LMI | Legemiddelindustrien

NorTrials

CLINICAL TRIALS
SOMETHING TO CONSIDER?

Clinical trials are important for adopting new forms of treatment. In these trials, pharmaceuticals are tested on human subjects in a systematic and carefully controlled manner in a hospital, at a doctor's surgery, or at other healthcare institutions.

Photo for illustration only

WHAT ARE CLINICAL TRIALS?

A clinical trial is our most important tool for obtaining reliable knowledge of the safety and efficacy of a new form of preventive care, treatment method or rehabilitation. This is a study to examine how safe a pharmaceutical or treatment is, as well as their effect on humans.

This brochure mainly focuses on clinical trials of pharmaceuticals.

Clinical trials of pharmaceuticals generally involve testing the effect of a new drug on a certain disease and comparing the drug to the treatment available today. In a clinical trial, researchers will try to determine the best dosage of a drug, the effect of the drug on the disease, potential side effects of the drug, and its efficacy over time. This is conducted through various trials in defined phases (see the fact box).

In order to compare new pharmaceuticals with current standard treatment, participants in the clinical trial are divided into two or more groups, who receive either the standard treatment or the new drug, possibly in different doses. It is essential that trial participants are randomly distributed across the different groups. . Often, neither the doctor nor the patient will know which treatment the patient will be given which treatment the patient will be given, so that the results are not influenced by the doctor's or patient's expectations.

If there is no standard treatment for comparison, a placebo may sometimes be administered. This is a "dummy" drug with no effect that is identical in appearance to the trial drug, so that test subjects do not know which drug they are receiving.

CLINICAL TRIALS ARE CONDUCTED IN FOUR PHASES

Before a drug is tested on human subjects in clinical trials, research is conducted in a laboratory, both with and without living organisms.

Phase 1: What happens when a human participant is given a drug?
The drug is tested in small doses over a limited period and on few people – either patients or healthy volunteers.

Phase 2: What is both an effective and safe dose? What are the side effects?
Here the test group is expanded to include 50–100 patients, and researchers study the effect of the drug on the disease in question, the safety of the drug, and the most effective dose.

Phase 3: Is the new treatment more effective than the current treatment?
Here the drug is tested on a large group of patients to study its effect and safety even more thoroughly. A phase 3 trial usually spans several years and may include up to several thousand participants.

Phase 4: How does the approved drug work over time, and are there any other side effects?
Here, researchers will study the use of the drug, as well as its effect, safety and side effects over a longer period. They will also determine whether the effect of the treatment is in reasonable proportion to its cost for healthcare services.

This is a simplified overview. Some studies may deviate from this plan, for instance, by merging certain phases.

WHO APPROVES CLINICAL TRIALS?

Before a clinical trial can be conducted in Norway, it must be approved by the Norwegian Medicines Agency and the Regional Committees for Medical and Health Research Ethics (REK). These approvals are intended to ensure that the clinical trial complies with Norwegian law and all ethical guidelines to protect patients' rights and safety, and that the benefit of the trial outweighs the risks to the participants.

WHAT DOES PARTICIPATION IN A CLINICAL TRIAL ENTAIL?

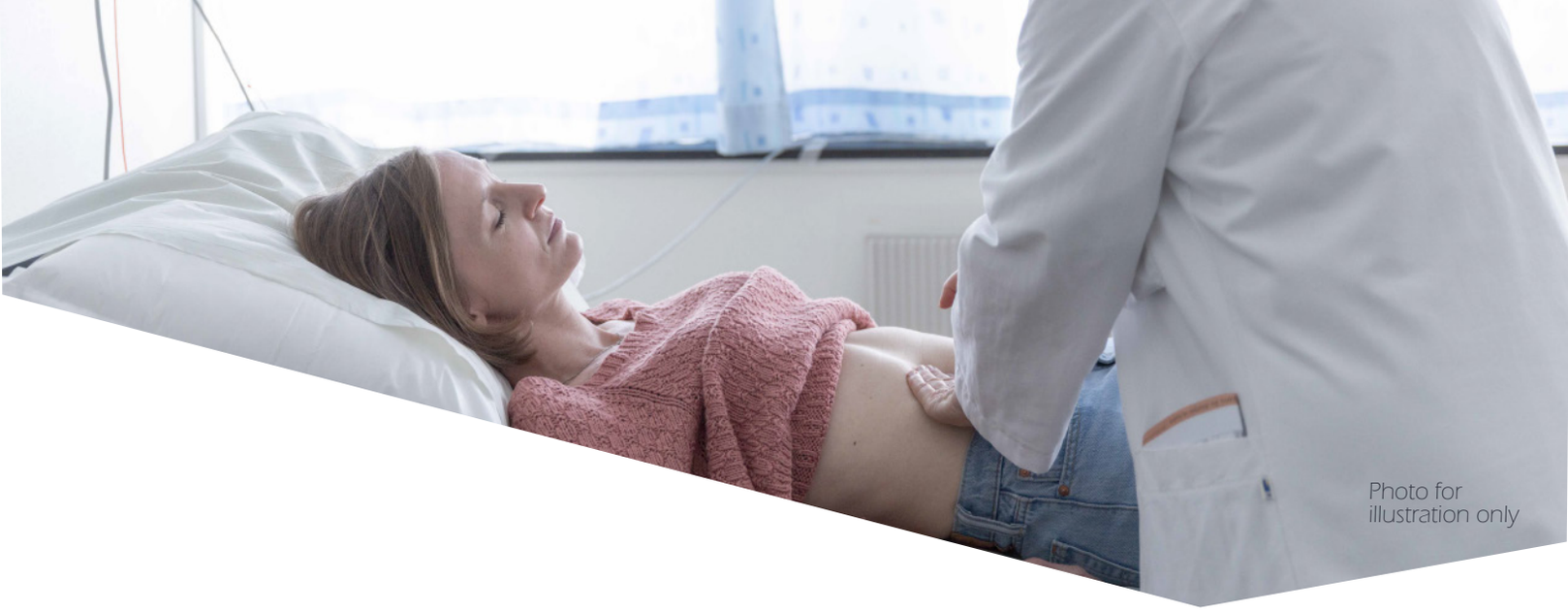
Whether or not to participate in a clinical trial is an important and personal decision. Before you decide whether to participate, you will be given all the relevant information about the trial through an initial conversation with healthcare personnel, as well as a written information letter that includes a consent form.

A doctor will be available to answer any questions you may have before signing the consent form.

Taking part in a clinical trial may have both advantages and disadvantages for you.

Advantages:

- You may be given access to new drugs before they are available on the market, and you might receive treatment that would otherwise not be offered if you had not participated in the trial.
- You will be closely monitored by healthcare personnel – in most cases, more closely than during standard treatment.
- You will be helping to acquire more knowledge of the trial drug and contribute to the development of a new treatment for the relevant patient group.



Disadvantages:

- The treatment may cause both known and unknown side effects. Rare side effects are often not detected until the drug has been tested on a large number of patients.
- Participating in a clinical trial may require a great deal of time and effort, because such trials often involve more controls, monitoring and lab tests than standard treatment.
- If you are given a new treatment where the effect has not yet been fully studied, it is important to be aware that you may not experience the expected effect

WHO PERFORMS CLINICAL TRIALS ON PHARMACEUTICALS?

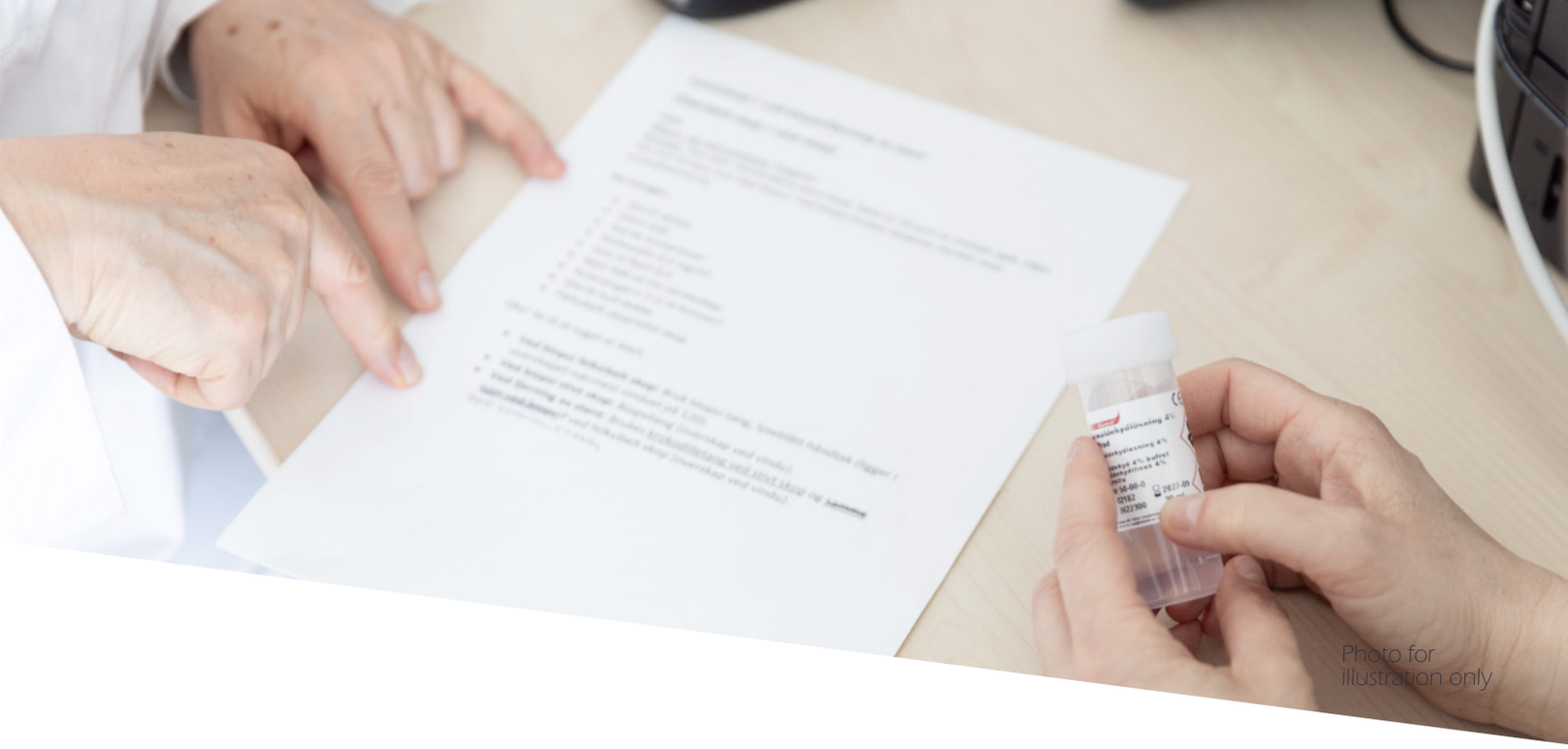
The development and testing of new pharmaceutical drugs is expensive. Clinical trials are generally financed by private companies (the pharmaceutical industry), but always in collaboration with health-care services.

The collaboration between private companies, healthcare services and trial participants is crucial when conducting clinical trials. Clinical trials are usually conducted at public hospitals or other public health institutions. Ask your doctor whether there are any relevant clinical trials for your specific condition.

All data collected from the clinical trials is used to apply for approval from pharmaceutical regulatory authorities to use the drug. In Norway, the Norwegian Medicines Agency is responsible for approving new pharmaceuticals. All personal data included in the documentation is de-identified. This means that it is not possible to recognise individual participants.

WILL I BE INFORMED OF THE RESULTS OF THE CLINICAL TRIAL I HAVE PARTICIPATED IN?

Once the clinical trial has ended, you will have the right to be informed of the results. You can ask the clinical trial staff about when and how the results of the clinical trial will be made available.



WHERE CAN I FIND MORE INFORMATION ABOUT CLINICAL TRIALS?

You can learn more at helsenorge.no/kliniske-studier and on hospital websites (search for "kliniske studier" - or "clinical trials").

GLOSSARY

Clinical trials: Research studies conducted on human subjects to examine the effect of various treatment methods that involve drugs, surgical procedures, medical equipment, exercise, diets, etc. Other terms for a clinical trial may be clinical study, drug trial, drug study, research project, clinical research, clinical testing, and experimental treatment.

Pharmaceutical: A product (drug, medicine) that can be used to prevent or treat a disease, the symptoms of a disease, or pain in humans or animals. Pharmaceuticals may include pills or tablets, powders, liquids, or aerosols. The form of each pharmaceutical will determine how it is administered to patients.

Clinical trial participant: a healthy or ill person who is participating in a clinical trial.

Standard treatment: Treatment based on national professional guidelines for the assessment, treatment and follow-up of patient groups or diagnostic groups.

Placebo: A treatment with no effect that is used as a basis for comparison in a clinical trial. A placebo can only be used if it is deemed ethically justifiable, which means that administering a placebo must not pose any risk to the patient/clinical trial participant, either in terms of safety or exacerbation of the condition. You will always be informed in advance if the clinical trial involves the use of a placebo.

Photo for illustration only

Side effects: An unintended effect of a treatment. This may include anything from mild, short-term symptoms to more serious and potentially fatal effects. All pharmaceuticals can cause side effects, but this does not mean that everyone who uses a drug will experience side effects, as this depends on the individual.

Information letter with consent form: A document that describes in detail what the clinical trial entails. This must be signed by the participant to confirm that they have received information about the trial and wish to take part. This consent is not legally binding. You may withdraw from the trial at any time without giving a reason. Participation in a clinical trial is voluntary.

This brochure has been prepared by the Norwegian Association of Pharmaceutical Manufacturers (LMI) and NorTrials in collaboration with patient organisations.