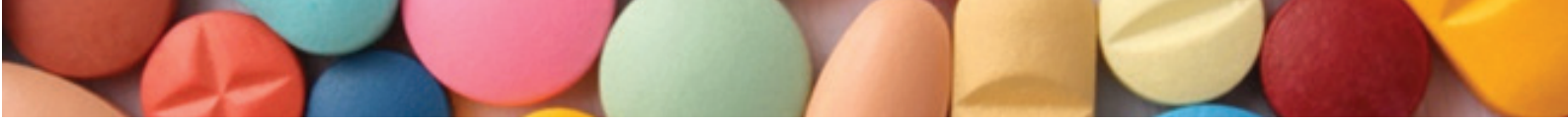

STAGES IN DRUG DEVELOPMENT

Before new drugs or vaccines can be approved for use in humans, they are first tested for:

SAFETY
Is the drug toxic or does it have harmful side effects?

EFFICACY
How well does the drug treat a disease or help with symptoms?

CORRECT DOSE
The amount which is high enough to be effective but low enough to be safe.

DISCOVERY

Drugs can be extracted from plants:
- Willow bark contains a chemical which is similar to aspirin.
- Foxgloves contain a chemical similar to the heart drug digitalis.

Today, scientists extract the active ingredient from plants and make them in a laboratory.

PRECLINICAL TRIALS

Drugs are tested on human stem cells and computer models. Data from these tests reveals whether the drug is effective and whether there are harmful side effects.

Drugs are also tested on animals. A known amount of the substance is given to animals in controlled laboratory conditions who are monitored for side effects.

CLINICAL TRIALS

Drugs are first given to healthy volunteers to see if they are safe in humans.

Drug are then given to patients with the illness to see if they are effective. Small doses are used at first, then larger doses to find the right dose.

Half the participants are given the real drug and half are given a placebo, the trial is double-blind which helps reduce bias.

APPROVAL

The results will be reviewed and approved by an independent group who issue licences for new drugs.

The drug will then be available for doctors to prescribe.

CAN WE IMPROVE PRECLINICAL TRIALS?

Millions of animals are still experimented on every year for drug development. Drugs are given to a group of animals in a laboratory, giving us data on the effects of drugs in a whole, living organism. It is believed that this reduces the risk of potential new drugs causing serious side effects in patients. Animals have been used in this way for years and many scientists and regulators understand and trust the data from these experiments.

While animal experiments give us data about a whole living organism, the results do not always translate well to humans. The genetic and cellular differences between species mean that drugs can affect humans and other animals in different ways. In fact, around 90% of drugs which appear promising in animal trials fail when they are tested on humans. Some drugs used by humans are also toxic in other animals, for example, aspirin is fatal to cats.

As our knowledge and technology advances, so too do our scientific models and methods. Many scientists believe that investing our time and money on humane research methods would lead to more reliable and safer medicine.

Humane research	Research methods which use human data instead of animals.
Animal experiment	A procedure likely to cause pain and distress to animals such as mice, rabbits or dogs.
Placebo	An inactive substance made to look like the drug, used as a control.
Double-blind trial	Neither the participants nor the researchers know who has taken the real drug and who has taken the placebo.

More Information
www.animalaid.org.uk