



Bladder Cancer Clinical Trials 101

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Part I: What You Should Know

Presented by



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Hello, everybody. I am going to jump right into the question: What exactly is a clinical trial? Clinical trials are a part of clinical research, and the heart of all medical advances. Clinical trials are designed to answer questions about new treatments, or ways of using existing treatments better. There are currently 156 bladder cancer studies all across the United States, actively recruiting patients. All of the bladder cancer treatments we have today are a result of clinical trials

What is a Clinical Trial?

- Clinical trials are part of clinical research and at the heart of all medical advances.
- They look at new ways to prevent, detect, or treat disease.



What is a Clinical Trial?

All bladder cancer treatments are a result of clinical trials. There are currently 156 bladder cancer studies that are actively recruiting patients in the US.

Clinical Trials | Exploring Possible Treatments:

- new drugs/new combinations of drugs
- new surgical procedures/devices
- new ways to use existing treatments



Let's look at a few potential benefits of participating in bladder cancer clinical trials: Each clinical trial offers its own set of opportunities and risks, but for the most part, have some of the same potential benefits. By being a participant in a trial, you might be able to help others, who have the same condition in the future, by helping advance cancer research. By being a participant, you could have access to treatments that are not otherwise available, which might be safer, or work better, than current treatment options. You may increase the total number of treatment options available to you, even if you haven't had all of the standard treatments yet; you may feel that you have more control over your situation, and are taking a more active role in your health care.

You will probably get a lot more attention from your Health Care Team, which is comprised of your routine doctor, and your clinic doctor's nurse. In addition, some study sponsors may pay for part, or all, of your medical care and expenses during the study. This is not true for all clinical trials; be sure you know who is expected to pay for what before you enroll in your study.

- The goal of a clinical trial is to determine if a new test or treatment works and is safe for the general public.
- They also look at other aspects of care, such as improving the quality of life for people with chronic illnesses.



Should I take part in a Clinical Trial?



- **Uncertainty is part of the process**
- No right or wrong choice when it comes to participation in a clinical study
- Personal choice dependent on many factors



Now comes the big question: **Should I participate in a clinical trial?** There is always a degree of uncertainty when you are thinking about clinical trial participation. Part of the reason is that the doctors themselves, in charge of clinical trials, do not know ahead of time how things will eventually turn out; if they did, there would be no reason to conduct a trial in the first place. The simple answer to the question, "Should I take part in a clinical trial? There is no simple answer.

As a patient, there is no right or wrong choice when it comes to deciding whether you want to take part in a clinical trial; the decision is a very personal one, and depends on several factors, some of which include the benefits and risks of the study itself, and what you hope to achieve by being a part of it? It also depends on your values, your preferences, and your priorities.

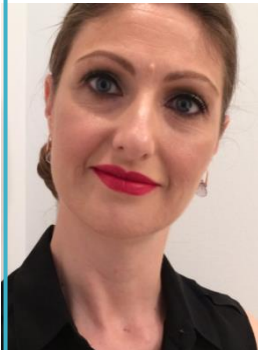
Depends on...

- Benefits/Risks of the study
- What you hope to achieve by participating
- Your personal values, preferences, and priorities

Knowledge is Key to making this decision

- Educate yourself on what to expect in a clinical trial
- Be aware of your baseline health
- Communicate with your doctors

The bottom line is knowledge; knowledge is key. Knowing all you can about clinical trials, and your baseline health, in conjunction with your medical doctors, can help you decide whether or not to participate in a trial. If you do decide to take part, it is important that you know what to look for, and what to expect head of time, because this can be very helpful in helping you make your decision.



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Phases of Clinical Trials

- Clinical trials are conducted in four 'phases.'
- Each phase has a different purpose and helps researchers answer different questions.



Clinical trials are conducted in a series of steps, called "phases," four of them, to be more specific. Each phase is designed to answer a separate question. For example, in **phase I** trials, the main question we are trying to answer is, "Is the treatment safe?" In these types of studies, a new drug or treatment is given to a small group of people for the first time ever to evaluate its safety, determine if the dose is safe, how the new treatment should be given, and to see how the new treatment affects the human body

In **phase II** trials, the main question is, "Does the treatment work?" In these cases, the drug or treatment is given to a larger group of people, to determine if the new treatment is effective, while still evaluating its safety.

Clinical Trial Phases I & II

- **Phase I trials:** Researchers test an experimental drug or treatment in a small group of people (20–80) for the first time. The purpose is to evaluate its safety and identify side effects.
- **Phase II trials:** The experimental drug or treatment is administered to a larger group of people (100–300) to determine its effectiveness and to further evaluate its safety.



Clinical Trial Phases III & IV

- **Phase III trials:** The experimental drug or treatment is administered to large groups of people (1,000–3,000) to confirm its effectiveness, monitor side effects, compare it with standard or equivalent treatments, and collect information that will allow the experimental drug or treatment to be used safely.
- **Phase IV trials:** After a drug is approved by the FDA and made available to the public, researchers track its safety, seeking more information about a drug or treatment's risks, benefits, and optimal use.



In **phase III** studies, the main question is, “Is it better than what is already available?” In these cases, the drug or treatment is administered to larger groups of people, *usually, we are talking about thousands of participants*, to confirm its effectiveness, monitor the side effects, compare to Standard of Care treatments, and collect information that will allow the drug or treatment to be used safely.

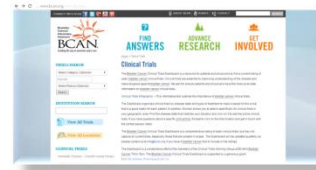
In **phase IV** studies, the main question is, “What else do we need to know?” These are the studies done after the drug or treatment has been marketed, and the purpose of the studies is to gather information on the drugs’ effects in various populations, and any side effects associated with long-term use.

Moderator: If you’re interested in looking for a clinical trial, BCAN tries to make it a little bit easier to help you find those clinical trials. If you went to our website, www.bcan.org, you’ll see a link to our clinical trials dashboard. It’s a resource that is specifically for patients and physicians to help find current clinical trial listings for trials that are actually open, because sometimes clinical trials may be listed, but they might not be open and actually recruiting patients.

How to Find Bladder Cancer Clinical Trials

BCAN’s **Bladder Cancer Clinical Trials Dashboard** is a resource for patients and physicians to find a current listing of open bladder cancer clinical trials.

www.bcan.org/clinical_trials/



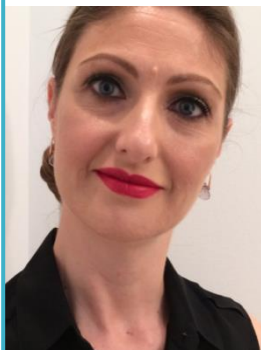
How to Use BCAN’s Dashboard



- Allows you to search specifically for clinical trials offered in your geographic area.
- Organizes clinical trials by disease state to make it easier to find a trial that is a good match for each patient.



If you go to our website, you’ll see the dashboard; once you’re there, you can actually search by disease state, and sometimes even by zip code, to be able to find a clinical trial that may be in your community; that helps to make it a little bit easier for you to identify trials that might be convenient for you. We’re going address some of the other issues about getting into clinical trials in just a few moments.



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The informed consent is a process, through which you learn the purpose, the risks, and the benefits of the clinical trial, before deciding whether you want to join the study or not. It is a critical part of ensuring your safety. In essence, during the informed consent, you learn important information about the trial, which can help you decide whether to take part or not.

As I said, the Informed Consent Document, which is a document that will be given to you at the time of the discussion, will typically include details about the study, such as the purpose of the study, the duration, the required procedures, and who to contact for further information.

Informed Consent

- **Informed consent** is the process of providing potential participants with the key facts about a clinical trial before they decide whether to participate.
- Document includes details about the study's
 - purpose
 - duration
 - required procedures
 - risks
 - potential benefits
 - who to contact for further information



Informed Consent

- The participant then decides whether to sign the document.
- Informed consent is **not** a contract.
- **Volunteers are free to withdraw from the study completely or to refuse particular treatments or tests at any time.**
 - Sometimes, however, this will make them ineligible to continue the study.



The informed consent also explains the risks, and the potential benefits. After you hear all of this information, it is up to you and your physician, but mainly up to you, to decide whether you want to participate or not.

I have to mention, and it's very important to remember, that informed consent is not a contract; it is a document that you have sign, and bears a signature, that you voluntarily sign that document. The same way that you volunteer to participate, it is at your will to withdraw consent at any time from the study, if you decide to do so, without having to give us any reason other than "I don't want to participate any further in the study."

Institutional Review Board (IRB)

- An IRB **must** have diverse membership from a number of careers and backgrounds
 - Doctors
 - Nurses
 - Scientists
 - Non-medical community members



There is also a term that comes up all the time, when participating in studies and clinical trials; it's called the "Institutional Review Board," or "IRB". An Institutional Review Board is a group of people responsible for protecting the welfare of the people who take part in the study, and making sure that studies comply with federal laws. They make sure the risks involved are reasonable, when compared to the possible benefits.

The boards are often made up of medical experts, such as doctors and nurses, other scientists, and also non-medical people, or members of the community, usually from diverse careers and backgrounds. All of the people on the IRB can have come from only one of these groups; in other words, an IRB could not be only a group of just doctors, or just nurses.

Many institutions have their own IRBs, but some smaller centers may use large, what are called "Central IRBs." The Federal Office of Human Research Protections oversees the activities of all the IRBs. Researchers who want to start a study must first submit a plan that describes the study in detail to the IRB for review. The IRB must then decide if the study will be acceptable, not only in medical terms, but also on ethical and legal grounds.

Institutional Review Board (IRB)

- The Federal Office of Human Research Protections oversees the activities of all IRBs.
- **Researchers must...**
 - 1) Submit a plan describing the study in detail to the IRB for review
 - 2) IRB decides if the study is acceptable on medical, ethical and legal grounds
 - 3) IRB follows the study's process to identify potential problems



Once the study begins, the IRB also follows its progress regularly to look for potential problems. If any of you take part in a clinical trial, and you have questions or concerns about safety, you can always contact the studies IRB directly, and that number should always be provided to you in the Informed Consent Document.



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Another term that comes up in clinical research is “eligibility criteria.” What are eligibility criteria? These are the questions the proposed research is trying to answer. Each clinical trial clearly states who can and who cannot join the study; in other words, eligibility criteria are guidelines that clearly state who will be able to join the study, and the proposed treatment plan. Common criteria for entering a clinical trial may include having a certain type or stage of cancer; having received a certain kind of therapy in the past; or being of a certain age group. Criteria such as these ensure that people included in a trial are as alike as possible. In this way, doctors can be sure that the results are due to the treatment being studied, and not other contributing factors.

Eligibility

- Each prospective participant must meet specific requirements in order to enter a clinical trial—important component of trial's protocol
- **Eligibility Criteria** varies from study to study and may include:
 - age,
 - gender,
 - medical history,
 - current health status.



Eligibility

- **Eligibility criteria help ensure the participants' safety**
- Current health problems could make treatments ineffective or worse during the study
- Depending on the study, you may not be able to join a clinical trial if you already have other treatments for your cancer



Another important aspect of why we have eligibility criteria is because it helps ensure participants' safety. Some people have health problems besides the cancer, which could make the treatments worse in the study. We want to be sure that you are not put at increased risk by participating in the study. Also, you may not be able to join a clinical trial if you already have had another type of treatment for your cancer; otherwise, the doctors could not be sure that the results produced were due to the treatment being studied, or as a result of an earlier treatment.