

Discovering new medicines? : Human bodies are good at fighting disease, but sometimes things go wrong and then we need medicines. It takes about 15 years to make a new medicine. This is how it's done / Biomedical Research Education Trust, Understanding Animal Research.

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DISCOVERING NEW MEDICINES

Human bodies are good at fighting disease, but sometimes things go wrong and then we need medicines. It takes about 15 years to make a new medicine. This is how it's done.

Basic research

Basic research is sometimes called 'pure' research. Scientists study how bodies and diseases work and search for 'targets' for new treatments.

Some basic research involves animals.



The target

Medicines need 'targets' to act on. A target is something that causes disease, often a protein molecule. It is called a 'target' because we can aim new medicines at it.

If a protein molecule is causing a disease, scientists can look for another molecule that will attach itself and neutralise it. This is sometimes called the 'lock and key' approach.



Finding treatments

When you have a target, you can look for an 'agent' that will act on it.



Many agents have been found in nature, such as digitalin which comes from the common foxglove. But these days we can also make new compounds in the lab or with computer models, and screen them to see if they attach to the target.

Modern technology makes it possible to screen hundreds of thousands of compounds to find a few hundred that work on the target. The ones that work are called 'drug leads'.



Pre-clinical testing

Screening tells us a lot but chemicals often work differently in living bodies. The most promising new treatments are tested in tissue samples and in some animals to see if they really work. Will they get changed by the digestive system? What are the side effects?



All mammals are more or less the same on the inside. This means that testing on animals can give us a lot of information about how chemicals will work in humans. We can't get this information any other way because nothing else is so complex and unpredictable as a living body.

PROT Every procedure using an animal in the UK requires three licences from the government.

Safety testing

PROT It is illegal in the UK to use certain types of animals in medical research, except for human safety, of course.



Only a few compounds make it past the pre-clinical tests. But before we can give them to people, we still need to know how much is safe to take. Nearly everything is poisonous if you take too much. The law requires that compounds are tested for safety on two species of animal.

PROT Signs out of the animals used in medical research are rules and rules.



Clinical trials phase 1

After a compound has passed safety testing in animals we can begin to test it on people. In the first phase of clinical trials a very small amount of the new treatment is given to a few healthy people to make sure there are no ill effects.



Most phase 1 trials only use men because men can't get pregnant.



Clinical trials phase 2

In phase 2 the treatment is given to a larger group of volunteers who suffer from the target illness.

Clinical trials can be stopped at any stage if there are bad side effects or other problems. Sometimes more animal or tissue tests will have to be done before they can restart. Many Phase 2 trials don't make it to Phase 3.



PROT Each new medicine is tested on 10 times as many people as animals.

Clinical trials phase 3



The third phase of clinical trials uses thousands of patient volunteers in double blind randomised tests.

The volunteers don't know if they are getting the active treatment or a placebo (a placebo looks like a real pill but it doesn't have an active ingredient). The people handing out the pills don't know who is getting the placebos either, that is what 'double blind' means.



The 'placebo effect' is what we call it when people feel or even get better just because they think they have taken a medicine. It can be very strong and very strange. A blue placebo works better than a white one, for example, and a placebo injection is much more effective than a placebo pill.

Approval

If a treatment is more effective than the placebo in the clinical trials it is possible to apply for a licence from the government. A licence means that doctors can give the new medicine to patients.



PROT On average, it costs more than £1 billion to create a new medicine.

Prescription and monitoring



When doctors start prescribing the medicine it is still monitored for side effects and effectiveness. This is sometimes called the 'phase 4 clinical trial'.

You can find out more about how animals are used in discovering new medicines here . . . www.understandinganimalresearch.org.uk

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