OUTpatients
The UK's LGBTIQ+ Cancer Charity

MSD

Understanding Cancer Clinical Trials

A Booklet for the LGBTIQ+ Community



This booklet is for LGBTIQ+ people with cancer considering a clinical trial as a treatment option.

This booklet has been fully funded and developed by MSD, with input from OUTpatients.

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MSD

MSD are a global biopharmaceutical company and have been an integral part of the scientific community in the UK for over 100 years. MSD globally has been at the forefront of research, bringing forward medicines, vaccines and innovative health solutions for the world's most challenging human and animal diseases. We are a committed partner to the NHS – with around 150 clinical trials running each year across 700 sites.

Through our partnership approach, we work to champion equitable opportunities for the communities we serve. We are deeply committed to supporting patients and communities through high quality, trusted information.

Find out more about MSD in the UK at: **msd-uk.com**

OUTpatients
The UK's LGBTIQ+ Cancer Charity

OUTpatients is the UK's LGBTIQ+ (Lesbian, Gay, Bisexual, Transgender, Intersex, Queer, and other diverse sexual orientations and gender identities) cancer charity. Proudly patient-led, it exists to shake up the system, advocate for equity, and stand up for every LGBTIQ+ individual navigating the cancer journey.

OUTpatients host peer support for LGBTIQ+ people affected by cancer, educate healthcare professionals, and help to shape national policy that supports the LGBTIQ+ community. Through this approach, OUTpatients are working towards a system where all LGBTIQ+ people and their loved ones can access cancer services with trust, safety, and dignity.

Find out more and access support at: **OUTpatients.org.uk**

This booklet provides information for LGBTIQ+ people who are thinking about taking part in a cancer clinical trial, including key considerations that may help you decide whether participation feels right for you.

In this booklet, **"you"** may refer to the person joining a cancer clinical trial or someone supporting them, such as a partner, friend, or family member.

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What is Cancer?

Cancer is when normal cells become abnormal and grow uncontrollably.[1]

There are two main types of cancers:

- **Solid cancers:** These are cancers that start in organs, tissues, or bones. The cancer cells lump together and form tumours.[1]
- **Blood cancers:** These are cancers that start in the blood or bone marrow. The cancer cells do not form solid tumours but instead circulate in the blood.[2]

Cancer can start in one area and sometimes **spread** to other parts of the body to form new tumours. When this happens, it is called **metastatic cancer**.[1]

What causes cancer?

Cancer is caused by changes to the genes that control how cells grow and divide.[1] Genes are pieces of DNA that tell your cells how to work.[3]

What are the treatments for cancer?

Treatments to reduce or remove the cancer may include:[4]

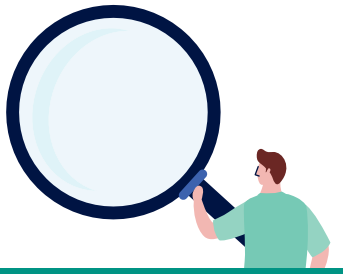
- Surgery[5]
- Chemotherapy[5]
- Immunotherapy[5]
- Targeted therapy[5]
- Radiotherapy[5]

Clinical trials may provide access to new treatments that are not yet widely available.[6]

At any stage of your treatment, you can ask your healthcare team or clinical trial team if a clinical trial may be an option.

What are Clinical Trials?

Understanding more about a **clinical trial** can help you understand if it is an option for you.



What is a Clinical Trial?

A clinical trial, also called clinical research, is a type of research designed to learn more about how the body responds to medicines, vaccines, or other treatments.[7] Clinical trials help researchers and doctors to:

- Find new treatments and improve existing ones.[8]
- Understand how treatments may affect people of different ages, genders, and race.[9]
- Offer access to innovative therapies.[10]

Clinical Trial Safety

In clinical trials, your safety is a priority.[11] There are laws to:

- Help protect the rights, safety and well-being of clinical trial participants.[10]
- Make sure trials follow strict scientific and ethical guidelines.[10]

If you join a clinical trial, the trial team will closely monitor your health and safety throughout the trial.[12]

Your participation is voluntary; you can withdraw at any time.[13]



Clinical Trial Inclusion and Exclusion Criteria



Every clinical trial uses **inclusion** and **exclusion criteria** to decide who can join that specific trial.[14]

Inclusion criteria are things about you and your health that **may allow you to join** a trial.[15]

These may include:

- Your type of cancer.[14]
- The stage of your cancer.[14]
- Specific features of your cancer, such as genetic changes or markers.[15]
- Cancer treatments you may have already received.[14]

Exclusion criteria are things about you and your health that **may prevent you from joining** a trial.[15]

These may include:

- Medicines you take that could interact with the trial treatment.[15]
- Having another serious health condition.[15]
- Having an infection that needs treatment.[15]
- Pregnancy.[15]



Your healthcare team or the clinical trial team can review a trial's inclusion and exclusion criteria with you and help you understand your options.

Things to Think About Before Joining a Clinical Trial



There are things about your health that you may need to share with the clinical trial team before joining a clinical trial.

☐ Use the **tick boxes** to tick things you may need to talk with your clinical trial team about.

☐ Gender Identity and Sex Registered at Birth

Tell the trial team your sex registered at birth.

The trial team needs to know this because your sex registered at birth may be an exclusion criteria.[16]

Things linked to your sex may change how a cancer treatment affects your body, such as:

- Hormones your body makes.[17]
- Your reproductive organs.[17]

☐ Fertility

Some cancer treatments may affect your ability to have children in the future.[18]

- The trial team may be able to offer options to protect your ability to have children if you can make eggs or sperm.[19]
- This may include freezing eggs, sperm or embryos before starting the study.[19]

☐ Pregnancy Testing

Some cancer treatments may be unsafe during pregnancy.[20]

- If you are able to get pregnant, your clinical trial team will test for pregnancy before you join the trial.[21]
- This testing may still be needed even if pregnancy is not expected based on your sexual activity or relationships.[22]

Gender Affirming Hormone Therapy (GAHT)

Tell the trial team if you are taking hormone therapy, whether it is prescribed, non-prescribed or self-medicated,[23] such as:

- Oestrogen[24]
- Testosterone[24]
- Anti-androgens[24]
- Gonadotrophin-releasing hormone analogue (GnRHa)[24]

The trial team needs to know this because these can affect blood test results,[25] and may affect how a cancer treatment is absorbed, broken down or moved around the body.[17]

Gender Affirming Surgery

Tell the trial team about any surgeries you have had[26] including removal of:

- Ovaries (oophorectomy)[27]
- Testes (orchidectomy)[28]

These surgeries may affect:

- The hormones you make[28] and affect blood test results[29]
- Interpretation of medical scans, such as magnetic resonance imaging (MRI) or computed tomography (CT) scans.[30]
- How you receive pelvic radiotherapy, if needed.[31]



Smoking

Tell the trial team if you smoke.

- Smoking may affect how a cancer treatment is absorbed, broken down, or moved around the body.[32]

Human Immunodeficiency Virus (HIV)

Tell the trial team if you have HIV.

- HIV infection affects your immune system.[33] The immune system helps to protect the body against foreign, damaged or cancer cells.[34]
- HIV infection may be an exclusion criteria for a clinical trial.[35]

Tell the trial team if you are taking PrEP (pre-exposure prophylaxis) or PEP (post-exposure prophylaxis).

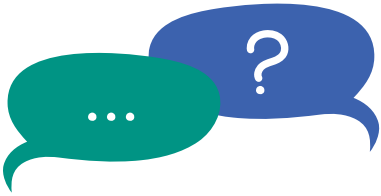
These medicines may change how some trial treatments work.[36]

Hepatitis B Virus (HBV)

Tell the trial team if you currently have HBV or have had it in the past, because:

- Treatments for HBV can control the hepatitis B virus.[37]
- Some cancer treatments may reactivate the virus.[38]
- If the virus becomes active again, it may change how the cancer treatment works with your body.[39]
- Some cancer treatments may affect liver function.[40]
- Your trial team may offer you medicine to keep the virus from reactivating and to protect your liver during cancer treatment.[37]
- Past or active HBV infection may be an exclusion criteria for a clinical trial.[35]

Questions & Answers



Diversity in clinical trials is important because it helps researchers understand how new treatments may affect and benefit different people.[41]

Q Can I keep taking my gender affirming hormones or PrEP while in a clinical trial?

A This will depend on the specific clinical trial. Each trial has different guidelines to follow, including what other medicine you can take during the trial.

Be open with your trial team about medication you are taking, whether these are prescribed, non-prescribed or self-medicated, and ask if they can be continued during the trial.[23]

Q Do I need to mention my gender affirming surgeries (past or planned)?

A Yes, do tell the trial team about any surgeries you have had or will have, as it will help to decide if the treatment option is right for you.[26]

Q Could joining a clinical trial affect my intimate relationships?

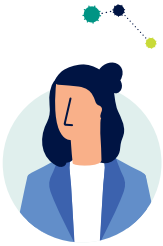
A A clinical trial may affect pregnancy,[20] or fertility.[18] You can discuss this with your healthcare team, who may be able to suggest steps to take to protect yourself and others during the study.

Q How can I find out if I am eligible to join a clinical trial?

A You can ask your healthcare team about joining a clinical trial and if it could be a suitable option for you.

Every clinical trial has its own inclusion and exclusion criteria. The trial team will go through these criteria with you to see if you are able to join.[14]

Hear from Healthcare Professionals about Clinical Trials



Representation from LGBTIQ+ people in clinical research improves the variety of data collected. Using scientific methods to address the specific needs of LGBTIQ+ people means that outcomes and recommendations are reliable.

Catherine Breen (she/her)
Senior Clinical Trials Pharmacist



Sometimes the language used in clinical trials is very gendered and or geared towards heterosexual relationships. Don't be afraid to raise this with your team so you can understand exactly how taking part might affect you. You can raise any questions related to your LGBTIQ+ identity with your oncology or clinical trials teams. It is helpful for us to know what is important to you so that your needs are met. Having open conversations can also help us make trials more inclusive overall.

Dr Alison Berner (she/her)
Clinical Senior Lecturer in Medical Oncology



The clinical trials of today will inform how people receive care in the future. LGBTIQ+ participation in clinical trials helps to ensure the benefits and side effects of new treatments are relevant to LGBTIQ+ people.

John Leggett (they/them)
Specialist Oncology Pharmacist

Ask your healthcare team to learn more about clinical trials.

Notes

Use these pages to write…

- Your questions.
- The name, phone number and email address for your healthcare team.
- Details about future appointments – who it's with, what time and where?
- Anything you want to talk about at the next appointment.

Notes



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Want to learn more about clinical trials?

Talk to your doctor or nurse about clinical trials that may be open to you. Further information, including a list of clinical research studies in the UK relevant to you, is available through the National Institute for Health Research (NIHR). Or use the QR code opposite to access the Be Part of Research website.

Taking part in research can help save lives

This booklet has been fully funded and developed by MSD, with input from OUTpatients.

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