Meet Our Presenters:

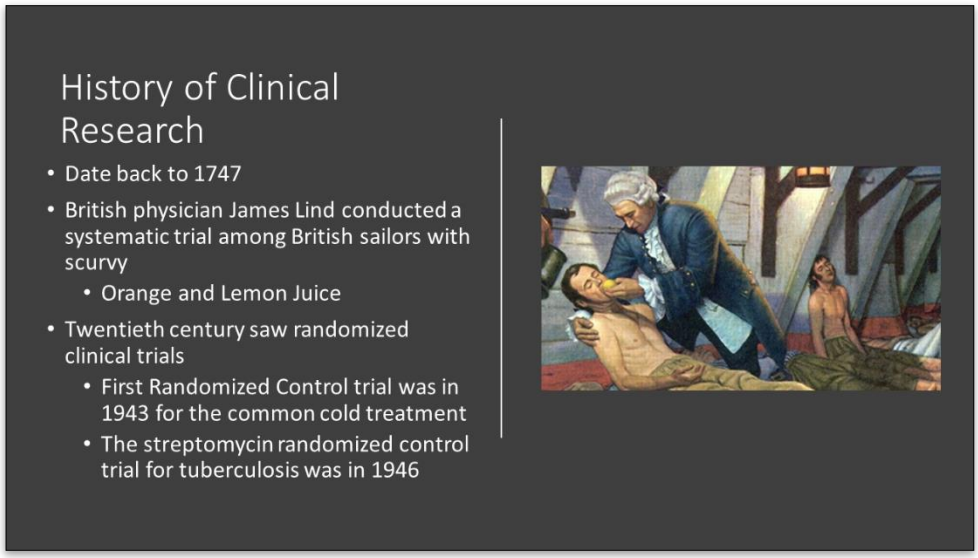
Katie Glavin: Katie is at the forefront of building a robust clinical research program in the department of urology at the University of Kansas Health System. She graduated from the University of Missouri Kansas City with a focus of chemistry and physics, and she's certified by the Society of Clinical Research Associates. She has worked to develop and foster clinical research program for the urology department by working with a skilled team of faculty residents, fellows, staff, and students. She began her career on the Clinical Research Organization (CRO) side of clinical trials. While at the CRO she gained knowledge on the regulatory process and studied management. She later furthered her experience at the University of Kansas Cancer Center where she worked in urological oncology research as a study coordinator. She's now broadened her research to include all urologic disease, diagnostics, and devices. We really are thrilled to have her here so that she can help to debunk some of the myths.

Explaining Clinical Trials

Welcome to Debunking the Myths About Clinical Trials. Bladder cancer is a devastating disease with more than 80,000 new cases expected to be diagnosed each year. BCAN recognizes that there would be no new treatment options for bladder cancer without clinical trials. They test the safety and efficacy, do they work as they're intended, before new treatments can be approved by the FDA.

There are many clinical trials around the country but not all patients consider them a treatment option. We're here today to help dispel some of the myths and share information about clinical trials.

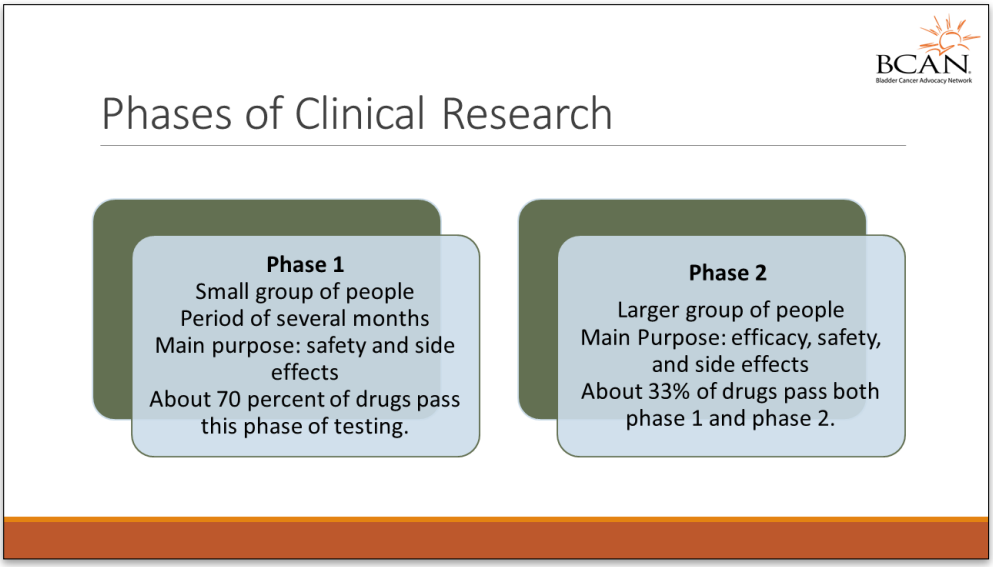
Katie Glavin: Thanks for having me. I'm going to go over different aspects of clinical research to really show you the broad area of where it started and where it is today. The clinical research dates back to 1747. The first trial that was conducted was on scurvy. They actually used orange juice and lemon juice to treat these patients and monitor what would happen.



Of course, this was not quite in the controlled setting in which we use in trials today. Randomized controlled trials, meaning they are randomized, such as a flip of a coin, to different types of treatment options were actually brought about in 1943. The first clinical trial was for the common cold, and then later was tuberculosis.

Clinical trials haven't been around for super long, so it's exciting to see how far it's come in a short period of time. I'm going to go over different phases of clinical research, common myths you may hear about research and clinical trials, how to find one for you, and what to know, ask, or do during a trial. To start there's multiple phases of research. We typically refer to them in four phases. Phase 1 is once a drug has been developed, or a device, or any kind of interventional purpose. They use small groups, usually anywhere from 10, to 20, to 30 people.

They're usually pretty short. They only last less than a year, usually about a month or so to really see what is the safety and dose levels that we use, and what kind of potential side effects? A good example of this is when you hear things like Tylenol, and it's 500 milligrams. That dose was chosen through clinical trials by starting at 100 milligrams, then 200 milligrams, and it gets up to a dose that they feel is safe with minimal side effects, or side effects they'll accept as part of the drug that can treat different illnesses.



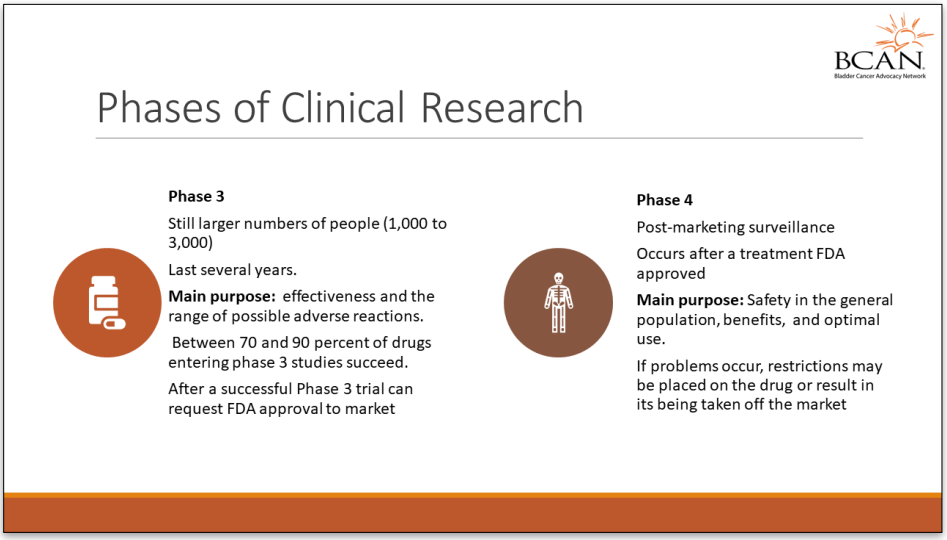
About 70% of drugs that make it to a Phase 1 actually make it past that

phase of testing. The next group is a Phase 2. This are typically when you see larger groups. This is when we know that the drug is safe to use in that small population and with a larger the group to really allow us to see if different diseases or conditions people have play a factor?

Katie Glavin: When we have that Phase 1 small group it's really about getting people in a group to really see if that drug can do anything. When we move to the larger group in Phase 2 we start ruling out different things. Maybe this isn't a drug for someone with diabetes. Maybe you can't have another type of malignancy. There's different aspects there where we're looking to really target the group that has the indication which the drug will treat.

The main purpose of this is the efficacy. We know it is decently safe as a Phase 2 but how well does it work? In such things like in cancer is it just reducing those tumor sizes? Is it just keeping them at the same size? How well does it work? Then again we always continue to look at safety and side effects.

About 33% of drugs that get to this portion actually move out of Phase 2. That's about one out of three drugs really make it to what we call a Phase 3. That Phase 3 trial is when we really look at large numbers. You're looking at a thousand or more. This is really broadening that patient population to really allow us to see how that drug works and in that population.



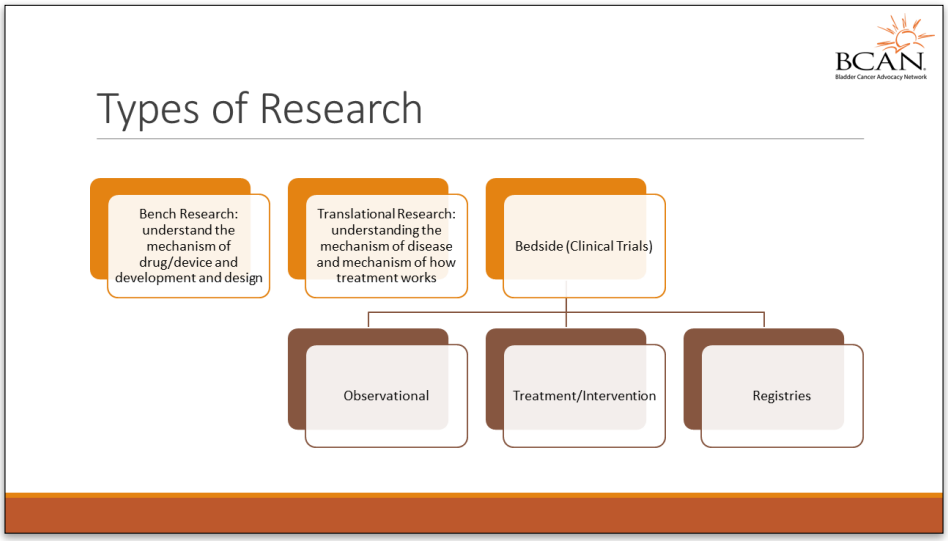
This is when we feel a little bit safer about that drug. We're going to get it to a larger number of people and really see what happens. These typical types of trials last for several years. An average drug that gets from a Phase 1 all the way to a Phase 4 can take about anywhere from 15 to 20 years. This is when these trials really build into what happens in a long-term use.

We look at effectiveness, also all sorts of different reactions. This is when you're looking again at those patients with other comorbidities such as diabetes or other cancers to really see the side effects. We need to know. Are they from those other illnesses? Are there medications people are taking? Or are they really from that experimental drug in which we're looking at?

If the drug makes it to this phase and the data shows that it is at least decent or better, if it shows negative effects it will actually be pulled at this point or not make it that far. At this point if it passes a Phase 3 clinical trial with FDA approval that drug will make it to market. About 70% to 90% of the drugs entering this Phase 3 typically succeed which is pretty high.

Katie Glavin: Phase 4 is when we really talk about post marketing surveillance. Once that drug's out there on the market and available, they look in the entire population of who's taking this, what other medications are they taking? What other illnesses do they have? This is really to just see when we put it in that ten to hundreds of thousands of people will we still see the same results? Sometimes when that happens then we'll go back and realize, oh maybe we can't give it to someone with hypertension because these drugs don't work well together.

That's when you see some of those things come out on the news that say, "Oh, if you have this you shouldn't be taking this medication." There are different types of research. Typically what you'll hear is bench to bedside. The bench research is really when you are in a laboratory. You're really looking at drug development, device development. We're testing out different types of products to see if it actually is feasible.



When you're talking about surgical oncology, this is when they're making those tools, even down to the robot arms that are coming in. We have to build these devices and different types of drugs in the lab and test them out to just see if they even work. We move to translational research. This is really understanding how the disease works, or how the treatment works, or how they work in unison together.

For example, this is when you might have a bladder cancer drug and we're going to test it in animal models. That allows us to see, how do those tumors react with the drug itself? Once we feel we have an approximate dose that's appropriate, and that we feel it's safe enough, we will move to what's called bedside.

This is when we move to the first in human trials. When you have bedside trials, or what we call clinical trials, there's three main areas: **Observational**, which really we just do things like quality of life. We ask you a lot of questions about your health, your social system, your environment, and different things about your cancer care or your treatment, like: “what treatments are you getting? How long did you get them?” This allows us to again see what sequence of drugs and other things can work well together.

The other ones we have are **treatment and intervention** which we kind of covered in those Phase 1 to Phase 4, and then the **registries** which is really just long-term use of us just really monitoring what's happening out there in the real world.

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