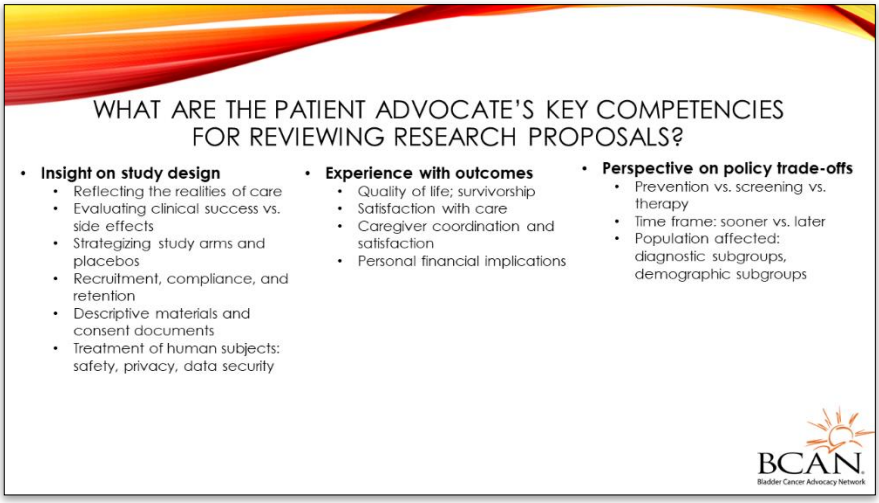
Participating in Grant Review as a Patient.

Bill Russell:

Our first speaker is one of our own, BCAN advocates by the name of Ralph Ullman. Ralph's bladder cancer journey started over six years ago, when it was necessary for him to have a radical cystectomy with a neobladder diversion. Ralph participated in BCAN's first research advocacy training seminar in 2016, and since then has been able to draw from his own professional career which was in medical care data and analysis.

This allowed him to effectively work with several BCAN affiliated researchers in developing proposals for funding written for BCAN's website, and he has participated in BCAN's annual fundraising walks. He also serves in BCAN's Survivor to Survivor program as a peer counselor, which typically helps newly diagnosed patients navigate through some very scary times.

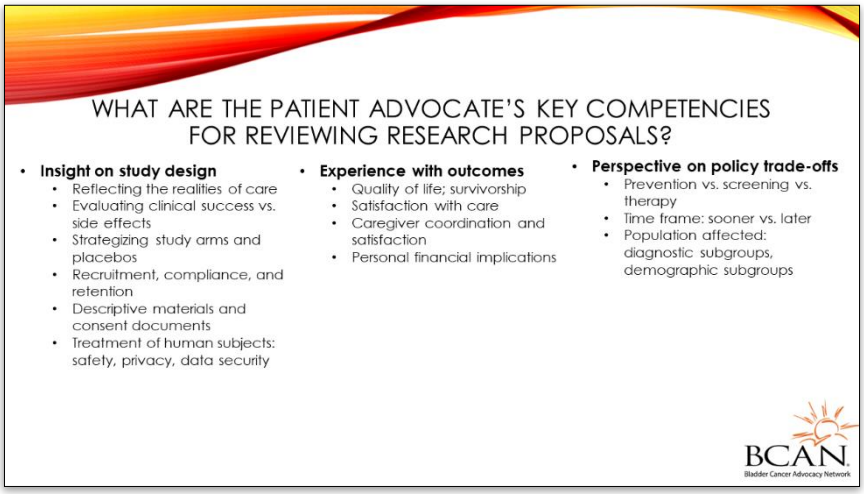
Ralph Ullman: No, thank you very much. It's a pleasure to be with you this evening and share another patient advocacy experience and congratulations on your 10th anniversary, I hope to join you with that in a few years. I'm talking to you from the patient's point of view or the patient advocate's point of view. Look at some of the issues involved in participating in grant review, and also giving you some examples.



First issue I wish to address is, what are the key competencies that the patient advocate brings to the

table? The first group, insight on study design, a variety of factors that really are the same as were discussed in the first two webinars in this series, working with pharma to develop, test and ultimately market their products and working with pharma and scientists on the design of the clinical trials, that same sort of thing. We're looking at proposals and evaluating them. And the patient has a lot to offer in this respect, and I look at particularly at recruitment, will this thing work? Will this study work? Will patients be willing to be recruited? Will they comply with the procedures? And ultimately, will they be retained? If you're looking at the proposal and you have your doubts, you're going to be negatively reflected accordingly. So things of that sort.

Ralph Ullman:

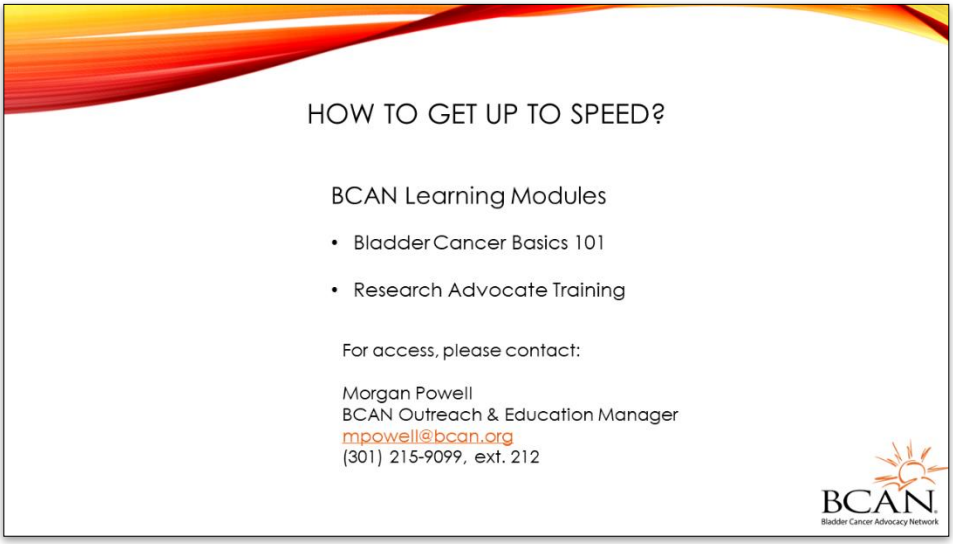


The next category, experience with the outcomes. Well, you might be reviewing a proposal that is specifically directed at patient level outcomes, quality of care, in particular, survivorship is a new term that I'm getting familiar with, satisfaction, caregiver satisfaction outcomes. And if the project is directed at outcomes specifically, of course, this is right in our wheelhouse. But we may be reviewing a proposal that, say a clinical trial, or otherwise not directly focused on outcomes, but maybe it should be saying more about outcomes and what it is. And so that's an opportunity for the patient advocate to insert some real life factors regarding, what is this project going to accomplish ultimately, with respect to the patient? And I'll tell you if we don't raise it, nobody else will. So it's all up to us.

The last category, policy trade offs, may or may not be appropriate, depending on the particular rules and circumstances of the review panel. But somebody's got to be thinking about this stuff because funding inevitably is limited and projects are going to have to be traded off against each other pro and con. Prevention, your project may be looking at prevention or screening or therapy, how do you compare and evaluate projects that are so different in orientation? So that's difficult. Timeframe, this is a favorite of mine. Sooner versus later, well, I think we all agree as patients, we prefer that this project come to fruition with respect to actual patient share sooner rather than later. That's pretty obvious. But that perspective may not be shared particularly by the scientists who are joining you in evaluating these proposals. So it's up to us to decide whether that is a fair criteria on which to evaluate a proposal.

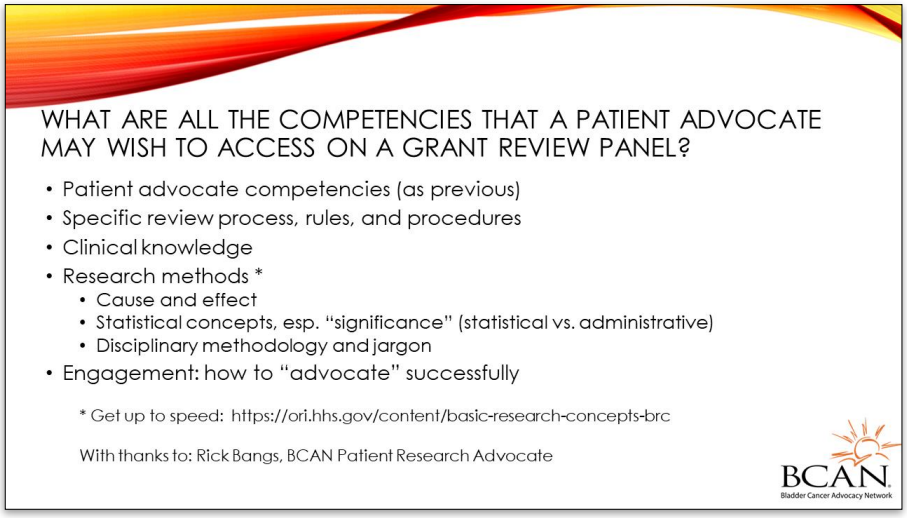
Finally, something even more difficult than population, the fact that you could have diagnostic subgroups and typically you will. Just within bladder cancer, you've got muscle invasive, non-muscle invasive, metastatic ... The proposal and the project is not going to involve all bladder cancer patients. And you'll have to decide, as soon as you subgroup the population of course, the number of patients ultimately affected is going to be reduced, and perhaps differentially from one proposal to the next. Demographic subgroups are even harder for me anyway, you could have a gender focused project, female, let's say, race focused, lets say African American. Again, as you subgroup the population the number of patients who ultimately may receive a benefit. But on the other hand, suppose that subgroup has been historically understudied or historically underserved. So that's a real tough one and you may or may not wish to consider that in your evaluation. But somebody's got to be looking at.

Ralph Ullman:



As a background for patient advocates to participate in research review, well, the more we know the better we can do. And a couple of things I can suggest to you if you haven't been through it already, BCAN offers a variety of materials on its website, of course. But they also offer a couple of learning modules, Bladder Cancer Basics 101. We all know something about bladder cancer. Typically, we're pretty good at our own particular diagnosis and our own particular therapy, but bladder cancer is going to be broader than that. And if we're going to be effective as advocates, it behooves us to be generally well informed about bladder cancer more generally. So that's a module you might investigate.

BCAN also has a research advocate training module that was developed just a couple of years ago, and many of us have gone through that. Bill has gone through it, our host and I have gone through it as well and we use it to get certified as patient research advocates. If you're interested, Morgan Powell with BCAN I'm sure will be happy to give you access to either or both of these modules.



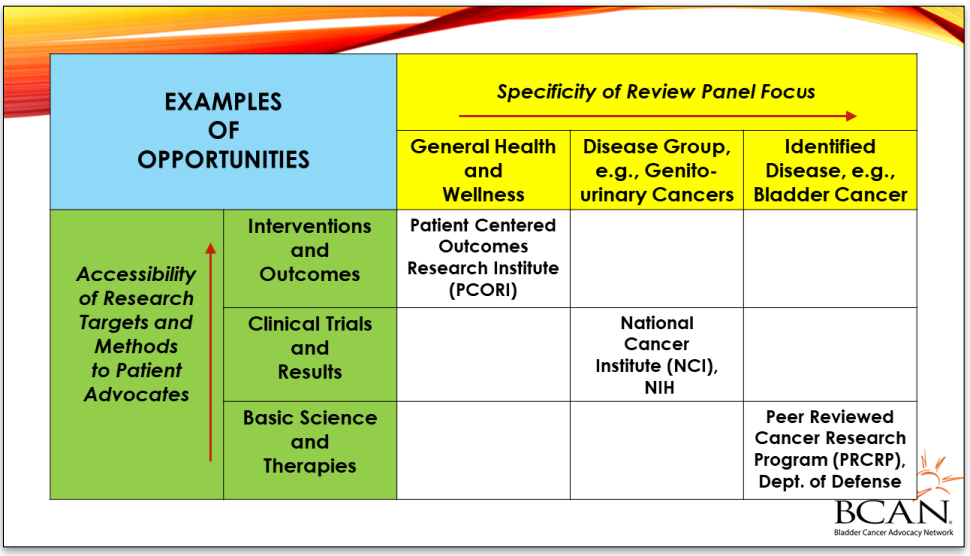
So you're coming to the table as a patient advocate with some specific competencies that you're expected to use in your evaluation of these grant proposals as just discussed. What else might you need to know? Or let's put it this way, the more you know, the more comfortable you're going to be. Well, firstly, you're going to need to take a look at this specific review process. It can be complicated. Various stages of evaluation have various roles including conflict of interest, and patient advocates may well have some conflicts of interest. Procedures for getting your commentary into a system, of course, you'll have help. There'll be people that help you. But the first time through a particular process, you can expect to spend a bit of time.

Ralph Ullman:

The next two bullets here are areas where you're not really expected to know much of anything. You're not certainly expected to be an expert but falls under the category of the more you now the more comfortable you'll be. Clinical mindset, well, you have a patient mindset, but the proposal is more likely to be written from a clinical point of view and with terminology that may not be immediately familiar to you. So you might well want to look up for some things and research methodology, of course. You want to have some background, some basic background in the way research tends to be structured and you can access some materials accordingly.

The last one that I think is interesting and I have to give my thanks to Rick Bangs, who's an experienced patient research advocate who I talked to, and he turned me on to this idea about engagement, other than the incompetency of us as patient advocates is how do we advocate successfully? How do we get our point of view across and talking to a group of clinicians, scientists? I think we sort of have to find our own way. That's something that you need to think about, and probably the more you do, the better you get.

I want to get into some examples of opportunities for patient advocates in reviewing grant proposals. And to get into that, I came up with this two dimensional grid of describing these opportunities. So let's take a look at the columns first reading from left to right, I call this the specificity of review panel focus. The funding organization may take proposals across general medicine, health and wellness and the review panel may not be segmented at any lower level. So you could really be reviewing proposals on a wide, wide variety of health and wellness topics. That's one extreme. At the other end, you could be looking at proposals where your panel has been restricted to a fairly narrow identified disease. And therefor, bladder cancer advocates, of course, that would be bladder cancer. And in the middle, there're all sorts of possibilities of categorization somewhere in between.



The second dimension here, defining the rows, I call it accessibility of research targets and methods for the patient advocates. Aside, here at the bottom, you could be looking at proposals that I would consider to be really basic science, bench level research where cellular change subject to chemical intervention might be looked at under the microscope and a level above that I might be testing out some ideas on mice, and so on. And this is pretty much beyond the purview of most of us, patient advocates. Relatively inaccessible in terms of targets and method.

Ralph Ullman:

Next level of clinical trials, well, now we're talking about humans participating in a trial to test out an intervention or a pharmacological drug, and that's going to be more accessible to us. We're more familiar with the terminology and so on. And then the top row is where we're looking at outcomes. The proposal is focused on the outcomes as I've described it, well, that should be right in our wheelhouse, very accessible project. Now, I don't want to imply though that our opinion as patient advocates would not be useful across all of these areas, I believe it can be quite useful. But this is just a way of looking at it and getting yourself into a particular situation.

So I've got three examples here. They happen, and they're all pretty important to BCAN into the bladder cancer community. So let's look at Patient-Centered Outcomes Research Institute first, we'll call it PCORI. I've got some bullets on the next slide. PCORI has been around since 2010, when it was created by the Affordable Care Act. And much to my surprise, has survived despite the change in administrations. They've been awarding grant funds for quite some time. As the description of the organization would indicate, they're very much oriented around the outcomes, patient-centered outcomes. So, we're naturally quite interested in what's going on at PCORI, even though they haven't done a whole lot of work on bladder cancer per se.

In recent years, there has been a couple of notable awards. I just want to mention them. The engagement awards from PCORI, a series of BCAN affiliated projects, Bladder Cancer Survey Networks, some of you may be familiar with, and then the patient research advocate training and implementation. The learning module I mentioned beforehand, the webinar series as Stephanie noted, funded by PCORI. So, we're very thankful for that. Another notable award has been in the clinical effectiveness research category, comparing outcomes of at least two healthcare options and that's the CISTO project, awarded to our research leaders, Dr. John Gore and Angie Smith. Compare it for non muscle invasive cancer patients, bladder cancer patients comparing surgery versus non surgical intervention. For this group of patients, you can hardly come up with a more important and relevant topic from a patient point of view.

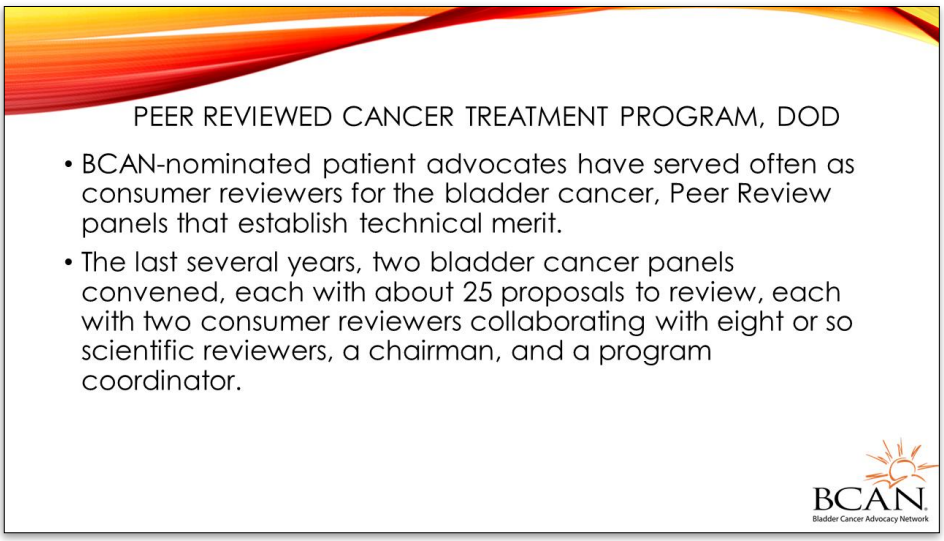
So this is a great project, $8.5 million and currently ongoing and we're very thankful to PCORI for that. And if you're interested in review activities as patient advocates, please do check out the PCORI website. As you would expect, they have quite a number of opportunities.

Ralph Ullman:

And let's talk about the National Cancer Institute in looking primarily at their supervision and sponsorship of clinical trials. But let's take a look at the next slide here. I'm not all that familiar. But I did talk to Rick Bangs, who again, has been very active at the National Cancer Institute. They have a Coordinating Center for Clinical trials, and they organize their supervision of these trials by disease category.

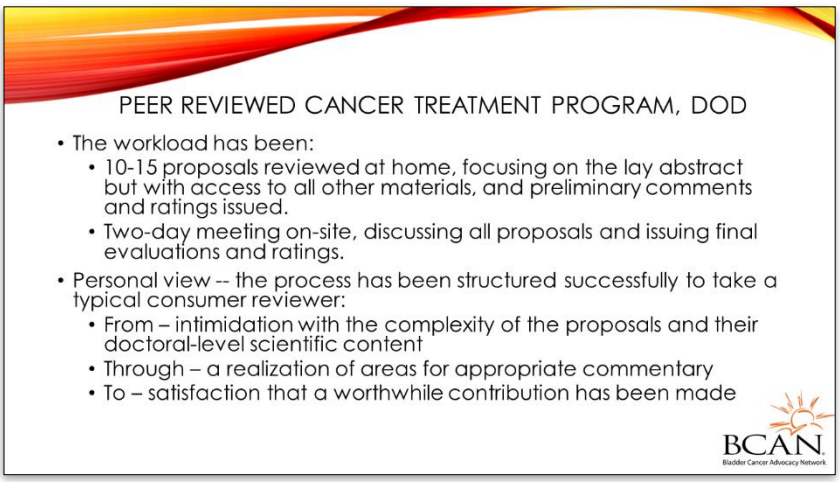
And so there's a genitourinary cancer steering committee, which includes two patient advocates, and their job is to consider projects submitted for bladder, prostrate and renal cancer. And under the genitourinary cancer committee are three task forces for each of the three particular cancer categories bladder, prostate, and renal. And each of these includes two patient advocates. So I would have to conclude that the National Cancer Institute has been very active in encouraging the involvement of patient advocates in their grant review activities.

Down in the right hand corner, is a program sponsored by the Department of Defense. I put it in the basic science category because as a reviewer myself, most of the proposals that I've reviewed under this program I would classify in basic science. Their orientation is changing somewhat. I understand that our next speaker may give us some more information about that and give us some more details about this Peer Reviewed Cancer Research Program is organized.



Ralph Ullman:

We've had a lot of folks nominated by BCAN over the years serving as reviewers on these panels. The last two years I've been involved. Now Bill Russell has been involved as well. There've been enough proposals on bladder cancer to organize the panels specifically for bladder cancer and there've been two bladder cancer panels. And I recall each having about between 20 and 25 proposals to review. And each of them has had two consumer reviewers collaborating with eight or so scientific reviewers.



So, you get the feeling that this program is attracting an enormous amount of attention on the bladder cancer research community. And I tell you, these are the top institutions and the top researchers in the field. So it's really quite an honor to have the opportunity to review these proposals. Our next slide, please.

There is a workload, it's not insignificant. The consumer reviewers are each given 10 to 15 proposals to review. You start off at home, you have access to all the materials and you issue some preliminary comments and ratings and then you join with the full panels in a one and a half to two day meeting in which you discuss the proposals, trade trade-off on your evaluations and come up with final evaluations and ratings. This is a pretty interesting experience for those of us who've been involved, there is an initial stage of intimidation because these proposals are highly complex. They don't necessarily relate all that well to what we know but you can be given their scientific complexity and what has been a basic science orientation.

And so you have to feel your way through it. Determining where the areas are that you can make appropriate commentary and discussion. Now, in end, and I've talked to a number of folks who've been through this, I think we all agree, we were pretty satisfied that we've made a worthwhile contribution. And that's what we hope to do. What we hope to accomplish is patient research avenues. So thanks for listening. I hope I haven't gone on too long. And Bill back to you.

Bill Russell:

Ralph, thanks so much. That was a very thorough presentation, and I'm sure you've invited all of us with regard to your experience.