How to better prepare patients for a cell or gene therapy trial

Doug Olson, Ph.D., Cancer survivor and CAR T-cell patient

A decade ago, Doug Olson was facing a grim prognosis. When first diagnosed with chronic lymphocytic leukemia (CLL) in 1996, he was treated with "watchful waiting." But as his CLL progressed, he went through two rounds of chemotherapy and, after experiencing thirteen years in remission, he'd become resistant.

By spring 2010, CLL had invaded 50% of his bone marrow and a bone marrow transplant—a treatment that works for many patients but can have serious side effects—looked like his only option. At that point, his physician, Dr. David Porter at the University of Pennsylvania, told him he might qualify for a clinical trial that was testing an experimental new treatment called chimeric antigen receptor (CAR) T-cell therapy. After joining that trial as Patient #2, Olson achieved a complete remission and is cancer-free to this day. He now volunteers for the Leukemia & Lymphoma Society's (LLS) peer-to-peer support program and First Connection, which allows patients and their loved ones to speak with someone who has been diagnosed with a form of blood cancer. Parexel spoke with him about how healthcare providers and trial sponsors can better communicate with patients about CGTs.

Q: Do you think patients are well informed about CGTs?

Doug: I regularly speak to cancer patients who are newly diagnosed or have relapsed and are considering CAR T-cell therapy. I've found it's a mixed bag as to what they come away with after speaking with their doctor. I think the medical community can do a better job of communicating.

First, medical personnel need to start by understanding that they are dealing with a scared human being—they have cancer that is unresponsive to standard treatment and are running out of options. Empathy is the primary context for a discussion of regulator-approved therapies or clinical trials.

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Second, while many patients are well educated and have researched their condition extensively, others know very little about it and are not comfortable with scientific concepts and terms. When investigators explain a CGT to a patient, they need to understand the person who they are speaking to and target their message for them: What is their education level? How sophisticated is their knowledge of their disease? Do they have a family support group? Do they understand how clinical trials work?

Q: Are the potential benefits and risks of CGT clinical trials communicated well?

A: There are strict rules around informed consent that dictate how risks are communicated to patients and their families. But beyond that, healthcare providers need to educate and provide context to patients. The initial discussion with a healthcare provider is critical to how the patient views participating in a clinical trial.

I know physician-investigators don't want to give patients false hope, but patients need hope. I don't mean that someone should promise a cure. But I believe that patients want to know they will be cared for throughout the trial. They need to understand that participating in clinical research has meaning; no matter the outcome, the trial will generate knowledge that could help others with the same condition.

Physicians give patients a long list of all the things that could go wrong. But it would help patients understand the likelihood of adverse side effects to weigh the risk against the possible benefit of the new treatment.

For me, participating in a clinical trial was empowering. I did not have to sit back and wait for cancer to beat me; I could try to beat it first.

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Q: What do you think might improve how physicians talk with patients about trials?

A: My physician was a very kind, honest, and caring individual. He was always upfront when there was bad news but never removed hope. If every physician were like him, I suspect patients would enter more freely into clinical trials.

But that is unrealistic: Someone could be an excellent physician with limited communication skills that might improve with a little training. If we could change the game of how principal investigators communicate about clinical trials through education, we could recruit and retain more patients in trials. Some of the skills needed to talk with a cancer patient are closer to those of a social worker—and perhaps bringing a trained individual into the discussion could help.

A patient who is afraid and has run out of treatment options needs to understand that enrolling in a clinical trial does not make them a guinea pig or a mouse in a cage. They will be taken care of during the trial, and if the treatment does not work for them, there may be other trials they can participate in—the science is moving fast.

Patients have one thing top of mind: I have cancer, and I don't want it.

Expert spotlight

Doug Olson, Ph.D.

Cancer survivor and CAR T-cell patient

Doug Olson received his bachelor's degree in Chemistry from Maryville College and his Ph.D. in Medicinal Chemistry from Purdue University. Most of Doug's career has been spent in the Medical Device and In Vitro Diagnostics industry. Doug served as President of DPC's Instrument Systems Division and corporate Chief Scientific Officer prior to its sale to Siemens Health Care. Doug is the holder of eight U.S. patents and author of a number of publications. Doug is a cancer survivor and patient number two in the initial CART 19 clinical trial. He is a former member of the Board of Directors of the Eastern PA chapter of LLS and is on the Board of Directors of BÜHLMANN Laboratories and BÜHLMANN Diagnostics Corp and currently serves as Chief Executive Officer of BÜHLMANN Diagnostics Corp.

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