Us TOO: Clinical Trials for Prostate Cancer Patients

Tony Crispino is the Us TOO Las Vegas Support Group Leader. Rick Bangs is a bladder and prostate cancer survivor and research advocate. They are both research advocates at SWOG and the National Cancer Institute. Tony and Rick outline for Prostatepedia the prostate cancer clinical trial process with commentary by prostate cancer warrior and clinical trial participant Bob Klingle and his wife Jean.

Clinical trials are key to the development of new (or proof for existing) drugs, processes, or methods in the treatment of prostate cancer, with many potential benefits for participating patients. Clinical trials exist to answer important questions about the care of patients or the experience of and outcomes from that care. Trials can test new therapies, compare therapies, test new drugs or surgical techniques, study cancer prevention, offer tools to make decisions, provide support resources—including people or software, further the knowledge about the disease, and much more.

For the research community, the participation by patients in trials is extremely valuable in answering important questions that can lead to new standards of care.

Patients and caregivers should recognize that clinical trials ask and answer important questions that are not just targeted to late disease stages (such as metastatic prostate cancer). Many trials are done today for prevention and for early stages of prostate cancer. People should always ask about the possibility of participating in clinical trials. Bob Klingle, prostate cancer warrior and clinical trial participant shares, “At the time I found my clinical trial, there was really no one to help you. There might have been tons of opportunities that doctors might not have even known about, and you would need to do the research yourself. A friend recommended the Stand Up To Cancer website which listed numerous clinical trials that looked potentially applicable. I worked with my doctor to cut the list down and we selected the best trial for me.”

The clinical trial process is a lengthy undertaking. Before a trial is open to patients and caregivers, planning and design of the trial has likely taken a year or more, sometimes several years. It requires experts to review and revise, along with government approval to assure that the design is solid and the implementation well planned to avoid wasting time and money. The only trials that can be labeled failures are those that do not get completed—even trials that do not get the expected or desired results help science move forward. A clinical trial is successful whether it proves a new drug or therapy works or does not work provided it is completed and gets reported.

For patients and caregivers, this may be undesirable because they want to believe that they received the best care possible and got the best results possible. The current treatment may actually have been the best care possible even if the current treatment is to monitor the disease without administering a therapy. That can happen if no drug that had been studied improved patients’ outcomes.

Patients and caregivers should understand the following about participating in a clinical trial.

1. It is a noble undertaking that will help many patients moving forward, but may or may not help them directly.

2. While their participation may have certain requirements for follow up and limit their control over decision-making, they always have the option of dropping out of a trial (even though that may seem to be an undesirable result for the researchers).

3. Patients and their caregivers own their own destiny and what is done to their body.

4. If the trial is negatively impacting their quality of life, they need to let their physician know and try to resolve the issues. But where it is too much to bear, they can stop participating at any time. There is no penalty for withdrawing from a study and when they do, they will be offered the best-known therapy currently available.

Klingle says, “Sometimes in a clinical trial, the doctor will see that the treatment did not achieve a desired outcome and when that occurs, a patient is withdrawn from the study. Similarly, sometimes the patient will need to start another care program and will need to quit the program. People should keep in mind that the trial doctors often are not your new doctors. They will likely be helpful and will hopefully monitor your progress throughout the trial, but you cannot count on this. You need to watch your own progress with your primary care doctor and if the cancer is not being controlled, or there is a delay in treatment, you need to be the one to decide to jump ship and leave the trial. Do not wait around for a trial doctor to tell you if you need to leave, as they might not.” However, this decision should be made carefully, as more time may be needed to prove that the treatment is not helping and may need to be changed. That is why each research protocol is designed with follow-up studies at specified times. If a person does decide to withdraw before those end points are reached, they may be missing out on something that could help them.

**Trial Phases**

Trials are categorized within differing phases reflecting how much is known about the intervention as it moves...
from the laboratory to individuals and then patient and caregiver populations. Phase I trials typically test the safety of a drug and expose potential side effects. Phase II trials test effectiveness of a therapy or drug and develop a hypothesis that can lead to a Phase III trial. This phase is designed to compare the new therapy to the best-known therapy at the time. A much greater number of patients participate in Phase III trials than the other two study phases. That is partly why Phase III trials offer the highest level of evidence and can change the standard of care or prove that a drug or procedure was or was not better than the standard of care.

Role of Caregivers
In most cases, trials are targeted to patients and not caregivers. Caregivers should always understand the details in the Informed Consent Form (ICF), which the trial participant signs before starting the trial. Caregivers can play a very critical role in identifying and immediately addressing possible adverse side effects and inform physicians where the patient cannot or does not recognize them. Caregivers are very important participants in any clinical trial. Jean Klingle, wife and caregiver of Bob, recommends, “Take great notes! You can’t always remember everything that was said. If you can’t be there, have your partner take video or record the conversations with doctors. You will have a fuller version of what is being said than would be possible based on memory. Depending on the results, you might not be in the right frame of mind to pay attention to or remember, some very important details.”

Placebos
Placebos, which may be sugar pills or some other inactive agent, are used in trials where there is no treatment today as the standard of care. If a procedure is being tested, often a sham or fake procedure is performed, which mimics the procedure without actually doing anything to the patient. Placebos are never provided as a substitute for an effective treatment. If a new cancer treatment is being tested, the control group will still get the best-known therapy at the time. Patients who get a placebo typically don’t know it and may never know if they received the experimental treatment or the placebo. But sometimes they may think they know, and that may cause them to withdraw from a trial as they search for an active agent. They should be aware, however, that sometimes not even the doctor doing the study will know whether someone is receiving a placebo. That is why follow-up testing is required to find out if the treatment is effective.

Some studies have a cross-over design, which means that if tests show the treatment is not working, patients are given the opportunity to take the other treatment. Remember, even if a treatment fails to improve the patient, that does not mean the person was taking a placebo, because even effective treatments do not help every patient. In randomized clinical trials (RCT) testing an experimental drug, a blind trial is where the patient does not know if they are receiving the drug or a placebo. A double blind trial is one where neither the patient nor the physician knows whether the patient is receiving the drug or the placebo. Typically, RCTs testing drugs are double blind unless there is a reason to know, such as when there are toxicities that need to be monitored.

Bob Klingle shares, “I have no experience with a blind trial involving placebos. I was told the drug that was to be used in my trial. This was a trial that was very appropriate for me, as that matched my chosen treatment option. In some cases, patients in trials are told they will be on the drug or placebo, and in some cases they will not be told. Once the trial ends, it ends. There is no immediate access to the new approach or treatment, and it might undergo more tests, or if submitted back to the FDA, subject to other approval processes before it can again be accessed on the market. As far as those requiring treatment that might be given placebos, ideally the doctors participating in the trial would be closely monitoring the situation, and if anything were to become needed in terms of treatment, that would be addressed and the patient might be let go from the trial. But there is no guarantee for this, so the patient must be sure to stay involved in the updates, and to keep his own primary care physician involved throughout the process.”

Those interested in the possibility of entering a clinical trial should first discuss it with their doctors. If it is agreed upon that you might be a good candidate, a great place to start would be the Us TOO Clinical Trial Finder at http://www.ustoo.org/HCP-Clinical-Trials. This free, confidential clinical trial finder will help you to locate any matching clinical trial based on your location and medical profile. You can search online or by phone. Responses to a 10-minute questionnaire will generate a list of clinical trials within patient-specific specifications that can include treatment preference, geographic area, medication type or brand name, and clinical trial phase (I, II or III). The patient questionnaire can be completed online or on the phone speaking with friendly, knowledgeable clinical trial navigators who speak English and Spanish. To search by phone, call 1-877-769-4830. 

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