

Presented by:



Rick Bangs is a MBA, PMP; and he's a bladder and prostate cancer survivor. He's worked as a patient advocate in a variety of roles including research advocacy, government lobbying, educational support, support groups, one-on-one support, and fundraising. Rick has long been a friend of the Bladder Cancer Advocacy Network. As a research advocate, Rick serves as a member of the National Cancer Institute Council on Research Advocates as a co-chair of the NCI Patient Advocate Steering Committee. He is one of two NCI Genitourinary Scientific Steering Committee patient advocates and one of the three NCI Cancer Care Delivery Scientific Steering Committee patient advocates. Rick is the Chair of the SWOG Patient Advocate Committee, a member of the SWOG Executive Advisory Committee, and Committee Chair for the SWOG Bladder Cancer Patient Advocate Group.

Rick: Clinical trials is an area that's near and dear to my heart and a very exciting area. I'm hoping to give you an introduction to the work that we do in clinical trials and how a patient might interact in that context. I'll also give you some information relative to where we are from a muscle invasive bladder cancer perspective, as well as being up to some questions and answers that, hopefully, will address some of the concerns that you might have as a patient.

I was diagnosed in October 2006. I had muscle invasive bladder cancer, so the discussion we're having today is very relevant to me on a personal level, but obviously very relevant to many bladder cancer survivors on a personal level as well.

I had a radical cystectomy and I have a neobladder. We're going to talk a little bit about some of the work that I do in the area of research advocacy. Then we'll talk about what research advocacy is in the clinical trial context. We'll give you a little bit of a taste for the work that we do with folks like Dr. Singh and Dr. Black. Then we'll talk about what's new.

I already told you that I'm a bladder cancer survivor. I do work with some of the groups that you're seeing on the screen now. I've done some work with the BCAN team, which does amazing things. I've worked with them on an early version of what we used to call Patient Tips. Also

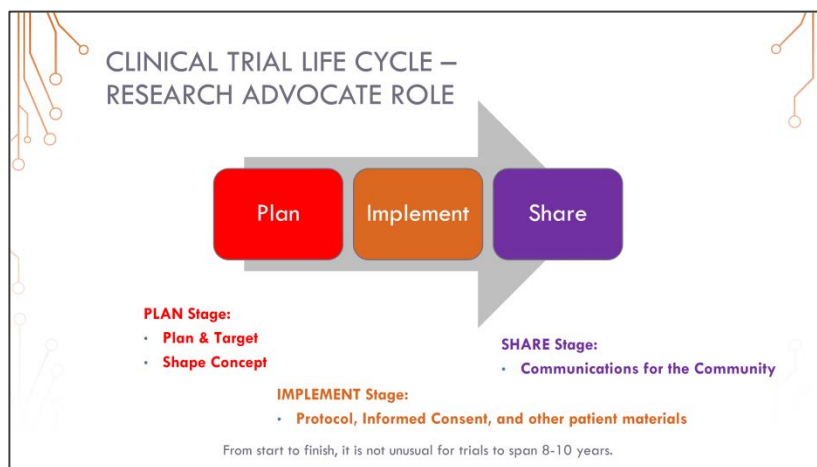


worked on the clinical trials dashboard and have done some webinars and some other things. I'm always thrilled when I have an opportunity to work with the BCAN team and the researchers that work with them

I do some work with SWOG. SWOG is a group that is funded by the National Cancer Institute. Think of it as a virtual team that's working on your behalf to define the clinical trials that should be done for various cancers, bladder cancer being one of the groups.

I do some work for the National Comprehensive Cancer Network. The National Comprehensive Cancer Network is one of the groups, and there are several, that will define the standard of care. When we talk about, well, what treatment should a patient have in these specific situation, a group like the NCCN or the SUO or the AUA or ASCO, those are all groups that define that standard of care, and the insurance companies often pay close attention to what these groups define as the standard of care in terms of determining what they will compensate for or not.

Then I also just work for the National Cancer Institute, which is under the National Institutes of Health, both within the cancer care delivery space, but also with my peer group of patient advocates. We've got an amazing group of research advocates.



This is the clinical trial lifecycle. I've really simplified it. We walked through several examples of clinical trials. They would have all gone through a lifecycle like this. The first stage in the process is the planning stage. That's where we would try to define where we want to have our clinical trial, what particular space in the disease, and we would shape the concept. What

drug are we using? Is there going to be a placebo? Those kind of things. It's very early part of the process to get it to the point where we are actually ready to involve our first patient.

In the implement stage, we're defining the protocol. That's the very detailed cookbook of the clinical trial. There's paperwork, if anybody on the call has ever participated in a clinical trial or is thinking about participating. There is a requirement that, as a patient, you know exactly what you're getting into. We developed this form called an informed consent to ensure that that happens.

Then there's the other collateral material that we might provide. There might be a brochure or there might be a video. Those are all done in the implement stage. Then we're going to share the results with the community, so that would be with other researchers, but it also would include the patient community and advocacy groups like BCAN.

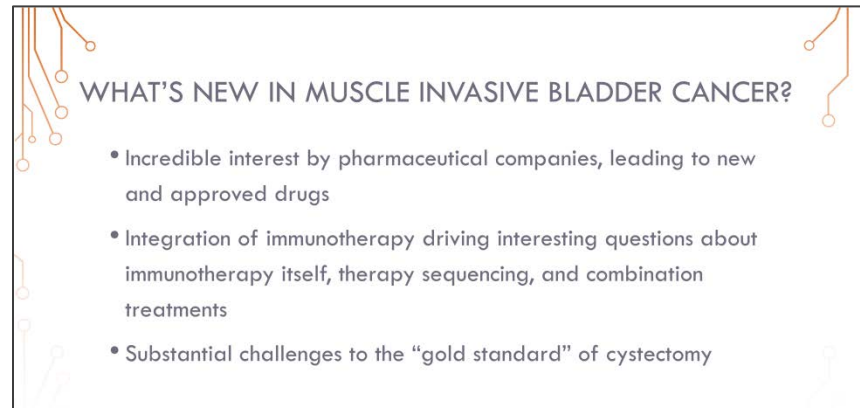
I think it's important for people to understand that this is not a quick process from start to finish. It's not unusual for our trials to span eight or 10 years, depending on what the goals are. We're trying to get the lifecycle down to a smaller time frame. But it does take a fair amount of time to get from the beginning to the end, and we do understand the urgency of doing so.

Let me stop here and talk about some things that are new in the muscle invasive bladder cancer space. I've been doing research advocacy with SWOG since 2009, and so I've seen some exciting things happen. The first noteworthy thing is that we have huge interest, incredible interest, by pharmaceutical companies and we've got new and approved drugs.

When I started, we didn't have the same enthusiasm from the pharmaceutical companies and we had not seen any new treatments for close to 30 years at the time that I started SWOG. It's really exciting to see this level of interest, and not just interest but actual drugs that are available for us to use in our clinical trials.

The second thing, which is related obviously, is that we have this concept of immunotherapy. In fact, bladder cancer is, interestingly enough, even though we haven't had a lot of new treatments, we were one of the early users of immunotherapy. Many of you may be familiar with BCG.

That's actually an immunotherapy drug.



WHAT'S NEW IN MUSCLE INVASIVE BLADDER CANCER?

- Incredible interest by pharmaceutical companies, leading to new and approved drugs
- Integration of immunotherapy driving interesting questions about immunotherapy itself, therapy sequencing, and combination treatments
- Substantial challenges to the "gold standard" of cystectomy

But in more recent years, we've had no immunotherapy drugs. You've heard talked about several of them on this call. They are driving some very interesting questions about immunotherapy, but also as we work through our immunotherapies, they'll be questions to answer in terms of when one should have immunotherapy versus some of the other kinds of treatments, whether it's the surgical treatment or the radiation treatment. What's the right sequence and what's the right combination? You saw some trials that were trying to address some of those questions on this call.

Then, also, this is particularly exciting for somebody who's had a cystectomy, but it's exciting to see some challenges to that gold standard of using a cystectomy. Those of us who've had a bladder removal, we know what that surgery's about. But in the long term, obviously we'd like to ensure that patients retain their bladder.

You heard about an exciting new outcome called bladder intact, disease-free survival. That's a new concept that we're trying to test with some of our clinical trials, and it's exciting to see.

BCAN staff wanted to let everyone know that BCAN actually has a clinical trials dashboard. If you go to **bcan.org**, you can get there, or you can type in **clinicaltrials.bcan.org**, and you'll get to our clinical trials dashboard where you can actually search by your disease state of non-muscle invasive, muscle invasive, or advanced metastatic.

Then also you can search by your geographic state. You can save trials. You can log in and then you can email them to people. If you want to send it to your doctor or to a loved one, you can certainly do that. But that's a great one-stop shop that's a little less overwhelming than **clinicaltrials.gov**, which is the large site, but we get all of the same trials that come through clinicaltrials.gov.

BCAN would like to thank our sponsors for their support.

