What are Clinical Trials?

Those of us who work at Fighting Chance are struck by parallels between the battle against cancer and the battle against Covid-19. In both cases, for example, there is heavy reliance upon the results of clinical trials—in which experimental medicines are tested on humans to see if they are safe and effective, and ready for widespread public consumption.

Phase 1 and Phase 2 Trials

The first step in most any clinical trial is known as Phase 1. It has a small group of trial participants and the main goal is to see if the new drug is safe; if so, then testing proceeds to Phase 2.

In Phase 2 the participant group is larger and the goal is to see if the drug is effective; if so, then it’s on the way to Phase 3 trials that can involve thousands of trial participants.

Phase 3 Trials

At the core of Phase 3 trials for new anti-cancer drugs is the concept of “competition.” In other words, is the new drug more effective than the best medicine already on the market? Passing that test makes the new drug ready for FDA approval.

Today there are several Covid-19 vaccine candidates that have completed Phase 1 and Phase 2 trials and are starting the Phase 3 process.

But these vaccines are not competing against an already established vaccine—because none exists. Instead, data will be compared from Phase 3 trials focused on several vaccine candidates such as those developed by Moderna, Oxford, and Novavax.

It may take months to gather adequate data and it is possible that no candidate will come up with satisfactory results.

Cancer Patient Selection of a Clinical Trial

Every participant in a Covid-19 vaccine trial must be healthy. In contrast, new anti-cancer drugs are only tested on very sick individuals since all trial participants must have cancer.

While there are only a handful of Covid-19 vaccines being tested, there are over 1,000 new anti-cancer drugs in clinical trials at this time. How does a patient decide which trial would be most beneficial? That’s where Fighting Chance’s counseling can be helpful.

First of all, we explain to patients that they should only focus on trials involving their tumor type. Also, some trials are geared to patients whose cancer was detected early, and others only want patients with late stage cancers.

With some trials you can only qualify for admission if you have not started any form of therapy; but in other trials patients are wanted who have failed to respond to other treatment options.

It all sounds complex, and it is; but with insightful guidance patients sometimes get into trials that give them access to an extraordinary medicine long before it becomes widely available.

All of a sudden they have a Fighting Chance.