# Development and evaluation of new drugs

## Drug development

Before the actual clinical development, there must be pharmacological and toxicological tests, the aim of which is to predict the therapeutic effect and toxicity for humans. Animal tests are most commonly used. We divide development into preclinical and clinical phases. We divide development into preclinical and clinical phases.

## Preclinical phase

The aim is to determine the pharmacokinetic and pharmacological profile:

- mechanism of action;
- response to dose and substance concentration;
- potential methods of application, dosage forms;
- systemic pharmacology including effect on key organs and physiological response;
- pharmacokinetics - absorption, distribution, metabolism, excretion.

## Clinical development

Clinical development has 4 development phases:

1. **1. administration of the drug to a healthy person** – Volunteers are selected to whom the drug is administered. Bioavailability is assessed (whether the drug gets to where it should). NCE (new chemical entity) is the designation for the 1st administration of a substance to a person, it must be approved.
2. **Indicative monitoring of pharmacodynamics** – whether the drug really works as it should (as an analgesic, anti-rheumatic... e.g. Viagra was originally developed as a drug against AP).
3. **Comparative study** – some patients are given a tested drug and some a placebo or an already tested drug. The condition is randomization (random selection of patients into groups).
4. **Post-registration monitoring** – verification of drug effects in broad clinical practice.

## Types of studies

1. **Human pharmacology** – metabolic studies and evaluation of pharmacological kinetics.
2. **Exploratory study** – "Will what we wanted show up?"..
3. **Confirmatory study** – comparison with placebo: "Is it more effective than placebo?".

Each type of study is typical of one of the I-IV phases.

## Testing conditions

To cooperate in drug testing, a company must have:

- ethics committee approval;
- consent of SÚKL (https://www.sukl.cz/) (State Institute for Drug Control);
- written consent of the patient;
- the research must have insurance (persons who are ill, those entering the research, medical insurance).

The use of a placebo is ethically questionable when a therapeutic procedure is already known to relieve the patient in life-threatening situations.

## Links

### External links

- Jak hodnotit výhodnost léku pro pacienta? (http://kardioblogie.blogspot.com/2012/09/tipy-triky-number-needed-to-treat-nnt.html)

### References


- LINCOVÁ, Dagmar. *Základní a aplikovaná farmakologie.* 1. edition. GALÉN, 2002. 601 pp. ISBN 80-7262-168-8.