How to invent and test a drug

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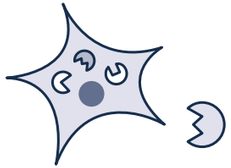
Focus on the disease
It all begins with a decision to develop a new drug for patients suffering from difficult-to-treat illnesses.



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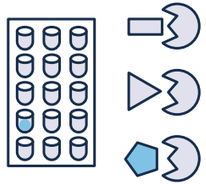
Look for a point of attack
Pharmaceutical researchers identify a suitable point of attack (target) in the pathological process. This is usually a molecule produced naturally in the body to which the active ingredient can attach itself in order to heal, alleviate or delay the progression of the illness.



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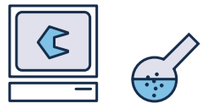
Search for starting substances
Reference points are collected to ascertain what an active substance could look like. One possibility: screening. This means combining up to two million substances – one after the other – with the target molecules. Substances that bind to the target, and thus may have an effect, are called 'hits'.



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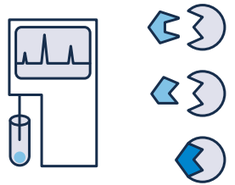
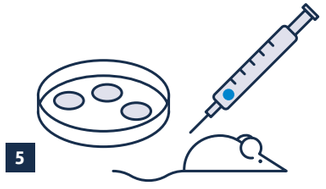
From optimization to drug candidate
Initially, based on hit-substances, the appearance of a substance that binds well to the target can be determined. Such substances are then synthesized and tested extensively. The criteria are, among other things, solubility, target binding, and the tendency to not break down too quickly in the body.



In subsequent rounds, variations of the substances are produced using experience and computer simulations; these are also tested. This continues until a number of substances achieve test results good enough to be considered useful as active ingredients.



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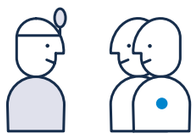
Tests for effects and tolerability
Promising substances are reviewed to determine whether they are truly safe and effective. This includes mandatory tests for toxicity and other adverse effects in cell cultures and animals. Only once a substance is proven safe and effective, may it be used as the active ingredient in a drug.



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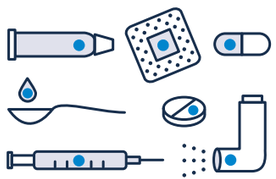
Studies with a few healthy people: Phase I
The next step is to test the active ingredient on healthy volunteers: How does it travel through the body? At what dosage strength do side effects occur?



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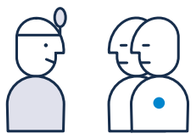
Development of the pharmaceutical form
A drug, tailored to the field of application, is developed from the active ingredient: e.g. a tablet, capsule, ointment, oral or injection solution, a spray, or drug patches.



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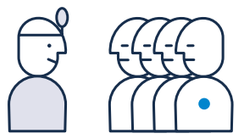
Studies with a few ill patients: Phase II
Typically, 100 to 500 patients, all volunteers, receive either the new drug or a comparable treatment. Doctors examine the efficacy, tolerability, and dosing.



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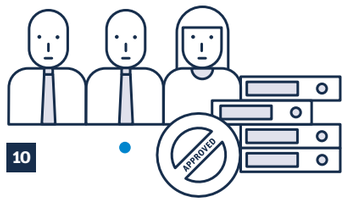
Studies with many ill patients: Phase III
Doctors in numerous countries test the drug, usually with thousands of adult patients – similar to phase II. Less common side effects can also be determined during this phase.



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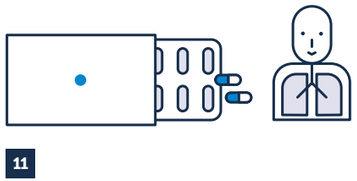
Review by regulatory authorities
Experts at regulatory authorities examine the results of all laboratory and animal tests and studies, including the technical quality (e.g. purity) of the drug. If the result of this review is positive, the drug is approved.



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Application, monitoring, new studies
The drug can now be prescribed to patients. Doctors, manufacturers, and authorities monitor for any possible, rare side effects. The package insert is constantly updated. If the drug could help with other diseases, new clinical trials are begun.

Source: vfa