The basics of clinical trials
A clinical trial is a research study, relying upon human volunteers, that allows scientists to investigate and answer specific medical questions. Yesterday’s research leads to today’s treatments and tomorrow’s cures.
What do trials accomplish?

Trials test new ways to...

- Prevent breast cancer
- Diagnose breast cancer
- Treat or cure breast cancer
- Improve quality of life during and after treatment
What do clinical trial “phases” mean?

Each clinical trial is classified into one of 4 phases, depending on what it is testing:

- **Phase 1**: Ensuring safety, Identifying side effects, Determining safe dosage
- **Phase 2**: Further evaluating safety, Testing effectiveness of a treatment
- **Phase 3**: Confirming effectiveness, Comparing to current standard treatments, Monitoring side effects
- **Phase 4**: Monitoring long term effects, Identifying new uses of the treatment
The doctor (Principal Investigator, or PI) in charge of the trial is responsible for a trial protocol, which includes:

- Why the trial is required
- Who is eligible to participate
- How many patients are needed
- What drugs, if any, will be given; how much and when
- What tests will be done, and when
- What patient information will be collected
Potentially eligible patients are identified.
They receive detailed information from their doctors about the trial.
They are asked to sign an “Informed Consent” form to show that they have been properly informed about the study.
How are patients recruited?

- Patients are chosen based on factors including age, gender, type and stage of breast cancer, treatment history and other medical conditions.
- Sometimes patients must be recruited from many countries in order to ensure that enough people will participate so that the study will have statistical validity.
All Phase 3 trials (and some in Phase 2) use randomization by computer to put patients into groups receiving different treatments. One group (the control group) receives the current standard of care. One or more groups receive the therapy being tested, sometimes in different combinations or schedules.
How long does a trial last?

- Researchers monitor patients for weeks, months or years, depending on the trial protocol.
- Some trials follow patients for more than 10 years, for example to track long-term safety.
The typical life of a trial

Protocol
- Recruitment: 6 months – 5 years
- Study: 6 months – 10 years
- Follow-up: 6 months – 10 years
- Review: Entire duration of trial

Interim Results

Final Results
What are the risks and benefits of participating in a trial?

**Risks include:**
- Experimental treatment could prove ineffective
- Known and unknown treatment side effects
- Additional time required at the hospital for tests and check-ups

**Benefits include:**
- Access to treatments under development not available outside the trial
- Close medical attention, including additional tests and check-ups
- Contribution to potentially improved treatments for future patients
Why support clinical trials?

- Clinical trials provide us with the knowledge we need to treat breast cancer better.
- Now is the time for scientists to make significant progress in answering questions about how to treat and cure breast cancer.
Support trials and enable progress towards a cure for breast cancer

Today’s donations support tomorrow’s trials and future cures.
For more information:

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