daily routines throughout the treatment process. Thus, we need to be involved in nearly every aspect of cancer care. The Cancer Team believes that all cancer patients should:

- Have access to integrated, outpatient care in the community where they live
- Receive high-quality, evidence-based, comprehensive care
- Have access to clinical trials studying the latest promising therapies

Providing novel therapies to patients in the community setting and participating in landmark clinical trials are core to the mission of Bellin Health and The Cancer Team. We are committed to treating the cancer patient through the collective use of our expertise, resources, and multi-pronged approach to cancer treatment. As we apply world-class evidence-based Level I Pathways, provide the latest clinical trials in the community setting, and use healthcare technology to enhance the overall patient experience, we offer the vision and resources to help ensure the long-term success of community-based cancer care.

The Cancer Team is eager to work with other physicians who share our vision — for our patients and for the health of the community oncology practice, where the vast majority of Americans fight cancer.

Clinical trials are critical to the scientific advancement of cancer care.

Clinical trials, or research studies, are studies of new or experimental treatments in patients. They are a critical component of any effort to expand treatment options for people with all types of cancer. Clinical trials rely on patient volunteers to investigate new and different ways to treat the disease. They often use investigational drugs — also called study drugs — and experimental ways of giving drugs to determine if they are safe and effective.

As all new therapies should be evaluated through clinical trials, increasing patient participation in clinical trials can accelerate the identification and development of promising new anti-cancer therapies. Patients with access to therapies that are still in development, may have a better chance of successfully treating their particular type of cancer.

Why Are Clinical Trials Important?

Clinical trials contribute to the overall knowledge and progress made in developing new therapies. If you agree to participate in a clinical trial, you may benefit from the research study, while receiving the best current standard treatment as well.

Clinical trials are conducted to collect data regarding the safety and efficacy of new drug and device development. There are several steps and stages of approval in the clinical trials process before a drug or device can be sold in the consumer market, if ever.

Drug and device testing begins with extensive laboratory research which can involve years of experiments in animals and human cells. If the initial laboratory research is successful, researchers send the data to the Food and Drug Administration (FDA) for approval to continue research and testing in humans.

Once approved, human testing of experimental drugs and devices can begin and is typically conducted in four phases. Each phase is considered a separate trial, and after completion of a phase, investigators are required to submit their data for approval from the FDA before continuing to the next phase.

Human Clinical Trial Phases

Clinical trials are structured into four phases.

Phase I studies assess the safety of a drug or device. This initial phase of testing, which can take several months to complete, usually includes a small number of healthy volunteers (20 to 100), who are generally paid for participating in the study. The study is designed to determine the effects of the drug or device on humans including how it is absorbed, metabolized, and excreted. This phase also investigates the side effects that occur as dosage levels are increased. About 70% of experimental drugs pass this phase of testing.

Phase II studies test the efficacy of a drug or device. This second phase of testing can last from several months to two years, and involves up to several hundred patients. Most phase II studies are randomized trials where one group of patients receive the experimental drug, while a second “control” group receives a standard treatment or placebo. Often these studies are “blinded” which means that neither the patients nor the researchers know who has received the experimental drug. This allows investigators to provide the pharmaceutical company and the FDA with comparative information about the relative safety and effectiveness of the new drug. About one-third of experimental drugs successfully complete both Phase I and Phase II studies.

Phase III studies involve randomized and blind testing in several hundred to several thousand patients. This large-scale testing, which can last several years, provides the pharmaceutical company and the FDA with a more thorough understanding of the effectiveness of the drug or device, the benefits and the range of possible adverse reactions. 70% to 90% of drugs that enter Phase III studies successfully complete this phase of testing. Once Phase III is complete, a pharmaceutical company can request FDA approval for marketing the drug.

Phase IV studies, often called Post Marketing Surveillance Trials, are conducted after a drug or device has been approved for consumer sale. Pharmaceutical companies have several objectives at this stage: (1) to compare a drug with other drugs already in the market; (2) to monitor a drug’s long-term effectiveness and impact on a patient’s quality of life; and (3) to determine the cost-effectiveness of a drug therapy relative to other traditional and new therapies. Phase IV studies can result in a drug or device being taken off the market or restrictions of use could be placed on the product depending on the findings in the study.

Who Participates?

Clinical research participants are men and women of all ages and races. Researchers are starting to understand that some drugs work differently in men, women, children, or minorities. It is important to develop drugs and procedures that work well for everyone. Trials can be for healthy volunteers or participants with serious medical conditions.

When thinking about joining a study, remember that it is being done to learn what works, what doesn’t work, or what works best. However, it is possible that subjects may not receive any benefit from the study and no guarantees will be made.

Making sure participants are safe is the top priority in all clinical research studies. For safety reasons, not every person will be eligible for every study. Patients considering participation in clinical research should talk about it with their doctors and medical caregivers.

What do you have to do to Participate?

Everyone must sign an Informed Consent Form in order to participate. You must also meet the inclusion/exclusion criteria set for the particular study. You must be willing to follow the directions and instructions of the research team. You must be willing to attend all study visits and you must take any study medications or complete any procedures exactly as directed.

Clinical research/trials are not for everyone, and sometimes new drugs or medical devices turn out not to work. However, many times the research leads to important medical advances that can benefit participants and future patients.

Who Performs Research?

Research is a collaboration between doctors, hospitals, pharmaceutical and sponsor companies. The research is performed by health care professionals in every specialty, from family practitioners to surgeons. It can be performed at large hospitals or small community clinics.

Why is Research Important?

From the medicines you pick up at the pharmacy to the most advanced surgery, modern medicine would not be possible without clinical research. Without research, medicine and technology cannot move forward. In fact, the government requires that clinical research be done on every new medicine before doctors can prescribe it.

Clinical research helps to take the guesswork out of designing new drugs and medical devices. A clinical research study allows doctors to find the most effective method of care.

Participant Resources and Support

Many changes have occurred over the years to protect people who decide to join a research project. If you decide to take part in research, you cannot be forced to do something you do not want to do, and you have the right to leave a study at any time, for any reason. Federal laws are in place to protect participants' rights.

The Bellin Health System Inc., Corporate Institutional Review Board is the group that reviews all research projects before they begin to ensure they are as safe as possible and that your rights are protected. No study can begin without their approval. The group includes doctors, nurses, hospital staff and community members, and can answer questions about your rights if you are thinking about taking part in research.

Cancer Screening

The following are guidelines for cancer screening. These are a basic health guideline to follow and to discuss with your health care provider.

Breast screening

- Breast self-exams (optional) after age 20
- Clinical breast exams (CBE) every three years in 20s and 30s and every year over the age of 40
- Yearly mammograms starting at the age recommended by your physician

Cervical Screening

- Pap smear every year with regular pap test (or every 2 years with liquid based pap test) 3 years after first sexual intercourse or at age 21
- After age 30 with three normal pap test results in a row, screening may be reduced to every 2-3 years
- May be screened every 3 years over age 30 with liquid based pap test
- Women age 70 and over with three consecutive normal pap tests may discontinue screening
- Women with a total hysterectomy (removal of uterus and cervix) may stop being screened, unless hysterectomy was due to cancer or precancer

Prostate Screening

- Men should talk with their doctor about beginning a screening regimen. If they decide to begin one, the following may be used:
 - Beginning at age 50, a yearly PSA (prostate-specific antigen) blood test and a digital rectal examination (DRE)
 - Men at higher risk (African-American and men with strong family history of prostate cancer) may begin at age 45
 - Men with multiple first degree relatives with prostate cancer history may begin screening at age 40

Colorectal Screening

- Men and women beginning at age 50 should have one of the following:
 - Colonoscopy every 10 years
 - Double-contrast barium enema every 5 years
 - Yearly Fecal Occult Blood Test (FOBT) plus flexible sigmoidoscopy every 5 years

Skin Screening

- The American Cancer Society recommends a cancer-related checkup by a physician, including a skin examination, every three years between the ages of 20 and 40, and annually for those 40 and older.

Lung Screening

- In recent years, efforts have been made to improve lung cancer screening with newer techniques; however, further research is needed to evaluate the effectiveness of these techniques as screening tools for lung cancer.

For more information on early detection and screening, see the following websites:

[United States Department of Health and Human Services - U.S. Preventive Services Task Force \(USPSTF\)](#)

For the most current screening guidelines refer to the U.S. Preventive Services Task Force (USPSTF) website.

[National Cancer Institute](#)

Screening and Testing to Detect Cancer

[American Cancer Society - Early Detection](#)

If you can't prevent cancer, the next best thing you can do to protect your health is to detect it early. Recognizing symptoms, getting regular check-ups, and performing self-exams are just a few ways you can do this. Refer to the resources above to find out more.

[Wisconsin Department of Health Services-Wisconsin Well Woman Program](#)

The Wisconsin Well Woman Program (WWWP) provides preventive health screening services to women with little or no health insurance coverage. Well Woman pays for mammograms, Pap tests, certain other health screenings, and multiple sclerosis testing for women with high risk signs of

multiple sclerosis. The program is administered by the Wisconsin Department of Health Services, Division of Public Health, and is available in all [72 Wisconsin Counties and 11 tribes](#). Well Woman pays for certain screenings for some of the most common women's health concerns.

<http://www.dhs.wisconsin.gov/womenshealth/WWWP/index.htm>

Prevention and Risk Factors

In order to prevent and control cancer, we must first understand what it is. Cancer is defined as the out of control growth of abnormal cells. The cells of the body are constantly dying and replacing themselves with new cells. With cancer, the abnormal cell does not die like a healthy cell, and continues to multiply, thus forming an overgrowth of the abnormal cells. While we cannot totally eliminate the risk for cancer, we can eliminate some of the factors that increase the likelihood of contracting the disease.

There are two kinds of risk factors for cancer. Modifiable risk factors are those that can be changed. Non-modifiable risk factors are risks that cannot be changed. Some examples of non-modifiable risk factors include:

- Age
- Race
- Sex
- Close relatives with cancer

Some reasons for cancer cannot be reduced, however many threats may be eliminated. From a low fat, high fiber diet to avoiding tobacco, the factors that can be reduced are called modifiable or environmental factors. These are some of the modifiable behaviors that contribute to the probability of getting cancer:

- Tobacco use
- Diet
- Ultraviolet radiation (sun exposure)
- Alcohol use
- Ionizing radiation
- Chemicals and other substances
- Hormone replacement therapy (HRT)
- Exposure to environmental carcinogens
- Radon gas in the home

Risks can be calculated by the quantity and duration of exposure to risk factors. There are many risk factor assessments available to assess your risk for getting certain cancers. See the left side of the screen for a link to interactive cancer assessment quizzes.

For more about prevention and risk factors, visit the following links:

[American Cancer Society - Environmental Carcinogens](#)

Environmental factors can include smoking, diet, sun exposure, and infectious diseases, as well as chemicals and radiation in our homes and workplaces. Learn more about these risks and how you can reduce them.

[American Cancer Society - What is Cancer?](#)

Cancer develops when cells in a part of the body begin to grow out of control. Although there are many kinds of cancer, they all start because of out-of-control growth of abnormal cells.

[National Cancer Institute](#)

Cancer Causes and Risk Factors

[National Cancer Institute - Cancer Risk: Understanding the Puzzle](#)

This interactive site is about cancer risk. It will help you make informed decisions about how you can lower your risk.

[You Can Quit Smoking Now!](#)

Call the Wisconsin hotline at 1-800-QUIT-NOW (784-8669).

[United States Department of Health and Human Services - Preventive Services](#)

Access to scientific evidence, recommendations on clinical preventive services, and information on how to implement recommended preventive services in clinical practice.

[United States Department of Health and Human Services - Tobacco Cessation](#)

The latest information to help people quit smoking, and to help health care professionals treat tobacco use and dependence.

As the search for a cure continues, research and clinical trials seek to further that progress. Many people have benefited from the research already done, but more is needed before we know how to most effectively treat cancer.

According to the Coalition of National Cancer Cooperative Groups (CNCCG), approximately 50,000 people are currently enrolled in cancer clinical trials. This is less than 5 percent of newly diagnosed cancer patients each year. They calculate approximately 1,600 new drug trials are available for investigation and trial participation is growing each year. The CNCCG estimates that it takes about 14 years to bring new research to the public. In addition to drug trials, social, psychological, and spiritual support, and the effects thereof, are being examined.

The only way to know if a cancer research trial is the right option for you is to talk with your doctor and educate yourself. There are several different types of trials, including preventative, treatment, and supportive care studies. On this page there are links to clinical trials, topics to discuss with your doctor if you are interested in a clinical trial, and links to more information about clinical research and trials.

As more information is disseminated about cancer research, opportunities for advancement in treatment will grow. In the years to come, we will benefit from the advancements of today. Clinical research and trials are working to make the dream of a cure come true.

For more information on clinical trials visit the following websites:

[American Association for Cancer Research](#) – Research, support, information

[Cancer Research and Prevention Foundation](#) – Clinical trials, therapy options, cancer glossary

[Coalition of Cancer Cooperative Groups](#)

Recent studies show cancer patients enrolled in cancer clinical trials generally do at least as well or better than those who are not enrolled in trials. Such patients often get more attention from doctors and tend to get higher chemotherapy doses. Despite these facts, the proportion of patients willing or able to participate in cancer clinical trials has remained stagnant for years at five to ten percent.

[Fred Hutchinson Cancer Research Center – Clinical trials, disease research](#)

[Midwest Cancer Alliance](#)

[National Cancer Institute - Clinical Trials](#)

[National Cancer Institute](#)

States That Require Health Plans to Cover Patient Care Costs in Clinical Trials

[National Cancer Institute – Educational Materials](#)

Learning About Clinical Trials

[National Cancer Institute – More Choices in Cancer Care](#)

Information for Beneficiaries on Medicare Coverage of Cancer Clinical Trials

[National Research Center for Women and Families](#) – Information

[Native American Cancer Research](#) – Information, advocacy, and survivors network

[Susan G. Komen for the Cure Advocacy Alliance](#)

The Advocacy Alliance engages policymakers and leaders at all levels of government to advocate for an increased investment in breast cancer research and greater access to breast health services.

[Women’s Cancer Network](#) – Clinical trials, support, information, bookstore

Toll Free Numbers & Websites

[American Cancer Society - Ohio Cancer Patient Center](#)

1-888-227-6446

[CancerConnect](#)

1-800-622-8922

[Cancer Information Service](#)

1-800-992-2623

[Cancer Information Service and Counseling](#)

1-800-525-3777

[American Cancer Society - National Cancer Information Center](#)

1-800-227-2345

[Candlelighter Childhood Cancer Foundation](#)

1-800-366-2223

[National Cancer Institute Hotline](#)

1-800-422-6237

[Susan G. Komen Breast Cancer Foundation](#)

1-800-653-5355

Please note that this is just a sampling of some of the most popular resources, not an exclusive or exhaustive list. You can also check your local public or university library for more information.