



LGBTQ+ Diversity in Clinical Trials

Every cancer treatment we have today was tested in a clinical trial to make sure it is safe and works well for people in need of treatment. There are now thousands of trials going on all over the world. These trials study new drugs and treatments that will become the therapies of the future. Clinical trials provide patients with access to new therapies and the next generation of cancer treatment.

Not all people have always experienced the highest standards of cancer care. Some people have historically been mistreated or excluded from high quality health care. This fact sheet is for one of these groups: LGBTQ+ cancer patients, survivors, and caregivers.

When thinking about cancer prevention and cancer treatment for LGBTQ+ people, very few clinical trials have deliberately included these communities, so doctors may know less about the impact of new treatments, side effects, and unique needs of LGBTQ+ patients.

The only way to understand how cancer therapies work for LGBTQ+ people is if members of LGBTQ+ communities join cancer clinical trials.

When you join a clinical trial, you help yourself, and you also help people with shared identities. In a clinical trial, you may try a new therapy that could work better than the standard treatment. You also provide important information that helps others in the future. Through your participation in clinical trials, doctors learn more about how to prevent and treat cancer for people like you.

WHAT IS A CLINICAL TRIAL?

A clinical trial is a research study that is used to find out if a new treatment works better or is safer than existing treatments. Not all clinical trials test cancer treatments. Some clinical trials test new ways of screening, preventing, or diagnosing cancer, or improving the quality of life for people with cancer.



GETTING THE BEST TREATMENT FOR YOU

Doctors are working to improve the ways cancer can be treated. They do research to develop new drugs or figure out how to better use existing drugs. They look for treatments that have fewer side effects or are easier for people to take. The goal is to make sure that every person facing cancer has the best available treatment at any given time.

If you have cancer, it is important to know about clinical trials and how they work. Not everyone with cancer will be or can be in a trial—and not everyone needs to be. But everyone should be aware that a clinical trial can be the best treatment option at some point, and everyone should have the chance to talk about clinical trials with their doctor.

The first step is to ask your doctor if a clinical trial might be right for you. They may refer you to another doctor or hospital to learn more about a specific trial. Going somewhere new can be a little scary, especially if you have experienced bias or discrimination at the doctor's office before. It may be tempting to walk away. Remember that clinical trials can offer an opportunity to try a promising treatment. You deserve that opportunity.



CLINICAL TRIALS: PROTECTING YOU

Only treatments that show great promise and have been tested thoroughly in the lab are ever studied in clinical trials. If you participate in a trial, you will be part of a research study. You will still receive the highest level of care while participating in the trial and your best interests always come first.

Joining a trial is always voluntary. If you agree to join the trial, you will then go through a process called informed consent. This is a very formal, step-by-step review of everything involved in the trial. If you agree to participate and give your consent to participate in the research activities, you will be asked to sign a consent form. This is a good time to ask questions and to bring someone with you as an extra set of eyes and ears. A trusted friend or relative can also be a source of support.



Before starting any clinical trial, your doctor will explain the goals and possible benefits of the study. They will also tell you about any possible side effects you may experience. This is a good time to think about what is important to you and what matters in your life and ask questions about how the trial will affect you and your quality of life.

During the trial, you can always ask questions. You also have the right to stop participating in the trial at any point.

GENDER, SEXUALITY, AND CLINICAL TRIALS

As you look into clinical trials, you may have questions about how your gender or sexuality could affect your ability to join a trial or your experience on a trial. These may include:

- Will I be able to join a clinical trial?
- Will I be able to enroll as my truest self or will I be misgendered if I participate?
- Will the health care professionals on the trial treat me and my loved ones with respect?
- If I have to travel to learn about a trial, how can I be sure the new hospital or doctor will be safe or provide a welcoming space?
- How will the trial affect the gender-affirming care I receive now or plan to receive in the future? Can I continue to take hormones?
- How will joining this trial affect my quality of life?
- How will members of my communities benefit from my participation in a clinical trial?



These questions raise real issues that may affect how you feel about clinical trials and whether you join. The answers will vary by trial and provider, especially if you are transgender, nonbinary, or two-spirit.

It is not possible to prepare for every situation, but these tips may help:

- **Know your rights.** You can protect yourself by knowing your rights in advance. Read more below about the rights of patients and research participants.
- **Do your research.** If you have to go to a new hospital or cancer center, try to learn about it before you go. Review their website.
- **Find a health care ally.** Share your concerns with a health care professional you trust. They might be willing to ask questions on your behalf. A trusted primary care doctor might help you learn more or relay your concerns.
- **Seek support.** Support can take a lot of forms. As you look into clinical trials, you may want someone to come with you to appointments. This person might be a trusted friend or relative. You also might want someone to talk to such as a therapist, clergy person, or patient advocate or to join a support group. Some cancer centers may have support groups specifically for LGBTQ+ people. Ask about the resources available at the hospital or cancer center.
- **Bring your questions.** Make a list of questions in advance. If you have questions about other drugs you take, know the names and doses of everything you are taking. Some trials may require

that you stop taking other medications including hormones. Talk with your health care team about what is involved. If you are concerned about the impact on your physical or mental health, ask to be referred to a specialist.

- **Ask about sexuality and fertility.** If you have specific concerns about sexual wellness or fertility, ask them early on. Your health care team may not bring up these topics, but cancer and its treatment may affect these aspects of your life.
- **Be persistent.** It is possible that your care team will not be able to answer all your questions right away. Let them know that you would like them to look into the questions and get back to you with answers.
- **Know how to contact the Patient Experience or Patient Advocate office at your hospital and for the clinical trial.** If you have a negative experience with your care team, these offices can help address your concerns.





PATIENTS HAVE RIGHTS

As a patient, you have rights. Most hospitals have a written document called a patient bill of rights and responsibilities. It is often based on the patient bill of rights published by the American Hospital Association (AHA).

Ask a hospital representative for a copy of their patient bill of rights. It may also be posted online or in the building. The list will vary but most begin with the right to be treated with respect. Other rights might relate to privacy, access to information, and participation in research.

Hospitals and cancer centers that conduct research also may have a research participant bill of rights. There is a staff person or office with oversight of these rights. If you feel that your rights as a participant in a clinical trial are being violated, reach out to the office that oversees human subjects.

As a LGBTQ+ individual, you may have specific concerns about how your identities


impact your rights. You deserve to be treated with respect. You have a right to an advance directive or legal document that outlines who makes medical decisions if you can no longer make them yourself. And you have a right to privacy: your health care team can only share the medical information necessary for your care if they have permission. It is important to talk with your doctor about your disclosure preferences. Let them know how or if you would your identities to be discussed when other people are present.

If you feel like you are being treated unfairly, or are being excluded from care because of your identities, make this known to your care team. Advocating for yourself not only helps you, but also other people who may have similar experiences. Whether you are receiving cancer care or other health care, you deserve respect and dignity. If you feel like this is not happening, make a formal complaint. You do not need to continue working with a care team if you are being mistreated.




CLINICAL TRIALS: HOW THEY WORK

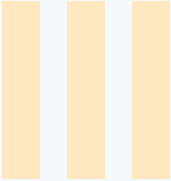
Every new treatment has to go through at least three phases of clinical trials before being approved for use. The phases are marked by roman numerals: I, II, III, and IV, which stand for the numbers 1, 2, 3, and 4. All trials compare new treatments to established therapies, but each of these phases has a somewhat different goal. Trials are usually done in order, beginning with Phase I.




PHASE I trials are the first test of the dose and safety of a drug or device. Doctors work with small groups of patients who may have different kinds of cancer. Many phase I trials are for people with cancers that have spread to other parts of their bodies.



PHASE II trials are done if a phase I trial showed that the treatment is safe and may work against one or more types of cancer. A phase II trial is a larger study, involving more patients, often done with specific cancer types. It looks at how well a treatment can work in that type of cancer.



PHASE III trials are large studies. They involve hundreds or thousands of patients. These studies are often done in many cancer centers in the United States or around the world. For this phase, you will be assigned to get the new treatment or the “standard of care” (current best treatment). In order to give everyone an equal chance at the new treatment, a computer decides randomly which treatment you will get. The doctor does not have any role in deciding which patients get which treatments. Depending on the study, the doctor may not know who is getting the standard of care.



PHASE IV trials are after a drug or new treatment is approved. Doctors continue to monitor it to learn how it works over the long term. They also look to see if there are any side effects that appear months or even years after treatment.

GETTING ACCESS TO NEW CANCER TREATMENTS

In the United States, every drug or treatment must be approved by the Food and Drug Administration (FDA). The FDA requires proof that drugs are safe and work well before giving approval. Many new treatments are only available in clinical trials as they go through the process established by the FDA. If you are interested in gaining access to the newest, most innovative treatments, it makes sense to find out about clinical trials.

For any new cancer drug or treatment, we need to know a lot about how it works before the FDA makes it available to all people. Among many things, the FDA wants to know if patients getting the new therapy live longer and/or better than those who receive

existing therapies. But there are other important questions asked during a trial.

Is the treatment safe?

- What is the safest amount of the new treatment that can be taken at one time?
- What side effects does it cause?
- Do people getting the new treatment have an overall better quality of life than those getting the established treatment?

Is the treatment effective?

Doctors measure this in a couple of ways:

- Do people getting the new treatment live longer than those who get the standard of care?
- Do people receiving the new treatment have longer periods of time in which their cancers are stable or do not grow?

QUESTIONS TO ASK YOUR DOCTOR

What kind of cancer do I have?

What stage is my cancer?

Do I have any genetic mutations that can be targeted?

What trials are available for my cancer?

Where are these trials offered?

What are the possible benefits of this trial?

What side effects might I experience?

Are there extra biopsies, tests, or visits that are part of this trial?

Have any other trials been done with this drug/treatment that are similar to my situation?

What support will be available to me? Who can I talk to while I am on this trial?

What costs will I have if I join this trial? Are all costs covered by my insurance or the trial? Can I be reimbursed for any other costs like transportation, childcare or lost job time?

Where can I get a second opinion?



WHO SHOULD THINK ABOUT BEING IN A TRIAL?

Everyone diagnosed with any cancer should be aware that clinical trials can be a good option for care. There are treatment trials for every type and stage of cancer. There are trials aimed at preventing cancer for people who are at high risk. Other trials are focused entirely on improving overall health or easing anxiety and stress. In recent years, for example, clinical trials have shown that exercising is often helpful to people with cancer. In addition, a clinical trial can also be a good option for people who are:

- interested in getting access to the newest cancer treatments
- no longer responding to other treatments
- at high risk for recurring or spreading after primary treatment
- interested in helping other cancer patients today and tomorrow by advancing cancer treatment
- diagnosed with a rare, aggressive, or difficult to treat cancer

You can always ask your doctor if there is a trial right for you. As you talk to your doctor about your treatment options, it is important to think about where you are in your life when you make decisions about your cancer treatment.

Your goals may depend on a number of factors including your age and overall health, your type and stage of cancer, any previous treatments you have had, how the trial might affect other care you are receiving such as gender-affirming care, and your interest in helping other people and advancing cancer research.

There is no one way to decide what is right for you. Ask your doctor all your questions.

Take the time to think about these issues. Bring someone to your doctor's visits to listen, take notes, and talk things over. Talk to your family and friends.

It can also be helpful to talk to someone who has been on a clinical trial. You can often meet these people in support groups or online communities. But remember, your experience is your own and will not be exactly the same as someone else's.

HAVING AN HONEST DISCUSSION

The main reason anyone participates in a clinical trial is the hope that they will benefit from the treatment. A second reason is the opportunity to have an impact on cancer research. The possible benefits of trials vary widely. They depend on the type and stage of the cancer and the new treatment that is being studied: everything from a cure to a few months of life, to a better quality of life. Talk to your doctor about what you can expect to happen if you are a part of a trial. Having this honest talk can sometimes be hard, but it helps everyone understand the goals of the trial upfront.

NEED HELP MAKING A TREATMENT DECISION?

If you are facing a cancer treatment decision, call the Cancer Support Community's **Cancer Support Helpline**. Our trained community navigators and resource specialists can help you create a written list of specific questions about your concerns for your doctor. **Call 888-793-9355.**



WHAT ABOUT PLACEBOS?

It is very rare for people with cancer in clinical trials to get just a placebo or sugar pill. In a cancer clinical trial, patients will usually get at least the standard of care. This means getting the best-known available treatment or practice. In the rare case that a placebo is used, it is often because there is no available treatment to compare against. Patients are clearly informed ahead of time if there is a chance they may receive a placebo.

WHAT ABOUT COSTS?

The costs of being on a clinical trial, including any drugs or care, are usually covered by your insurance company or the trial's sponsor. There can be some costs such as transportation, childcare, or lost job time from the additional doctor's visits or tests. If these are a problem, talk to your treatment team or the financial counseling office. In many cases, there are ways of helping you with these costs.

WHERE ARE TRIALS AVAILABLE?

Any cancer center or doctor who treats cancer may offer clinical trials to patients, although not all centers participate. Comprehensive cancer centers and large academic medical centers generally offer

more trials for more cancer types. But community cancer centers also participate in these studies.

Sometimes you may have to change doctors or treatment centers in order to enroll in a trial that is right for you. This can mean moving from a smaller, community-based center to a larger cancer center. But it can also mean moving from one big cancer center to another.

It can be hard to leave your doctor or deal with the logistics of going to a different treatment center. Yet there can be real benefits in enrolling in a trial that may help you. Even if you have to change doctors or treatment centers.

CLINICAL TRIAL RESOURCES

To find clinical trials that may be options for you, talk to your care team and check out these trusted websites.

American Cancer Society's Clinical Trial Matching Service · 800-303-5691 · www.cancer.org/clinicaltrials

BreastCancerTrials.org · 415-476-5777 · www.breastcancertrials.org

CenterWatch · 617-856-5900 · www.centerwatch.com

Cancer Support Community · 800-814-8927 · www.cancersupportcommunity.org/clinicaltrials

National Cancer Institute's Clinical Trials Registry · 800-422-6237 · www.cancer.gov/clinicaltrials

National Library of Medicine's Clinical Trials Search · www.clinicaltrials.gov





TRIALS ARE FOR EVERYONE

People from historically marginalized groups, including LGBTQ+ people, often do not participate in trials in large numbers. There are many reasons for this. In some cases, health care providers do not bring up the opportunity to be on a trial. In others, people may distrust the medical profession and fear being on a research study because of previous negative experiences or the history of medical procedures being forced upon or done to their community without their knowledge. Or there may be issues in getting to extra doctors' visits, missing work, or having childcare covered.

Yet, joining a trial benefits people who share your identities. It is important for people from all groups to participate in trials because there can be differences in how people's disease responds to treatment. One group could have more side effects to a treatment compared to another.

Some people may have specific aspects of their quality of life that are affected more than others. By more people from all groups being involved in trials, doctors can better understand these differences and make sure the treatment fits the person. As you think about what is right for you, here are some tips:

- Ask your doctor if there is a clinical trial right for you and your cancer.
- Schedule a special visit to talk about being on a clinical trial, so you and your doctor have the time to answer all your questions. If English is your second language, ask if there is a trained interpreter available to help you and your family.
- Tell the doctor the reasons you might be worried or hesitant to go on a trial. Have a discussion about these things.
- Bring someone you trust with you to the visit so you can talk about it after. This person can help you talk through what you heard.



- Ask about resources—financial support, help with transportation, or emotional support.
- Talk to the nurses or nurse practitioners. They can be great ways to learn about clinical trials.

WHY SHOULD I BE ON A TRIAL?

The main reason to be on a clinical trial is because you and your doctor believe you may benefit from the treatment. It is important to have a realistic talk about what that benefit might be. Most patients take part in clinical trials so they can live longer and better lives.

Everyone who is affected by cancer needs to know that clinical trials are the key to making progress against cancer. Talk to your doctor about whether there are trials that are right for you. For many people, they are not only an option, they are the best option. Ask your questions and know that you can get a second opinion if you would like to learn more about joining a clinical trial.

Another benefit is that every trial helps move cancer treatment forward. This is true whether it works for you or not. You are still making a difference. Researchers use what they learn from every clinical trial to create new and better treatment for cancer. By joining a trial, you provide real hope for a better future.

SEEK SUPPORT

Whether you join a clinical trial or not, it is important to take care of your emotional health and mental well-being. People with cancer often feel alone. It can be helpful to join support groups or talk with a counselor.

This can be hard in some locations, and some people find support through online communities. Ask a member of your health care team or use the resources at the end of this booklet to find support.

USE YOUR VOICE

If you are unhappy with your experience in a health care setting, talk about it. Let your clinical trial coordinator know if you have negative experiences. Fill out hospital surveys. Join CSC’s Cancer Experience Registry. Share your experiences with LGBTQ+ advocacy organizations. By sharing our experiences, we make progress toward a more equitable health system.



LGBTQ+ RESOURCES

Healthcare Bill of Rights · www.healthcarebillofrights.org

National LGBT Cancer Network · 212-675-2633 · www.cancer-network.org

National Center for Transgender Equality · 202-642-4542 · www.transequality.org

Sage Advocacy and Services for LGBTQ+ Elders · 877-360-5428 · www.sageusa.org

CANCER SUPPORT COMMUNITY RESOURCES

Cancer Support Helpline® — Have questions, concerns or looking for resources? Call CSC's toll-free Cancer Support Helpline (888-793-9355), available in 200 languages Mon-Fri 9am-8pm ET and Sat 9am-5pm ET.

Open to Options® — Preparing for your next appointment? Our trained specialists can help you create a list of questions to share with your doctor. Make an appointment by calling 888-793-9355 or by contacting your local CSC or Gilda's Club.

Frankly Speaking About Cancer® — Trusted information for cancer patients and their loved ones is available through publications, online, and in-person programs.

Services at Local CSCs and Gilda's Clubs — With the help of 170 locations, CSC and Gilda's Club network partners provide services free of charge to people touched by cancer. Attend support groups, educational sessions, wellness programs, and more at a location near you. www.CancerSupportCommunity.org/FindLocation.

Cancer Experience Registry® — Help others by sharing your cancer patient or cancer caregiver experience via survey at www.CancerExperienceRegistry.org.

MyLifeLine — CSC's private, online community allows patients and caregivers to easily connect with friends and family to receive social, emotional, and practical support throughout the cancer journey and beyond. Sign up at www.MyLifeLine.org.

Grassroots Network — Make sure your voice is heard by federal and state policy makers on issues affecting cancer patients and survivors by joining our Network at www.CancerSupportCommunity.org/become-advocate.

Photos are stock images posed by models.

The Cancer Support Community and its partners provide this information as a service. This publication is not intended to take the place of medical care or the advice of your doctor. We strongly suggest consulting your doctor or other health care professionals to answer questions and learn more.

This publication is available to download and print yourself at www.CancerSupportCommunity.org/clinical-trials. For print copies of this publication or other information about coping with cancer, visit Orders.CancerSupportCommunity.org

Frankly Speaking About Cancer:
Clinical Trials in the LGBTQ+ Community
PROGRAM PARTNER



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