HOW DRUGS ARE STUDIED

Words

Look for the following words as you read the passage. Match each word with its correct definition.

Words	Definitions
1. absorb	A. v., to improve
2. alleviate	B. n., a small part
3. ascertain	C. v., to produce
4. chronic	D. v., to lessen, ease
5. combat	E. v., to take in
6. culture	F. n., result
7. deem	G. adj., poisonous
8. desirable	H. v., to believe; judge
9. enhance	I. v., to watch; observe
10. fraction	J. v., to focus on
11. interval	K. v., to happen or occur again
12. investigation	L. adj., long-lasting
13. manufacture	M. n., a study
14. monitor	N. adj., abstract; based on theory
15. outcome	O. v., to determine; find out
16. recur	P. n., the growing of organic materials in a laboratory setting
17. substance	Q. n., the period between two times or events
18. target	R. n., material
19. theoretical	S. v., to fight against
20. toxic	T. adj., wanted; worth having

Reading

How Drugs Are Studied

A

It takes years, and sometimes decades, for a drug to move from the theoretical stage to the pharmacy shelf. Of the thousands of drugs under investigation at any one time, only a small fraction will produce the desired result without unacceptable side effects.

B

First, scientists target a step in the disease process where they believe a drug can have an effect. Then they manufacture compounds or take them from organisms such as viruses and fungi and test them in laboratory cultures. Once scientists isolate a chemical that produces a desirable effect, they analyze[1] its structure and alter it as necessary to enhance the outcome.

C

The next step involves testing the drug in animals. Scientists look at how much drug is absorbed into the bloodstream, how it distributes to different organs, how quickly it is excreted or leaves the body, and whether it has any toxic effects or by-products. Researchers usually test at least two animal species because the same drug may affect species differently.

D

If a chemical passes laboratory and animal testing and is deemed appropriate to analyze in human volunteers, it is ready for clinical trials. Researchers follow a protocol that describes who may participate in the study, tests and procedures to follow, the length of the study, and outcomes to be measured. Drug trials may focus on treating a disease, preventing a disease from occurring or recurring, or enhancing the quality of life for people living with incurable, chronic conditions.

E

There are four phases of clinical trials; the first three phases study whether the drug is effective and can be safely administered to patients, and the fourth phase evaluates long-term safety and use once a drug is on the market.

F

Phase I clinical trials test a drug in small groups of healthy volunteers (fewer than 100) to ascertain its safety and the appropriate dose range. These studies last for six months to one year.

[1]BrE: analyse

G

Phase II clinical trials test several hundred volunteers to determine how effectively the drug combats the disease being studied. These trials continue to evaluate safety, side effects, and optimal dose. Phase II studies also last for six months to one year.

H

Phase III trials test thousands of volunteers for several years, with researchers closely monitoring study participants at regular intervals. These studies typically compare the drug under investigation with a control: either a drug known to cure or alleviate a specific disease or, if one does not exist, a substance that has no medicinal effects, known as a placebo. Phase III trials are typically blind studies (participants do not know which drug they are receiving) or double-blind studies (neither participants nor researchers know which drug an individual is receiving until the trial is completed).

I

Once a drug passes the first three phases and is found to be safe and effective, drug companies may apply for the right to market the product. After a drug is approved and on the market, Phase IV trials may investigate longer-term effects, effects in different groups of patients such as the elderly, or use of the medication for a different condition such as using a cancer drug to treat AIDS.

Answer the questions about **How Drugs Are Studied**.

Questions 1–4

The reading passage contains nine paragraphs, ***A–I***.
Which paragraph discusses the following information?
Write the correct letter, ***A–I***.

_____ 1. Drug tests that involve growing biological material in a laboratory

_____ 2. Investigations of the effects of drugs on animals

_____ 3. Studies to determine how safe a drug is and how much a patient should take

_____ 4. Studies to monitor how well a drug fights a disease

Questions 5–7

*Choose the correct letter, **A**, **B**, **C**, or **D**.*

5. Drug tests on animals look at
   - **A** how the drug is absorbed by the body.
   - **B** how effective the drug is for chronic conditions.
   - **C** how well the drug prevents a disease from recurring.
   - **D** how quickly the drug alleviates the disease.

6. During Phase II clinical trials, study participants are monitored for
   - **A** chronic conditions.
   - **B** toxic doses.
   - **C** speed of cure.
   - **D** possible side effects.

7. After a drug is deemed safe and effective, a drug company may do further tests to ascertain
   - **A** the best way to market it.
   - **B** possible effects over time.
   - **C** how it compares with other drugs.
   - **D** the best group of people to use it.

My Words

Write the words that are new to you. Look them up in the dictionary and write their definitions.

Words	Definitions