Approved by Sterling IRB, IRB ID: 11049

About Clinical Research Studies

Clinical research studies, also called clinical trials, are carefully designed scientific evaluations of an investigational medication. Research studies are conducted by a sponsor, which is usually a pharmaceutical company, academic institution, or non-profit group, and are run by a team of doctors and researchers.

Sponsors use research studies like this one to learn more about an investigational medication. Participating in a research study is not the same as standard medical care. However, participants in a research study do receive additional study-related care and ongoing evaluations from the study doctor/staff.

To conduct a research study, doctors need volunteer participants like you. However, before you can volunteer for a study, you must go through the informed consent process and sign an informed consent form. The informed consent form confirms that you understand the study details and agree to participate in the study.

If you would like to learn more about this study, contact the study clinic listed in this brochure. The study staff will answer your questions and help you decide if this study opportunity is right for you.

Diversity in Clinical Research Studies

Research has shown that certain diseases and medications affect people differently depending on their age, sex assigned at birth, gender identity, sexual orientation, race, ethnicity, access, genetic background, and disabilities.

As a result, it is important for research studies to be as inclusive and diverse as possible. When there is diversity among research study participants, doctors and researchers can learn even more about an investigational medication, which may help all prostate cancer patients in the future.

For more information, please contact:

Janssen Research & Development, LLC
56021927PCR3020-ENG06
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LIBERTAS

janssen
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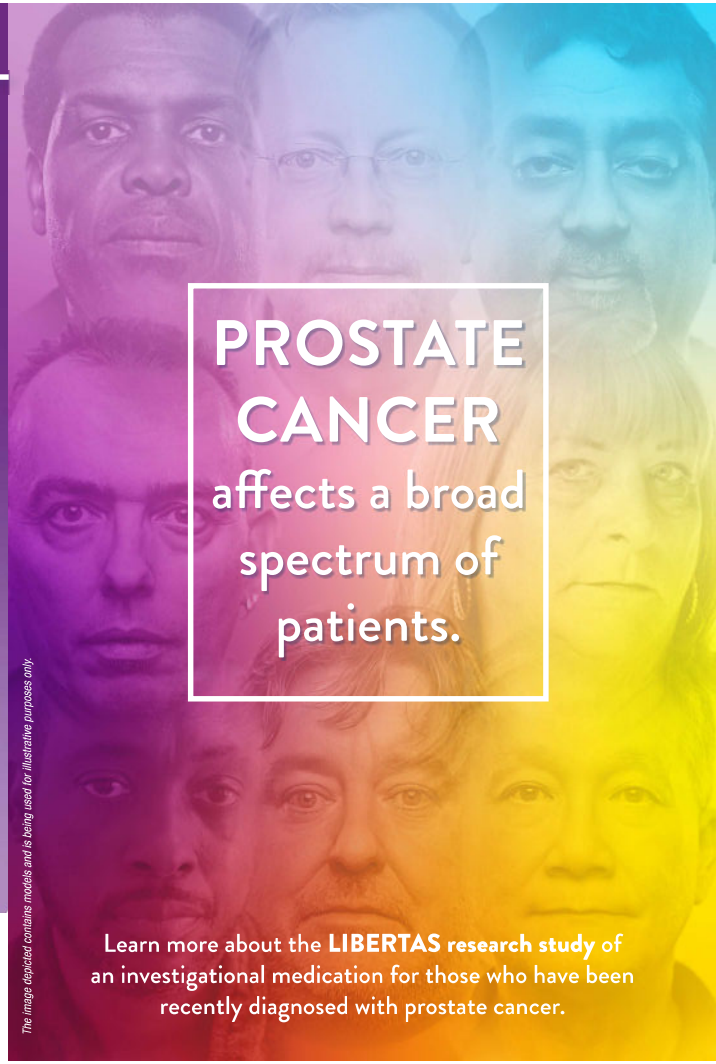

PROSTATE CANCER affects a broad spectrum of patients.

The image depicted contains models and is being used for illustrative purposes only.

Learn more about the **LIBERTAS research study** of an investigational medication for those who have been recently diagnosed with prostate cancer.

Since you were diagnosed with prostate cancer, you have likely talked with your doctor, other medical professionals, your family, caregivers, and/or friends about your next steps. As you consider your path forward, one option that may be available to you is the LIBERTAS research study of an oral investigational medication for prostate cancer.

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What is the purpose of this study?

The purpose of the LIBERTAS study is to help doctors and researchers learn more about the safety and efficacy of the investigational medication. In this study, doctors want to evaluate the investigational medication when it is taken with or without androgen deprivation therapy (ADT), which is standard care for most prostate cancer patients.

The results of this study may provide more information about the investigational medication when prostate cancer patients take it alone or with ADT.

Who can participate in this study?

To qualify for this study, you must:

- Be 18 years of age or older
- Have been diagnosed with prostate cancer
- Have been assigned male at birth
  - Inclusive of all gender identities

Additional criteria will apply, which you can discuss with the study doctor/staff.

What happens if I join this study?

If you are eligible for this study and agree to participate, you will take the investigational medication by mouth once a day. The investigational medication will be given to participants in recurring 28-day cycles.

For the first 6 cycles, you will also receive ADT. During Cycle 6, your prostate-specific antigen (PSA) level will be tested to evaluate your prostate cancer. If your PSA level meets the study requirements, you will begin Cycle 7. If it does not, the study doctor will stop your study participation.

At Cycle 7 and for the remainder of the study, you will receive either:

- The investigational medication (and ADT only when necessary), or
- The investigational medication and continuous ADT

If you are taking gender-affirming hormone therapy (GAHT), you can continue your therapy and receive the investigational medication.

How long will I be in this study?

Your total study participation will last until your prostate cancer progresses or the study doctor decides it is in your best interest to stop receiving the investigational medication.

You will have regularly scheduled study clinic visits for health exams and tests. At first, these visits will occur once each cycle, but as you continue in the study, they will take place every 3 or 6 cycles.

All study-required visits, tests, and medication will be provided at no cost to you. In addition, reimbursement for study-required travel may be provided.

If you complete this study, you may be able to continue receiving the investigational medication. The study doctor will talk with you more about this.

What are the potential benefits and potential risks related to this study?

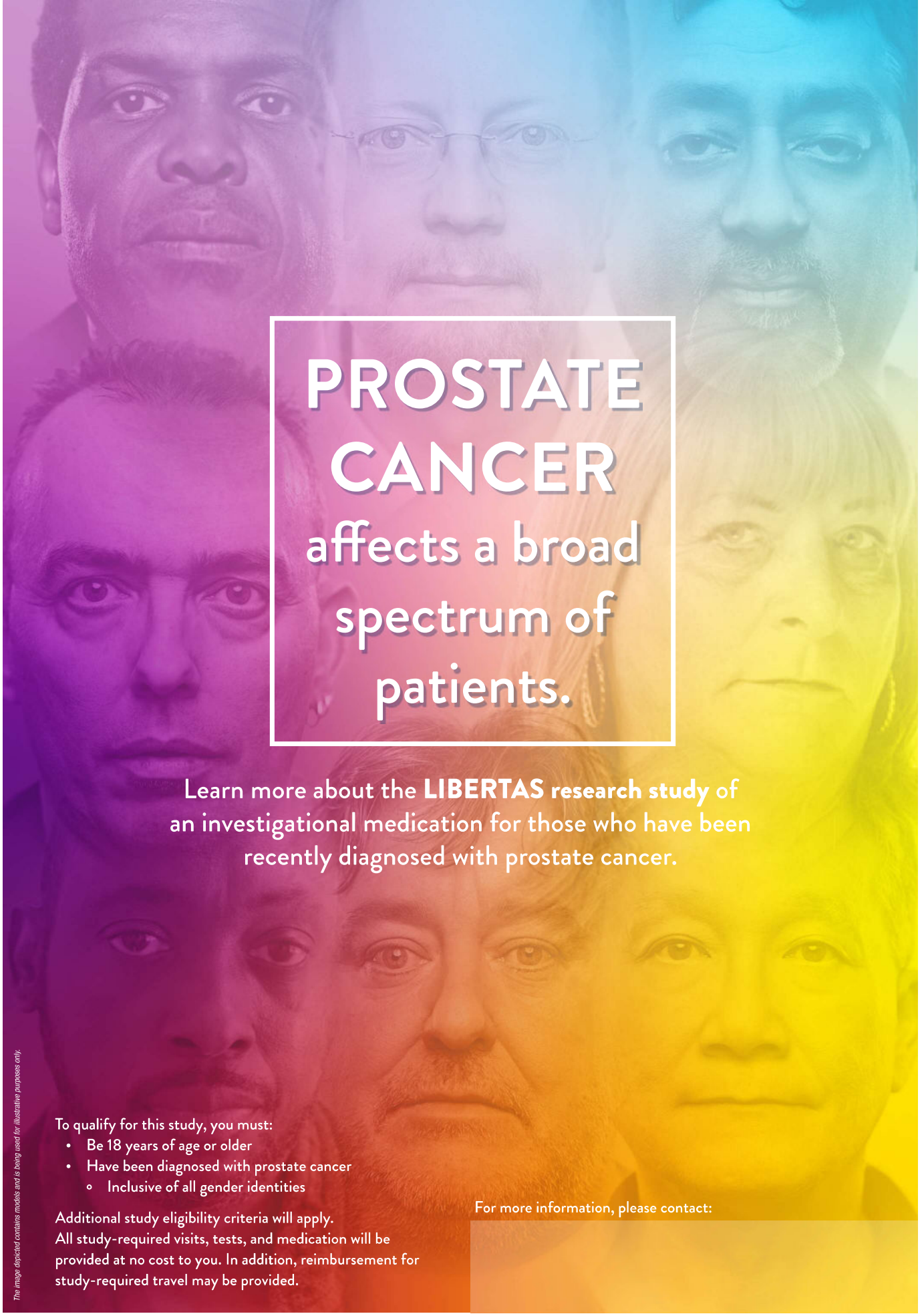
You may not receive any benefit from this study, but your participation may help contribute to research for people with prostate cancer in the future.

It is also possible you could experience side effects while in this study. Before you begin study participation, the study doctor/staff will review a full list of potential study risks and possible side effects with you. During the study, you will be closely monitored for any side effects related to your study participation.

The sponsor of this study was required to design a protocol, which explains all study procedures in detail. A formal review board with responsibility for study participant safety has reviewed and approved this protocol.

Can I change my mind about study participation?

Yes, if you join the study, you may leave the study at any time and for any reason.



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