

A Fact Sheet on Cancer Clinical Trials

Clinical trials are the necessary link between cancer research and improved options for patients. The scientific advances in cancer prevention, screening, diagnosis and treatment that we have seen over the past several decades are available today because individuals consented to participate in clinical trials.

In addition to receiving quality up-to-date care from health providers, people who take part in cancer clinical trials play an important role in contributing to the advances in cancer prevention and treatment and progress against cancer. The more people who participate in clinical trials, the faster we can find better treatments and prevention options for cancer. Physicians rely on the results of clinical trials to make choices about the best care for their patients.

Almost 1.5 million cancer cases are expected to be diagnosed in the United States in 2009 and more than a half mil-

Major Milestones in Breast Cancer Research

- The Breast Cancer Prevention Trial (BCPT) found that Tamoxifen reduces the risk of invasive breast cancer by 43% and the risk of DCIS and LCIS by 37%.
- The Study of Tamoxifen and Raloxifene (STAR) found Raloxifene to be equal to Tamoxifen in preventing invasive breast cancer.
- Several randomized clinical trials have found breast conservation therapy (involves lumpectomy, lymph node evaluation and radiation therapy) to be as effective in treating early stage breast cancer as mastectomy.

lion Americans will die of cancer (about 1,500 per day). However, only about 3% of U.S. adults with cancer participate in clinical trials.

What is a Clinical Trial?

Clinical trials are controlled research studies involving people to test new ways to prevent, screen for, diagnose or treat a disease. The purpose of a clinical trial is to determine whether a new prevention, screening, diagnostic or treatment option is safe and effective, and if it is better than current therapies.

A clinical trial is one of the stages of a long research process. There are several types and phases of clinical trials. Types

of clinical trials include:

- **Prevention trials** - test new approaches (e.g., medications, vitamins or supplements, exercising), that may lower the risk of developing a certain type of cancer. Most prevention trials include healthy people who have not had cancer, but some include people who have had cancer and want to prevent recurrence or reduce the chance of developing a new type of cancer.

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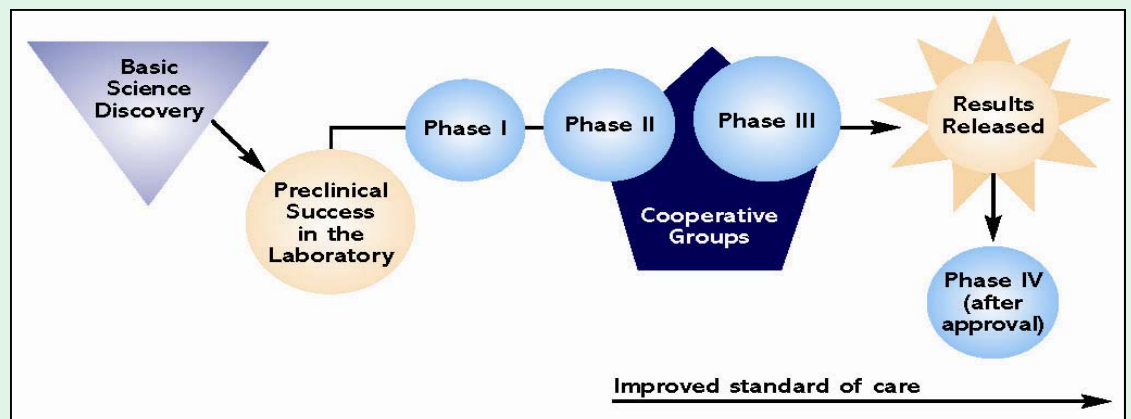


Figure from Coalition of Cancer Cooperative Groups' "Knowledge is Power: Educate Yourself Now on Cancer Clinical Trials"

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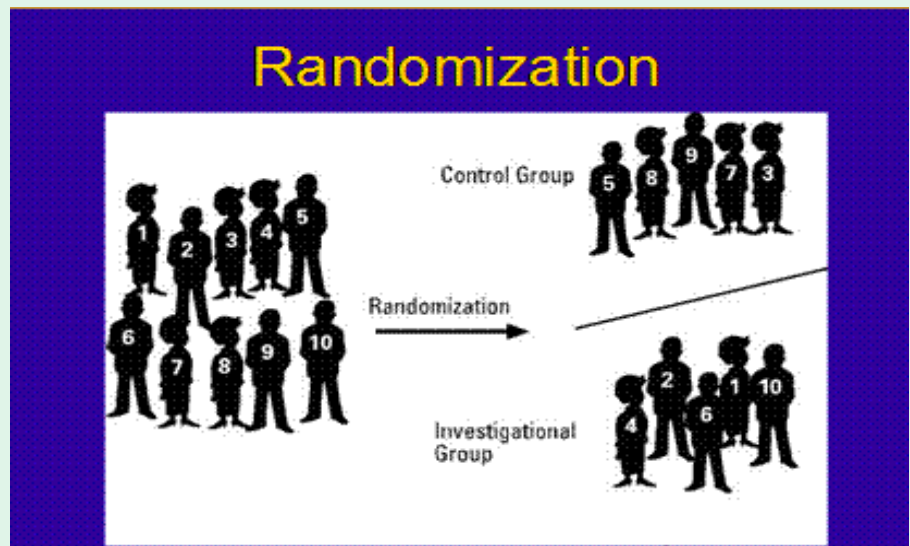
- **Screening trials**- study ways to detect cancer earlier.
- **Diagnostic trials**- study tests or procedures with potential to identify cancer more accurately.
- **Treatment trials**- evaluate the effectiveness of a new treatment or new way of using a standard treatment. These trials involve people who have cancer and may include testing new drugs, vaccines, surgical approaches, radiation therapy or combinations of treatments.
- **Quality-of-life trials**- explore ways to improve the comfort and quality of life for cancer patients and survivors. For example, these trials may study ways to help alleviate nausea or other side effects from cancer or its treatment.
- **Genetics studies**- investigate how one's genetic makeup can affect detection, diagnosis, or response to cancer treatment.

Clinical trials are conducted in a series of phases (see figure, page 1). **Phase I** trials evaluate safety; **Phase II** trials measure effectiveness; and **Phase III** trials test against the best known treatment or current standard of care, allowing researchers to compare the effectiveness of the experimental treatment with the

standard of care treatment and determine whether the experimental treatment is better. In **Phase IV** trials, new uses or long-term effects of the treatment are examined.

Some clinical trials use a method of randomization in their design. **Randomization** prevents bias in research by ensuring participants have an equal chance of being assigned to one of two or more groups (often the experimental group or the control group). (See diagram below) Sometimes clinical trials will assign participants to a control group in which a **placebo** (or sugar pill) with no active ingredient is used. Placebos are not used in place of standard treatment in clinical trials.

Participants of a clinical trial work with a research team, which may include doctors, nurses, research coordinators, social workers, dietitians, and other health professionals. The research team provides care, monitors participants' health, and offers specific instructions about the study.



Participant Safety and Protection

Many safeguards are in place to make clinical trials as safe as possible and protect patient rights. Clinical trials are conducted according to strict scientific and ethical principles. This is done by ensuring well-designed protocols, a dedicated Institutional Review Board (IRB) and a careful informed consent process.

A **protocol** is a detailed plan that explains what will be done in a clinical trial and why. It outlines how many patients will participate, what medical tests they will

receive and how often, and the treatment and monitoring plan. Before any clinical trial begins, the protocol must be approved by an IRB, which includes researchers and physicians. The **IRB** considers whether proposed studies are safe and well planned and whether they will ultimately advance patient care. The IRB also reviews studies to ensure patients are adequately informed about the risks of participating in clinical research.

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People who participate in a clinical trial go through a process of **informed consent**. During this process they learn the purpose, procedures, risks and benefits of a clinical trial before deciding whether to join. Participants who consent to a study have the right to withdraw at any time.

It is important to understand that risks and side effects exist with most any treatment whether it is standard care or a clinical trial. Clinical trials of new treatments may cause expected side effects as well as unexpected side effects. In addition to the safeguards mentioned above, clinical trial participants are carefully monitored throughout a study (e.g., blood tests, x-rays) to detect and record any changes, good or bad, in a patient's condition. Such close monitoring is an important part of documenting care decisions and research results.

Costs Associated With Clinical Trials

Payment of patient care costs in clinical trials varies by health insurance plan and by study. It is important to ask your doctor, nurse or research coordinator from the study about associated costs to determine in advance which costs are covered by the study and which costs you and your health insurance will be responsible for. Health insurance and managed care providers often do not cover patient care costs associ-

ated with a clinical trial if the care is considered "investigational." Many states have passed legislation or developed policies requiring health plans to cover the costs of certain clinical trials. Medicare reimburses patient care costs for its beneficiaries who participate in clinical trials designed to diagnose or treat cancer.

For More Information:

- National Cancer Institute Clinical Trials webpage at <http://www.cancer.gov/clinicaltrials>
- ClinicalTrials.gov at <http://clinicaltrials.gov>
- <https://www.breastcancertrials.org>
- Vermont Cancer Center at <http://vermontcancer.org>

Avon Army of Women

The Army of Women is a revolutionary new initiative in breast cancer research with two key goals:

- To recruit one million healthy women of every age and ethnicity, including breast cancer survivors and women at high-risk for the disease, to partner with breast cancer researchers and directly participate in the research that will eradicate breast cancer.
- To challenge the scientific community to expand its current focus to include breast cancer prevention research conducted on healthy women.

To date, the Army of Women has signed on more than 270,000 women. To learn more go to their website at <http://www.armyofwomen.org>

Getting Back to Healthy

Support Group

Who: Women at increased risk for breast cancer, who have been diagnosed with breast cancer or who are survivors of breast cancer.

What: A support group led by Dietician Jennifer Ohler-May offering education, discussion and support on achieving and maintaining a healthy weight and lifestyle.

When: Meetings are on the 2nd and 4th Fridays of the month at noon until May 2010.

Where: Fletcher Allen Health Care

Why: To help educate on the benefits of a healthy weight in decreasing risk of cancer development or progression, prevention of chronic diseases, and improving general health and quality of life.

Contact Jennifer May at 802-847-4649 or Jennifer.L.May@vtmednet.org

H R**B P**

HIGH RISK
BREAST
PROGRAM
OF VERMONT

Summer 2009

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Contributors

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Caprese Salad with Heirloom Tomatoes

A delicious, fresh and light salad for hot summer days.

Ingredients

- 1 – 2 lbs mixed heirloom tomatoes (Brandywine and Striped German varieties work well), cored, thinly sliced
- 1 8 oz package of fresh mozzarella (in water), sliced 1/4-inch thick
- 1/4 cup extra-virgin olive oil
- 1/4 cup of fresh basil leaves, torn into thin strips.



Arrange sliced tomatoes and mozzarella on a platter, drizzle with olive oil, top with basil strips and season with salt and pepper. ~Enjoy!

SAVE THE Date!



12th Annual Breast Cancer Conference

Saturday, October 24th, 2009

<http://www.vtbreastcancerconference.org>