



A Patient's Story

The other side of the needle: An investigator's experience as a patient

Jürgen Venitz, MD, Ph.D. thought he understood every aspect of the clinical trial process.

During the 1980s, as a medical student in Germany, he'd participated in at least ten Phase I trials as a healthy volunteer.

The experience sparked his interest in research and led him to a career in clinical pharmacology. Having "experienced life on both sides of the needle", Dr. Venitz thought he had a 360-degree view of the process. But it wasn't until he became gravely ill that Dr. Venitz came to fully appreciate that therapeutic trials are days in a life.

Life in the ICU

Dr. Venitz first knew something was wrong when he began slurring his speech during a lecture. Most people might have suspected stroke, but Dr. Venitz suspected myasthenia gravis, an autoimmune neuromuscular disorder characterized by fluctuating muscle weakness in the voluntary muscles.

"My scientific training led me to rule out stroke," he says. "Everything pointed toward myasthenia gravis." A neurologist confirmed Dr. Venitz' suspicions.

Although there is no cure for myasthenia gravis, treatment can help relieve symptoms.

Despite treatment, his immune system continued to attack itself. Six weeks after his symptoms appeared he was admitted to the hospital's intensive care unit (ICU): an experience that would become all-too familiar over the course of the next three years.

Ultimately, his neurologist settled on a course of treatment that forced Dr. Venitz to undergo plasmapheresis. The process is similar to dialysis. But the catheter often became infected, resulting in extended stays in the ICU.

Then what?

Not surprisingly, when Dr. Venitz' neurologist approached him about a therapeutic trial, after another visit to the ICU for a blood infection, his interest was instantly piqued.

But there was a sticking point.

"I asked my doctor, 'So let's assume this is my miracle drug and it works. The trial lasts a year. Then what?' But he didn't have an answer for me. There was no end game."

Assuming it worked; the disclosure form didn't say whether patients would be allowed continued access to the drug on a compassionate-use basis.

He explains, "I've been doing clinical trials for 25 years and what happens after the investigation – was something I had never thought about. But as a patient I wasn't going to take the chance that this might work for me but I might not be able to have access to it after the trial, so I said no."

Instead, Dr. Venitz opted to participate in a non-interventional trial to help clinicians establish a quality of life assessment tool for myasthenia gravis patients. That study involved periodically answering survey questions about how his condition was affecting his quality of life and lead to the creation of an assessment tool.

"It helps focus the conversation," Dr. Venitz says. "The assessment tool really forces you to figure out what changes have occurred since your last visit in a much more formal, organized way."

Trials through a new lens

Today, Dr. Venitz' condition has stabilized. Although he takes about 20 pills a day, he hasn't had to undergo plasmapheresis in nearly three years.

He's used his experience to affect what he can. For a decade, Dr. Venitz has served as a member of an Institutional Review Board (IRB) and he brings his experience as a patient to that role.

"Now, when I'm reviewing a trial, I understand how patients might feel if they couldn't have access to a drug after the trial ended and we make sure it's in the disclosure. They have to think about the rest of their lives."



Jürgen Venitz,
MD, Ph.D

Can you take part in a trial while working full time?

Many potential volunteers worry whether becoming a clinical trial participant will interfere with their job or create problems with their boss. While clinical trials volunteers may need to do some careful planning, you don't need to be a super hero to hold a job and still volunteer.

"We want to dispel the idea that you will have to take a whole day off from work to be in a clinical trial," says Lisa Pacitto, of [MassResearch](#). "Usually the first screening visit takes longer, because there may be a medical exam and you have to read the Informed Consent form. But in most studies, the other visits are shorter and are easier to work around your schedule."

Often, people who work non-standard hours can talk with the trial site staff to schedule visits around their available time. "For example, shift workers can often get to their site visit before going to work, or before going home at the end of their shift," says Karri Venn at [LMC Endocrinology Centres](#). "However, it's a little trickier if their visit requires having fasting blood drawn, because people want to have it done early in the morning."

If you're worried about a potential conflict between work and your trial commitments, it's wise to consider these steps:

1) Find out exactly what's required.

Ask how often you'll have to visit the site, how long each visit is likely to last, the schedule of visits, and how long the trial will go on.

Dr. Charles Wilcox of [Pharmacology Research Institute \(PRI\)](#), advises asking these questions which can give you a sense of how much time you'll spend on the trials: What is expected of me? If I arrive on time for my appointments, will I be seen within fifteen minutes or less of my scheduled appointment time? Will my calls always be answered by a "live voice" during business hours?

2) Be aware that many research sites try hard to accommodate volunteers.

Don't be afraid to speak up about your schedule concerns.

Patricia Larrabee of [Rochester Clinical Research \(RCR\)](#) says, "We do whatever we can to make visits convenient. Most patients try to come in early in the day; at lunch hour, or at the end of the day, so we are set up to see them at those times. If a trial requires fasting blood, we open up more slots early in the morning."

Dedicated research sites also work to eliminate waiting time, which helps to keep the visit short. "Coming for a clinical trial is

different from going to your regular doctor," says Larrabee. "We've trained our staff that nobody sits in the waiting room longer than a minute."

Pacitto agrees that working with the volunteer helps make visits more convenient. "One gentleman who is a research subject travels a lot for work. When he starts traveling, we ask him for his travel dates. We look at his schedule and see how we can work around it so that he can get to his site visits. Also, we can start at 6:00 a.m. and get people in and out so they can get to work before it starts."

Research sites also try to accommodate volunteers by providing extra services that can help them save time in related areas and gain other benefits.



Still, there are some jobs, such as factory workers with very limited breaks and rigid lunch schedules, that may not always lend themselves to clinical trials. Other situations may make it stressful to volunteer. "Some people's place of employment is not respectful of the fact that they need to take care of their health or wellness," says Venn. "So they keep their disease secret from their jobs." This may make volunteers worry about making time for their site visits.

3) Think honestly about your motivation.

"Maintaining your scheduled visits could seem burdensome if the trial lasts months or years," says Wilcox. "If the trial has been going on and the subject realizes or suspects that the treatment isn't working for him, it becomes harder to stay motivated and do all the things that are required for the trial protocol."

Motivation to improve your own condition and to assist in developing new medical treatments helps offset some of these challenges.

Since it's important to the trial that volunteers complete their scheduled visits, volunteers should weigh the challenges they face in fulfilling their trial responsibilities and discuss them with research site staff. These candid interactions will lead to the most positive—and least frustrating—situation for volunteers.