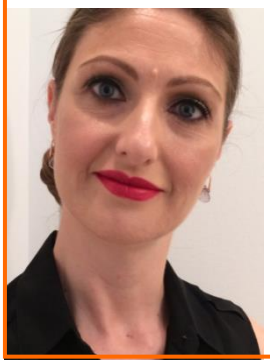
Bladder Cancer Clinical Trials 101

Tuesday May 3rd, 2016

Part III: Question and Answer

Questions Answered by



Marisa Lozano is currently a research nurse-manager at MD Anderson Cancer Center's Department of Urology. She has extensive experience in the care and management of patients on clinical trials, particularly in urologic-oncology. Marisa holds a nursing degree from the University of Barcelona, and is officially certified as an OCN and CCRP.

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

Moderator: **How can I get my husband in a clinical trial that would be best for him? Can you just highlight for us what are some of the things a caregiver and patient should consider in terms of looking for a clinical trial in bladder cancer that might be the best for a patient at any stage? What are some things they should be thinking about?**

Marisa Lozano: I think first of all it's very important to have a physician that is actively involved in research, and of course taking care of patients, but also very involved in willing to move treatments forward. Really, these physicians are mainly in big institutions, but we also have a lot of physicians training in big institutions like MD Anderson that later on they go work for smaller institutions or private practice and so forth. It's very important to get in touch with one of these physicians that are highly invested and willing to move the treatment for bladder cancer and to kill this disease.

Number one, getting your physician, a good one, is very important. Then in terms of being open with the physician and discuss with him what you expect from your participation in a clinical trial and what are some of the options that you have nowadays in the market and compare that to the clinical trial options and see which one is better for you and which one fits better your needs.

You can always go to the web and search. Nowadays with internet access, a lot of people go in and Google everything. As a word of caution, I like to tell my patients also be careful where you go to. You have to trust those sites that you go to, the source. You have to go to sources that are truthful and that

do not give patients false information and misguide patients in that sense. One of the websites is of course BCAN, it's your site. There are other sources out there.

There is another website that is called clinicaltrials.gov. That is very important to have handy. Patients can search by disease, by “bladder”. You just put “bladder” and you just do a search and it populates all the bladder studies there are available right now. It not only mentions phase one or two. It mentions all the bladder cancers, so you will have to be a little bit more specific of the stage of your disease in order to pull up specific protocols that you might be benefiting from. That is when your research team, your physician, your nurse, will come in very handy to help you navigate through that website and finding out which options you have.

Moderator: Great. Thank you so much. The clinicaltrials.gov is another good resource and we very often will check that as we begin to add trials to the BCAN clinical trial dashboard as well. **How do you suggest they bring it up to their community based doc who might not be part of a clinical trial and might say you don't need a clinical trial? How do they bring it up if they really are interested in pursuing being part of a clinical trial?**

Marisa Lozano: A lot of patients do not realize, and of course it depends on their insurance, that they can refer themselves to bigger institutions without the need to go through a local physician. You will be surprised to know how many people does not now that information. That's number one. Number two is getting all the facts and going to that local physician very informed, pull up all the information that you have in hand and just lay down your terms and tell him that you would like a second opinion. You're not double guessing or you are not putting his reputation on the line. It's just that you would like another opinion. That is a very honest conversation that you have to have with him, and most of them would not have a problem with that.

Moderator: **If a patient participated in one trial, can they never take part in another trial for the same disease, or is that something that they could do?**

Marisa Lozano: It definitely depends on the eligibility criteria for that second trial that that patient is willing to move on. In general terms, that is not completely accurate. It just depends on the specific eligibility criteria that particular patient is willing to move on. I can tell though that there are some clinical trials for newly diagnosed patients that will not allow patients to have had any other treatments for cancer at all, period, or if there is a history of another treatment, like for example a bladder cancer patient who a couple of years ago had leukemia, myeloma or something, and received chemo for that.

That patient might not be eligible to participate on another clinical trial just because there is a lot of contributor factors that could impact the results of the clinical trial if we put a person with a second malignancy on the study, and if something happens to that person we don't know if it's because of this current malignancy or it's a recurrence of the previous one or a complication of the previous treatment.

Moderator: That makes really good sense, because again remembering what you said earlier, that they're really trying to determine if the new treatment being studied is better than the old treatment. I think a lot of people need to remember that many of the treatments, or most of the treatments that we have today wouldn't be approved by the Food and Drug Administration if there weren't clinical trials out there, so that's really important. **What percentage of people might go through to the place of getting**

to informed consent and then decide that they don't want to participate in a trial and what might some of the reasons be for somebody to go that far and then decide not to do it? Do you have any stories maybe you could share, some patients that you might have seen that have done something like that?

Marisa Lozano: You mean as far as patients signing the informed consent and then wanting to drop out?

Moderator: Right, or even getting to that place where they're asking and being considered for a trial and they say, "No, maybe I'm not going to do it." **What percentage get that far and don't do the actual trial?**

Marisa Lozano: I don't know that I can put a percentage on it, but it's very, very minimal. A very small number of patients actually get to that part and find out yes, they're eligible, yes, the doctor thinks it's a good idea for them to participate, yes, they would benefit from it, the potential benefits outweigh the risks, and they're ready to go forward and then suddenly decide no, I don't want to do this. We do have a few patients that do that. Some of the possible reasons would be, "I went home and had a chance to discuss with my family members or with my spouse and I don't think that I can make these extra additional trips. Do you know for sure ... I called my insurance and they're not willing to cover these expenses," or the travel becomes a burden and stuff like that.

Moderator: Great. Those are really important reasons. Can you talk a little bit ... I know that you have a wide array of trials going on at MD Anderson, but maybe talk a little bit about some of the trials. We're going to talk specifically about non-muscle invasive, muscle invasive, and advance bladder cancer clinical trials in future webinars and I'll share that information in just a moment. **Are there any trials going on that you know about that really focus on quality of life issues more so than actual medical treatment? Anything that you know of that's really focused on that?**

Marisa Lozano: We have a study that is focused on quality of life of patients after a cystectomy, not really before surgery. We don't have any quality of life protocol in patients with non-muscle invasive bladder cancer right now. This protocol that I'm talking about is a multi-center effort led by Dr. Shaw here at MD Anderson, and it's looking at coming up with perimeters that patients complain or, let's put it this way, complications after the surgery. We are trying to grow in between ten thousand and twenty thousand patients to come up with a list of quality of life issues after a cystectomy so we can improve upon.

Moderator: Really it's more than just looking at specific treatments of course that's going to improve quality of life, but how can we take a look at some of the things that we're doing in care to improve overall patients' quality of life, **so there's a lot of reasons I guess to be part of a clinical trial?**

Marisa Lozano: Yes. It's not until we've put all of these people together, all the data together, that we know what's going on and what things we can do to improve on it. If we see isolated cases here and there, it's not enough information to tell us that there is a problem, so it's very important to come together and put as many patients as possible in this trial to find out how we treat patients after a cystectomy now and how we can improve upon in the future.

Moderator: This has been a terrific program. Thank you so much. These patient insight webinars are sponsored by Merck and Genentech, and we thank them for their support of these important programs.