

DEBUNKING THE MYTHS ABOUT CLINICAL TRIALS
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 BCAN Walk Ambassador

BCAN
 Bladder Cancer Advocacy Network

Clinical Trial Eligibility

Katie Glavin:

Every clinical trial has a protocol. These can be anywhere from 10 pages to 300, 400, 500 pages long and even longer. This book is our basically step by step instruction to tell us what to do, who's allowed to be on these trials, why we are using this drug in this setting, How it works. You name it, this protocol has the answers to what we're doing for this clinical trial.

Clinical Trial Eligibility

- Clinical trial have a protocol, with specific rules and regulations to follow.
- Including a very long and intense eligibility criteria that can include:
 - disease status (# lesions, size of lesions, location of lesions) – imaging/clinically/pathologically
 - Lab values being in specific ranges
 - Vitals (BP, weight, frailty assessments)
 - Timeframes – such as time from surgery or time from/to treatments
 - Medical history (BP, diabetes, autoimmune disorders, dialysis, additional cancers, etc)
- If you are deemed ineligible to participate in a trial, it is for your safety.

Katie Glavin: The biggest thing we hear a lot of times is people tell us it's unfair when they're deemed ineligible to participate in a clinical trial or think that we're just being mean and don't want them in the trial. This is again another common myth I hear.

I usually have to do a lot of explaining to make people feel more at ease that really why you're chosen or not chosen is for your safety. Inclusion and exclusion criteria in clinical trials can sometimes be up to 10 pages long. These can get into such specific criteria such as disease status, lesion size, the number of tumors, the location, etc...

Sometimes we have to see certain things done on imaging. Again there's a clinical disease status: How do you feel? Are you frail? Those different aspects. Then pathologic, which is what is your tissue staging? This can be a whole page of eligibility inclusion, exclusion criteria just to meet eligibility for us to screen you.

Then what we have is lab values. We run multiple panels and you have to be within range. Often times with bladder cancer the big ones on this area we see for a lot of patients being ineligible comes down to the creatine value which is related to your kidney function. Really that's the biggest one I see knocking people to ineligible.

We can take those lab values multiple times over that screening of the clinical trial to really see if it's a one off or if it's really an underlying issue. You get that extra screening level for different diseases and diagnosis. We also take vitals, such as your blood pressure, your weight, and we look at things like if you're frail or are you using a walker? Different things like this allow us to know how will you take this drug?

When we talk about different platinum-based chemotherapies or immunotherapy on bladder cancer we really have to make sure your body's in a good setting so that you can handle those toxic, systemic therapies. Because they can sometimes knock you down. Really making sure those lab values, and that disease, and your vitals, all of this information is so important to make sure that you receive the best treatment and the best care you can.

Another aspect often overlooked is what's called timeframes. For instance, for a different clinical trial you might have had to have a resection such as a TURBT. That resection might have had to be within 45 days. You might have had yours 50 days ago and that just is too far. It might seem like not a big problem or a big issue but really what we're seeing is if that disease had the chance to grow and we need to re-resect that to really make sure there's as minimal tumors inside as possible so that treatment can really attack what's left of those microscopic cells.

There's different aspects like that that seem very simple but actually have a big impact should we let someone that had their surgery 50 days ago versus 45, again these are all different based on the different protocol. Every trial has different eligibility criteria and standards that we have to meet.

Another big aspect is medical history. This is really important when you have to be what's called a good historian, or a good storyteller about your history. We'll ask patients all sorts of different information,

and then about 2 months in they always tell me, "Oh, I forgot I had diabetes." Well, that's a big important piece that we need to know. Making sure you have a good idea of what your medical history is. Different surgeries you've had. Different diagnosis. Any medication. Even things like supplements, those are important for us to know.

Katie Glavin:

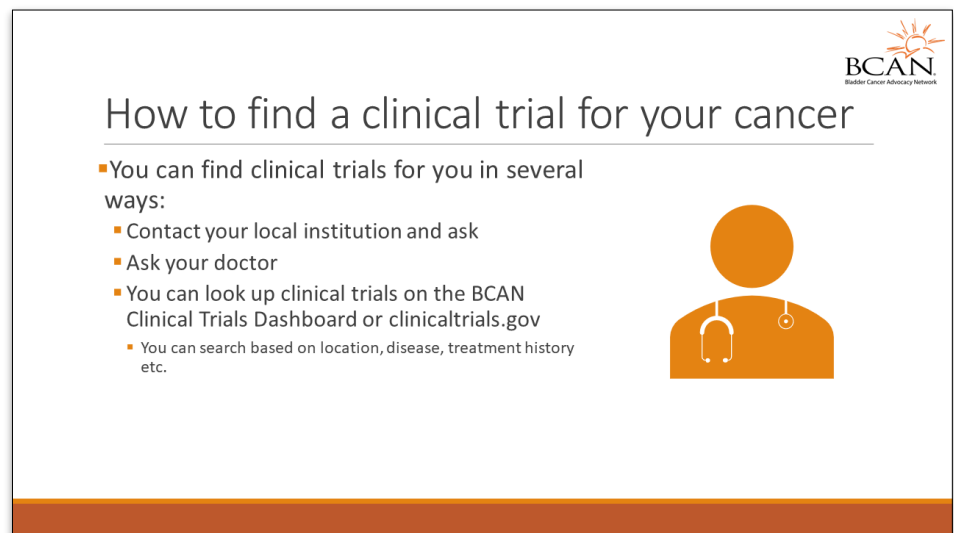
Even things like drug use, alcohol use, even CBD use is important for us to know as different treatments can work differently with those different interactions. That's when that medical history or what kind of medications you're taking are really important to know.

Again, if you're deemed ineligible it's for your safety and we will do everything that we can to find you a different trial that fits your specific disease criteria to really make sure we can get treatments for you. Sometimes they're just not out there and we just have to wait until new opportunities come about. But we always have ideas in every space of bladder cancer. And by space I mean newly diagnosed to non-muscle invasive, muscle invasive, different types of treatments, and even down to the metastatic immunotherapy types of treatments.

We try to always capture every area of bladder cancer, and every stage and disease setting so that we can really make sure we have options. It's important to look for them. Sometimes you have to be your own advocate to really find that clinical trial for you. Different areas and different physicians you go to will have different knowledge of different trials that are going on. For example at KU we have probably 8,000 clinical trials going on.

Probably only 500 or so are related to cancer. I'm going to be an advocate of knowing what we have at our institution but I might not be able to know what an institution down the street has, or in a different state, or even in a different country. A lot of times there's different ways you can look up different diseases and treatments.

ClinicalTrials.gov is a great one. You can look up by disease site. You can look up location in the country. You can look up specific drugs that you've read about that you want to know if they're in clinical trials. This really allows us to see what options there are out there and if they're appropriate for us. I've had patients bring me information. "I want to be a part of this trial."



The infographic features the BCAN logo in the top right corner, which includes a sun icon and the text "BCAN Bladder Cancer Advocacy Network". The main title is "How to find a clinical trial for your cancer". Below the title is a list of ways to find clinical trials, with a stethoscope icon to the right of the list. The list items are: "You can find clinical trials for you in several ways:", "Contact your local institution and ask", "Ask your doctor", "You can look up clinical trials on the BCAN Clinical Trials Dashboard or clinicaltrials.gov", and "You can search based on location, disease, treatment history etc.".

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How to find a clinical trial for your cancer

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I do everything I can to find them a location, the coordinator of that site, oraA physician. Do they need a referral letter? Do we need to do preliminary testing before they travel to that location? Is this something they can do via telemedicine? There's many different aspects we can do to really find that clinical trial that's best for you.

Katie Glavin: Don't feel limited based on what's in your community. If no one informs you about different clinical trials you can ask those questions. You can say, "Hey, Doctor Smith I would love to know what types of clinical trials fit my care." If they know about them they will tell you. We won't always ensure we provide all options for different treatments for your care. And we'll weigh the pros and cons with you but again different people have different knowledge on different disease and different clinical trials. It's always important to look and do your own searching just to make sure nothing's overlooked, or we didn't know that they existed for you.

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