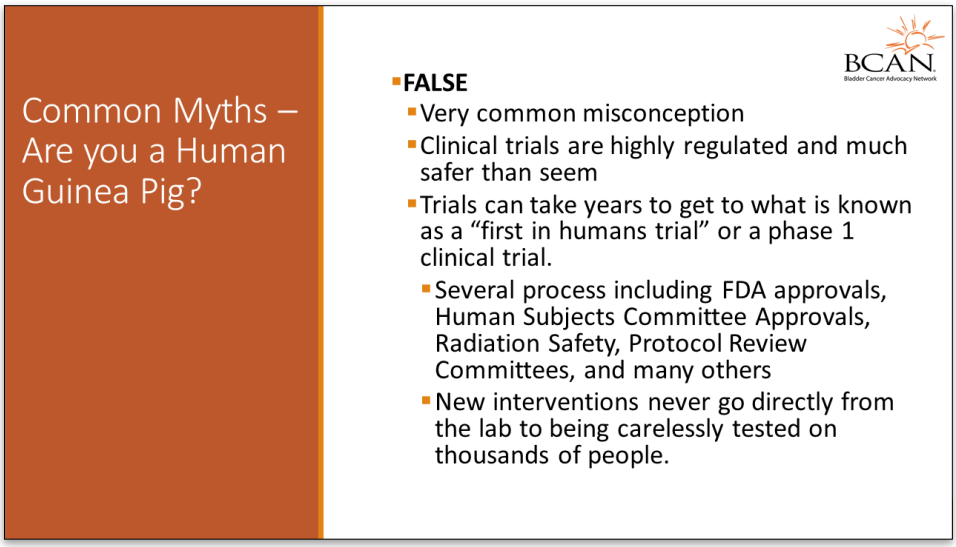
Clinical Trial Myths

Katie Glavin: Often times when you hear about clinical trials people often say, "I don't want to be a guinea pig." Know that this is definitely not the truth. This is a very common misconception that I hear a lot from patients when I talk to them about participating in clinical trials. Clinical trials are heavily regulated.



There are several different committees that are required for us to submit and receive approval in order to move forward, even on something such as a registry where we're just collecting information. They can take years to get off the ground. I've seen clinical trials from idea conception to execution just to get a patient in the door on it take eight years. I've also seen them take a few months on those more observational type trials.

If you even receive imaging or a CT scan on a study, even if it's per your routine clinical care it still has to go through a committee, such as a radiation safety committee. They have to deem that this is

appropriate to receive that amount of radiation even though it's per your routine care because it is part of the clinical trial.

Katie Glavin: There are many others that are also included, FDA approval if it's a new drug and device, and then the human subjects committee, also known as an "IRB". All these committees together really help us ensure that patients are safe. The goal is that everyone is safe and well taken care of, and that hopefully we can find you a treatment that is going to either be equal to standard of care or even better.

New investigations never go directly from a thought straight into humans or people. I hope that makes people feel a little bit more comfortable about how long it takes for us to get these conceptions. The average drug, such as a cancer drug, from bench to bedside takes about $2.2 billion, and takes about 15 to 20 years. It's a lot of effort and time put into that. And we take it very carefully. We definitely don't want anything to go wrong.

Clinical trials take so long so if anything goes wrong during that time when we're conducting that trial you can imagine how long it would take for us to restart or do it over. That's why it's so crucial for us to have all this information and go through all the proper channels to really make sure it's safe.

Whenever you're approached about a clinical trial, first and foremost you'll be consented, or be provided an informed consent. Most of the time people think of this, "As I signed it and am I giving away my life?" That is never the case.

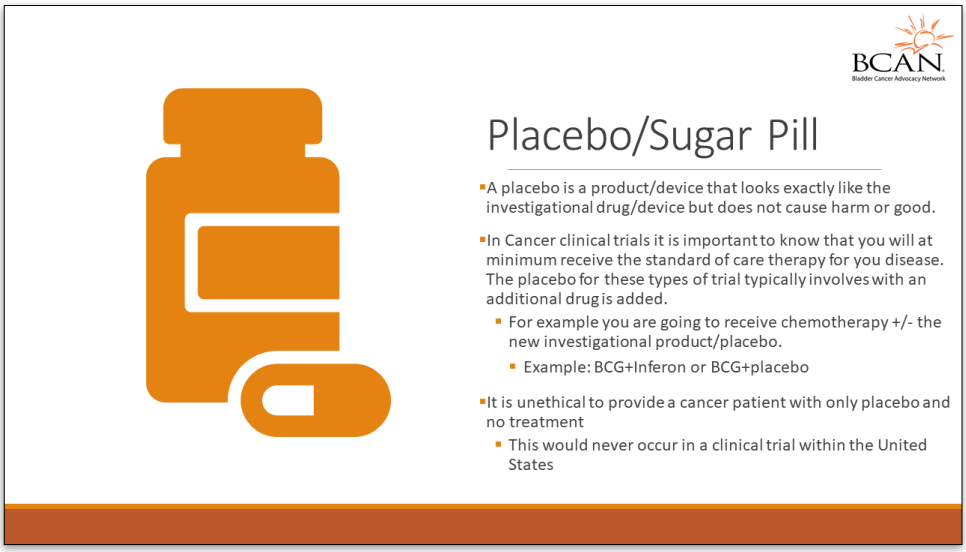
We like to think of a informed consent as a process. It's more than reading and just agreeing to what we're telling you. It's really important to go over all those aspects of that consent and not just sign the piece of paper. The consent always provides you with information such as the purpose of the trial, background information. How many patients they are looking at. What phase it is, insurance coverage, HIPAA privacy, duration, and what are risk and benefits.

This is something that is really important to review and make sure that those possible risk and benefits are something that are appropriate for the potential gain of this clinical trial. The purpose of really having a consent is to really make sure you know what's going on and what you're agreeing to do. At each visit that you have with a doctor that you are participating on a clinical trial with really should go over their consenting process with you again.

Katie Glavin: Your healthcare team should constantly be checking in. How are things? Is this something you still want to do? Do we need to go over any side effects, any of the information again to really make sure that this is still the best fit for you at this time? Know that research is always voluntary no matter what.

If you sign a consent form, you get through the screening of a clinical trial and then you decide you're not interested you can always just say, "Nope. I'm not interested." It's not a contract. You're not bound by that. We get a lot of questions about those items as well.

Often you hear about the placebo, or “sugar pill”. When you have randomized controlled trials we talk about placebos a lot. Know that when we talk about placebos **you will never get less than the standard of care for a disease that is chronic, or something like cancer.**



If you had a flip of a coin and were randomized to a treatment you would, as a cancer patient, never get no treatment and just receive a sugar pill that looks the same as a cancer treatment. They would never do that because that would be deemed unsafe. What you will actually receive the standard of care plus or minus the new drug or placebo. At minimum you're still receiving what you would receive if you were not participating in that trial.

A really good example you hear is BCG. That's a very common treatment. You will see there's the Tokyo Trial where they have three different arms or treatments. You have BCG plus the Tokyo strand, you can have BCG with interferon, or you can have BCG with “placebo”. What this really does is allow us to do is place you in a group based on a demographic, maybe a prior treatment, maybe the stage of your disease.

This really allows us to see how well that drug works with the other drug. We know BCG works, but does it work better with the additional drug, or is the BCG with placebo the strongest arm? That then tells us, well BCG alone is probably our best case scenario if that's the data that shows.

Katie Glavin:

Often times I hear a lot of, "Clinical trials won't help me." And that's not necessarily true. I always like to clarify when you're thinking about ever participating.

This is a really important time to review the treatment options, the risk, the benefits. Even the frequency of the visits in which you're coming in. This is great to talk with your doctor, your family, your caregivers, friends, and really make sure that this is a good fit for you. Make sure that it's something that you're interested in. If you're indecisive you don't have to commit immediately.

You really should take the time to really weigh out the pros and cons of this opportunity for you. If you are eligible you receive different treatments that might not be available to the general public. If someone is doing a trial for bladder cancer you might not get the drug through routine standard of care for maybe another 10 years because that's how long it might take for the trial to finish and make it to market.

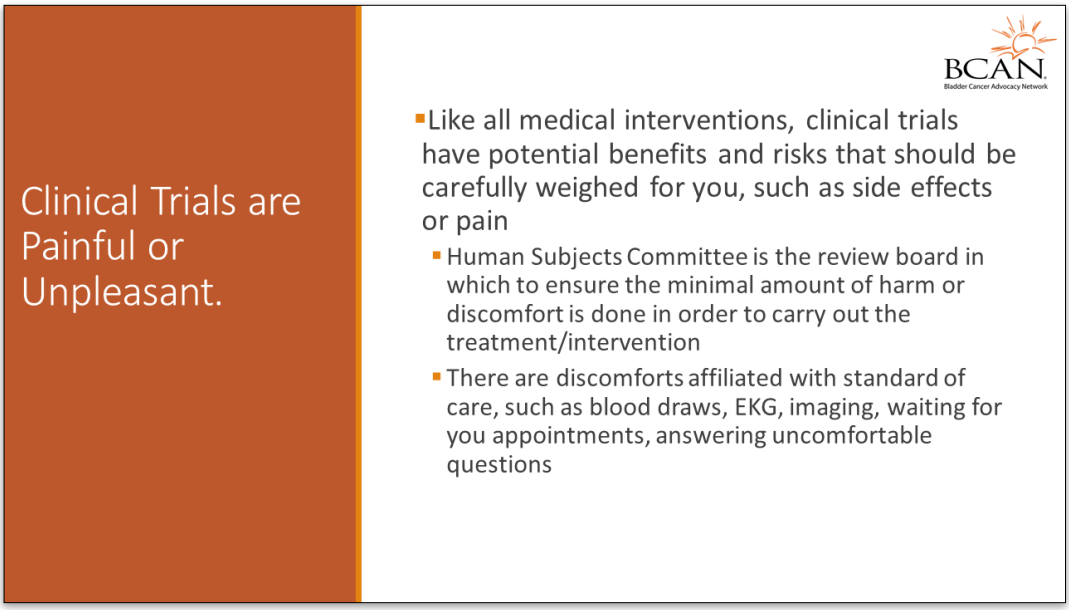
That's a different perk of actually being on a clinical trial. Sometimes when we talk about the observational trials. People will tell you that it might not help you directly but it would actually benefit the general public. That's really when you're able to do what you can to help people in the future with the same disease that has burdened you.

Then during clinical trial participation, another perk is that you're actually closely monitored. You have an extra few hands in your care. As a coordinator, I don't have as many patients to take care of as my physician does as a doctor. I'm able to really hone in and look at those schedules, make sure all those labs are ordered, and really be that extra liaison between you and the institution in which you're being seen in, along with being a part of your personal care and development along this trail, and really be that support person for you.

Katie Glavin: This really, helps people. You have that “go to” to be able to get into the health system. Sometimes when you call, it can be a bit of a challenge to just get someone on the phone. Definitely having that direct contact is always beneficial. We look at different things like, what's going on with your disease, and frequency of treatments. There's a lot of information that's collected during the course of your participation, again always to make sure that safety is our number one priority.

These clinical trials have super detailed protocols that may require additional tests or lab work. That might not be part of your usual care. This is something to really make sure you understand what those extra treatments are that you might not be used to, like lab tests or lab work. It might require an extra bone scan. If you don't like small spaces that can be a little bit more anxiety provoking. Definitely making sure that if you have those extra things that are required for the trial, that you're aware of what they entail and really what you're responsible for there.

Clinical trials are painful or unpleasant. We have many different types of medical interventions that have potential risk and benefits, and again should be weighed out. However, would we say they're painful or unpleasant? I would say no, however I don't typically participate in these clinical trials. I'm more of the conductor, but again we go through Human Subjects Committee to really review these protocols and make sure we're doing the minimal amount of harm as we can along with any discomfort.



We have different groups at KU called PIVOT, where patients can actually give us feedback about clinical trials when we're developing them. Such as, "Hey, you have way too many blood draws. No one wants to come in that frequently." That's a great thing to know. We have very analytical minds and so we think, "Oh, we need these numbers. It would be great to have." Really having someone tell us that extra blood draw a week is just a lot for us.

That's a different side of things we don't always see, and so it's great to have that kind of input to really make sure these are as pleasant and not painful as possible. The other kind of aspect is the part be the amount of questions that we ask. Sometimes they're invasive, or uncomfortable, or personal. That can be really challenging.

Katie Glavin: Going through cancer diagnosis, and treatment, and appointments, is just, it's a lot and it can be overwhelming. As a coordinator we want to do everything we can to ensure that we're not making this a bigger burden for you to get treatment. We really want to make sure it's smooth, and easy, and makes something that's achievable for everybody to participate in and get the accomplished goals to get these drugs that are beneficial to patients and our treatments out on the market.

Clinical Trials, Are They Dangerous? There's always different levels of risk with different things that we do, but really they're designed to have as little risk as possible. Again, when we talk about things like risk it could be something such as when we draw your blood you might have some bruising, discomfort, or bleeding at the draw site. This is something that can be uncomfortable and it can also do things such as being infected which can be dangerous.

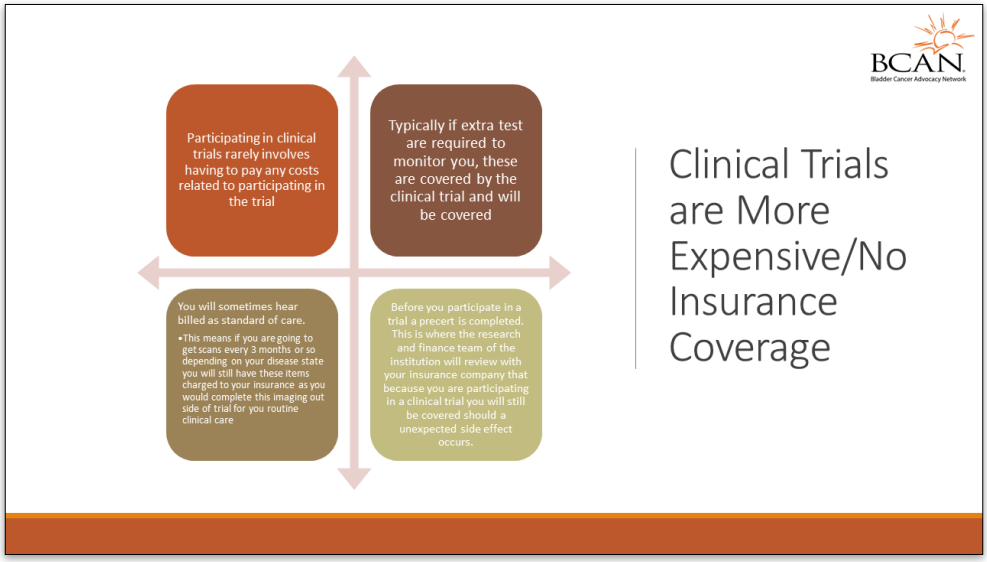
We really try to educate people about all those different levels of risk. Some are a little bit more uncomfortable. Some might actually cause potential side effects or even allergic reactions. That's when we really do everything we can to go over your medical history, what's going on with you and to really make sure that that's a good fit for you.

Before a drug makes it out it goes through rigorous testing. The indication of the drug is likely to be effective and safe for use. Again, this is when we talk more about that basic laboratory science. Again, multiple review committees to prove that it's safe. Multiple times I've even had this IRB committee come back and say, "You're asking too many questions. It's going to put a patient in an uncomfortable setting."

We actually have to go back and debate what types of questions do we need and what can we eliminate to really make sure this is more comfortable for our patient? It can occur with different lab draws. Maybe we do them less frequently. Maybe it's the number of treatments. All of those different aspects are really looked at by several different people to really ensure that one, we can actually execute this trial, but protect the rights and safety of our patients.

Often times they can be misunderstood. It's extremely important to really be a part of clinical trials because we can't advance medicine without them. It's hard to really get to that next step without participants. Again we want to make sure that's always healthy for you. I often get a lot of questions about the cost of clinical trials, and that it's so much more expensive.

Katie Glavin: This is a big myth. It's actually in my opinion probably the opposite. Most of the time if you're participating in a clinical trial you really don't have to pay any of those extra costs. For example if we ask for an extra bone scan, and this would not be part of your routine care, or a CAT scan, we actually invoice that to the pharmaceutical company that is conducting the trial and they will actually pay for these things for you.



We take care of all of that for you. Sometimes when you hear that they might be expensive it's also because we will do what's called billing to your standard of care. If you are going to get a cystoscopy, every treatment is with your physician and we need that information for the trial. It's very likely that you would still have that charged to your insurance because you would be receiving that outside of the clinical trial participation anyway.

But maybe that bone scan would be that extra piece that we don't typically get in a routine clinical care for bladder cancer, and that's when we can really get those sponsors and pharmaceutical companies to pay for those extra costs to really make sure that we can get those patients on trial without having additional financial burden.

The other aspect that's really nice is if there's ever an experimental drug such as that BCG plus Tokyo Strand, it's not something you would have to pay for. Because that drug's not on market they will never make you pay for an investigational product. That typically is free of charge. However if you receive the BCG only arm that BCG might be charged to your insurance.

There's different aspects, and this is why it's really important to really ask those questions when you're being consented to understand what you're responsible for. Another aspect is what's called a pre-cert. We do this at KU. I'm sure most people do this across the country. But really what it is is there's a two step insurance pre-cert for you when you participate.

Katie Glavin: One, we pre-cert can you participate in a clinical trial? That insurance company comes back to us and says, "We approve for them to participate in this trial." The reason we do that is because should you experience a side effect such as this drug made you dizzy while driving and you ended up in the emergency room. Those additional costs will be covered by the trial if it was direct from the drug itself.

That way should you have a repercussion or a side effect that ends up being bad enough that you need to see someone for it then we know that your insurance company will cover those costs because we pre-certed your participation in that clinical trial. This is typically when you're really looking at those investigational products or those new devices.

The second pre-cert is your standard of care, so what treatment are you getting. That way you're participating in a clinical trial and you're also covered for a treatment you're receiving if you receive the standard of care. We really like to make sure that we do everything we can to really make as little financial impact on our patients as possible.

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