

# Lymphoma drug development, approval and funding

The page explains why drug development takes so long, why drugs are so expensive and how you can find out whether a drug might be funded on the NHS.

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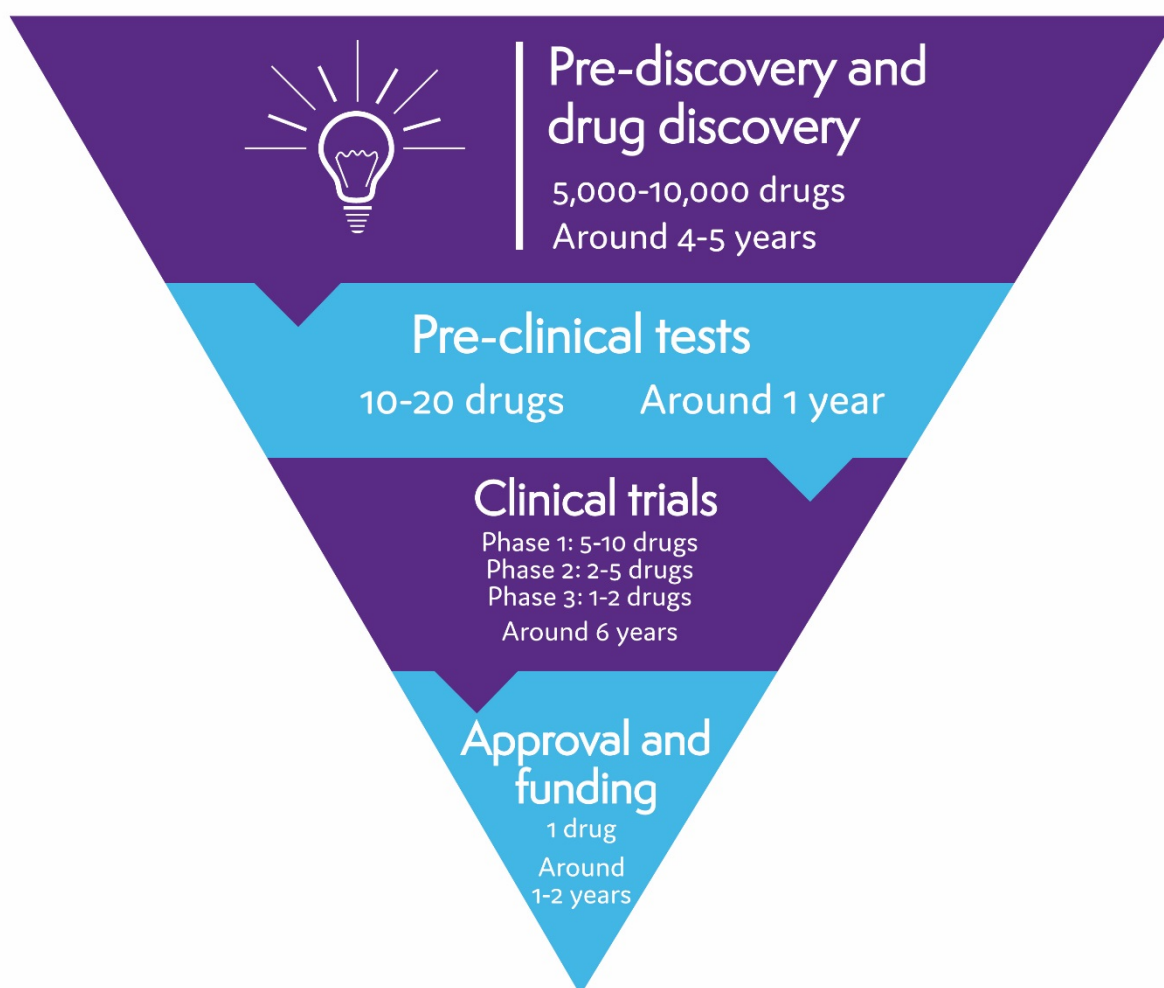
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## Drug development

There is much excitement about **new, targeted drugs** for people with lymphoma, but drug development and approval is a long and expensive process. It can be frustrating hearing about new drugs that could improve outcomes for people with lymphoma when these are not yet available to you.

The time and cost to develop a drug varies hugely but on average, it takes around 12.5 years for a large pharmaceutical company to develop a drug from discovery to approval and costs around £1.15 billion. Thousands of drugs are tested for use in lymphoma treatment, but out of those, only very few are safe and effective in treating lymphoma and are approved. Although many won't be approved, results from tests with these drugs are very useful in informing future tests and drug development. This process means that pharmaceutical companies have a lot of costs to cover, and is one reason why new drugs can be very expensive.



**Figure: The drug development process for drugs in general**

## Pre-discovery and drug discovery

The first stage in drug development involves research to understand a disease. This research underpins the search for possible drugs – it helps to identify targets for a drug to act on. Researchers then search for drugs that act on the targets they've identified. Thousands of possible drugs are tested in this way for each drug that eventually becomes approved for use in people.

## Pre-clinical tests

Before a drug can be tested in humans, it undergoes extensive testing in laboratories and on animals. These tests help find out how the drug works, what effects it might have in the body, and what dosage should be safe to start with in clinical trials. If serious problems are detected in pre-clinical tests, a drug won't be tested in people.

## Clinical trials

Although pre-clinical testing gives researchers an idea of how a drug might affect people, these findings have to be tested thoroughly in people with the disease. Clinical trials are where the drug is tested in people. Only a very small proportion of the drugs identified in research are tested in clinical trials. The clinical trial testing process usually takes several years, but the exact time can vary greatly depending on the drug and the health conditions it is being tested for. Clinical trials are done in phases. Drugs proceed from small phase 1 trials involving a few people to large phase 3 trials, often involving hundreds of people, as more is learnt about them. It is very common for drugs not to show enough benefit in early phase trials for their development to continue. Cancer drugs often start out being tested in lots of different types of cancer, and are eventually only tested in the types of cancer in which they are most effective.

Visit [Lymphoma TrialsLink](#) to find out more about clinical trials. You can search our database of lymphoma trials to find a trial that might be suitable for you.

The next sections explain what happens if a drug shows benefits in clinical trials and the pharmaceutical company apply for it to be approved.

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## Drug approval

Your doctor can only give you treatments that are approved for use in Europe (unless you are in a clinical trial).

The approval process is designed to keep you safe and to make sure you only have treatments that are likely to benefit you.

Being approved is not the same as being funded on the NHS. When a drug is approved, it is assessed by funding bodies in the UK to decide whether the benefits of the drug are worth its costs.

### Who approves new drugs?

If clinical trials show that a new drug significantly improves outcomes for people with lymphoma, the pharmaceutical company that produced the drug applies for it to be licensed (approved) for use.

The drug company has to apply to different authorities in different parts of the world. For example:

- the **Food and Drug Administration** (FDA) approves drugs in the US
- the **European Medicines Agency** (EMA) assesses applications and recommends whether drugs should be licensed in Europe; the European Commission (EC) then makes a decision.

At the time of writing, it is not certain how Brexit (the UK's decision to leave the European Union) will affect this process.

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## Funding

Once a drug has been approved in Europe, national authorities need to assess it to decide if it should be funded in each country.

In the UK, health and technology assessment bodies decide whether to make drugs available on the NHS. These are:

- the **National Institute for Health and Care Excellence** (NICE), whose guidance is followed in England and Wales, and often in Northern Ireland if agreed by the Department of Health, Social Services and Public Safety
- the **Scottish Medicines Consortium** (SMC)
- the **All Wales Medicine Strategy Group** (AWMSG), which looks at some drugs before a decision is reached by NICE.

## How can I find out if a drug is available for me?

Different ways of funding cancer drugs apply in each part of the UK, so it is important that you look at the right information. The websites for each of the health and technology assessment bodies have up-to-date information on which drugs are recommended and which are currently being assessed. If the drug is still being assessed, these sites often give a date that a decision is expected. Search for your type of lymphoma or a drug name using the links below.

- If you live in England or Northern Ireland, visit the NICE website.
- If you live in Scotland, visit the SMC website.
- If you live in Wales, visit the NICE website but if a drug is not yet available, the AWMSG sometimes makes it available earlier than NICE, so you can check there too.

Our **news section** reports regularly on drug approvals and NICE decisions.

Funding for new drugs can change very quickly as more is learnt about the risks and benefits of each drug.

Some drugs are funded in England through schemes that give access to new drugs for a limited time while more evidence is being gathered about them. These schemes include the **Cancer Drugs Fund (CDF)** and the **Early Access to Medicines Scheme (EAMS)**.

**Remember to talk to your own consultant about drug availability. Even if a drug has been approved for use in your type of lymphoma, it might not be suitable for you. Some drugs might not be recommended if you have other medical conditions or are taking certain other medicines, as the drugs may interact with each other.**

## What is the Cancer Drugs Fund?

The **Cancer Drugs Fund (CDF)** is a source of funds that allows access to cancer drugs that are not routinely funded on the NHS. It is managed by NHS England.

In England, NICE sometimes recommends that drugs should not be available routinely on the NHS but should be made available through the CDF.

All drugs are assessed by NICE first, who decide:

- to recommend drugs for funding on the NHS
- not to recommend drugs for funding on the NHS
- to recommend drugs for funding through the CDF until more evidence is available.

If NICE decide to put a drug on the CDF list, the drug is funded through the CDF for a limited time while the drug company gathers further evidence. The drug is then assessed by NICE again to decide if it should be funded routinely on the NHS.

There is a central list of **drugs available on the CDF**, which details who might be able to get funding. The list is regularly updated and drugs can be added or removed.

There are currently no similar funds in Scotland, Wales or Northern Ireland. However, in those countries your doctor may be able to make an individual funding request in exceptional cases if the treatment is not routinely available on the NHS. You should discuss this with your doctor if you think that this applies to you.

## What is the Early Access to Medicines Scheme?

The Early Access to Medicines Scheme (EAMS) is run by the **UK Medicines and Healthcare Products Regulatory Agency (MHRA)**. This is a Government organisation that is responsible for making sure that medicines and medical devices used in the UK work well and are acceptably safe.

The MHRA can assess promising new medicines with the aim of making them available to people with no other treatment options before they are **licensed in Europe**. There are only a few drugs on the EAMS list at any time, but drugs for people with lymphoma sometimes appear on the list.

The MHRA assesses the available evidence to decide whether the benefits of the drug are likely to outweigh the risks. As the drugs in the scheme are new, researchers are continuing to find out more about their safety and how well they work and these are still experimental treatments until they are licensed. Once they are licensed, drugs are no longer available through EAMS.

EAMS drugs are funded in England. They may be available through drug company access schemes or through individual funding requests in other parts of the UK. If you are eligible for a drug that is on the **EAMS list**, you and your doctor can look at the evidence together to decide if the drug is suitable for your situation.

## How can I access drugs that are not funded?

If a drug is approved for your type of lymphoma but is not funded in the UK, you will need to organise funding from alternative sources. **Macmillan** have further information on what you can do if you and your doctor think you would benefit from a drug that is not available on the NHS.

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## References

The full list of references is available on request. Please email [publications@lymphoma-action.org.uk](mailto:publications@lymphoma-action.org.uk) or call 01296 619409 if you would like a copy.

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