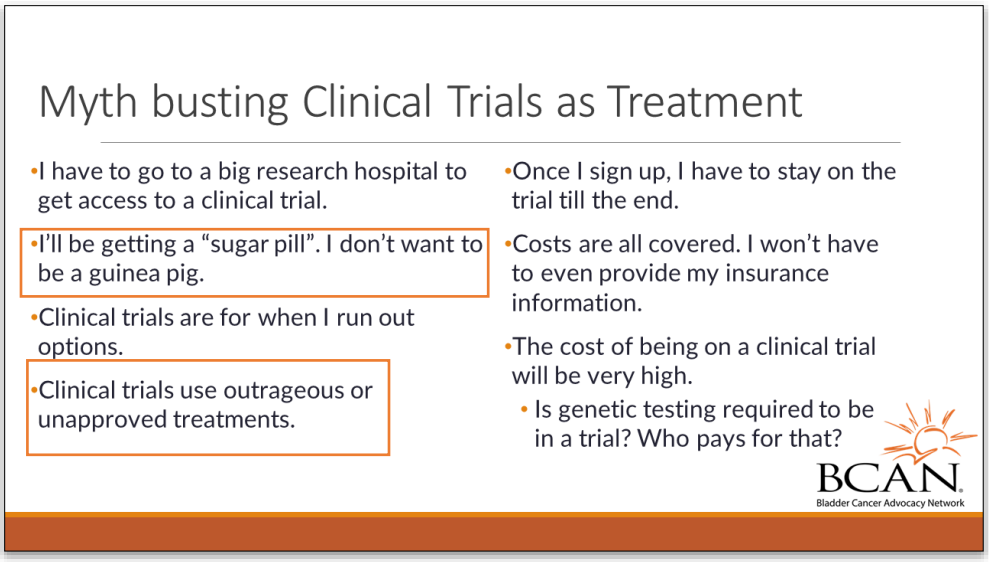

Stephanie Chisolm:

In most clinical trials they're going to give you either the new treatment option or they're going to give you standard of care when it comes to clinical trials that are being used in the cancer space. **Those clinical trials are not necessarily testing outrageous or unapproved treatments, right?** Can you, as the doctors, talk a little bit about that? I think that's one of the things that also makes patients a little nervous. They're afraid they're going to get a sugar pill and they don't want to be a guinea pig and not get anything. That's not the case when it comes to cancer clinical trials. Then they're afraid that you're going to try some crazy thing on them and it's not an approved thing, or it's not a logical thing. You're just doing an experiment. How do you all come up with these clinical trial ideas?

Dr. Shore:

When I talk to patients about clinical research, first of all I explain that whether it's an actual therapy, whether it's an oral therapy or something that's given intravenously. Or maybe it's just a blood draw or urine based test to look at a new predictive marker that could help us better diagnose bladder cancer or a response to a treatment, and it might even be, eventually, we look at different kind of imaging tests. Newer scans that might be more beneficial. I tell patients first and foremost that this is a decision that they'll have time to review. We send them home with a consent form. By law the consent form cannot be higher than an eighth grade education. It's written purposefully, not to dumb it down, but so that it's not filled with a lot of confusing medical language. I always encourage the patients to take it home and review it with their partners, their family members, their friends, and then come back and let's talk about it.

If they choose to do a study, which is going to help potentially, potentially, themselves, as well as advance healthcare, not just in the US but arguably throughout the world, they only stay involved in the study as long as the study is helping them. The moment we see that they're not getting benefit from it we move to something else. I usually like to say, "You're not signing a 30 year mortgage. You're giving your consent to be involved and the moment you don't like what's going on we'll move to something

else." I find that, that's remarkably reassuring and I hate the word guinea pig but everybody brings that up. "I don't want to be a guinea pig." This is how we cure cancer. This is how we cure heart disease.

Dr. Shore:

Fortunately our patient advocates who are on the call today, Bob and Kevin, they get it and we need more folks like that to understand this is how we help all of our fellow friends and colleagues who have bladder cancer and other cancers.

Dr. O'Donnell:

Stephanie, you asked where do these therapies come from, right? A lot of times these therapies that we are testing in clinical trials have been studied in other clinical trials before. They go through different phases of clinical trials and so often times it's that these trials are in the last stage of development, meaning they're in the final clinical trials that the government needs before approval, but we actually have a lot of experience with these drugs in earlier clinical trials so patients shouldn't feel that they're the first ones where these therapies are being tested. In most cases that's not the case. We actually already have a lot of prior experience about how these drugs work and the side effects, the potential side effects of these drugs, which I think really makes it much more palatable to patients.

Stephanie Chisolm:

Some patients are doing the early, what they call, phase one clinical trials. You can look on the BCAN.org website for information about what all these different phases mean, and those are the really early trials. They're much smaller groups of people where they're just testing the concept. Then most patients are going to be involved in a phase two or phase three clinical trial where they're really trying to see, "How does this happen and how does it work in the general population?" Again, as you just said, they've tested it out so they're not using crazy, outrageous stuff. Dr. Shore, you talked about... I think saying that eloquently, like a mortgage. You're not committing to it forever. If it doesn't work we find something else. I think that's really great.