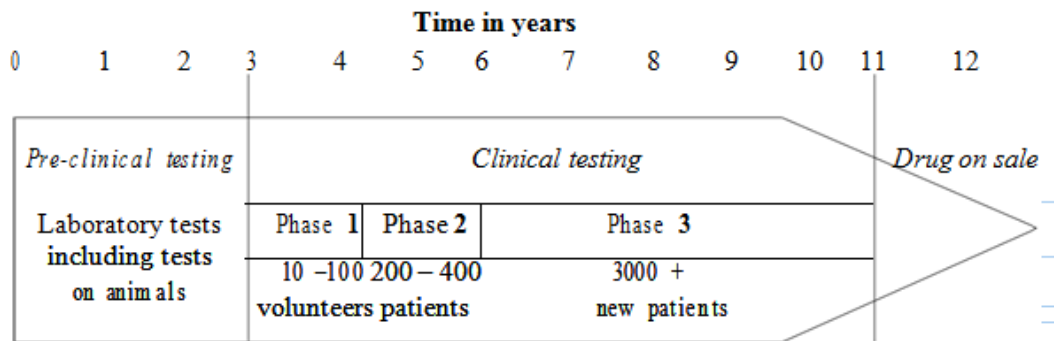


Developing Drugs

Q:1 New drugs need to be tested before going on sale.

The diagram shows a time line for the testing of a new drug.



(a)(i) How long do trials on humans take? _____ years

(1 mark)

(a)(ii) What is the minimum number of humans the drug is tested on throughout clinical testing? _____

(1 mark)

(b) Draw a ring around the correct answer to complete each sentence.

(b) (i) A new drug is first tested in the laboratory to find

- if it is toxic.
- if it is cost effective.
- the optimum dose.

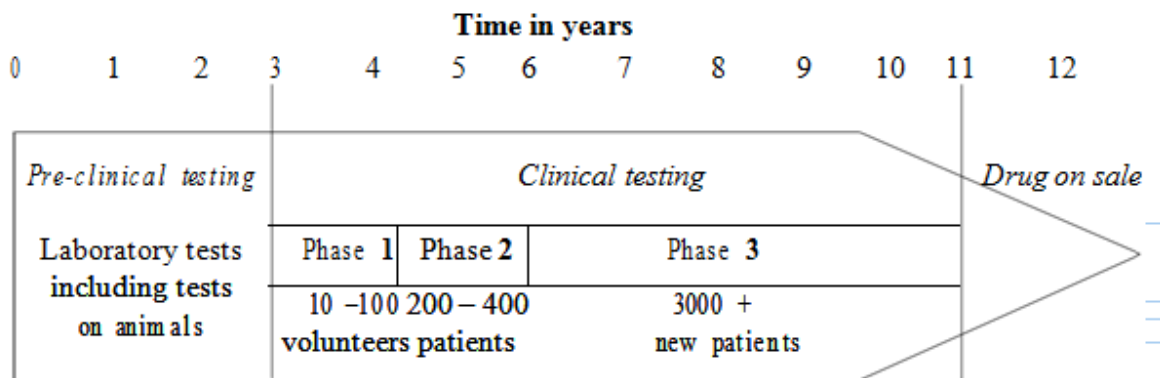
(1 mark)

(c)(ii) The drug is then tested on a few volunteers to find

if it is cost effective.
if it has side effects.
the optimum dose.

(1 mark)

Q:2 New drugs have to be thoroughly tested before they are sold. The diagram shows a time line for the testing of a new drug.



(a) What is the main purpose of pre-clinical testing?

(1 mark)

(b) In Phase 1 of the clinical testing, very low doses of the new drug are used on a small number of volunteers.

(b)(i) What is the main purpose of Phase 1 testing?

(1 mark)

(b)(ii) In Phase 1 testing, healthy volunteers are used rather than patients. Suggest one reason for this.

(1 mark)

(c) What is the main purpose of the Phase 2 and Phase 3 testing?

(1 mark)

(d) During Phase 3 testing, many of the patients are given a placebo.

(d)(i) What is meant by a placebo?

(1 mark)

(d)(ii) During the testing, who knows which patients are receiving the placebo?

Tick (☑) one box.

Only the patients

Only the doctors

Both patients and doctors

Neither patients nor doctors

(1 mark)

Q:3 Nicotine is a drug in tobacco smoke. Smoking tobacco is harmful.

(a) (i) Many smokers find it difficult to stop smoking.

Complete the sentence.

It is difficult to stop smoking because nicotine is very _____

(1 mark)

(a) (ii) Nicotine affects synapses in the brain.

What is a synapse?

(1 mark)

(b) A drug company has developed a new drug, Drug A, to help people stop smoking.

Doctors tested the drug in a double-blind trial with over 2000 volunteers who were smokers.

The volunteers wanted to stop smoking.

The volunteers were divided into three groups. Each volunteer took a tablet once a day for 12 weeks:

- group 1 took Drug A
- group 2 took Drug B (a drug already in use to stop people smoking)
- group 3 took a placebo.

The smoking habits of each group were recorded for a year.

(b) (i) What is a placebo?

(1 mark)

(b) (ii) Why is a placebo group used in drug trials?

(1 mark)

(b) (iii) Which people knew what was in each tablet, in this trial? Tick (☑) one box.

Both doctors and volunteers

Doctors but not volunteers

Neither doctors nor volunteers

(1 mark)

(b) (iv) It is important that the three groups of volunteers should be similar. Give two factors that should be similar in the groups of volunteers.

1 _____

2 _____

(2 marks)

(c) The table shows the results of the trials.

Tablet	Percentage of volunteers who had stopped smoking	
	After 12 weeks	After 1 year
Drug A	44	23
Drug B	30	15
Placebo	18	10

A doctor looked at the results of the tests.

The doctor suggested that a smoker who wanted to give up smoking should use Drug A.

Why?

(1 mark)

Q:4 Drugs must be trialled before the drugs can be used on patients.

(a)(i) Before the clinical trials, drugs are tested in the laboratory.

The laboratory trials are not trials on people.

What is the drug tested on in these laboratory trials?

(1 mark)

(a)(ii) Drugs must be trialled before the drugs can be used on patients.

Give three reasons why.

(3 marks)

Q:5 Scientists have trialled a new statin called rosuvastatin.

17 802 people took part in the trial.

All of these people had high levels of a protein called CRP in their blood.

The higher the level of CRP in the blood, the higher the risk of a heart attack.

None of these people had heart conditions at the beginning of the investigation.

None of these people had high LDL (low density lipoprotein) levels.

All of these people were aged 50 or above.

Half the people were given a rosuvastatin tablet each day; the other half were given a placebo.

The trial was stopped 7 months early when it was found that the people given rosuvastatin were 54 % less likely to have a heart attack than people given the placebo.

(a) Give two control variables in this investigation.

1 _____

2 _____

(2 marks)

(b) What would the placebo be in this investigation?

(1 mark)

(c) The trial gave reliable results.

Give one reason why.

(1 mark)

(d) The trial was stopped 7 months early.

Give one reason why.

(1 mark)

(e) The manufacturers of rosuvastatin paid for the trial.

However, the manufacturers took no part in the trial.

Suggest one reason why the manufacturers did not take part in the trial.

(1 mark)

(f) The table shows some of the results of the trial.

Substance	Concentration in blood in mg per 100 cm ³ after 3 years of trial	
	People given rosuvastatin	People given placebo
LDL cholesterol	53	106
HDL cholesterol	50	49
Saturated fats	106	123

Rosuvastatin reduces the risk of heart attacks.

Use the data in the table to explain why.

(2 marks)

Q:6 (a) List A gives the names of three stages in trialling a new drug.

List B gives information about the three stages.

Draw a line from each stage in List A to the correct information in List B.

**List A
Stage**

**List B
Information**

Tests on humans including a placebo

Used to find if the drug is toxic

Tests on humans using very small quantities of the drug

The first stage in the clinical trials of the drug

Tests on animals

Used to find the optimum dose of the drug

Used to prove that the drug is effective on humans

(3 marks)

(b) Read the passage.

Daily coffee dose delays development of Alzheimer's in humans.

Alzheimer's is a brain disease that causes memory loss in elderly people. Scientists studied 56 mice that had been genetically engineered to develop Alzheimer's.

Before treatment all the mice did badly in memory tests.

Half the mice were given a daily dose of caffeine in their drinking water. The dose was equivalent to the amount of caffeine in six cups of coffee for a human.

The other mice were given ordinary water.

After two months, the caffeine-drinking mice did better in memory tests than the mice drinking ordinary water.

The headline for the passage is not justified.

Explain why as fully as possible.

(3 marks)

TOTAL MARKS=36