Lobular Breast Cancer Alliance

Questions to Consider for People with ILC

Who Are Thinking of Participating in a Clinical Trial

Background on Clinical Trials

Patients with invasive lobular carcinoma (ILC), also known as lobular breast cancer, can participate in many clinical trials, even if those trials are not specifically studying ILC. There are four types of clinical trials as defined as Phase I, Phase II, Phase III, and Phase IV.*

Phase I is a small trial that is done to evaluate a potentially new drug (an investigational drug) for its proper dosage, safety of administration, and side effects. It is usually given to patients who have completed all standard treatment.

Phase II trials enroll a larger group of patients to test the effectiveness of the drug and monitor side effects at the established dose.

Phase III trials typically enroll 100-3,000 patients to confirm effectiveness, monitor side effects, and collect additional information. This trial compares the new drug to the standard of care treatment. Sometimes, it will add the new drug to the standard of care and compare to standard of care alone. These trials usually have two or more "arms," (i.e., study groups). The patient agrees to be treated with whichever arm she is randomly assigned, and she and her doctor may be "blind" to (not aware of which drug they may be taking) so that bias is not introduced into the analysis. It is not known at the onset if the new treatment is better, equally effective or less effective, so that the patient would not be at a disadvantage if assigned to the standard of care.

Phase IV trials enroll much larger numbers of patients to assess treatments already FDA approved and marketed. This phase, which occurs after FDA approval, is known as Phase IV Clinical Trial/ Post-Market Surveillance/Report Adverse Events, and confirms the safety as well as benefits and optimal use, observed over a longer period of time. These studies can identify rare side effects and long-term effects that may not be identified in earlier Phase studies.

How Clinical Trials Benefit Patients

Clinical trials can be offered to a patient when first diagnosed or when she experiences a recurrence. Usually, participation in a clinical trial is an opportunity for a patient to get cutting edge treatment with the possibility of a better outcome. Patients often choose to participate when first diagnosed or when experiencing a recurrence. Patients frequently cite that they like the attention of close monitoring and follow up. It is important to note that all clinical trials have specific eligibility criteria that must be met

to qualify for enrollment. Talk to your doctor and review the eligibility requirements to establish your eligibility for a particular trial.

Once you have determined that you are eligible for a clinical trial, there are many factors worth considering before enrolling. We have assembled key questions that we believe are important to explore in your enrollment decision making process.

What questions should I ask to help me decide?

- **What is the *objective* or *goal* of the study**? Ask if it is a new drug or combination of drugs being tested and what the expected benefit is. It is also helpful to understand if the study will be analyzing the impact on ILC in particular, or not. This may make a difference to you if you have more than one clinical trial to choose from and you want to help advance ILC research.
- **What are the chances of receiving the drug being investigated**? If it is a randomized study (with two or more groups called "arms" into which participants are assigned randomly), understand what drugs are being offered in the different arms and ask about the chance you will get the drug(s) being investigated or not. It is also important to know whether you will be informed what drug you will get once you have been assigned to an arm of the trial.
- **What are the risks to me and how do they compare with the benefits of participation?** It is important to ask about what risks, if any, are associated with the clinical trial and to determine for yourself if these risks are acceptable and are not greater than potential benefits.
- **What is the *time commitment* required and where will I have to go to participate?** It is important to understand what tests and procedures, visits for medicine pickup, and follow-up will be required as well as the frequency of these. It is also important to be aware of whether you will have to travel to more than one location or a significant distance to comply with the various procedure and visit schedule, as well as to understand how they will be scheduled and what flexibility there will or won't be in scheduling times and dates.
- **How will participation in this trial affect my work/childcare schedule?**
- **If I need to travel for treatments, tests and visits:** Can some of these treatments and visits be done near my home? Will they keep my local doctor informed of my treatments and progress? How can my local doctors contact the investigators if needed and on weekends?
- **If I have to join a trial outside of my oncologist's hospital, who will my oncologist refer me to who can assist with my enrollment?**
- **What are the financial costs?** Is there any financial or social support available beyond that which is covered by insurance such as travel expenses, childcare, and loss of work?
- **How long will I be followed after finishing the treatment?** That is, how long will I keep being seen by the oncologist who enrolled me in the clinical trial after the clinical trial has ended?

Other tips for how to decide to join a clinical trial

- If you have any questions about the Informed Consent you should ask them and feel satisfied with the answers before you sign.

- Understand that to participate is voluntary. It is helpful to remember that participation in a clinical trial is ultimately your decision, your choice, and not the decision of your doctor, family or friends.

To find out about clinical trials that focus on ILC or include a specific group of patients with ILC in the study, please visit the clinical trials page on our website. Information on new trials will also be shared with those who subscribe to our newsletter.

*The following websites were used for information on clinical trial phases:

https://www.fda.gov/patients/clinical-trials-what-patients-need-know/what-are-different-types-clinical-research

https://www.nccn.org/patients/resources/clinical_trials/phases.aspx

https://www.healthline.com/health/clinical-trial-phases#phase-iv

https://www.brightfocus.org/clinical-trials/how-clinical-trials-work/phases-clinical-trials