MEDINOVA

Dedicated Research Centres

HELPING RESEARCH

JOIN THE TRIAL

MEDINOVA

HELPING RESEARCH
JOIN THE TRIAL

ABOUT MEDINOVA

Thank you for attending our Dedicated Research Centre, we appreciate your time and interest. We rely on volunteers to help with the development of medical therapies that may offer better treatments in the future.

We hope the following information provides an overview of the clinical trials process and answers any further questions you may have regarding your possible participation in one of our trials.

Choosing to participate in a clinical research trial is an important decision. MeDiNova Research is a company dedicated to conducting clinical trials and has been investigating the effectiveness of new medicines and treatments for more than 20 years. We are committed to ensuring our volunteers are treated with the utmost care and respect whilst maintaining the highest standards of research. We provide a friendly, relaxed environment where you have the chance to help shape the future of world health for yourself and future generations.

We have 5 Dedicated Research Centres in the UK and a further 20 such Centres around the world, each with its own experienced research doctors who are supported by their teams of dedicated nurses, healthcare professionals and administrators. Our Centres are welcoming and we pride ourselves on our friendly and professional approach.

We wish you to be fully informed on all aspects of your participation in our studies and we are always available to answer any queries or concerns you or your family may have throughout.

WHAT IS A CLINICAL TRIAL?

We tend not to give much thought as to how treatments have been made available to us, but everything from paracetamol to insulin has been carefully tested through clinical research before being prescribed by your doctor.

A clinical trial is a research study in which volunteers receive investigational treatments under the supervision of a research doctor and other health care professionals. These treatments are developed by pharmaceutical and biotechnology companies who select appropriately qualified doctors known as Investigators to conduct clinical trials to determine the benefits, risks and safety of these new treatments.

Clinical trials are usually conducted in three phases (I,II and III). Only a small number of volunteers, usually so called 'healthy volunteers', participate in phase I trials, while the later phases involve a larger number of patient volunteers. At MeDiNova, we focus on what's known as "late phase" clinical trials. These studies look into the effects the treatments being researched have on the conditions they were designed to treat and all will have undergone some earlier phase testing.

A clinical trial can only be offered to our trial patients once it has been approved in the UK by the MHRA (Medicines and Healthcare Products Regulatory Agency), as well as an independent ethics committee who look to ensure that the rights and wellbeing of all trial patients are not being compromised. All our clinical trials are fully approved by both national and local ethics committees.

Many trials, particularly phase III studies are conducted worldwide with a large number of patients participating in them. They will have to be approved by the regulatory agencies in their countries (e.g the FDA in the United States) and the results collected from all trial participants globally are monitored closely during the trial process.

Our clinical trials are also rigorously monitored by both internal and external audits along with regulatory inspections throughout.

We have many different trials to suit different treatments and conditions, the results of which will assist the development of new treatments.

MEDINOVA

WHO CAN PARTICIPATE IN A CLINICAL TRIAL?

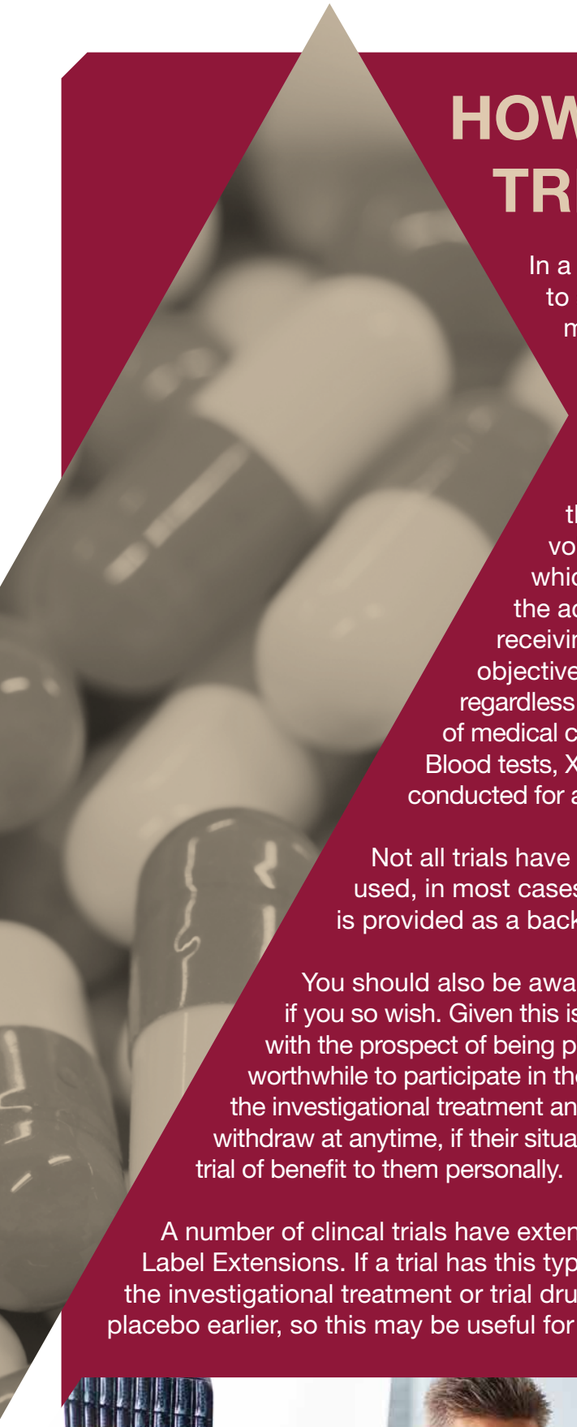
Participation in a clinical trial is a personal choice and we will provide you with the information you require to make an informed decision. We encourage you to discuss your decision with those close to you.

All clinical trials have guidelines about who can participate. Before joining a clinical trial a volunteer must qualify for the trial. The factors that allow volunteers to participate in a clinical trial are called' inclusion criteria' and the factors that disallow participation are called 'exclusion criteria'. These criteria can include age, gender, the type and stage of a disease, previous and current treatments and other medical conditions.

Volunteers usually contact us to find out more about the clinical trial they are interested in. You may have heard about the trial from your GP, the radio, the press, or our websites www.improvingtreatments.co.uk and www.medinovaresearch.com.

A member of our research team would then follow up your interest on the telephone to ask a few more questions because it is important that we learn more about you so that we can find the right clinical trial for you. If after the call, you seem eligible for the trial and are interested to know more, we will invite you to the Research Centre for a Patient Interest visit for you to discuss your potential participation further with one of our doctors.

If you decide you are interested in potentially taking part, we will make your journey as easy and informative as possible. The section of Next Steps later provides more information on this journey.



HOW DOES A CLINICAL TRIAL WORK?

In a clinical trial a volunteer is usually assigned randomly to a specific trial group. Volunteers in one trial group may receive the investigational treatment or trial drug while other volunteers may receive a placebo (dummy treatment) or another treatment that is already available.

A placebo is an inactive product used to assess the investigational treatments' effectiveness. The volunteer, the doctor and research team may not know which volunteer receives placebo and which receives the active treatment. Not knowing which participants are receiving the active treatment allow the research team to objectively observe the volunteers during the trial. However, regardless of which treatment the volunteers' receive, the level of medical care and attention is the same. All procedures eg. Blood tests, X-rays, MRIs etc, as required for the trial, will be conducted for all volunteers and they will attend all visits for the trial.

Not all trials have placebo's and in those trials where placebo's are used, in most cases there is the availabilty of 'relief' medication which is provided as a back up.

You should also be aware that you can withdraw from the trial at anytime, if you so wish. Given this is the case, many patients who may have concerns with the prospect of being placed in the placebo arm of a trial, still consider it worthwhile to participate in the trial as it provides them the opportunity to obtain the investigational treatment and regular monitoring, whilst knowing they can always withdraw at anytime, if their situation does not improve or if they do not consider the trial of benefit to them personally.

A number of clincal trials have extensions after the main trial has completed called Open Label Extensions. If a trial has this type of extension, all previous participants are offered the investigational treatment or trial drug. This applies to volunteers who may have had a placebo earlier, so this may be useful for you to know.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

Volunteers in a clinical trial participate in the development of medical therapies that may offer better treatments for life threatening and chronic diseases.

The possible benefits for Volunteers include to:

- Play an active role in your health care.
- Gain access to research treatments before they become available, if approved.
- Obtain medical care at our dedicated research centre during the trial.
- Regular monitoring at trial visits and the results of any investigations such as XRays, MRIs, blood tests, etc being forwarded to your GP.
- Helping future generations with new treatments by contributing to medical research.

However, the possible and/or potential side effects and risks must also be considered. These are always fully documented in the Patient Information Sheet. We ask you to take time to discuss these and any other questions you may have with our research team.

MEDINOVA

NEXT STEPS

Now the Research Team have assessed your suitability for the clinical trial and discussed what is involved for you, please read through the detailed patient information sheet enclosed.

You may also wish to discuss your possible participation with family and friends. If you have any further questions or queries please do not hesitate to call our dedicated research centre and speak with the Research Doctor.

Meanwhile you may have already booked a provisional appointment for a 'screening visit'. At this appointment we will again check your suitability for the trial. We will also ensure you have read and fully understood the patient information sheet and we will address any questions relating to any aspect of your participation in the trial. Only then will you be asked to sign the consent form. Please remember that even when you have signed the consent, you are always free to withdraw from the trial at any time and for any reason.

At the screening visit you will have all the examinations, blood tests, etc that are required, as detailed in the patient information leaflet. We will also request confirmation of your medical history from your GP (with your prior approval of course). Only after we have performed all these detailed checks and tests, will we be able to finally determine your eligibility and confirm that you may start the treatment phase.

At all stages of your participation in the trial, your GP will be kept informed and your normal healthcare will not be affected. During the trial you would continue to visit your doctor for any health issues not related to your participation in the trial and we will keep your doctor informed about your trial participation and condition. On completing or leaving the trial, your usual healthcare will not be affected as your doctor will care for you exactly as before the trial.

We aim to make your overall experience with MeDiNova a positive one on every level. We are able to reimburse you for your travel and parking for trial visit attendances. When required we can also arrange a taxi at no cost to you. Some trials offer inconvenience payments, these are usually documented in the patient information sheets. Please discuss with the research team to see if this applies to your trial. Refreshments are also available.

Please feel free to bring along a family member or friend if you wish. We are always happy to reschedule appointments and aim to accommodate your life and work commitments within the requirements of the clinical trial.

WHAT DO OTHER PATIENTS SAY

PATIENT TESTIMONIALS

"Having completed the COPD trial at your clinical research centre, I felt the need to write with regard to the care and service I received from your staff. Their professionalism in care is amazing and to be honest you forget you are there as a patient as they make you feel more like a visiting friend"
- Volunteer for a COPD trial

"I came for my appointment today with a little trepidation as I had no idea what was in store for me. I'm writing to express my delight with and thanks to your wonderful nurse who took me through the whole process with patience and kindness. I am grateful to your company for giving me an MOT (!) much nicer than going to a GP's surgery"
- Volunteer for an Asthma trial

"Since being on your diabetes trial my friend and family have commented on how well I look and the dramatic change in my appearance from the weight loss. Deciding to take part in this trial has made a real difference to my confidence levels"
- Volunteer for a Type 2 Diabetes trial

"Medinova staff are brilliant they are so friendly and the doctors take so much care, they make you feel very special. I wouldn't hesitate to recommend putting yourself forward for a clinical trial, what have you got to lose?"
-Volunteer for an Osteoarthritis trial

"Medinova staff are so kind and helpful. Everything is explained very clearly and nothing is too much trouble" ***- Volunteer for a Migraine trial***

VIDEOS PICTURE

Please view our patient stories at **www.medinovaresearch.com/videos** and **www.improvingtreatments.co.uk/videos**

MEDINOVA

FREQUENTLY ASKED QUESTIONS

It is perfectly normal to have questions about taking part. Our friendly research team will be happy to answer your questions and explain the informed consent process which is designed to help provide you all the information that you need to consider participating in a trial. There is no pressure to commit to anything you are not comfortable with.

Set out below are some frequently asked questions:

What is an Informed Consent?

When a person decides to participate in a Clinical Trial, they must sign an “Informed Consent” document containing information about the Clinical Trial. The physician then provides information about possible risks and benefits and what is required by the participant during the Clinical Trial. The participant then decides whether to or not to sign the Informed Consent. It is very important to emphasise, that the Informed Consent is not a contract and that the participant may withdraw from the trial at any time, without giving any reason.

How is the participant protected in a clinical trial?

The participant’s safety is paramount and beyond the public and scientific interests of the trial. All participants are under continuous care of qualified clinical teams during the trial period. The Clinical Trial follows a protocol, which includes a trial plan that describes what researchers will do in the trial. As the Clinical Trial progresses, all results are reported to scientific meetings, medical journals, and to various government agencies, like Ethical Committees, the Medicine Agency and others. The names of the participants will remain secret and will not be mentioned in any reports.

What are my responsibilities?

While you may benefit in different ways from participation, you should also be aware that participating may have an impact on your life in a number of ways. As a participant in a Clinical trial at MeDiNova you are expected to comply with the specific requirements of the trial. They include:

- Following the directions of the researchers
- Taking your medication as prescribed
- Informing the research staff of any negative experiences you have while participating in the trial, if any
- Arriving for all scheduled appointments or calling ahead if you are unable to keep an appointment
- Making sure your contact information is up to date
- Providing information about your medical history if it is relevant to the clinical trial
- Seeing your general practitioner as scheduled and for any medical conditions unrelated to the clinical trial

As a participant in a clinical trial you have the right to withdraw from the trial at any time. However it is important that you thoroughly consider if participating in a clinical trial is the right choice for you. If a large numbers of participants leave the trial prematurely it may have an impact on the outcome of data quality or even lead to cancellation of the trial. In that case, a lot of effort and time is wasted for all the other participants, who wish to conduct the trial. Your responsibility will be thoroughly explained to you by our Doctor.

What are my rights as a participant?

All volunteers who participate in clinical trials at MeDiNova are guaranteed rights that ensure they are treated professionally and respectfully. As a participant in one of our trials you have the right to:

- be treated with respect
- withdraw from the trial at any time
- make your decision without feeling any pressure from the research staff
- know the purpose of the trial
- know the risks of participation in the trial
- know what alternatives are available
- know the name, credentials and contact information of the trial’s principal investigator
- know what procedures may be performed and what medicines may be used
- know who will have access to your information
- seek additional help or clarification during the informed consent process and at any time during the trial
- ask all the questions you need

What if new information becomes available during the trial?

Sometimes, during the course of a clinical trial, new information becomes available about the treatment that is being studied. If this happens, your research trial doctor will tell you about it, and discuss with you whether you want to continue in the trial. If you decide to stop taking part in the trial, your doctor will advise on the most suitable treatment for you. If you decide to continue in the trial, you will be asked to sign a new Consent Form.

What happens at the end of a clinical trial?

About 12 - 18 months after the trial ends your doctor will then be able to tell you which of the treatments you were taking during your trial participation. You can be given a copy of the results once they are publicly available, if you want a copy. Any report that is published about the trial will not identify you or any other patient taking part.

Will my taking part in this trial be kept confidential?

Your data will be coded and collected on a paper record and it will be kept confidential. To make sure the information collected in the trial is accurate, it will need to be checked by researchers and authorised persons working on behalf of the pharmaceutical company and for government health departments. You are asked to give permission for these authorised people to see your medical records, who will keep the information confidential.

What will happen if I don't want to carry on with a trial?

You are free to withdraw from a trial at any time, without giving any reason, and without your medical care or legal rights being affected. All data up until the date of your withdrawal will be used. You retain the right to decide whether data from any post-withdrawal assessments can be used. If you withdraw from the trial, researchers, authorised persons from the medical company and the regulatory authorities will still require access to your medical notes to verify the data collected up to the date of your withdrawal.

Do I get paid?

An Ethics committee must approve all payments to patients. It is usual for all reasonable travel expenses to be paid. Some clinical trials make patient inconvenience payments to volunteers for their participation in trials and this will be summarised in the Participant Information Sheet for each trial. All trial assessments, investigations and the investigational treatment will be provided to you at no cost.

MEDINOVA

HELPING RESEARCH

JOIN THE TRIAL

The contents of this Patient Information Brochure has been reviewed and approved by the Generic Review Committee of the Health Research Authority based at 3rd floor, Barlow House, Minshull Street, Manchester M1 3DZ.

MEDINOVA

MEDINOVA

Dedicated Research Centres

North London Dedicated Research Centre

Batchworth House, Mount Vernon Hospital,
Rickmansworth Road,
Northwood HA6 2RN
01923 834230

South London Dedicated Research Centre

Block A, Level 1, Queen Mary's Hospital,
Frognal Avenue, Sidcup DA14 6LT
02033 013000

East London Dedicated Research Centre

Blackburn House,
22 - 26 Eastern Road,
Romford RM1 3PJ
02033 012990

Yorkshire Dedicated Research Centre

Pegasus House, 90 Otley Road,
Shipley BD18 3SA
02031 986471

Lakeside Dedicated Research Centre

Cottingham Road, Corby,
Northamptonshire NN17 2UR
01536 748282

MeDiNova Research Centres are located in the UK, South Africa, Spain and United States

info@medinovaresearch.com
www.medinovaresearch.com