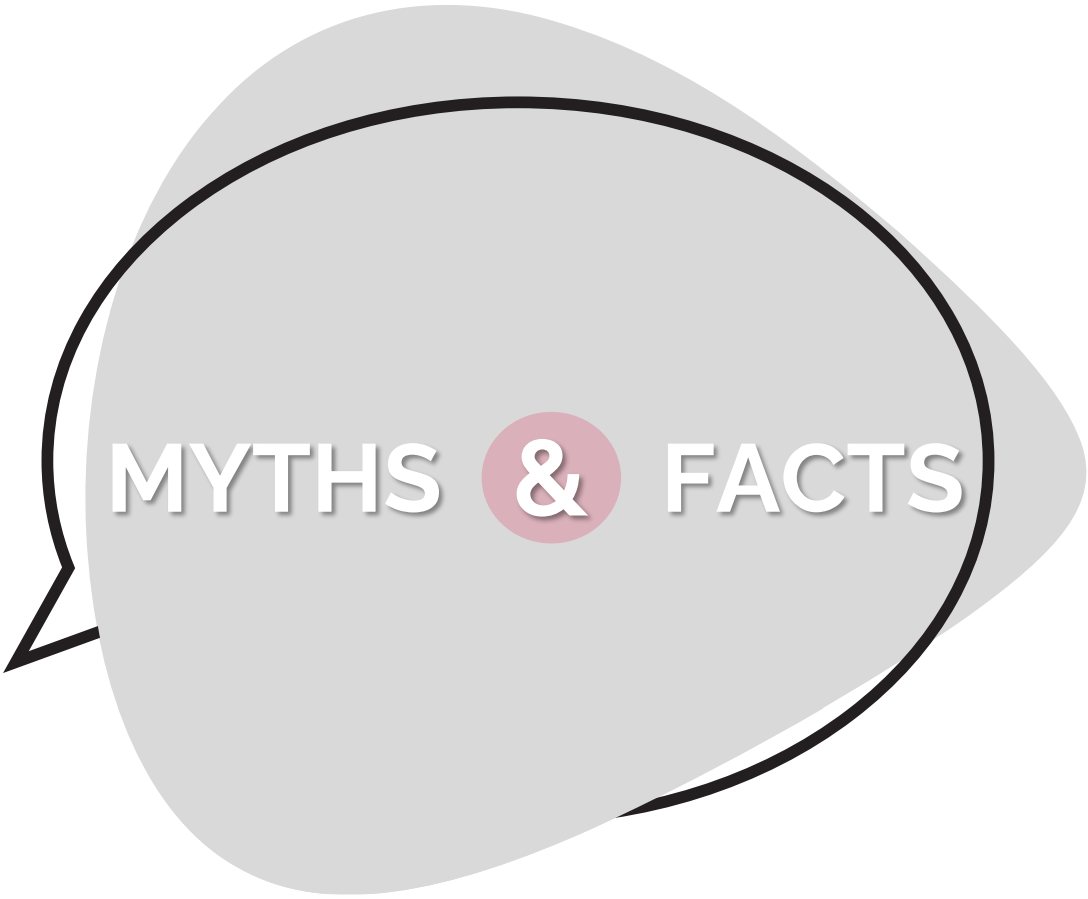
MEDICAL RESEARCH AGENCY



ABOUT CLINICAL TRIALS

Fact sheet

Patient
in Clinical Trials

MYTHS AND FACTS
about clinical trials

MYTH	FACT
Clinical trails are just a matter of profit for pharmaceutical companies.	**FACT:** Clinical trials are needed to confirm the efficacy and safety of new therapies. Pharmaceutical companies bear the cost of research, while contributing to medical advances and improving standards of treatment.
Clinical trials are risky and dangerous.	**FACT:** Each clinical trial is carefully planned and monitored to minimise the risks to all participants. Many laboratory tests and studies are carried out to test potential future therapies before a trial begins.
I can participate in any clinical trial.	**FACT:** Each clinical trial has inclusion and exclusion criteria for who can – or cannot – participate. People can take part in a clinical trial if they meet the inclusion criteria, for example, if they are of a certain age or sex or have a certain health condition. These requirements are designed to ensure that each trial is as safe as possible.

MYTHS AND FACTS
about clinical trials

MYTH	FACT
Taking part in a clinical trial is dangerous. I am not protected as a participant.	**FACT:** Every clinical trial has detailed documentation that is reviewed by multiple experts. The review is designed to ensure that a trial is as safe as possible. Each participant is protected from unnecessary risks. Experts also monitor the trial itself. If the potential risk to the participant is too great, the trial plan will not be approved. Doctors monitor patients' health throughout the trial. In addition, as part of patient protection, the **Compensation Fund** has been set up to compensate clinical trial participants and their next of kin for any harm suffered as a result of participating in a clinical trial.
Taking part in a clinical trial will be very expensive for me.	**FACT:** Participation in a clinical trial is usually free of charge. However, depending on the specific trial and the location, there may be additional costs such as travel, parking or hotel accommodation. Many trials offer to reimburse participants for these additional expenses.

MYTHS AND FACTS
about clinical trials

MYTH	FACT
If I take part in a clinical trial, I will not receive any information about it.	**FACT:** If you decide to participate in a clinical trial, you will be given full information about it, including the purpose of the trial, the potential benefits and risks, and all relevant details about the trial. You will also receive an informed consent form that details all aspects of the trial, including potential side effects and conditions of participation.
The informed consent form is a difficult document to understand. It is written in medical and legal language.	**FACT:** If you have difficulty understanding the document, you can always ask the Researcher or the research team for clarification. Ensuring that the patient fully understands and is comfortable with the decision to participate in a clinical trial is crucial to the entire research process.
All clinical trials focus on new drugs only.	**FACT:** Clinical trials also involve research into medical procedures and technologies, psychology, vaccines and rehabilitation.

MYTHS AND FACTS
about clinical trials

MYTH	FACT
After signing the informed consent form I cannot withdraw from the trial.	**FACT:** Every participant in a clinical trial has the right to withdraw from it at any time without any cosequences.
As a participant in a clinical trial, I do not have access to information about my health status.	**FACT:** At any time during a clinical trial, the patient has the right to obtain information from the doctor about their condition and to see their medical records.
Clinical trials are only for people with serious illnesses.	**FACT:** Clinical trials cover a wide range of conditions and diseases. They may focus on improving the quality of life, preventing disease or diagnosing disease earlier.
Only adults can take part in clinical trials.	**FACT:** There are also clinical trials for children. Paediatric trials are key to adjustng treatments to the specific needs of children.

MYTHS AND FACTS
about clinical trials

MYTH	FACT
If there is a clinical trial that I might be able to take part in, my doctor will tell me about it.	**FACT:** Your doctor may not know about all the clinical trials available. You can find clinical trials through patient support groups, NGOs and patient organisations. There are clinical trial search engines that list current clinical trials.
The results of clinical trials are targeted and unreliable.	**FACT:** To ensure the reliability and credibility of results, clinical trials must meet ethical, scientific and regulatory standards. The conduct of the trial and the documentation kept are systematically monitored and subject to strict control and supervision. In addition, the results of clinical trials must be subjected to statistical analysis to assess their safety and efficacy.
If I participate in a clinical trial, I will be treated like a guinea pig.	**FACT:** The safety and well-being of participants is paramount. Before a clinical trial begins, the trial protocol is carefully evaluated by the Bioethics Committee and participants are informed of any potential risks.

MYTHS AND FACTS
about clinical trials

MYTH	FACT
Taking part in a clinical trial will not help me.	**FACT:** Clinical trials evaluate new potential treatments that are not yet widely used, but may be more effective than those currently available over the counter. In this way, even if a particular person who takes part in a clinical trial does not benefit directly, they contribute to the improvement of healthcare, the development of new therapies and the enhancement of the quality of life for other patients. The fundamental purpose of clinical trials is to gain general knowledge about an investigational product, medical device or procedure.
People are always given a placebo in clinical trials.	**FACT:** Some clinical trials use a placebo control group, but this is not always the case. Most often, clinical trials are divided into two groups: the treatment group (participants who receive the investigational product) and the control group (participants who receive the available standard therapy or a placebo if the standard treatment is not available).

Summary of the **facts** about clinical trials

Participant safety:

Patient safety is paramount and clinical trial protocols are designed to keep the risks as low as possible.

Transparency of results:

The results of clinical trials are publicly available and scientific practice includes verification and reproducibility of results.

Strict ethical standards:

Trials are conducted with respect for the rights of participants and protocols are subject to rigorous ethical standards.

Diversity of participants:

Both healthy and sick people from different age and social groups are included in clinical trials.

Trial locations:

Clinical trials are not limited to large cities, they are also conducted in smaller towns and even in rural areas to obtain more representative results.

Diversity of interventions:

Clinical trials are conducted to evaluate the safety and efficacy of new therapies, procedures, medical technologies, and the use of existing drugs for various indications.

Patient
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Learn more

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