Intelligent CLINICAL

A guide to

Taking part in clinical trials

Taking part in a clinical trial may be a daunting decision to make. Having the right information and guidance can help you assess whether taking part is right for you.

Our guide to clinical trials covers the key questions that we are often asked by potential participants as they research their options. Our aim is to provide you with as much information as possible to help you make an informed choice.

If you do choose to take part in a clinical trial with us, you will be fully supported and guided through the process by our friendly, approachable and professional clinical team of nurses and doctors.

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Section 1:
Clinical trials

What is a clinical trial?

Clinical trials are research studies, which assess the effect a new test or treatment might have. During clinical trials, the aim is to learn if the new test or treatment is safe and effective. Treatments studied in clinical trials might be new drugs or new combinations of drugs, new surgical procedures or devices, or new ways to use existing treatments or new therapies relating to general health and wellbeing. The purpose of a clinical trial may be to learn more about:

- Health
- Diseases
- Medicines
- New treatments

What are the phases of clinical trials?

Most of the clinical research that involves the testing of a new drug moves ahead in an orderly series of steps, called phases. This allows researchers to ask and answer questions in a way that results in reliable information about the drug and protects the patients throughout their participation. Most clinical trials are classified into one of four phases:

- **Phase I trials:** These first studies in people evaluate how a new treatment should be given (by mouth, injected into the blood, or injected into the muscle), how often and what dose is safe. A phase I trial usually enrols only a small number of patients, sometimes as few as a dozen.

- **Phase II trials:** A phase II trial continues to test the safety of the drug and begins to evaluate how well the new drug works.

  → Intelligent Clinical is involved in this type of study.

- **Phase III trials:** The study drug or treatment under investigation is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.

  → Intelligent Clinical is involved in this type of study.

- **Phase IV trials:** After a treatment has been approved and is being marketed, the drug's maker may study it further in a phase IV trial. The purpose of phase IV trials is to evaluate the side effects, risks and benefits of a drug over a longer period of time and in a larger number of people than in phase III clinical trials. Thousands of people are involved in a phase IV trial.

  → Intelligent Clinical is involved in this type of study.

Why do people take part in clinical trials?

People can have many different reasons for thinking about taking part in a clinical trial. These can vary from:

1. You may have a specific condition and feel there may be limited options for how symptoms can be managed and hope to find a better way of managing it.

2. You may know of someone in your family with a health-related condition and you understand the impact it can have on their life and those around them and understand only advances in research may find new ways of helping manage their condition better.

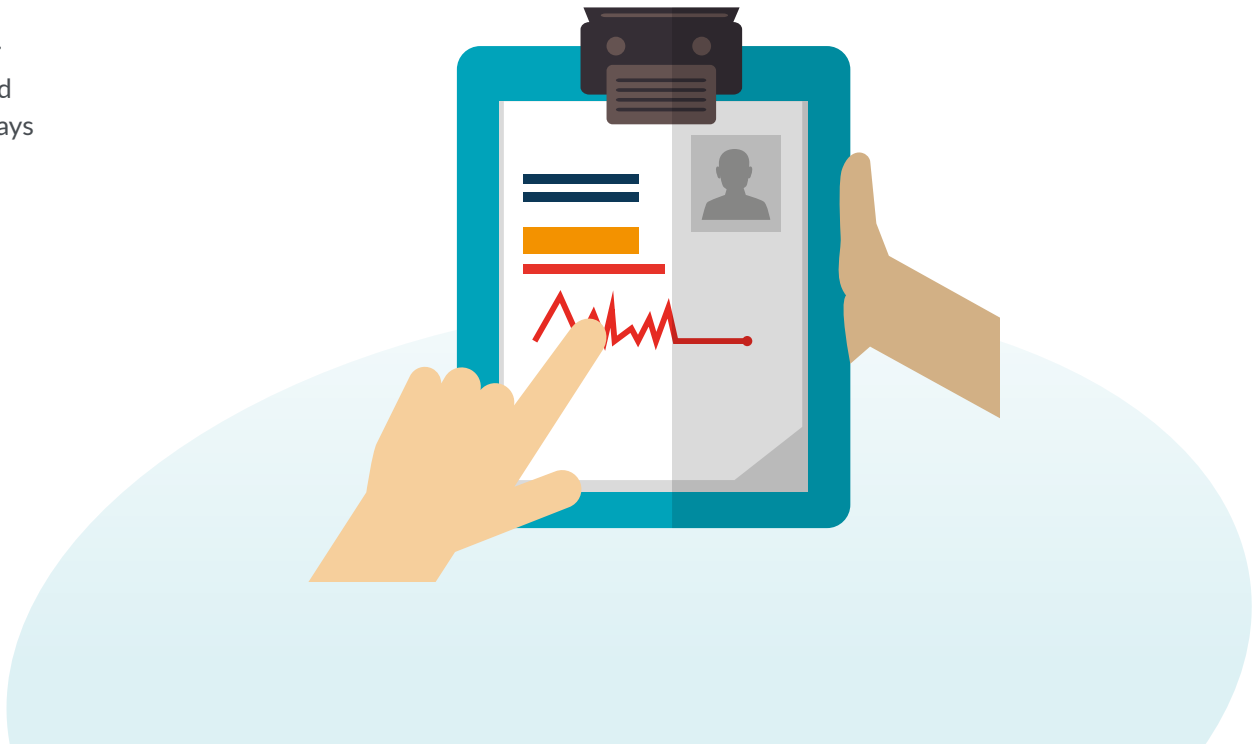
3. You may want to take part to learn more about your condition and the research around it and have that added input of contact with the clinical team for the duration of your participation.

4. You want to play your own part in supporting research and finding new advancements in medicine.

These are just some of the reasons our participants have chosen to take part in a clinical trial with us. Everyone has their own reasons for helping medical research and our participants are fully supported throughout any clinical trial with us.

Where do the ideas for clinical trials come from?

Ideas for clinical trials usually come from researchers. After researchers test new therapies or procedures in the laboratory and in animal studies, the treatments under investigation with the most promising laboratory results are moved into clinical trials. During a trial, information is gained about a potential new treatment, its risks and how well it works.



Section 2:

Clinical trials with us

What research does Intelligent Clinical take part in?

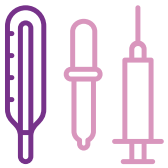
Research is a specifically designed and planned search for new information about health, disease, medicine, and treatments. Researchers use this information to confirm if new treatments are helpful in treating many different conditions. Research can also include finding new tests to detect disease or find new ways of caring for people with many different types of disease. Research may also be called a “research study,” “medical research,” “clinical research study” or a “clinical trial.”

Why do we need Intelligent Clinical to carry out research?

Without research it would be impossible to find new ways to improve health care and offer new or improved solutions to help manage symptoms. Research can offer hope of a better treatment option in the future.

Research also helps find new or improved diagnostic tools, medications, devices, health supplements or treatment guidelines. For research to be successful, it relies on the help of those most likely to benefit from it. In other words, research on a new drug, test or treatment must be done with the participation of people who have the kinds of illness or injury that the drug, test or treatment is being made for. Research studies with healthy people are also important, this type of research is carried out at other centres, Intelligent Clinical are focused on patient studies.

What type of clinical research do Intelligent Clinical carry out?



Treatment Studies

Treatment studies test experimental treatments, new combinations of drugs, or new approaches to a type of therapy.

Diagnostic Studies

Diagnostic studies are conducted to find better tests or procedures for diagnosing a particular disease or condition.

Quality of Life Studies

Quality of life studies explore ways to improve comfort and the quality of life for individuals with a chronic illness.

Prevention Studies

Prevention studies look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vaccines, vitamins, minerals, or lifestyle changes.

Screening Studies

Screening studies test the best way to detect certain diseases or health conditions.

Observational Studies

Observational studies address health issues in large groups of people or populations in natural settings. In this type of study people are observed or certain outcomes are measured. No specific treatment is given by the researcher.

Who sponsors Intelligent Clinical trials?

Clinical trials are sponsored or funded by a variety of organisations involved in the pharmaceutical, medical device, health, and food industry.

Who can take part in a clinical trial at Intelligent Clinical?

All clinical trials have guidelines about who can participate. The main guidelines that allows someone to participate in a clinical trial are called “inclusion criteria” and those that exclude someone from participating are called “exclusion criteria.” These criteria are based on many factors such as age, gender, the type and stage of a disease, previous medical history, current medication use, possibly some test results, and availability to take part. It is important to note that inclusion and exclusion criteria are not used to reject people for any other reason than to ensure all those taking part meet the criteria listed, this ensures appropriate participants are kept safe. Before joining a clinical trial, a participant must qualify for the study. This qualification may be based on you being healthy or having a specific condition.

Why participate in a clinical trial at Intelligent Clinical?

Research studies depend on the people who agree to be a part of them. By taking part, you can further medical knowledge and potentially help others. You can also:

- Play an active role in potential new options for your health care
- Get access to new research treatments before they are widely available
- Be seen regularly by a clinical team throughout your participation
- Help others by contributing to medical research

Is there anything I should consider before participating in a clinical trial at Intelligent Clinical?

Your participation in a clinical trial will always be voluntary. Before agreeing to take part, you will receive an informed consent document that explains the details of the study, including its purpose, duration, required procedures, potential risks and benefits, as well as your rights and responsibilities and any data protection information relating to the data collected during the trial.

Informed consent is a process that helps you to learn the key facts about a clinical trial before considering whether you wish to take part. It continues throughout the study with new information always provided as it becomes available. As you receive information you continue to be able to choose on whether you continue in the trial. A member of the clinical research team will discuss the study with you, you will have time to review the informed consent document and have all your questions answered so you can make an informed decision about whether or not to participate. Informed consent is not a contract, and you may withdraw from the trial at any time. If you decide to withdraw the clinical research team may ask if you would be happy to allow them to keep in contact for a period of time to check up on how you are doing. You do not have to agree to this either.

The informed consent document will help you to understand:

- It is your choice whether or not to take part
- Why the research is being done
- What will be done during the research and for how long
- What risks and/or side effects, if any, are involved
- What possible benefits you can expect
- What other options are available
- How your personal data is managed
- What sharing of information you agree to e.g. your GP being contacted with results or to obtain your medical history
- You have the right to leave the study at any time without interfering with your regular care

Are there any risks to participating in a clinical trial at Intelligent Clinical?

All research is overseen by a panel of people, including some from our community, called a Research Ethics Committee (REC). The REC's primary concern is for the safety and well-being of those people who agree to take part in the research. It is their job to decide whether the benefits of the research outweigh any concerns and to also track how the research is progressing. If you ever have a concern about research being done at Intelligent Clinical, you can contact the REC, their details will always be listed on your informed consent document.

If you have any changes to your health while participating in the research study, your standard health care will continue within the National Health Service with the research physician providing information to your GP as required and as you have agreed.

There can be potential risks to clinical trials:

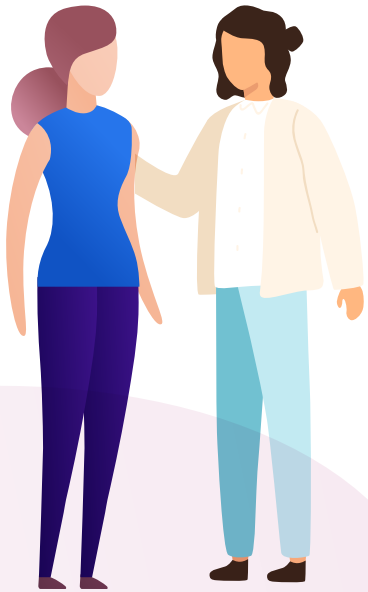
- There is the potential of unpleasant, serious or even life-threatening effects to treatments being investigated. As noted, the role of the REC is to assess the risks and benefits to ensure the risk does not outweigh the potential benefits.
- The treatment under investigation may not be directly effective for the participant either because you have received a 'dummy' of the treatment or because the treatment is not as effective as had been thought.
- The research study may require more of your time than would be expected during standard treatment, this might include additional trips to the research facility.

How is my safety protected by Intelligent Clinical?

The standards for research physicians and nurses that govern NHS medical practice also apply to clinical trials. In addition, every clinical trial in the United Kingdom must be approved and monitored by a Research Ethics Committee (REC) to make sure the risks are as low as possible and are worth any potential benefits. The REC also ensures that a clinical trial is ethically based on a core set of research rules for practice and the rights of study participants are protected as a priority for all those involved in research. Intelligent Clinical research facility will also be approved by the REC to carry out a clinical trial. All our doctors and nurses must be licenced to practice with either the General Medical Council or the Nursing & Midwifery Council.

Can I leave a clinical trial after it has started?

Yes. Anyone taking part can leave a clinical trial at any time. When withdrawing from the trial, it is hoped that you will let the research team know you are leaving, and the reasons for this as well as possibly allow them to keep in touch for any follow up questions relating to your health and safety if you agree. We hope you would remain in a study and our team will do their utmost to ensure it is a positive experience for you.



Is there any payment for taking part?

Yes, most research studies will provide two forms of payment:

- A fee for travel reimbursement
- A fee for inconvenience around the time involved in taking part

When Intelligent Clinical advertise for any new clinical trial we will provide a summary of what is involved in taking part including:

1. The number of study visits
2. The time period of the overall trial
3. Travel/inconvenience payments (per visit or for duration of trial)

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Get in touch

You can find out more about our current clinical trials at **participants.intelligent-clinical.com/current-trials** or **register** to sign-up to our database and we'll email you about upcoming trials.

Don't forget to follow us on **Facebook** and **Twitter** to see the latest news, content and trials from Intelligent Clinical.