Participating in MS Clinical Trials

by LIBBY SELINSKY

Is an MS Clinical Trial for You?

MSer Libby Selinsky shares her experiences with clinical trials — one in 2008 and the other in 2016.

“You are lucky to be getting MS now.”

Those are the most annoying words my neurologist has ever said to me. After some time I was able to dial back my guttural reaction and realize my chances of thriving with this disease are incredibly high, simply because I have it now, when science is making incredible strides.

If you want to take part in a clinical trial, it is important to remember to weigh out the pros and cons for yourself and the way that they will affect your life.

Phases of Clinical Trials

Clinical trials go through three phases before the medicine that the scientists are testing is reviewed and approved by the FDA:

- **Phase I:** Researchers test a new MS medication or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
- **Phase II:** The drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
- **Phase III:** The drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
- **Phase IV:** Studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.

Health risks must be looked at seriously. If you are in great health and your progression is moving slowly, then a phase I or phase II trial might not be the best thing for you to try. The earlier phases can pose a higher negative risk to your health than the positive benefits you might receive.

Phase III and IV studies are more stable and a lot less risky. However, if you are further along in your disease progression or if you have the primary progressive form of MS, then you might find a phase I or II trial could suit your needs better.

The important thing to remember is many of these trials can carry serious or even fatal side effects. Think deeply about how much you are willing to risk and compare it to what you might gain before taking that first step.

Reaching Out

Once you have found a clinical trial that interests you, it is time to reach out to the researchers who are running it. All of the clinical trials I have been a part of have been run out of my neurologist's office — it is a good probability that your neurologist is running clinical trials too.

In any case, the trial researchers will take the time to screen you to see if you are a strong and eligible candidate for their study. This is a process that can easily be taken personally. It is hard to get emotionally ramped up for a study only to find out that you have been denied because of some strange caveat.

The reasons for being ineligible may seem arbitrary, but they are just the scientific parameters that have been placed on the study in order to ensure a consistent and replicable result. The reasoning has nothing to do with you personally — and this leads me to my next point: you are going to become a number.

What to Expect

You will find your appointments within the trial will be much more clinical and your tests and results will not belong to you. Oftentimes you will not know the results of many of the tests they run.

For example, I was on the fingolimod (Gilyena) phase III trial. My body was run through the full gamut of tests, during which I had to go through several MRIs to check for disease progression, and I was not privy to the results!

However, you basically get free medical treatments during the study. MS is an expensive disease — clinical trials will often run thorough tests that go above and beyond what your normal neurology visit or even annual physical will do.

I had to get a full body checkup during my screening for the fingolimod trial. It was important that everything in my body was cleared as healthy so I could be deemed an acceptable candidate for the phase III trial.

I was never allowed to see the exact numbers for these screening results; however, if they had found anything of concern I would not have been permitted to move forward. I loved going through all of these tests because it was a free, in depth, full-body health assessment.]

Fingolimod was a great trial for many people to be a part of. I was a part of the trial during the year of 2008, when there were zero disease modification treatments on the market that could be taken orally. For many people, the fingolimod trial was a great way of getting their hands on the newest treatment, which was orally administered, and for free!

Next page: Libby discusses her most recent experience with an MS clinical trial.

2016: Desperate Times Call for Desperate Measures

This year I decided my neurologist had not been as aggressive as I needed, and I switched to another, more current neurologist. I believe it was a moment contrived by fate.

My new doctor has been working on a clinical trial that sounds almost too good to be true. The phase III trial has already finished, and they have moved onto the dosage trials while the FDA reviews the drugs safety and efficacy.

There are only 24 patients in the country who can sign up, and my doctor’s office was approved to join the day before my appointment!

Considering a Clinical Trial

The drug is similar to Gilenya — it’s in the same family of drugs — with a shorter half-life and designed with a reduction of the serious side effects compared to what is already commercially available, and my doctor thought I'd be a good fit for the trial. I had not expected that appointment to go so well.

Clinical trials are a big commitment, not to be jumped into without thought. The benefit of this particular trial, for me, was that all of the footwork had already been done in learning the efficacy of the medication, and the severity and types of side effects the medication posed.

Another great benefit of this trial is there is no placebo — I was guaranteed to receive the medication being studied. This meant that I would not be placing my mind in a state of uncertainty over whether or not I would be actually treating my disease progression.

I had promised my husband and son many years ago that I would commit to treating this disease every day. I have no plans of breaking that promise today.

It begins…

To begin a clinical trial, you are first given a lot of paperwork to read. Like I said, a clinical trial should not be taken lightly. It is wise to read every word and think on things a bit to be sure you are ready to take the leap.

The next step involves a lot, and I do mean *a lot* of physical evaluations. The researchers pay for these, so they are of no cost to you.

Finally, the first date of my trial arrived. I was lucky to be one of the first two people in the United States to begin this trial. As special as I felt for being first in line, I was reminded of reality and made to sign a lot of waivers, explaining all of the bad things that could happen.

For this trial, the first few days of taking the medicine meant many long days and late nights in the medical center — I'm talking forget what the sun looks like in the middle of July, good luck having dinner with your family, kind of late. I have a lot of patience when it comes to medical tests. However, even for me, the experience of having my blood drawn every hour for 14 hours straight was demoralizing.

All of the positivity that had been cultivated had come crashing down. I had to allow for many nights of crying when I returned home. Too many hours of quiet aloneness in that silent medical room — with only interruptions of nurses trying to find a good vein after the eight vials of blood they took the previous hour blew my other vein — just added up.

The clinical trial paid me for my time, but the pay really was not enough. It was my promise to my son and husband that kept me in that room. It was my hope for the promise of a better way of life that kept me coming back.

Was It Worth It?

After a few weeks, many hours, countless ounces of blood and every physical test and assessment possible, I am still on the medication. The visits have slowed down; my current visits are every few weeks and for only and hour or so, with one final 14-hour day, as a proper sendoff.

I have learned what to expect when they poke and prod me. Meanwhile, the medication itself feels like nothing to me; the entire time I have been on it, I have not felt any of the terrible MS medication side effects we're often used to. I take a small pill at breakfast and move on with my day.

I am uncertain of where I will end up with my disease progression, but my neurologist totally geeks out over this medicine. I wish I could tell you what it is called, but it doesn't have a name yet.

Since I am on this clinical trial, I will be automatically rolled over into a maintenance trial, of sorts. If all goes well, I can remain in the trial and receive the medication for free until the FDA approves the drug for the commercial marketplace.