



# DRUG DISCOVERY AND DEVELOPMENT



**The process takes 12-25 years**

The development of a single original drug can take more than two decades



**Cost: \$400 million to \$1 billion**

The cost of developing a new drug is enormous



**Only one in 50,000 substances becomes a drug**

Only one in thousands of synthesized compounds successfully passes all stages

## The main stages of creation



### 1. Development and justification of scientific thought

The purpose and direction of the research are defined



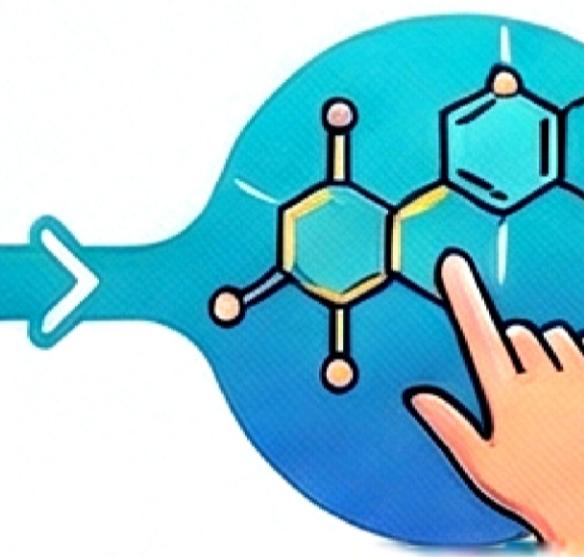
### 2. Active ingredient extraction

A potential drug substance is synthesized or isolated from natural sources



### 3. Testing on biological models

The biological activity of the substance is initially assessed



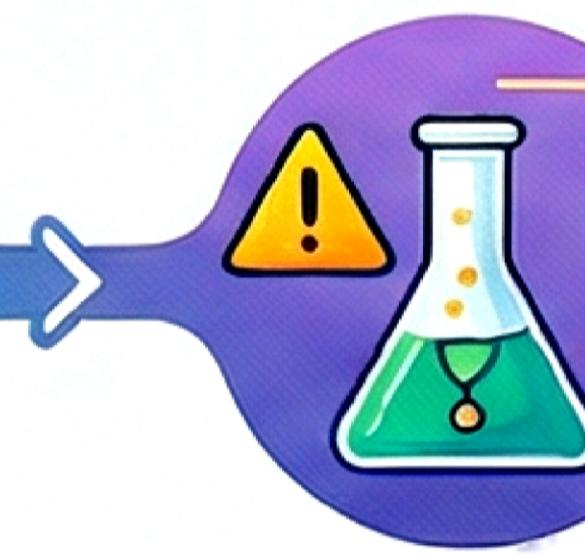
### 4. Lead selection

The most promising compound is selected through pharmacokinetic studies



### 5. Development of quality analysis methods

Criteria for checking the quality of pharmaceuticals are established



### 6. Toxicological studies

The safety of the substance is studied and the composition of the drug is developed



### 7. Development of production technology

The process of industrial production of the drug is being created



### 8. Preclinical (non-clinical) studies

The effects and toxicity of a drug are studied in laboratory animals



### 9. Clinical trials (Phases I, II, III)

The efficacy and safety of a drug are evaluated in humans (volunteers: healthy and sick)



### 10. Preparation of registration documents

A registration application is prepared based on all research data



### 11. Drug Registration

A drug receives permission from a regulatory authority to be sold on the market and used by the public.



### 12. Manufacturing and Marketing

The drug becomes available to doctors and patients



### 13. Post-registration monitoring (Phase IV)

Continued monitoring of the safety and efficacy of the drug also under the conditions of use

The creation of a new drug is a multi-stage process that includes scientific research, laboratory and clinical studies, the development of quality standards, and state registration. It requires years of work and significant financial investments.