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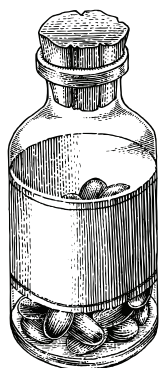
MEDICINES ARE MADE

FOUNDATION FOR BIOMEDICAL RESEARCH



HISTORY OF MEDICINE

Biomedical knowledge and treatments have evolved and become increasingly sophisticated over time. One constant, however, is the necessity of animals in biomedicine. Take a look at the major milestones of biomedicine below.



1862 President Lincoln appoints a chemist, Charles M. Wetherill, to serve in the new Department of Agriculture. This was the beginning of the Bureau of Chemistry, the predecessor of the Food and Drug Administration.

1813 Lawmakers passed the first federal biologics law, which ensured a reliable smallpox vaccine for citizens.



1906 Food and Drug Administration (FDA) was formed in 1906 to protect and promote public health through the control and supervision of food and drugs.



1938 Food, Drug and Cosmetic Act passed to ensure drugs are safe and **efficacious**.

ef-fi-ca-cious (adjective)
(of something inanimate or abstract)
successful in producing a desired or
intended result; effective



1951

Durham-Humphrey Amendment defines the kinds of drugs that cannot be safely used without medical supervision and restricts their sale to prescription by a licensed practitioner.

1963

Harris-Kefauver Amendment to the Food, Drug and Cosmetic Act Increases the Food and Drug Administration's regulatory authority.



1966

Animal Welfare Act regulates animal research and testing in the U.S.

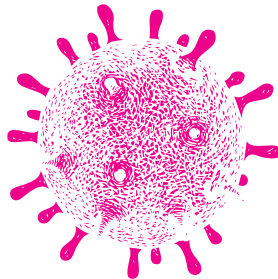


1968

U.K. Medicines Act for drug safety and efficacy testing passed.

1985

ANIMAL WELFARE ACT AMENDMENT ESTABLISHED THE ANIMAL WELFARE INFORMATION CENTER.



TODAY

20,000

The number of prescriptions currently available in the U.S. to fight disease and illness.

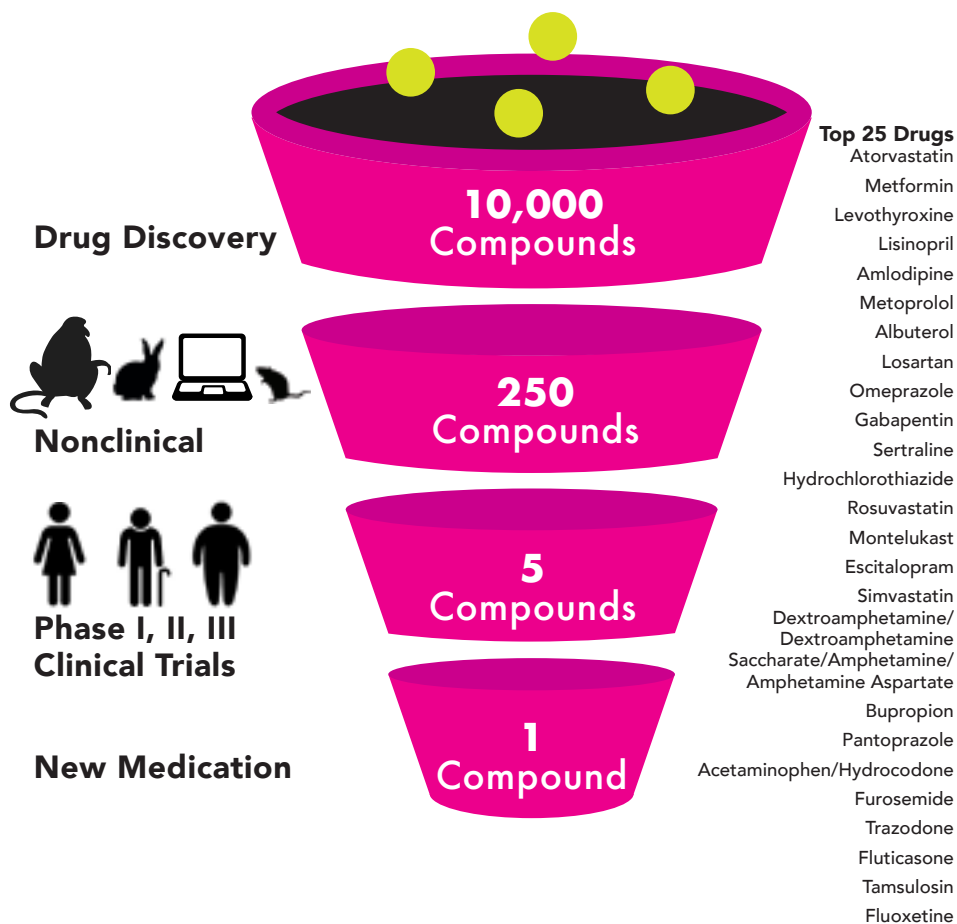
QUESTION

WHAT PERCENTAGE OF OUR DNA DO WE SHARE WITH MICE?

ANSWER: 85%

DRUG DISCOVERY AND CLINICAL DEVELOPMENT

The top of the funnel represents how many ideas there are at the start and how it's then narrowed down at each phase. Only the most successful discoveries get to move on to the point of a single new medication making it to the market. Discovery includes in silico (via computer), in vitro (in a test tube), and early animal work. The nonclinical ("pre-human") phase is where the testing gets more focused and it is determined if the medication should go into a human or not.



ANIMAL RESEARCH REGULATIONS

DID YOU KNOW?

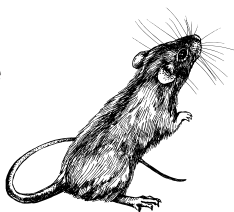
Animal research
and testing are
highly regulated.

The 1966 Animal Welfare Act and its 1985 amendment set standards for the humane care and treatment of animals in research. As a result of the 1985 amendment, registered research institutions have an Institutional Animal Care and Use Committee (IACUC). This committee must review and approve proposed animal studies to ensure they comply with these standards. This includes verifying that the proposed research does not unnecessarily duplicate previous studies and appropriate alternative methods have been considered.

IACUCs also must review and approve the rationale for involving animals and the justification for the number and species of animals.

Enrichment of laboratory animals is an important part of their daily care in the lab. Highly specialized veterinarians and their staff use pain assessment methods for animals, such as the grimace scale, and sophisticated analgesia and anesthesia techniques. Scientists follow the 3Rs of animal research:

reduction, refinement and replacement.



95%

**of animals
in research
are mice, rats
and zebrafish**



Registered animal research facilities in the U.S. undergo unannounced inspections by the U.S. Department of Agriculture (USDA) at least annually and must submit an annual report on the number of animals studied each year. Research institutions receiving federal government funding must comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, which is administered by the National Institutes of Health's Office of Laboratory Animal Welfare (NIH OLAW).

In addition, many institutions go above and beyond USDA and NIH OLAW requirements and seek voluntary accreditation with AAALAC International.

As you learned on the previous pages, human clinical trials must take place after a drug or vaccine has made it through the nonclinical animal research process to obtain additional measures of safety and efficacy. Human clinical trials are also strictly regulated by the Office for Human Research Protections at the U.S. Department of Health and Human Services.

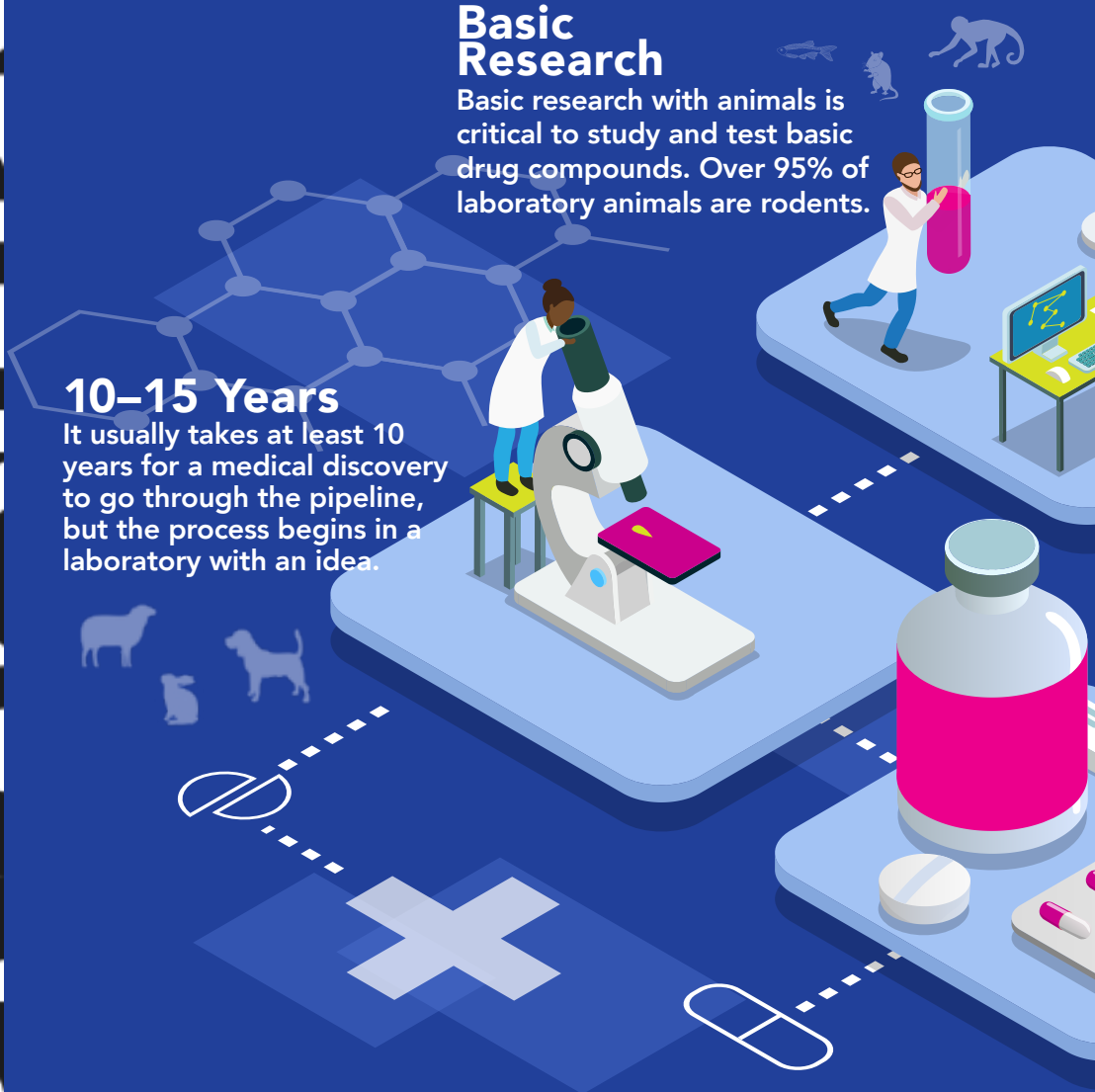
THE DISCOVERY PROCESS

Basic Research

Basic research with animals is critical to study and test basic drug compounds. Over 95% of laboratory animals are rodents.

10–15 Years

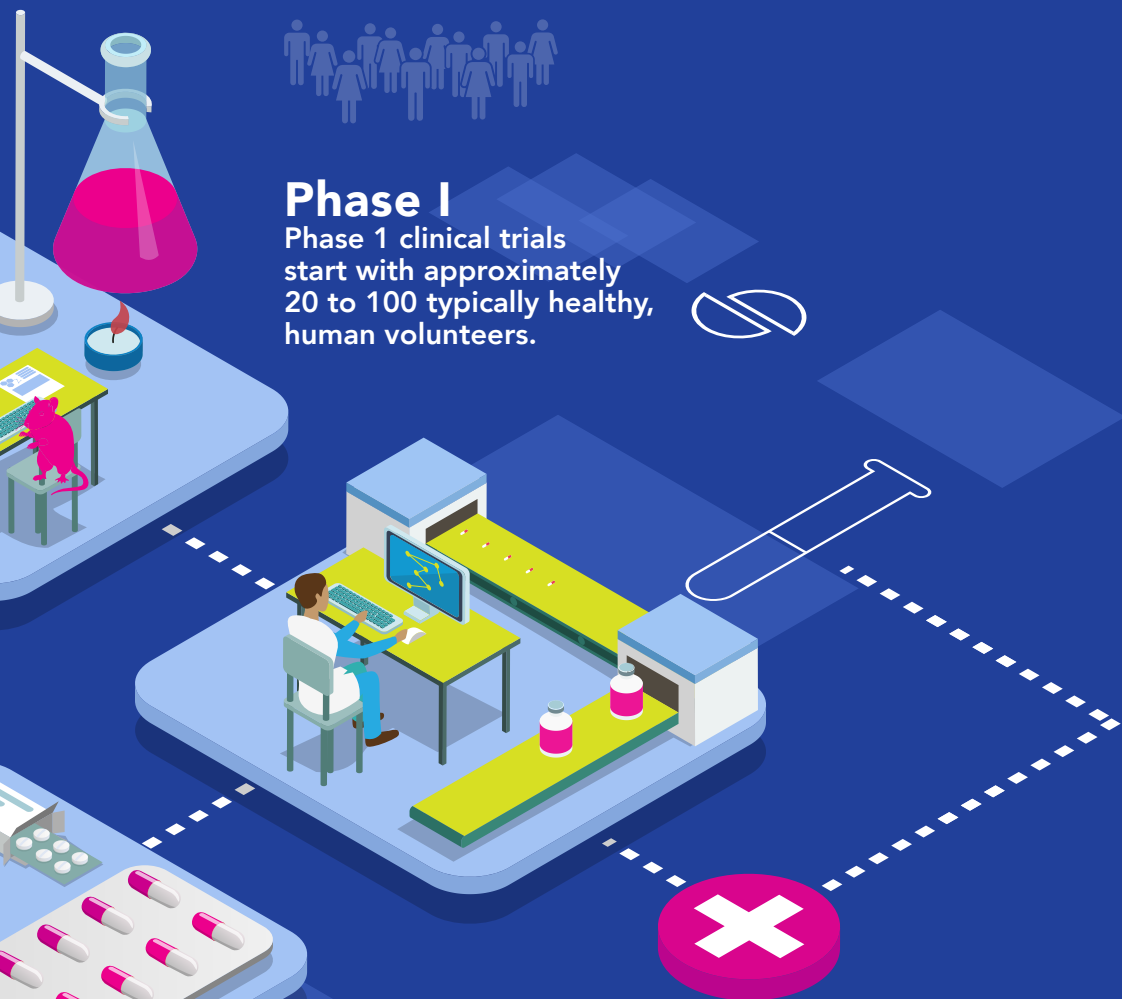
It usually takes at least 10 years for a medical discovery to go through the pipeline, but the process begins in a laboratory with an idea.





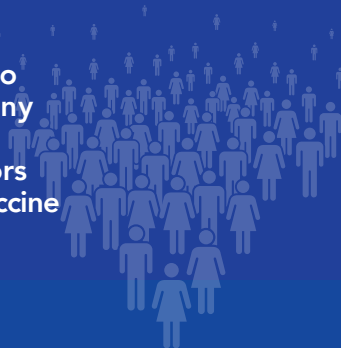
Phase I

Phase 1 clinical trials start with approximately 20 to 100 typically healthy, human volunteers.



Phase II

Clinical trials can last up to a couple years with as many as 3,000 volunteers with the disease, allowing doctors to monitor if the drug or vaccine works as intended.



THERAPEUTIC DEVELOPMENT ACCOMPLISHMENTS

Unlocking Secrets:

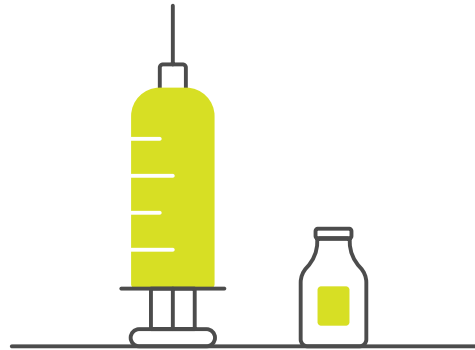
Animals in Medicine Adventure!

Hey there, future scientists! Ready for a wild journey into the incredible world of animals and their superhero role in medicine? Buckle up, because it's about to get fascinating!

Meet the MVPs: Mice and Nonhuman Primates

Did you know COVID-19 vaccines owe a huge shout out to mice and nonhuman primates? Drs. Katalin Karikó and Drew Weissman even won a 2023 Nobel Prize for paving the way for mRNA vaccines! Animals are the unsung heroes behind the speedy mRNA vaccine rollout that relied on decades of animal research.

The future is bright for mRNA technology, with groundbreaking cancer therapies and other vaccines on the horizon too. Melanoma, the tricky skin cancer, might soon meet its match with an experimental mRNA vaccine. Recent trials show a combo of vaccine and immunotherapy bringing positive outlook to high-risk melanoma patients! Other trials are looking at mRNA vaccines for pancreatic and colorectal cancer, among many other possible disease applications.



QUESTION

WHICH NONHUMAN PRIMATE SPECIES IS USED MOST FREQUENTLY TO DETERMINE THE SAFETY AND EFFICACY OF DRUGS IN THE U.S.?

ANSWER: LONG-TAILED MACAQUES, ALSO KNOWN AS CRAB-EATING MACAQUES

BIOLOGICS

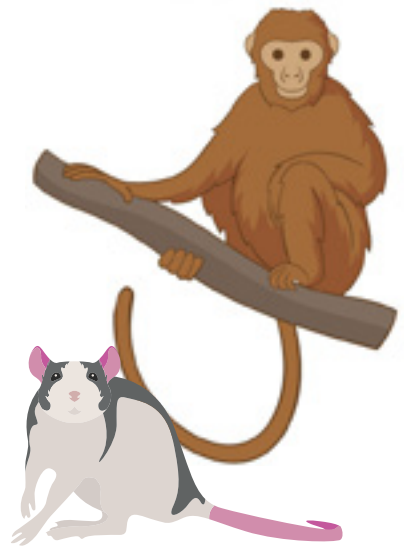
What's the secret behind these life-changing medicines? Research with animals! It is at the core of the science behind these breakthroughs.

Long-tailed macaque monkeys are the real MVPs, helping test new immunotherapies for cancers (and other diseases!). Genetically modified monkeys are unlocking the power of CRISPR for leukemia, breast cancer, lymphoma and more. Without long-tailed macaques 57% of oncology drugs and biologics may never make it to market.

bi•o•log•ic (plural noun)

A biologic drug (biologics) is a product that is produced from living organisms or contain components of living organisms. A biologic can be made from proteins, sugars, DNA, cells or living tissue.

Ever heard of rheumatoid arthritis, diabetes or multiple sclerosis? Well, say hello to the promising field of biologics. Researchers have tested live organism-produced drugs for these conditions and more with monkeys, mice, rats, hamsters, rabbits, chimpanzees and dogs. Offering hope for the toughest conditions, biologic medications are like a squad of superheroes for your health.



Scan the QR code for more about the animals behind these life-changing drugs.

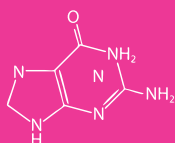
DISCOVERY QUESTIONS



1

What is the first phase for developing a new medication?

D _ _ _ O _ _ _ _



2

What animal is most often used in laboratory research?

_ _ _ E _ T



3

In Phase I clinical trials the volunteers are:

- a. healthy
- b. sick



4

What part of the brain do nonhuman primates share with humans and no other mammal?

5

How many prescriptions for medicine would you guess are filled each year?

- a. 896 thousand
- b. 2.2 million
- c. 6.4 billion



THE RESULTS OF BIOMEDICAL RESEARCH

The Importance of Animal Research

- Treat disease and disorders
- Improve quality of life
- Extend lives
- Create safe medicines, medical devices, surgical procedures and therapies

9 IN 10

top prescription
drugs involved
research with
canine models



**23 of the top 25
prescription drugs
involved some
research with
nonhuman primates**

Some top human prescription drugs also get prescribed to pet dogs and cats, including lisinopril for blood pressure, prednisone for allergies and alprazolam for anxiety disorders.

Research with animals is one of the keys to unlocking medical mysteries.

Basic research with animal models is helping carve a way toward better treatments and a better future for patients living with depression, Parkinson's and illnesses of all kinds.

CANCER

Canine and feline cancer research sheds light on treating human cancers.



READY FOR MORE:

Scan the QR code to view FBR's
"How Medicines are Made" video



Visit our webpage at:
<https://fbresearch.org/makingmedicine>

ANSWERS: 1) Discovery 2) Rodent
3) healthy 4) the pre frontal cortex
5) 6.4 billion

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animals, for the
common good**



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