Meet Our Presenters

Dr. Angela Smith: Dr. Smith is a urologist and assistant professor at the University of North Carolina, Department of Urology in Chapel Hill. She has led PCORI Engagement Awards with the Bladder Cancer Advocacy Network to engage patients in the research process.

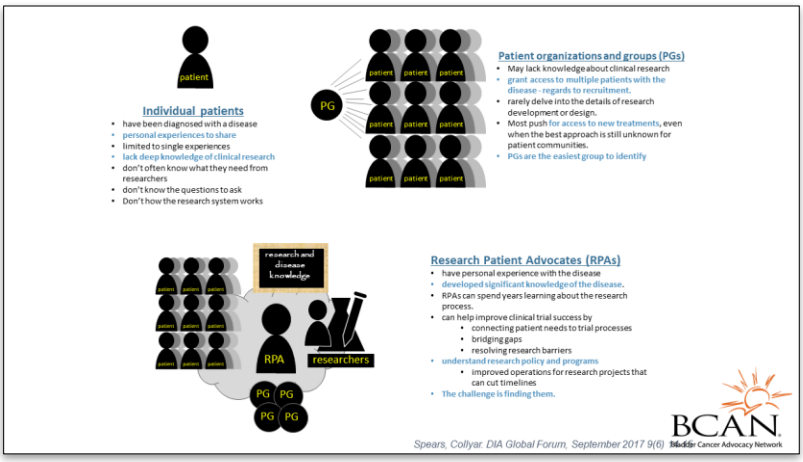
Patty Spears: Patty is a 20 year breast cancer survivor and cancer research advocate. Patty is currently working as a scientific research manager and patient advocate at the University of North Carolina at Chapel Hill, where she leads the UNC Lineberger, Patient Research Advocacy Group and the UNC Breast Cancer advocates.

Bob Lipman: Bob is a BCAN research patient advocate has been an ardent volunteer for BCAN since our founding in 2005. He's been a BCAN Research Patient Advocate since the beginning of the program in 2015 and is active on BCAN's online community through Inspire. Bob will share his experiences as an active advisor in clinical trial.

What is a Patient Research Advocate

Patty Spears: I'm a research patient advocate and I've been a research patient advocate for a long time. What I'm going to talk about is engagement with patients in the cooperative groups, the Alliance for Clinical Trials in Oncology, one of the government funded groups. Today I'll talk about who are Research Patient Advocates. Why is advocate involvement important? Why do we even do this? What do we do? What do advocates do in research advocacy? What specifically do we do in the Alliance for Clinical Trials in Oncology? I think giving you an example of the real things that we do in a group setting like that is really important, to get a feel for what research advocates actually do.

Who are Research Patient Advocates? There are many types of patient advocacy and they can be defined by what we advocate for. For example, you can be a political advocate, a support advocate, fundraising, watchdog, and research is one of them. It's not that I'm just a research advocate, actually, I am also an advocate that fundraises for different cancer groups and do some political advocacy as well. Research advocacy is just one of those and it's very different from all of the others. Who are those that are involved in research advocacy? You can be a patient, like we all are, like most of the group is, that's watching. You can be patient group or organization. BCAN is an advocacy group.



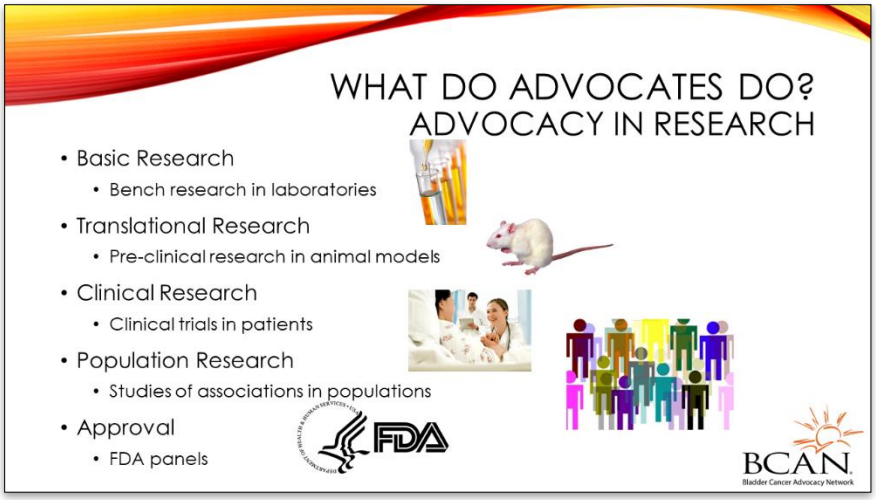
Patty Spears: I'll describe the difference and what each one can bring to the table. I think all of us collectively are so important that I think it's really, really important a lot of times to get just that individual patient experience. In a lot of the clinical trials and research, they bring the personal experience to the table. They might not have knowledge of science and research, but that's perfectly okay. They're the expert in their disease. Patient organizations and groups are really important and these groups have access to a lot of different patients. They are usually really interested in moving new treatments forward. One of the things when researchers and drug developers are looking for patient involvement is, these patient organizations are really easy to find. They can easily go to these organizations and get their input, as well as, maybe get information on patients that might be interested in being involved.

Patty Spears: Then, Research Patient Advocates are the next section. Research Patient Advocates, this what I consider myself. I'm actually a patient, so I have knowledge about the disease. I also connect with other patients and when I am a research advocate in the room, I try to bring the collective thought of all the patients with me. I used to facilitate a support group for about 10 years and I remember all of those experiences. I also try to learn more about the research because that's an interest of mine, and that's why I'm a Research Patient Advocate. It doesn't happen overnight, but it's something that you can really build over time, like learning. When you go to school, you learn early things first and develop your knowledge over time.

Then, I belong to different patient groups. I belong to several different organizations and I bring that with me as well. I feel like we bring a lot to the table, but it's different than just like I think of, when we developed something for patients that are just being diagnosed, that's not me. It's like, my mom also had cancer, and she understands what you're saying and things like that. I always think of the patient off the street versus the patient that's educated themselves in the science.

Who are we? We're cancer patients. We have loved ones with cancer. I've had breast cancer. My mom had breast and bladder cancer. We bring all that to the table, when we're out and motivated to reach out to others. We're also motivated to learn more about the science and the treatments and keep up on different things, and really become trained in the different areas of science. It's not like you're going to be trained in everything, you pick your niche of what you're really interested in. I happened to be really interested in clinical trials. The more you do it, the more you learn. I feel like even though I've been doing this for many years, every time I do something, I learn something. As long as you keep learning, and you become more seasoned in what you're doing.

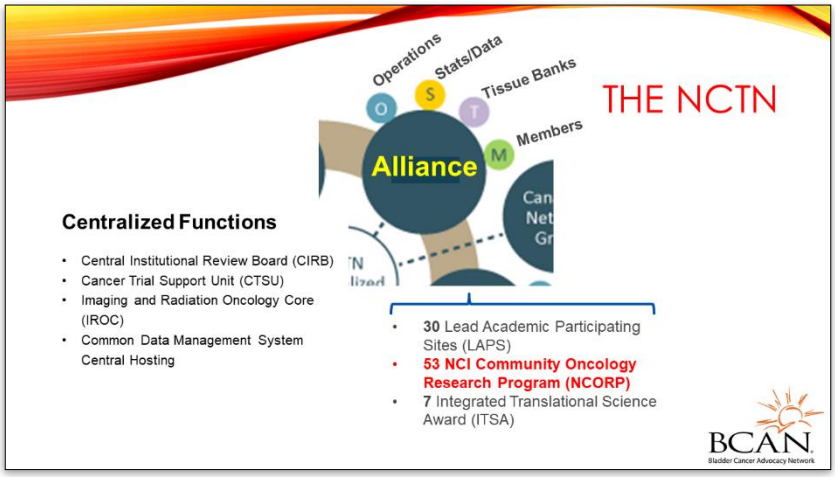
Why is advocate involvement important? I would say it adds urgency to the research process. I know that sometimes research seems to take a long time, trials seem to make take a long time, drugs seem to take a long time to be developed. I think that patient engagement early and often keeps that urgency right up front from the get go. Patients understand the burden of treatments. We know how long it takes to get an infusion. Patients know what is important to them. They can really help design clinical trials that will accrue and retain participants, because many of us have participated in clinical trials, and can help identify those barriers and those accrued problems before they even open, so that it can really alleviate, saving time and money and less changes of the protocol over time, they accrue faster, things like that. I think it's really important to have that involvement early.



Patty Spears: What do advocates do? When are we involved? We can be involved in basic research. I think it's always important for basic researchers to have an eye for where their research is going to be impacting patients eventually, because eventually it will. Just keeping that urgency in grounding the research is really good. I'll never tell you what mouse to use, but I work with a lot of basic researchers and I think we mutually just get to know each other. Translational research, the preclinical and mouse models, also in tissue, which I think is really important these days to get enough tissue to do those preclinical studies. We can be involved in that. Clinical research, we'll go more into that in more detail in clinical trials and what we do.

Population research. A lot of the epidemiology studies that look at populations of people. We have a couple of studies that you can see and so it's really interesting to have patient involvement because we know the patients out there because we're one of them, and we can give our input on those as well. Really, in drug approval, we also have a voice. The FDA has a big patient representative program. If you're interested in it, I would definitely look it up if you're interested in getting involved with the FDA. They use a lot of patients.

What do the Alliance for Clinical Trial Advocates do? This is where I'll give you some practical things about what we actually do in the Alliance for Clinical Trials in Oncology. What is the Alliance for Clinical Trials in Oncology? It's part of the NCTN, the National Clinical Trial Network, which is part of the National Cancer Institute, which is part of the National Institutes of Health. It's our government-funded large trials and there's five groups. They're all a lot of initials, except for the Alliance for Clinical Trials in Oncology. One is, the Children's Oncology Group. There's also a Canadian group.



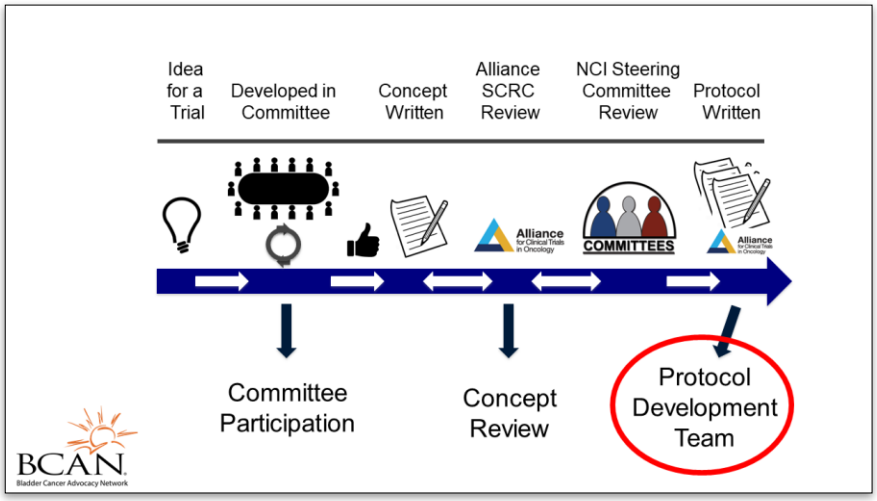
The Alliance is this group of people. We have operations, we have statisticians, we have tissue banks, we have members and there are centralized functions that are run through the National Cancer Institute, the Central Institutional Review Board, different things that all the different groups need. Then at our specific group, we have different members that come from large academic cancer centers, as well as communities cancer centers, the NCI community oncology research program. We can get our trials that we do within the Alliance into the community cancer centers, because we know most patients are treated in the community. That really allows for a more diverse population getting into clinical trials.

It's a big operation and as part of that operation, the patient advocates have, I think, a significant role. We have a committee of about 20 advocates and we've just had some community advocates join our group as well. We came up with this role and goals. The role of patient advocates in the Alliance is really to represent the perspective of the patient and their families in the development and delivery of innovative clinical trials. Our goal is that the patient advocates work together with all the other cancer professionals to develop these trials and care of cancer patients and prevention of cancer. We work together with nurses, clinical research professionals, oncologists, radiologists, surgeons, who are together with everyone within the team. Then, who are we? We're the same as I went over before. We come from all over the United States, all walks of life, all backgrounds, all diseases, we are all different cancers and so that we can really address the different patient issues.

Patty Spears: We are all members of a committee. Every patient advocate that comes on board is a member of a committee. It might be a disease committee, like I'm on the breast cancer

committee, or it might be a mortality committee like health outcomes or health disparities, which is different. It covers a lot of different cancers.

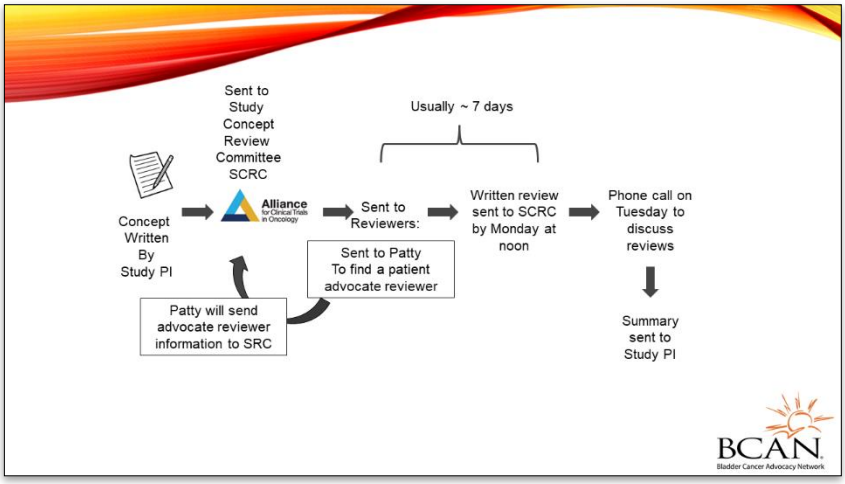
Key roles at the Alliance. We participate in committees, we do concept review protocol development teams and public summaries. I'll go over that in more detail. I'm a picture person, so I like to look at things over time. Here's a timeline of how a study gets thought up and conducted within the Alliance for Clinical Trials in Oncology. An idea comes forward, and it's developed in the committee. I'll use the breast cancer committee or I can use the GU committee. A concept will come forward, it'll be discussing in committee, the advocate is in the room during the discussions, and they come back over and over again. Then, once the committee says, "Yes, this is a great idea, go ahead and write it up." It gives it the thumbs up, they write a concept. That's about 10 pages.



Once that's written, it goes to the central review committee at the Alliance to get reviewed and the advocate on that committee reviews the concept. Then it goes to the NCI steering committee for review, which is a higher-level review. Sometimes they get accepted and sometimes they don't. If they get accepted and okayed for study, then a protocol is written, and they do a protocol development team and we're part of that team as well. Those protocols tend to be about 150 pages. You get to see it all along. It's not over at that point. It still comes back to the committee. Once the trial is open, so you monitor accrual, you monitor all the different things going on to the trial, see if any changes need to be made and advocates are heavily involved in that, the data safety monitoring board to make sure that things are going, Okay. That's always done throughout that thing.

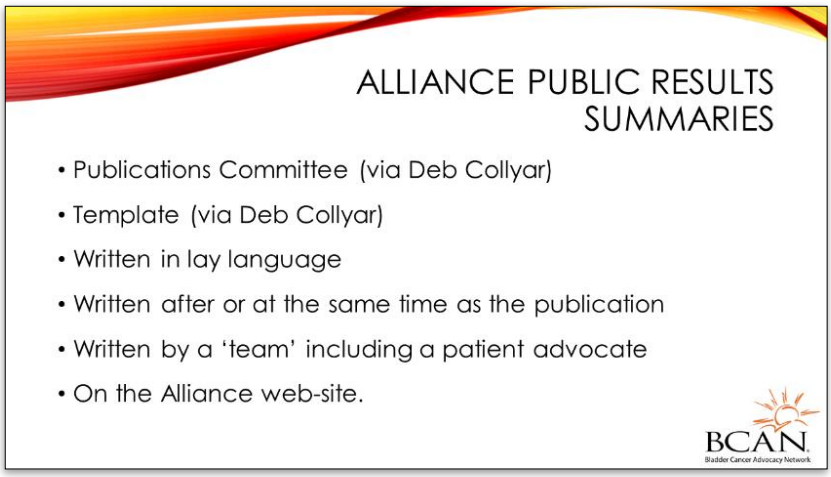
We actually have an advocate representative on the data safety monitoring board. Then the trial's done. Then after the trial's done, and when it gets published, we write public summaries of each study and the advocates who are involved in that. We're involved in all of these different parts. To give you just a little bit more detail about what you might do in the committee, so you're sitting in the committee, what would you think about as an advocate and as a patient, that

somebody else isn't going to think about? Really, it's, I think, a lot about the outcome and whether it's important to patients. Is this going to be practice changing, a change that I would like to see, and I think patients would like to see? Is participation going to be hard? Are there lots of visits, lots of biopsies? Randomization, does the randomization look equipoise or not, and high cost? There's a lot of different things. I have some things written here, but it can go on and on and on, what you think about, because we think of things differently than the oncologist think. Then the concept review that happens there. That's something that we have a process for it, where, once it comes in, I select an advocate to review it. I usually have the advocate on that committee review it and they have about seven days to write the review. They send it in on a Monday, the phone call is on a Tuesday, and then a summary is sent to the principal investigator and we actually help the advocates by giving them a guidance on how to review the concept. We look at study impact, feasibility, innovation, relevance and study design.



Patty Spears: Protocol development teams. This is happens at the 150-page thing. The team is very diverse. There's a lot of different people on it because you need all that input to make a good protocol and good study. This is about a two to three-month process. It starts as 10 pages and ends up as 150. This is where the consent form is drafted. You're involved as the patient advocate on all of these drafts and it might be a couple of phone calls. Really, I look at different things like the consent form and eligibility criteria, the review questionnaires and schedules and burdens, different things like that. It's kind fun to see it go from committee all the way through. It is a lot of work on your part too, so there's a lot to learn there. I was just on one that's come back from NCI. It's pretty exciting actually.

Public summaries. We think that we can really help with making the public summaries more life-friendly and understandable by everyone. This was started by Deb Collier, and we participate in that as well. All of our summaries can be found on the Alliance website. Here's a view that you can't read, but you can visually see how we do the summaries. We have a template for doing it. My final thoughts are engaging patients. It's really important during research and clinical trials and throughout during development. We value things a little differently from the patient perspective, and it really needs to be there front and center very early and all throughout the whole process. Patient-centered research is collaborative, and it really focuses on the patient. Really, I think patient-centered trials might improve accrual on retention. Really, that ensures that meaningful benefits to patients are done. I know I went fast, but I know you'll have access to these slides. If any questions came up, just put them in the chat box, and we'll answer them later.



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