



Clinical research trials and insurance

Information for people who are planning to take part in a clinical research trial

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This information is subject to change depending on medical advances

Types of insurance

Information is provided on the following types of insurance:

- Travel insurance
- Protection insurance
 - Life insurance
 - Income protection
 - Critical illness cover
- Private medical insurance

Types of clinical research trial

A clinical research trial is a planned study designed to answer questions about health interventions.

Clinical research trials on interventions such as drugs tend to have four phases:

- Phases 1-3 check the safety and efficacy of the intervention, for example a new drug. Insurers would consider drugs used in these phases of a trial to be **experimental** or unproven.¹
- Phases 3-4 establish the effectiveness of the intervention.
- Phase 4 could include monitoring the intervention after it has been proved safe and accepted for marketing. This could include:
 - Monitoring a person with a diagnosis who is taking a new medication
 - Monitoring a person with a diagnosis who is taking their regular medication
 - Monitoring healthy volunteers to provide a comparison
 - Comparing the results between any of these study groups

Clinical research trials on health interventions can be evaluated in different ways:

- Research, interviews, data analysis
- Imaging studies such as CT scans, X-rays, and mammograms
- The use of clinical devices or products for example in surgery

For example, clinical research trials on surgical and radiotherapy interventions tend to not use the phase 1-4 model, and these may be evaluated differently.

¹ Drugs not licensed in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA) and/or the European Medicines Evaluation Agency (EMA).



When you are thinking about taking out insurance

Insurers need to be able to assess the risk to know what terms and conditions to offer, and to set fair premiums.

If you are a healthy volunteer who is being monitored to provide a comparison to other people on the clinical research trial you should have no difficulty in obtaining cover.

If you are not a healthy volunteer the cover you could get will depend on the type of insurance and what is wrong with you

Travel insurance

You might get cover if you take part in a clinical research trial of **established**² drugs, research, imaging studies or comparisons of established surgical interventions (to identify which treatment is better in certain circumstances) that are prescribed by your doctor.

It is unlikely that you would get cover if you take part in a clinical research trial of:

- Drugs that are in the **experimental/unproven** phase, even if you are healthy with no **pre-existing conditions**³;
- New or innovative surgical procedures.

Protection insurance (Life and Critical Illness)

Taking part in a clinical research trial of itself is unlikely to affect the cover you could get, but will also depend on what you have been diagnosed with and what is found during tests or investigations.

Protection insurance (Income Protection)

Taking part in a clinical research trial of established drugs, research, imaging studies or comparisons of established surgical interventions (to identify which treatment is better) that are prescribed by your doctor is unlikely to affect the cover you could get. It will also depend on your diagnosis.

You are unlikely to get cover if you take part in a clinical research trial of:

- Drugs that are in the **experimental/unproven** phase even if you are healthy;
- New or innovative surgical procedures.

Private medical insurance

The cost or any consequences of experimental or unproven treatment or drugs is not usually covered but the insurer might make discretionary payments to cover participation in clinical research.

² Proven drugs that are licensed in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA) and/or the European Medicines Evaluation Agency (EMA).

³ A pre-existing condition is any illness you are currently suffering from or have already had. This includes any symptoms or any form of treatment or prescribed medication, medical consultation, investigation or follow-up/check-up that has been required or received.



Before you take out insurance

Ask your Clinical Research Trial Programme Manager what cover you will have from the insurance provided by the clinical research trial programme – does this include:

- Loss of earnings, cover/indemnity against possible side effects, medical negligence?
- Consequential injury, sickness or disability from taking part in a trial that was not recommended by your doctor?
- Holiday cancellation, medical repatriation abroad?

Check your existing insurance policies and ask your employer if you have cover through your job.

Ask your Travel insurer what cover you will have if you are travelling abroad for the purpose of participating in a clinical trial. Will this make your policy invalid?

When you apply for insurance

What you may be asked

Insurers will make their assessment of the risk depending on the type of insurance you apply for, the answers you have given to their questions and any other information provided. Taking part in a clinical research trial might affect the cover you get from your insurance.

You need to answer all questions the insurer asks you including whether or not you are taking part in a clinical research trial. You must answer any question you are asked as fully and as accurately as you can, to the best of your knowledge and belief. If you do not, your insurer may refuse to pay your claim and could cancel your policy.

You are likely to be asked questions about your health, including medical history and pre-existing medical conditions, even if these are diagnosed as part of a clinical research trial. If you have a diagnosed condition, even as a result of information you found out about as part of a clinical research trial, the insurer may limit the offer of cover, apply exclusions, or increase the premium.

Always make sure you know what you need to disclose, what the insurance policy covers before you take out insurance. If in doubt, ask your insurance company or broker.

Test results

You will also need to answer questions about the results of tests you have taken or are waiting for. Some insurers might make a decision not to cover you for the condition (or related conditions) you are being tested for until the test results are known.

Insurers will not ask you about any results for genetic tests taken during clinical research. However, insurers can ask about diagnostic genetic test results, diagnoses, advice or treatment taken outside of the clinical research trial programme, even if you found out about the condition through clinical research.



Until your policy starts

There might be situations where your health changes between the time you apply for insurance and the time your insurance cover starts. Most insurers require you to disclose any new information about your health or tests being carried out during this time.

If you are waiting for the results of any tests, other than genetic tests taken as part of the clinical research trial, some insurers might make a decision not to cover you for the condition (or related conditions) you are being tested for until the test results are known. The insurer will decide whether you can continue with the application, or whether they will change the cover and/or premium, or wait for the results of any outstanding investigations before making a decision.

To ensure your insurance cover remains valid check with your insurance company if you are not sure if something should be disclosed.

WHEN YOU ALREADY HAVE INSURANCE

Travel insurance

Most travel insurers require you to tell them about test results you are waiting for and health changes that arise during the period of insurance. Health changes include a new diagnosis, symptoms, treatment, change of status of an existing condition, and prescription medication that may have been recommended following or as part of your clinical research trial.

If you are travelling abroad to participate in a clinical research trial, check your current policy to find out if you are covered.

Life insurance and critical illness cover

Existing life insurance and critical illness cover policies are unaffected if you participate in a clinical research trial. With an existing life insurance or critical illness cover policy it is not necessary for you to inform your insurer that you are participating in a clinical research trial, even if you are found to have a previously undiagnosed condition such as diabetes, heart disease or kidney disease.

Income protection insurance

Existing income protection policies are unaffected if you participate in a clinical research trial for drugs or research, imaging studies, or comparisons of established surgical interventions to identify which treatment is better in certain circumstances if:

- You are a healthy volunteer; or
- You are prescribed the drugs or surgery to treat your condition.

Private medical insurance

Private medical insurance does not usually cover the cost, or any consequences, of taking experimental or unproven treatment or drugs, but the company covering you might make discretionary payments to cover participation in clinical research.



Insurance you want to take out at a later date

Health problems identified as a result of a clinical research trial might affect whether you are eligible to take out insurance in the future, or the terms that you might be offered when you apply, for example, a decrease in cover offered or an increase in the premiums you pay.