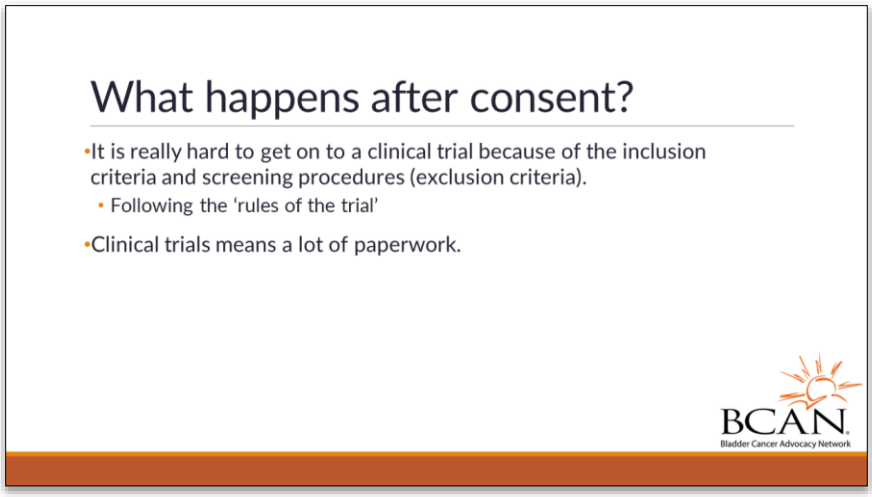

Stephanie Chisolm:

Let's switch gears a little bit and talk a little bit about what happens once you sign that consent form. There are certain inclusion and exclusion criteria that you need to meet. Why is it so challenging to be accepted into a clinical trial? Dr. O'Donnell, can you mention that a little bit? I know they have criteria that you have to meet to be included, but then if you have some other quirky criteria you can be excluded because you have, maybe, another health condition. Why is it such a tight window for what you need to have to get into a clinical trial?

Dr. O'Donnell:

Right, this is a good topic. I'll explain what happens. When you have that initial conversation with the doctor about your interest in a clinical trial, a lot of times by the end of that conversation the patient is really excited that they're going to hopefully do this trial, that they're going to get access to one of these really exciting new drugs ahead of the general population. So you have that discussion and you sign a consent form, and as Dr. Shore said, this is not a contract that you're signing. It's consent. It means that you understand the risks and the potential benefits of doing that study. Once you sign that it really starts what we call a screening process. In my office a screening process can take usually around two weeks or less. What happens during that screening process is you're going to go through a battery of tests that are screening procedures or screening tests, to make sure that you're actually eligible to qualify for the study.

It can feel a little bit frustrating during that time because you're waiting, right? Your cancer probably was just progressing and you're waiting to get into that clinical trial and now you're being forced to go through all these tests. These tests are required to make sure that it's safe for you to do the trial. They also form as a baseline so that we know exactly what your cancer looks like, what are your lab work as you enter that trial? So that we can know if anything changes once you start on that treatment. It's really important to do those baseline procedures and if those baseline procedures come back as qualifying you. Actually, some panels will go through and check off the boxes to make sure you sort of have parameters from each of these test results to make sure you meet the safety criteria for going into the trial, then they will allow you to go into the trial. It's not really your doctor that gets to decide that, you don't get to decide that, it's an independent set of rules that you have to meet, That process can

take about that two week time that I talked about. That's the screening. Patients can feel really uncertain during that time, but it's a joyous day, really, when we're able to call the patient and say, "All your tests came back, you qualify for the study and now you're going to start."

Stephanie Chisolm:

I think you talked earlier, Dr. Shore, about the consent form and it means an awful lot of paperwork. There's somebody in the office. There's somebody in your practice or in a large institution that can help with all of that paperwork. It's not something that should be really daunting - but there is paperwork, obviously, in being involved in all of that. When it comes to asking questions do you ever have a problem if people ask questions about what they want to know about being in a clinical trial, Dr. Shore?

Dr. Shore:

No. I kind of have two rules of thumb. A physician who says, "Look, you're asking me too many questions I'm not going to answer," or, "You're asking for a second opinion and I'm not going to recommend one for you," it's time for you to get another physician.

Dr. O'Donnell:

Yes.

Patient Advocate Bob W.:

Amen.

Dr. Shore:

It's super important for patients and their families to have a full throated discussion about all their treatment options, approved therapies, or within research. I just want to amplify a point that Dr. O'Donnell made, the rigor of being involved in a clinical trial is oftentimes much more detailed and costs are not even brought into the consideration that then what you would get by commercial payer standards and, oftentimes, even Medicare. There's incredible rigor and thoughtfulness that goes into these clinical trials. Real exceptional attention to detail.

Now, I will say, in all honesty, it's not an abundance of paperwork on behalf of the patients or what we typically call. If you're in a clinical trial you're a subject. The sites have to do all the paperwork and I'll be honest and say this paperwork is onerous but it's not on the part of the patient. We have to do it and we have to dot the 'i's and cross the Ts because there's incredible scrutiny by all sorts of monitoring agencies, including the FDA. We have to really be on our game. Sites that do this, community, academic, it's a passion and there's a lot of dedication to it. Patients get state of the art monitoring and care. Sometimes, even though the patients are not having to do a lot of paperwork, they do have to come in for some, oftentimes, for some additional visits so there are some patients who just say, "You know what? It's just not for me. I'm fatigued by having to make too many visits," or maybe, "It's too hard for me to get there."

We try our best to work within patients calendars of their lives and sometimes if there's a cost consideration for travel we try to help out with that, with patient approved stipends. I just want to be completely clear about that. Paperwork isn't the burdensome issue of the patients, it's for us who do the actual studies and all of our personnel.

Stephanie Chisolm:

Right. You bring up a really good point, Dr. Shore. Let me ask Kevin and Bob, did you feel, at any point that, "Wow, I'm just so tired of going into that office. I don't want to go in today," and yet you have to because you're scheduled within the trial for another test or another procedure, something along those lines? Was that at all a challenge to you or did you find ways around it by talking to the people that are on the trial team? Kevin, do you want to start? Were there any issues you had?

Patient Advocate Kevin W.:

I mean, at first it's different, right? When you get cancer you're not used to going to the doctor a long time. When you have cancer you go to the doctor all the time. There's a shift, for sure. I never really felt it was all that onerous. You can schedule these things out, usually, fairly well in advance. Up front, when you're trying to get into the trial, yeah a lot of that you just got to kind of jump when they say jump. But you're the only one who benefits or doesn't benefit when you jump, whether you jump or don't jump. It's a pretty personal decision and when it comes down to your life I think you just kind of try to make that work. I was fortunate enough to not have transportation issues or things like that. I can understate how those would be a problem for people. I thought that the University of Chicago did a great job of helping me schedule everything out and really doing everything for me. All I really had to do was show up.

Stephanie Chisolm:

Bob, did you have any thoughts on how much time it took for you to be in a trial?

Patient Advocate Bob W.:

Yeah, as far as the busy schedule's concerned, my schedule is not very busy anyway. The doctor's office is one of the places that I go most anyway, not just to Dr. Shore's office but he happens to be on 82nd Avenue here and 82nd Avenue is full of doctor's offices. I think I have a home in each place there. But anyway, I haven't seen any difference in being in the trial or not being in the trial from a stand point of time involved in treatment and so forth. Like my friend said, you got cancer, you make your schedule around it and that's pretty much what you do. But no, I haven't had any real hardships about that.

Stephanie Chisolm:

Well, because we're talking about this as a topic, there are lots of big academic institutions, big hospitals, that are doing big clinical trials, but Dr. O'Donnell if you had a patient who lived in the outskirts, a little too far to come in on a regular basis, and then Dr. Shore you're there in a more rural... Not rural, but beach-like community, and it's not so much of a big, large, urban, academic center. **How do you work together, let's say, to have somebody participate in a trial that might be happening at a large academic center but maybe do some of their routine care in a local doctor's practice?** Does that happen often, Dr. Shore? Do you know if there are other doctors that are doing that?

Dr. Shore:

One of the things that I've noticed in the arch of my career is the collegiately and the breakdown of the ‘town and gown’ phenomenon. The tertiary academic centers, whether they're medical oncologists or urologists, are now working so much better with the community based physicians because let's face it 85% of cancer care happens in the community. We have so many amazing clinical studies. Well, you just want to get patients enrolled so that's how we find out our data and we come up with an answer. Is it working or not? Being collegial, being communicative with the leading academic centers of excellence is

absolutely key to community practice, and working together if patients decide to move. Many patients will say, "Hey, you know what? I'm getting on in years, I want to go and move back to where my children are in Pittsburgh," or North Dakota or somewhere and so we reach out. BCAN is a great resource for getting people connected. Whether they're moving from Florida to Los Angeles, et cetera.

The collegiality, I have to say, has really improved dramatically. At the end of the day, it is our pioneering academic researchers who are leading the way in new, early phase studies but ultimately when we want to get volume of patients involved in research we have to work well with the community centers, too.

Stephanie Chisolm:

Dr. O'Donnell, do you have opportunity to do that on a regular basis? Where somebody comes in periodically to your practice, maybe into the city, but then they get their regular care and maybe their routine examinations out in a local community in Illinois. Does that happen?

Dr. O'Donnell:

Certainly. The trial does have rules that only sites that have the trial open can actually conduct the procedures related with the trial and administer those treatments. However, a lot of the academic sites nowadays have satellite facilities, right? Satellite clinics that are open out in those more non-urban centers. I think the whole idea of that is to make sure that we have access to everyone or as many people as we can for these trials. That's really important. I do have a lot of my patients that say, "It's tough to fight traffic and drive into the city and worry about parking," and so forth. A lot of times our patients will come for an initial second opinion, we'll find that a clinical trial might be the best option for them, and we'll go ahead and get them enrolled in the trial, but they can actually do a lot of the procedures at one of our satellite clinics that's much closer to their home.

Then they might come back and see me every few months, say when they have a scan or a reevaluation, and I can sort of weigh in on the case to make sure we're on track and the patient really likes keeping that continuity with their doctor at the academic center but could get those things done close to home. We've really made a lot of strides in that recently, I'd say.