What is CLINICAL RESEARCH?

Clinical research is an essential part of the **drug development process**. It is the study of medicines, devices, products or treatment options to determine **safety and effectiveness** (efficacy) for **potential human use**.

Clinical research may be used for **prevention**, **treatment**, **diagnosis** or for **relieving symptoms** of a disease.

KEY FACTS

More than **260,000 STUDIES**[1] have been collected around the world since 2008[2]

Testing a new medicine can take **6 TO 12 YEARS**

More than **100** UCB-SPONSORED **CLINICAL STUDIES** in different disease areas

FOR EXAMPLE

- EPILEPSY
- PSORIASIS
- RHEUMATOID ARTHRITIS
- ANKYLOSING SPONDYLITIS

...

4 PHASES OF Clinical Research STUDIES

1 — TYPICALLY

HEALTHY VOLUNTEERS
50-100

- Assess drug safety
- Determine the side effects
- Evaluate how the drug should be taken

2 — TYPICALLY

PATIENTS
100-300
WITH THE CONDITION FOR WHICH THE **MEDICINE, DEVICE, PRODUCT OR TREATMENT** HAS BEEN DEVELOPED

- Assess short-term safety and effectiveness
- Find the dose at which the drug works best with the least side effects
- Small-scale placebo comparison

3 — TYPICALLY

PATIENTS
+100 - +1000

- Confirm safety and effectiveness
- Compare the new drug to other compounds (e.g. a placebo or other therapies)

4 — TYPICALLY

Many thousands OF PATIENTS

- Conducted after the drug is approved
- Study the effectiveness of the drug in a wide variety of patients
- Monitor safety in a large group to enable the development of new uses for the compound

All medicines must pass **safety and efficacy tests** if they are to be approved by regulators.

If a potential new medicine shows **positive results** when tested in animals and in human cells then it **may be studied in clinical research volunteers.**

Can I take part in clinical studies?

Thousands of patients and healthy volunteers participate in clinical research studies. Every study has its own **guidelines** explaining the **'inclusion criteria'** and **'exclusion criteria' for participation**.

+ BENEFITS OF PARTICIPATING IN A CLINICAL RESEARCH STUDY

+ Assessment by highly-qualified medical professionals
+ Possibility of accessing a new drug that is not yet available
+ Increases knowledge of diseases and supports drug development

– POTENTIAL DISADVANTAGES OF PARTICIPATING IN A CLINICAL STUDY

– Treatment is not always effective
– Some patients may experience side effects
– Some patients may be given a placebo instead of the active new drug
– Patients may find treatments, hospital stays and frequent trips to the study site to be demanding

REFERENCES: [1] https://www.clinicaltrials.gov/ct2/about-site/for-media#ClinicalTrialsStatistics [2] https://www.clinicaltrials.gov/ct2/resources/trends

FIND INFORMATION ON CLINICAL STUDIES

Find details about UCB's **Clinical Studies**

OR

Search independent registries: **clinicaltrials.gov** AND **EudraCT**

Inspired by **patients.**
Driven by **science.**