AQA GCSE Biology | 8461

SPECIFICATION POINT 4.3.1.9

Discovery and development of drugs

Past-paper questions

Tier	**Higher**
Question groups	**28**
Available paper years	**2007–2025**

Using this booklet

1. Answer the questions in order and show your working.
2. Original question numbers and marks are retained.
3. Print at actual size (100%) for measuring questions.
4. Use the companion answer booklet to check your work.

Name: _____ **Date:** _____

Whole questions are retained for context, so some parts assess other specification points. Current and legacy sources are labelled. Continue on extra paper if needed.

4.3.1.9 Discovery and development of drugs

Question 01

January 2007 | BLY1H | Original Q8 | Legacy

8 Hormones are used in contraceptive pills.

(a) Explain how a contraceptive pill works.

.....

.....

.....

.....

(2 marks)

(b) Read the information about the trialling of the first contraceptive pill.

> The Pill was developed by a team of scientists led by Gregory Pincus. The team needed to carry out large scale trials on humans.
>
> In the summer of 1955, Pincus visited the island of Puerto Rico. Puerto Rico is one of the most densely populated areas in the world. Officials supported birth control as a form of population control. Pincus knew that if he could demonstrate that the poor, uneducated women of Puerto Rico could use the pill correctly then so could women anywhere in the world.
>
> The scientists selected a pill with a high dose of hormones to ensure that no pregnancies would occur while test subjects were taking the drug. The Pill was found to be 100% effective when taken properly. But 17% of the women in the study complained of side effects. Pincus ignored these side effects.
>
> The women in the trial had been told only that they were taking a drug that prevented pregnancy. They had not been told that the Pill was experimental or that there was a chance of dangerous side effects.

4.3.1.9 Discovery and development of drugs

Question 01 · continued

BLANK

Evaluate the methods used by Pincus in trialling the contraceptive pill.

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(5 marks)

7

4.3.1.9 Discovery and development of drugs

Question 02

June 2007 | BLY1A | Original Q7 | Legacy

QUESTION SEVEN

7A Cholesterol is carried around the body by . . .

1 blood cells.

2 LDL.

3 mono-unsaturated fats.

4 polyunsaturated fats.

The bacterium *Lactobacillus acidophilus* is thought to reduce the amount of saturated fat absorbed by the intestine. The bacterium is found in yoghurt.

40 people took part in a trial to see if the bacterium could reduce blood cholesterol levels. The people were divided into two groups. Both groups followed their normal diet.

Group A was given yoghurt containing the *Lactobacillus acidophilus*.

Group B was given a placebo as a control.

The trial lasted four weeks.

The results are shown in the table.

	Group A Normal diet plus yoghurt containing *Lactobacillus acidophilus*	**Group B Normal diet with placebo**
	Percentage change	**Percentage change**
Total cholesterol	+2.3	+1.4
LDL cholesterol	−0.2	+1.8
HDL cholesterol	+2.5	−0.4
Change in body mass	+0.3	−0.5

7B In the trial, the placebo given to **Group B** would have been . . .

1 yoghurt without *Lactobacillus acidophilus*.

2 no yoghurt.

3 yoghurt containing a different bacterium.

4 *Lactobacillus acidophilus* only.

4.3.1.9 Discovery and development of drugs

Question 02 · continued

7C Which of the following is true?

1 In **Group A**, the change in the total cholesterol level was 0.7 percentage points greater than in **Group B**.

2 In **Group A**, the change in the LDL cholesterol level was 1.6 percentage points less than in **Group B**.

3 In **Group A**, the difference between the percentage change in LDL cholesterol and the percentage change in HDL cholesterol was 2.7.

4 The difference in the percentage change in body mass between the two groups was 0.2.

7D Scientists concluded that *Lactobacillus acidophilus* in the diet . . .

1 changes the ratio of LDLs to HDLs.

2 causes weight loss.

3 reduces the level of HDLs in the blood.

4 lowers the total blood cholesterol level.

4.3.1.9 Discovery and development of drugs

Question 03

June 2007 | BLY1H | Original Q7 | Legacy

7 (a) Describe the relationship between the types of lipoprotein in the blood and heart disease.

.....

.....

.....

.....

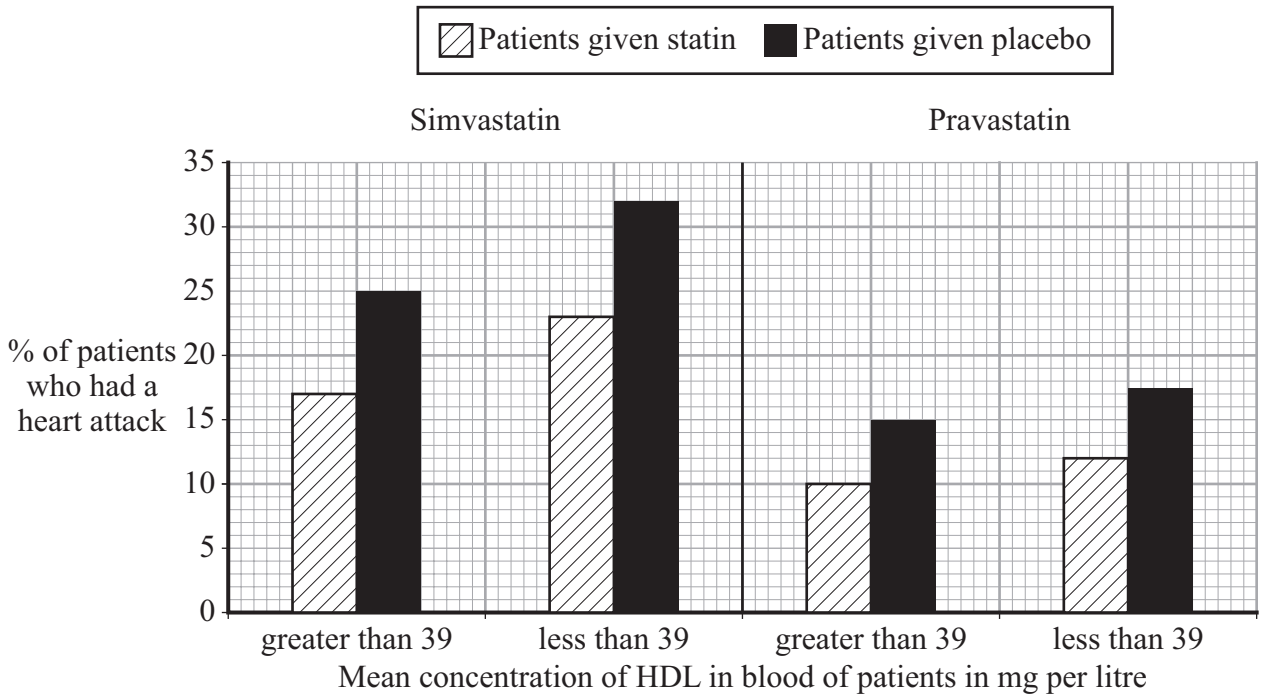
(2 marks)

(b) Statins are drugs used to reduce the risk of heart disease.

The graph shows the results of trials into the effectiveness of two different statins: simvastatin and pravastatin.

Different groups of patients were used in the trials of the two statins. The groups of patients had different initial concentrations of HDL in their blood.

In each trial, half of the patients were given pills containing statins and the other half were given placebos (pills containing no statins). The patients did not know whether or not their pills contained statins.



4.3.1.9 Discovery and development of drugs

Question 03 · continued

BLANK

State **two** conclusions that can be drawn from the results of the trials.

1 .....

.....

2 .....

.....

(2 marks)

4

Turn over for the next question

4.3.1.9 Discovery and development of drugs

Question 04

March 2008 | BLY1AP | Original Q3 | Legacy

QUESTION THREE

Thalidomide is a drug.

3A What was thalidomide originally used for?

1 to treat morning sickness

2 as a sleeping pill

3 to treat diabetes

4 to reduce high blood pressure

A new drug called prednisolone was trialled on leprosy patients. 12 500 patients were given prednisolone and 12 500 patients were given a placebo. 70 % of the patients given prednisolone reported an improvement in their health.

3B The patients given the placebo were used as a . . .

1 control group.

2 continuous group.

3 dependent group.

4 variable group.

3C How many of the patients given prednisolone reported an improvement in health?

1 700

2 875

3 7000

4 8750

4.3.1.9 Discovery and development of drugs

3D In which group of people must prednisolone rather than thalidomide be used for treating leprosy?

1 men aged 21–45

2 boys aged 5–16

3 women aged 15–45

4 girls aged 5–12

Turn over for the next question

4.3.1.9 Discovery and development of drugs

Question 05

March 2008 | BLY1AP | Original Q9 | Legacy

QUESTION NINE

Some drugs are used in medicine because they affect reflex pathways.

9A In the 1940s, the drug curare was introduced because it prevents muscles from contracting, thereby making surgery easier.

At what place in a reflex action does curare most probably act?

1 the junction of receptors and sensory neurones

2 between relay neurones in the brain

3 the junction of a motor neurone and a sensory neurone

4 the junction of a muscle and motor neurone

Dentists inject the drug procaine into gums so that they can drill into teeth without causing pain.

9B What is the most probable reason for procaine preventing pain?

1 It prevents impulses passing along the sensory neurones to the brain.

2 It blocks the synapses between sensory neurones and motor neurones.

3 It makes the tissue of the gums numb.

4 It prevents the brain from interpreting impulses from the teeth.

9C What would be the best way of investigating the effects of drugs such as procaine on the human nervous system?

1 test the effects of drugs on animals

2 test the effects of drugs on healthy human volunteers

3 observe the effects of drugs on addicts

4 test the effects of drugs on people with diseases of the nervous system

9D A manufacturer tests a new drug that affects the nervous system and makes claims about its effectiveness.
The credibility of the claim is decreased because . . .

1 the drug was tested on a wide range of age groups.

2 the drug was tested only by the manufacturer.

3 some of the test subjects were given placebos.

4 only volunteers were used in the test.

END OF TEST

4.3.1.9 Discovery and development of drugs

Question 06

June 2008 | BLY1AP | Original Q9 | Legacy

QUESTION NINE

Testing a new drug on healthy humans is regarded as essential before making it widely available for the treatment of patients.

9A Drug trials do **not** . . .

1 establish how effective a drug is at treating a particular illness.

2 find out what method is best for giving the patient the drug.

3 identify any possible side effects that result from being given the drug.

4 prove that a drug is completely safe for use by the general public.

9B During drug trials, some patients are given a placebo.

Who knows which patients are being given the placebo?

1 the patients only

2 the doctors only

3 both patients and doctors

4 neither patients nor doctors

In 2006, six healthy young men suffered massive unexpected reactions to the drug TGN1412 given to them in a UK drug trial. Their reactions were severe enough to make some of them critically ill.

9C The severe reaction to the drug that was observed with the six male volunteers had not been seen when the drug was given to laboratory animals.

This suggests that . . .

1 all drugs will produce reactions of this magnitude if not administered correctly.

2 it is important to use animals whose body chemistry is as similar as possible to that of humans.

3 testing drugs on animals should be stopped altogether.

4 testing drugs on animals is a waste of resources.

9D Appropriate doses of a drug need to be established through clinical trials before the drug can be marketed. This is done by trialling new drugs on human volunteers.

Which of the following would reduce the risks to volunteers?

1 giving all volunteers a different dose of the drug at the same time as each other

2 giving all volunteers increasing doses of the drug at the same time as each other

3 giving each volunteer a different dose of the drug at the same time as each other

4 giving each volunteer a different dose of the drug at a different time from the others

END OF TEST

4.3.1.9 Discovery and development of drugs

Question 07

November 2008 | BLY1AP | Original Q6 | Legacy

QUESTION SIX

Drugs have to be tested before they can be approved for use.

6A New drugs are often tested in which sequence?

1 first on animals → then on humans → then laboratory analysis

2 first on humans → then on animals → then laboratory analysis

3 first laboratory analysis → then on humans → then on animals

4 first laboratory analysis → then on animals → then on humans

6B During drug trials, some volunteers are given a placebo.

This is to . . .

1 increase the number of volunteers involved to make the findings more acceptable.

2 avoid the risk of too many volunteers suffering side effects.

3 act as a control so that the effects of the drug can be assessed more accurately.

4 reduce the costs of the trials.

6C Drug trials are carried out on human volunteers to . . .

1 wipe out a disease.

2 discover any side effects.

3 find out if the drug can be produced cheaply.

4 find out if the drug reacts with any other drugs.

6D Which of the following is **not** a valid reason for testing a new drug on humans?

1 Scientists cannot always predict with certainty what will happen when a drug is used to treat humans.

2 Scientists cannot say with certainty that the results of any tests on laboratory animals will be the same as the results on humans.

3 Scientists cannot get a drug passed for public consumption without finding out how safe it is.

4 Scientists need to find out how much a drug will cost to market.

4.3.1.9 Discovery and development of drugs

Question 08

January 2009 | BLY1H | Original Q3 | Legacy

3 Nicotine is the addictive substance in tobacco.
People can be helped to stop smoking by giving them nicotine replacement therapy (NRT).

The table gives the results of trials of different types of NRT.

Type of NRT	Smokers given NRT		Smokers given placebo	
	Number of smokers in trial	Percentage of smokers who gave up smoking	Number of smokers in trial	Percentage of smokers who gave up smoking
Gum	7387	20	9319	12
Patch	7708	14	5969	8
Nasal spray	448	24	439	12
Inhaler	490	14	486	8
Tablet	243	20	245	13

3 (a) (i) What is a placebo?

.....

.....

(1 mark)

3 (a) (ii) Why was a placebo used in these NRT trials?

.....

.....

(1 mark)

3 (b) (i) In which trial was the data most reliable?

.....

(1 mark)

3 (b) (ii) Give the reason for your answer.

.....

.....

.....

(1 mark)

4.3.1.9 Discovery and development of drugs

Question 08 · continued

for mark

3 (c) (i) Which type of NRT was most effective?

.....

(1 mark)

3 (c) (ii) Explain the reasons for your answer.

.....

.....

.....

.....

.....

(2 marks)

7

Turn over for the next question

4.3.1.9 Discovery and development of drugs

Question 09

March 2009 | BLY1AP | Original Q5 | Legacy

QUESTION FIVE

Nicotine replacement therapy (NRT) is used to help people to stop smoking.

5A NRT is used to help people to stop smoking because nicotine . . .

1 reduces the amount of oxygen carried by the blood.

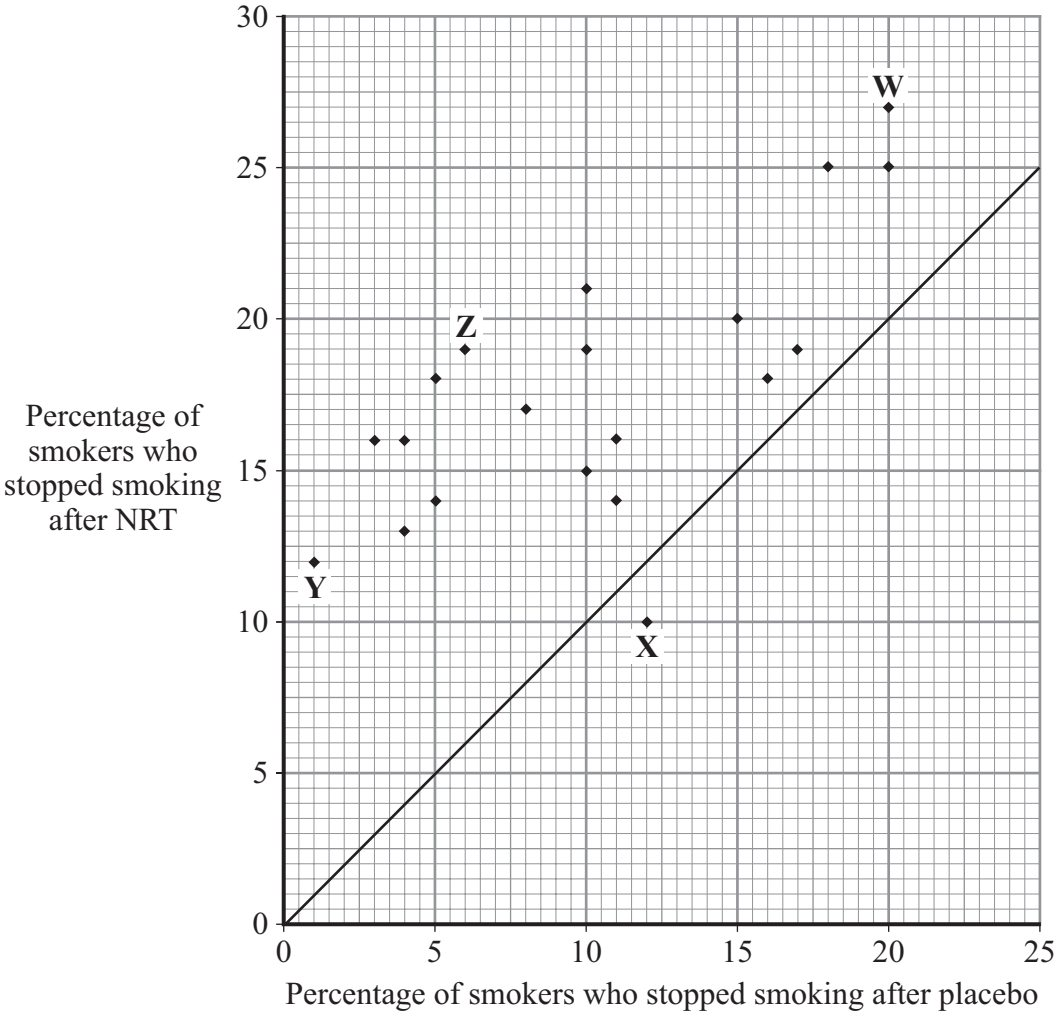
2 causes lung cancer.

3 alters chemical processes in the body.

4 increases appetite.

The scattergram shows the results of 20 investigations into the use of different types of NRT tablets. In each investigation, some smokers were given NRT and some were given a placebo.

Each plot represents **one** investigation. Each plot represents the percentage of smokers who stopped smoking after NRT and the percentage of people who stopped smoking after being given a placebo in that investigation.



5B In these investigations, the placebo would be . . .

1 a tablet that tasted of nicotine.

2 a white tablet.

3 a tablet with sugar.

4 a tablet with no nicotine.

5C In which investigation did more people stop smoking after using the placebo than after using NRT?

1 **W**

2 **X**

3 **Y**

4 **Z**

5D What conclusion can be drawn from the results of the investigations?

1 NRT was more effective than a placebo in most of the investigations.

2 Patients given a placebo do not stop smoking.

3 All the people given NRT stopped smoking.

4 Most of the people in the investigations gave up smoking.

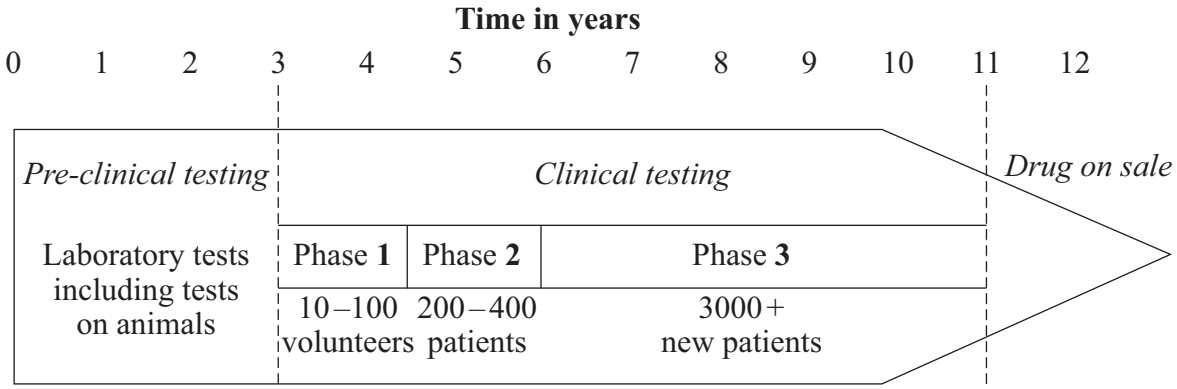
4.3.1.9 Discovery and development of drugs

Question 10

January 2019 | BLY1H | Original Q4 | Legacy

4 New drugs have to be thoroughly tested before they are sold.

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



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

.....

.....

(1 mark)

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

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

.....

.....

(1 mark)

4 (b) (ii) In Phase **1** testing, healthy volunteers are used rather than patients.

Suggest **one** reason for this.

.....

.....

(1 mark)

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

.....

.....

(1 mark)

4.3.1.9 Discovery and development of drugs

Question 10 · continued

for mark

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

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

.....

.....

(1 mark)

4 (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)

6

4.3.1.9 Discovery and development of drugs

Question 11

March 2010 | BLY1AP | Original Q4 | Legacy

QUESTION FOUR

Read the passage about the discovery of thalidomide.

> A small German drugs company first made thalidomide in 1953. The company scientists could not find any beneficial effects of thalidomide, including antibiotic activity, in mice and rats. However, the new chemical seemed to be harmless. Very high doses did not kill rodents, rabbits, cats or dogs. In addition, the animals showed no other side effects.
>
> In further testing, the animals did not appear to become sleepy or calmer when given thalidomide. However, the company thought that selling thalidomide as a sleeping drug would make them lots of money.
>
> Soon the drug was being sold in 46 countries without any additional independent testing. Thalidomide became the drug of choice for pregnant women with morning sickness.

4A Nowadays, all drugs are thoroughly tested before being marketed.

Which stage of drug testing was not done by the company scientists?

1 tests on animals

2 toxicity tests

3 tests on humans

4 antibiotic activity

4B The company marketed thalidomide quickly because . . .

1 they thought that they could make a big profit.

2 they wanted to cure morning sickness in women.

3 it was a good sleeping drug.

4 it was a good antibiotic.

4.3.1.9 Discovery and development of drugs

Question 11 · continued March 2010 | BLY1AP | Original Q4 | Legacy

4C When clinical trials of a new drug are carried out, half the volunteers are given a placebo.

A placebo contains . . .

1 only inactive substances.

2 a small quantity of the drug.

3 an antibiotic.

4 a painkiller.

4D Thalidomide was banned when its side effects became known.

It has recently been approved for the treatment of . . .

1 morning sickness.

2 leprosy.

3 limb abnormalities.

4 mental illness.

4.3.1.9 Discovery and development of drugs

Question 12

June 2010 | BLY1AP | Original Q8 | Legacy

QUESTION EIGHT

Some crocodiles live in lakes in Africa. These lakes may contain rotting meat and vegetation.

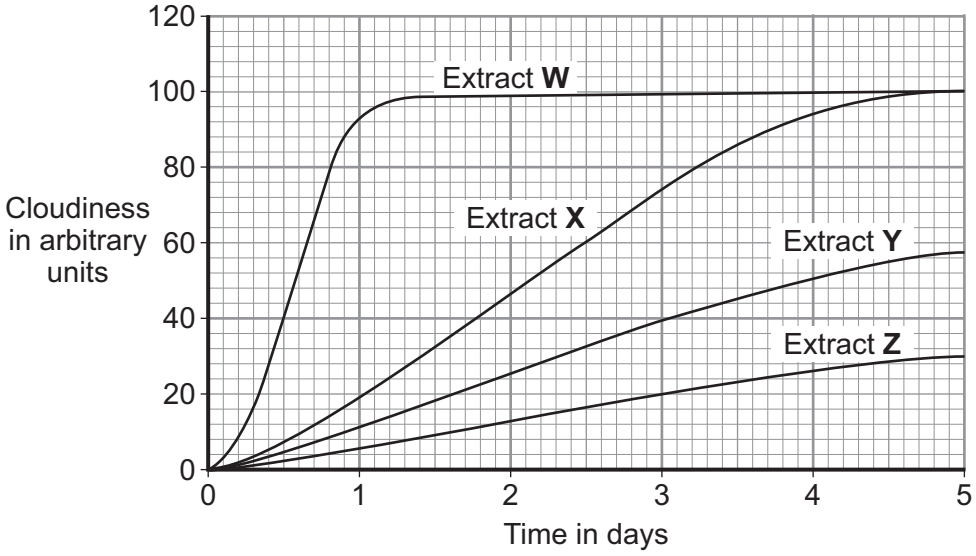
- Crocodiles often get cuts but these rarely become infected.
- However, local people notice that when they bathe in the same lakes, **their** cuts often become infected.

8A Which row in the table correctly identifies the two statements?

	Cuts on crocodiles rarely become infected	Cuts on local people often become infected
1	Theory	Hypothesis
2	Hypothesis	Theory
3	Observation	Observation
4	Hypothesis	Observation

- A researcher took a sample of crocodile blood and made four extracts, **W**, **X**, **Y** and **Z**, from it.
- He added these extracts to MRSA bacteria in tubes of nutrient solution.
- The tubes were kept in a warm place for five days.
- As bacteria grew, the nutrient solution became cloudy.

The graph shows how the cloudiness of the nutrient solutions changed over the five days.



4.3.1.9 Discovery and development of drugs

Question 12 · continued

8B The researcher decided to purify one of the extracts to isolate the bacteria-killing chemical.

Which extract would he most likely choose to purify?

1 Extract **W**

2 Extract **X**

3 Extract **Y**

4 Extract **Z**

8C After several pure chemicals had been isolated from one extract, the chemicals were trialled.

The table shows four stages in the trialling of a new chemical.

Stage	Trialled on
P	human volunteers who do not have disease
Q	cell cultures
R	animals
S	humans who do have disease

Which is the correct sequence for these stages?

1 **R → S → Q → P**

2 **Q → P → S → R**

3 **Q → R → P → S**

4 **S → P → R → Q**

8D Volunteers in trials of new chemicals . . .

1 should always be paid for taking part.

2 should always be told about the risks of side-effects.

3 should be able to choose whether to take the new chemical or a placebo.

4 should be told whether they have been given the placebo or the new chemical.

4.3.1.9 Discovery and development of drugs

Question 13

June 2019 | BLY1H | Original Q4 | Legacy

4 Diet and exercise affect health.

4 (a) Many people are obese (very overweight).

Obesity can lead to heart disease.

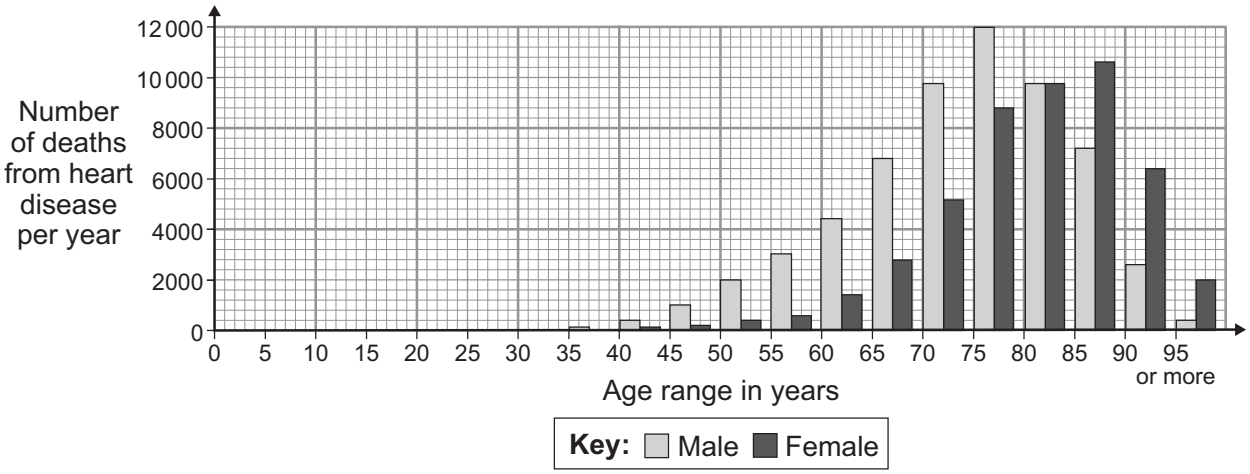
Other than heart disease, name **two** conditions which are linked to obesity.

1 .....

2 .....

(2 marks)

4 (b) The graph shows the number of deaths from heart disease each year in the UK.



The pattern for deaths from heart disease in men is different from the pattern in women.

4 (b) (i) Give **two** differences between the patterns for men and women.

1 .....

.....

2 .....

.....

(2 marks)

4.3.1.9 Discovery and development of drugs

Question 13 · continued

4 (b) (ii) Suggest **two** reasons for the difference in the number of deaths from heart disease in men and women between the ages of 40 and 60.

1 .....

.....

2 .....

.....

(2 marks)

4 (c) Scientists have developed drugs to reduce the concentration of cholesterol in the blood.

Give the **three** main stages in testing a new drug before it is sold to the public.

1 .....

.....

2 .....

.....

3 .....

.....

(3 marks)

9

4.3.1.9 Discovery and development of drugs

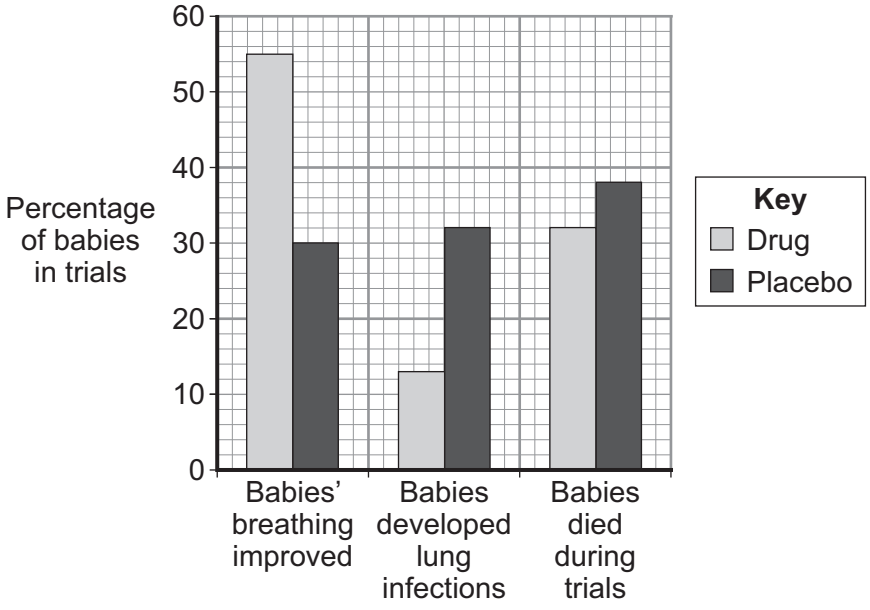
Question 14

November 2010 | BLY1AP | Original Q5 | Legacy

QUESTION FIVE

Some babies have life-threatening breathing problems. A company developed a new drug to help the babies. The company tested the drug against a placebo on 180 babies.

The results of the trial are shown on the graph.



5A What percentage of the babies given the drug did not show any improvement in breathing?

1 16 %

2 30 %

3 45 %

4 55 %

5B Many people are against doctors using placebos in drug trials on children.

This is because . . .

1 no-one knows which child gets the placebo.

2 some children die who might have benefited from the drug.

3 it makes the trials more expensive.

4 it slows down testing of the drug.

4.3.1.9 Discovery and development of drugs

Question 14 · continued

5C Some babies in the trial died, but this did not stop the trial.

The reason for this was that . . .

1 the company did not think it was important.

2 other babies in the trial developed lung infections.

3 the percentage of babies who died was greater for the babies taking the placebo than for the babies taking the drug.

4 many of the babies given the placebo were showing improvement in breathing.

5D Why is it important that an independent company also carries out the tests on a new drug?

1 The results will be more accurate.

2 It is illegal for just one company to test a drug.

3 The drug can be put on sale more quickly.

4 The results will not be biased.

4.3.1.9 Discovery and development of drugs

Question 15

March 2011 | BLY1AP | Original Q7 | Legacy

QUESTION SEVEN

Some infections can be treated using antibiotics.

7A Antibiotics can . . .

1 relieve the symptoms of infectious diseases by acting as painkillers.

2 kill viruses inside body cells.

3 cause white blood cells to produce antibodies.

4 kill some strains of bacteria.

Often, a doctor will prescribe antibiotics for an ear infection the first time a child goes to the doctor with earache.

Scientists investigated 240 young children with earache to see if the antibiotic was really needed. Some of the children were given the antibiotic. Other children were given a placebo.

The results are shown in the table.

	Children given an antibiotic	Children given a placebo
Average time for which the child had a fever	2 days	3 days
Average time for which the child had severe pain	3 days	3 days
Average amount of painkilling medicine given in the first 10 days	2.3 doses	4.1 doses
Difference in the redness of the infected eardrum after 4 days	No difference between the two groups	
Difference in the redness of the infected eardrum after 11 days	No difference between the two groups	

7B Compared with the children given the placebo, the children given the antibiotic had . . .

1 fever and severe pain for a shorter time.

2 severe pain and painkilling medicine for a longer time.

3 less redness of the eardrum after 11 days.

4 no difference in the redness of the eardrum after 4 days and the period of severe pain.

7C The best conclusion that can be drawn from these results is that children with ear infections . . .

1 should always be prescribed antibiotics.

2 recover from all symptoms more quickly if given antibiotics.

3 should be given a placebo on the first visit to a doctor.

4 do **not** really need to be prescribed an antibiotic on the first visit to a doctor.

7D Doctors are concerned that antibiotic resistance is increasing in some bacteria.

The increase is because . . .

1 antibiotics cause bacteria to mutate into resistant forms of bacteria.

2 bacteria mutate spontaneously, then antibiotics do not kill the resistant forms of the bacteria.

3 the strongest bacteria mutate into resistant forms of bacteria.

4 after being in contact with antibiotics, bacteria decide to mutate.

4.3.1.9 Discovery and development of drugs

Question 16

March 2011 | BLY1AP | Original Q8 | Legacy

QUESTION EIGHT

After operations, patients can have large scars.

Scientists have developed a new drug. The drug can help to reduce scarring if it is injected during the operation.

The scientists carried out double-blind trials. The purpose of the trials was to find out how much of the drug should be injected to reduce scarring.

- Each patient in the trial had a large vein removed from their left leg and a large vein removed from their right leg.
- Two surgeons operated at the same time. One surgeon operated on the left leg and the other surgeon on the right leg.
- During the operation, a hospital researcher injected a dose of the drug into one of the patient's legs and a placebo into the other leg.

8A A double-blind trial was used so that . . .

1 the surgeons could operate on both legs at the same time.

2 neither surgeon nor patient could influence the outcome of the trial.

3 the hospital researchers would know into which leg to inject the drug.

4 equal amounts of the drug or the placebo were used.

8B One year after the operation, the hospital researchers measured and photographed the scars on both legs.

Which factor might have made the trial unreliable?

1 Both legs belonged to the same patient and so would have the same natural healing power.

2 The researcher did not know whether he was injecting the drug or the placebo.

3 Both legs were operated on at the same time.

4 Two different surgeons did the operations.

8C In the year after the operation, each patient had to fill in some questionnaires. The patients also went back to the hospital to be examined. After all the testing was finished, the patient volunteers were paid £300 each.

Giving the volunteers £300 meant that . . .

1 the volunteers' opinions on the scars were unbiased.

2 the volunteers were more likely to complete all the requirements of the trials.

3 the risk of having the drug injected would be less.

4 the volunteers would say that the scar on the leg that had the drug injected would be smaller.

8D Only a small quantity of this new drug is available at present.

In the circumstances, which of the following might people think is an unethical use of the drug?

1 using the drug on children in operations to correct inherited deformities

2 using the drug on patients that need a life-saving operation

3 using the drug on women in operations to increase the size of their breasts

4 using the drug on patients having operations after a car crash

4.3.1.9 Discovery and development of drugs

Question 17

June 2011 | BLY1AP | Original Q7 | Legacy

QUESTION SEVEN

A protein called 'C-reactive protein' is found in the blood. High levels of blood C-reactive protein have been linked to heart attacks.

In 2006, a double-blind trial was started to see if a new statin could lower levels of blood C-reactive protein.

7A In the trial, people with low levels of blood cholesterol but high levels of blood C-reactive protein were chosen because . . .

1 low levels of blood cholesterol are not linked to heart attacks.

2 cholesterol would react with protein.

3 statins do not affect people with low levels of blood cholesterol.

4 cholesterol is needed for the statins to have an effect.

7B The double-blind trial would have included . . .

1 both the patient and the doctor knowing who is getting the placebo.

2 the patient, but not the doctor knowing who is getting the placebo.

3 the doctor, but not the patient knowing who is getting the placebo.

4 neither the patient nor the doctor knowing who is getting the placebo.

7C The trial was planned to last for five years. The trial was stopped after less than 2 years because the risk of heart attack was reduced by 54 % in the group given the new statin.

The decision to stop the trial was because . . .

1 statins are known to reduce heart attacks and strokes.

2 the researchers decided that the drug was not working.

3 it was unfair on the people taking the placebo to continue taking part in the trial.

4 the scientists ran out of money.

7D The trials were supported financially by the company that produced the drug.

This means that the results . . .

1 might be less reliable than if they had been supported by the National Health Service.

2 might be less reliable than if they had been supported by a university.

3 might be biased.

4 should be disregarded even though many patients' lives were saved.

Turn over for the next question

4.3.1.9 Discovery and development of drugs

Question 18

June 2011 | BLY1H | Original Q2 | Legacy

2 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 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.

2 (a) Give **two** control variable in this investigation.

1 .....

2 .....

(2 marks)

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

.....

.....

(1 mark)

2 (c) The trial gave reliable results.

Give **one** reason why.

.....

.....

(1 mark)

2 (d) The trial was stopped 7 months early.

Give **one** reason why.

.....

.....

(1 mark)

4.3.1.9 Discovery and development of drugs

Question 18 · continued

2 (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)

2 (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)

8

4.3.1.9 Discovery and development of drugs

Question 19

November 2011 | BLY1AP | Original Q1 | Legacy

QUESTION ONE

The flow chart shows how new drugs are tested.

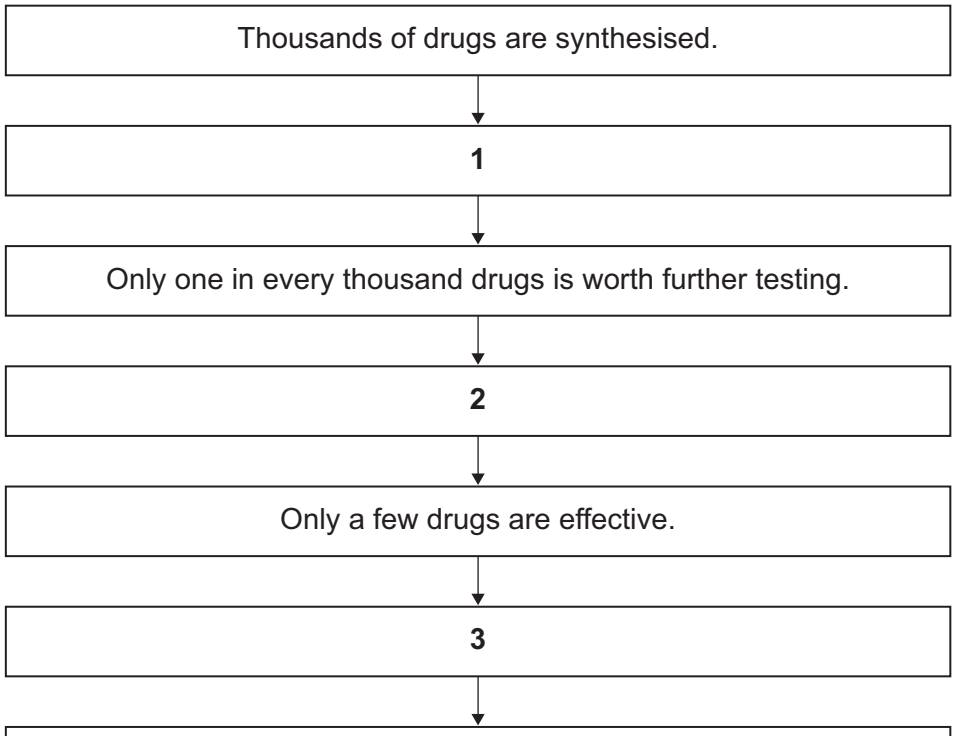
Match statements, **A**, **B**, **C** and **D**, with the stages **1**–**4** in the flow chart.

A Drugs are tested on animals to see if the drugs work.

B Low doses of drugs are tested on volunteers to detect any side effects.

C Drugs are tested on cells to see if the drugs are safe to test on organisms.

D Drugs are tested on patients to find the best dose.



4.3.1.9 Discovery and development of drugs

Question 20

January 2012 | BL1HP | Original Q6 | Legacy

6 Drugs must be trialled before the drugs can be used on patients.

6 (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)

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

Give **three** reasons why.

.....

.....

.....

.....

.....

.....

(3 marks)

6 (b) Read the information about cholesterol and ways of treating high cholesterol levels.

Diet and inherited factors affect the level of cholesterol in a person's blood.
Too much cholesterol may cause deposits of fat to build up in blood vessels and reduce the flow of blood. This may cause the person to have a heart attack.
Some drugs can lower the amount of cholesterol in the blood.

The body needs cholesterol. Cells use cholesterol to make new cell membranes and some hormones. The liver makes cholesterol for the body.

Some drugs can help people with high cholesterol levels.

Statins block the enzyme in the liver that is used to produce cholesterol.
People will normally have to take statins for the rest of their lives. Statins can lead to muscle damage and kidney problems. Using some statins for a long time has caused high numbers of deaths.

Cholesterol blockers reduce the absorption of cholesterol from the intestine into the blood.
Cholesterol blockers can sometimes cause problems if the person is using other drugs.

4.3.1.9 Discovery and development of drugs

Question 20 · continued

Evaluate the use of the two types of drug for a person with high cholesterol levels.

.....

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.....

(6 marks)

10

4.3.1.9 Discovery and development of drugs

Question 21

June 2014 | BL1HP | Original Q6 | Legacy

6 Drugs may harm the human body.

6 (a) The drug thalidomide was originally developed in the 1950s.

6 (a) (i) What was the drug thalidomide originally developed to treat?

[1 mark]

.....

6 (a) (ii) Soon after it was developed, thalidomide was found to be useful in treating another condition.

What was this other condition?

[1 mark]

.....

6 (a) (iii) Describe **one** harmful effect of thalidomide.

[1 mark]

.....

6 (a) (iv) Suggest why this harmful effect had **not** been detected during clinical drug trials on thalidomide.

[1 mark]

.....

.....

6 (b) Using a recreational drug may cause a person to become dependent on the drug.

6 (b) (i) What happens in the body to make someone dependent on a drug?

[1 mark]

.....

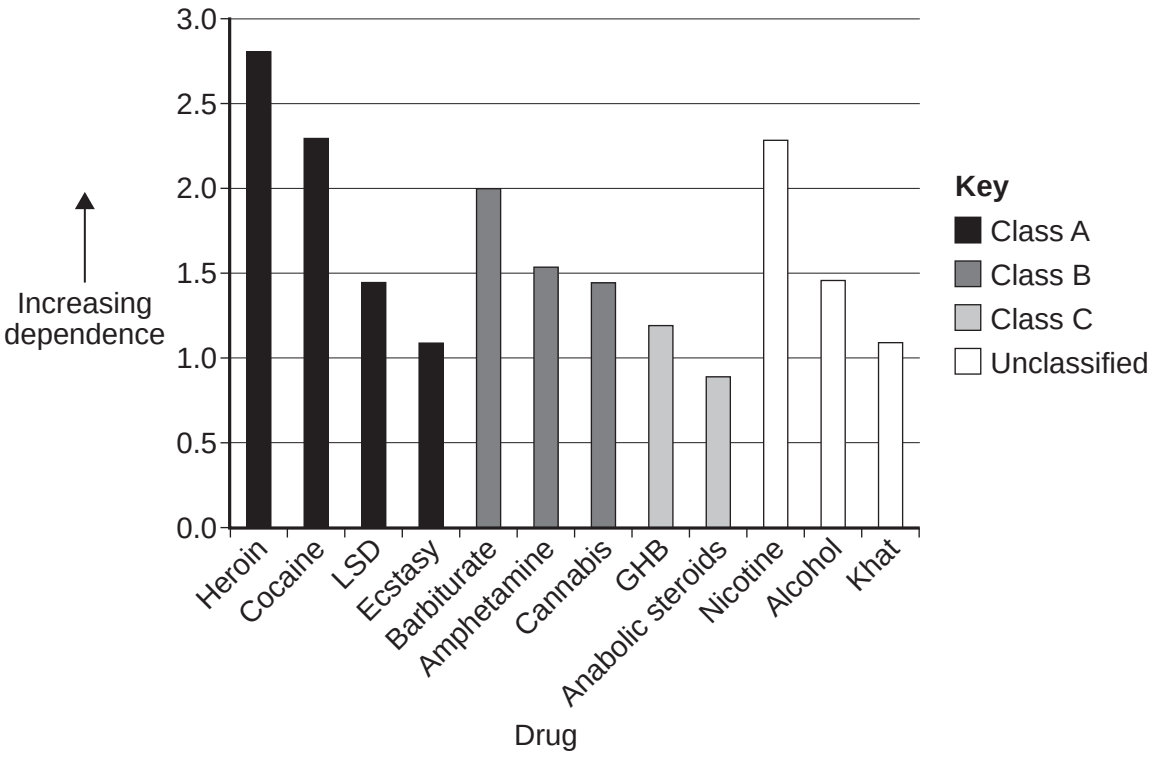
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4.3.1.9 Discovery and development of drugs

Question 21 · continued

6 (b) (ii) Doctors rated different recreational drugs according to how dependent users had become on them. **Figure 4** shows the results.

Figure 4



It is illegal (against the law) to take Class A, B or C drugs.
Unclassified drugs are legal.

Some people think that some legal drugs should be made illegal.
What evidence is there in **Figure 4** to support this view?

[2 marks]

.....

.....

.....

.....

6 (b) (iii) Suggest **one** other piece of information about legal drugs that would need to be considered before the classification of these drugs was changed.

[1 mark]

.....

8

4.3.1.9 Discovery and development of drugs

Question 22

June 2015 | BL1HP | Original Q1 | Legacy

1 Many people in the UK take sleeping pills.

1 (a) The drug thalidomide was developed as a sleeping pill in the 1950s.
In the 1960s thalidomide was banned.
Recently thalidomide has been used to treat other diseases.

Name **one** disease thalidomide is used to treat now.

[1 mark]

.....

1 (b) **Table 1** shows information about the development of a new sleeping pill.

Table 1

Type of test or trial	Preclinical	Clinical phase 1	Clinical phase 2	Clinical phase 3
Tested or trialled on	Cells, tissues or animals	20–100 healthy volunteers	100–500 volunteer patients	1000–5000 volunteer patients
Number of compounds tested	>10 000	5–10	2–3	1 (new sleeping pill)
Time taken for test or trial in years	1–4	2–4	1–3	2–4

1 (b) (i) What is the shortest time taken to develop a new sleeping pill?

[1 mark]

..... years

1 (b) (ii) What is the **range** for the number of volunteers needed to complete all the clinical trials for the new sleeping pill?

[1 mark]

.....

4.3.1.9 Discovery and development of drugs

Question 22 · continued

1 (c) Drugs are trialled to check for side effects on people.

Give **one** other reason why drugs are trialled.

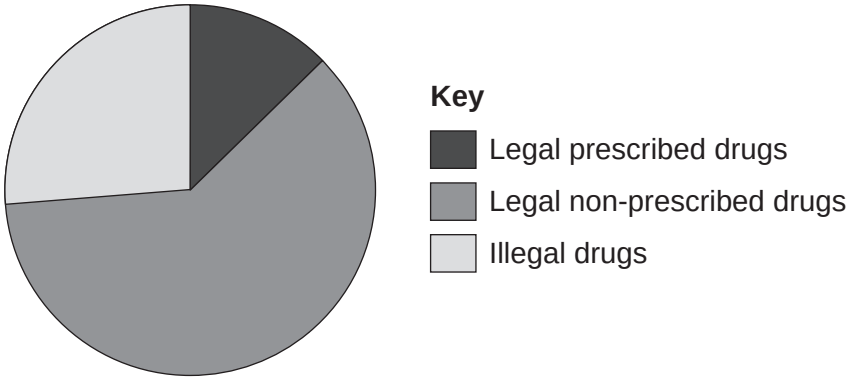
[1 mark]

.....

.....

1 (d) **Figure 1** shows the impact on the health of the population caused by drugs from different sources.

Figure 1



1 (d) (i) Legal non-prescribed drugs have a greater impact on the health of the population than illegal drugs.

Suggest **two** reasons why.

[2 marks]

.....

.....

.....

.....

.....

.....

1 (d) (ii) Drugs change chemical processes in a person's body.

Why is it difficult for a person to stop taking certain drugs?

[1 mark]

.....

.....

7

4.3.1.9 Discovery and development of drugs

Question 23

June 2017 | BL2HP | Original Q5 | Legacy

5 Scientists investigated the effect of drinking glucose solution during long-distance athletic events.

The scientists selected seven racing cyclists.

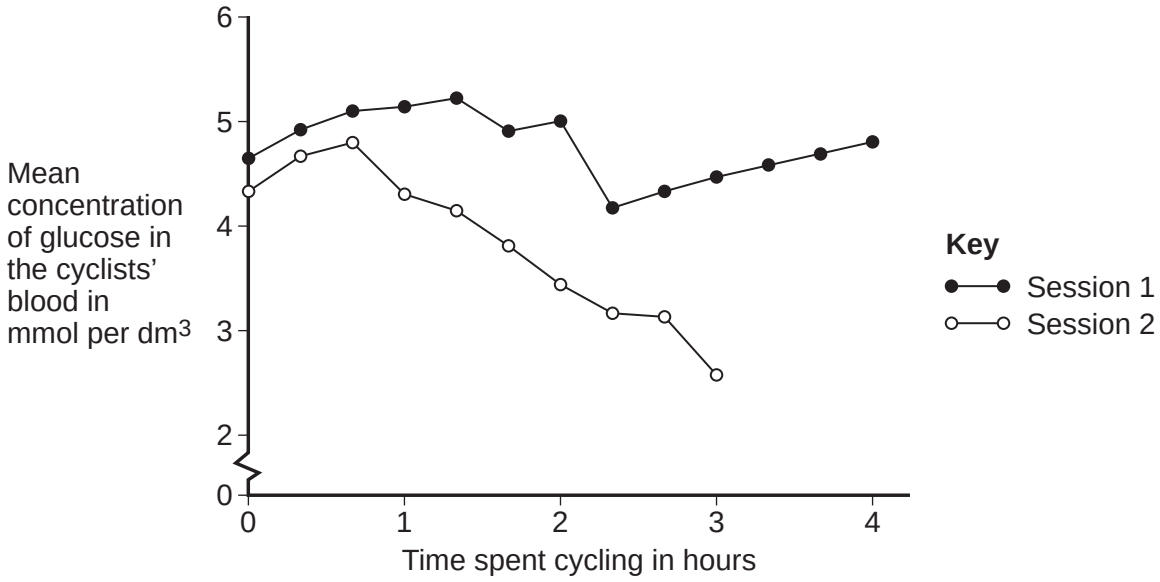
In two separate sessions, the cyclists pedalled stationary bicycles at a constant speed until they could not continue.

- **Session 1**: the cyclists drank 60 grams of glucose per hour in an energy drink.
- **Session 2**: a week later, the same cyclists drank a placebo drink that tasted the same but did **not** contain glucose.

The scientists measured the concentration of glucose in the cyclists' blood at intervals during each of the two sessions.

Figure 6 shows the results.

Figure 6



5 (a) In each session, the cyclists did not know whether they were drinking the glucose drink or the placebo.

Why was this important?

[2 marks]

4.3.1.9 Discovery and development of drugs

Question 23 · continued

5 (b) (i) The scientists concluded that drinking glucose during a race would improve athletic performance.

Evaluate the validity of the method used in this investigation and the evidence for the scientists' conclusion.

[4 marks]

Question 5 continues on the next page

4.3.1.9 Discovery and development of drugs

Question 23 · continued

5 (b) (ii) During both sessions, the cyclists' heart rates and breathing rates were much higher than at rest.

Describe how increased heart rate, increased breathing rate and increased blood glucose concentration would improve athletic performance.

[4 marks]

10

4.3.1.9 Discovery and development of drugs

Question 24

June 2019 | 8461/1H | Original Q8

0 8 Pancreatic cancer develops when a malignant tumour grows inside the pancreas.

0 8 . 1 The pancreas produces digestive enzymes.

What is an enzyme?

[2 marks]

0 8 . 2 Carbohydrase is an enzyme produced by the pancreas.

Name **two** other organs in the digestive system that produce carbohydrase.

[2 marks]

1 _____

2 _____

0 8 . 3 One symptom of pancreatic cancer is weight loss.

Explain how pancreatic cancer may cause a person to lose weight.

Do **not** refer to hormones in your answer.

[4 marks]

4.3.1.9 Discovery and development of drugs

Question 24 · continued

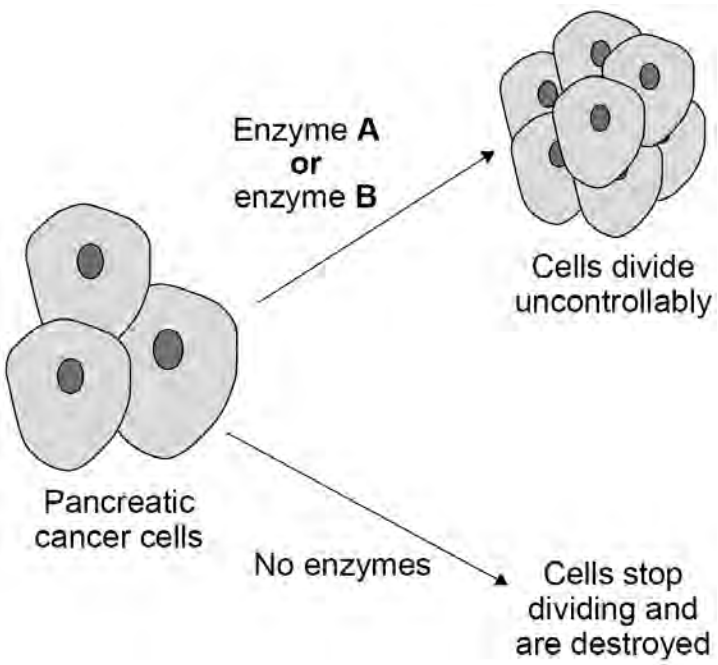
Enzyme **A** and enzyme **B** are involved in controlling cell division in pancreatic cancer cells.

Most cancer cells produce both enzyme **A** and enzyme **B**.

Some people have a gene mutation that stops cancer cells producing enzyme **B**.

Figure 9 shows how cell division is controlled in pancreatic cancer cells.

Figure 9



4.3.1.9 Discovery and development of drugs

Question 24 · continued

Scientists have developed a drug that inhibits enzyme **A**.

The drug is given to pancreatic cancer patients who have the gene mutation that stops cancer cells producing enzyme **B**.

The drug only targets cancer cells.

0 8 . 4 Explain why the drug can be used to treat pancreatic cancer in patients with the gene mutation.

Use information from **Figure 9**.

[3 marks]

0 8 . 5 Explain why the drug could **not** be used to treat pancreatic cancer in a patient that produces both enzyme **A** and enzyme **B**.

[2 marks]

Question 8 continues on the next page

4.3.1.9 Discovery and development of drugs

Question 24 · continued

0 8 . 6 The drug was trialled before it was licensed for use.

To improve validity of the results in the trial:

- some patients were given a placebo
- a double-blind trial was used.

Give reasons why a placebo and a double-blind trial were used.

[2 marks]

A placebo _____

_____

_____

A double-blind trial _____

_____

_____

0 8 . 7 One stage in a drug trial is to test the drug on healthy volunteers.

What is the next stage in the drug trial?

[1 mark]

Tick (✓) **one** box.

Testing on all patients with the disease ☐

Testing on human tissue ☐

Testing on live animals ☐

Testing on volunteers with the disease ☐

4.3.1.9 Discovery and development of drugs

Question 24 · continued

0 8 . 8 A monoclonal antibody has been produced to treat pancreatic cancer.

Explain how the monoclonal antibody works to treat pancreatic cancer.

[3 marks]

19

4.3.1.9 Discovery and development of drugs

Question 25

November 2020 | 8461/1H | Original Q7

0 7 Monoclonal antibodies (mAbs) are usually made using mouse lymphocytes.

Candida albicans infection produces serious symptoms in patients with a poor immune system.

Recently scientists have produced mAbs to *Candida albicans* using human lymphocytes produced naturally after an infection.

0 7 . 1 *Candida albicans* lives in the throat of infected patients.

A sample is taken from the throat of a patient with a suspected *Candida albicans* infection.

The sample is transferred onto a microscope slide.

Describe how the mAbs and a fluorescent dye could be used to see any *Candida albicans* pathogens on the slide.

[3 marks]

4.3.1.9 Discovery and development of drugs

Question 25 · continued

In a laboratory the human lymphocyte mAbs were injected into animals infected with *Candida albicans*.

The mAbs caused increased phagocytosis of the *Candida albicans* pathogens.

Doctors intend to start a trial to give the mAbs to patients severely ill with *Candida albicans.*

0 7 . 2 Explain how increased phagocytosis of the *Candida albicans* pathogen will help the patient.

[2 marks]

Question 7 continues on the next page

4.3.1.9 Discovery and development of drugs

Question 25 · continued

0 7 . 3 It has been shown that this mAbs treatment is effective in the laboratory using both:

- infected tissue culture cells
- infected live animals.

The mAbs treatment for *Candida albicans* is now ready for clinical trials on people.

Describe how the clinical trials should be carried out.

[6 marks]

4.3.1.9 Discovery and development of drugs

Question 25 · continued

0 7 . 4 Scientists have also used human lymphocytes to make mAbs to other pathogens and to some types of cancer cells.

Suggest **one** reason why these new mAbs have been more successful in treating diseases in humans than mAbs made using mice.

[1 mark]

12

4.3.1.9 Discovery and development of drugs

Question 26

0 1 A root is a plant organ.

Plant roots contain many different types of tissue.

0 1 . 1 What is a tissue?

[1 mark]

0 1 . 2 Tissue in the tip of a plant root contains stem cells.

Stem cells can differentiate into any type of cell.

Name the type of tissue in plants that contains stem cells.

[1 mark]

In the past many drugs were extracted from plants.

0 1 . 3 Aspirin is a painkiller.

Which plant does aspirin originate from?

[1 mark]

Question 1 continues on the next page

4.3.1.9 Discovery and development of drugs

Question 26 · continued

Scientists have extracted chemical **A** from the deadly nightshade plant.

Chemical **A** can be used as a painkiller.

Table 1 shows information about where chemical **A** is found.

Table 1

Part of deadly nightshade plant	Mass of chemical A in 100 g of plant tissue in grams
Roots	1.3
Leaves	1.2
Berries	0.7

0 1 . 4 The scientists usually extract chemical **A** from the berries of the deadly nightshade plant.

Suggest **one** reason why berries are used instead of leaves or roots.

[1 mark]

4.3.1.9 Discovery and development of drugs

Question 26 · continued

A deadly nightshade plant has chlorosis (yellow leaves).

The mass of chemical **A** found in the **leaves** of the plant is 60% of the mass shown in **Table 1**.

0 1 . 5 Calculate the mass of chemical **A** in 200 g of the **leaves** with chlorosis.

Give your answer in mg.

[4 marks]

Mass of chemical **A** = _____ mg

0 1 . 6 Suggest **one** reason why the leaves of the deadly nightshade plant have chlorosis.

[1 mark]

Question 1 continues on the next page

4.3.1.9 Discovery and development of drugs

Question 26 · continued

Chemical **A** has **not** been tested in large-scale clinical trials in the UK.

0 1 . 7 It is important for drugs to be tested in clinical trials before the drugs are approved for use by the public.

Give **two** reasons why.

[2 marks]

1 _____

_____

2 _____

_____

There are many online reports making claims about the effects of chemical **A**.

Some of these reports are biased.

0 1 . 8 Suggest **one** reason why a report making claims about the effects of chemical **A** may be biased.

[1 mark]

_____

_____

4.3.1.9 Discovery and development of drugs

Question 26 · continued

0 1 . 9 How can scientists be sure that claims about new drugs are valid?

[1 mark]

Tick (✓) **one** box.

- Advertise the claims on social media. ☐
- Ask an international company to produce the drug. ☐
- Have the claims peer reviewed. ☐
- Publish the claims in a newspaper. ☐

13

Turn over for the next question

4.3.1.9 Discovery and development of drugs

Question 27

June 2024 | 8461/1H | Original Q8

0 8 Cancer is caused by changes in cells that result in uncontrolled cell division.

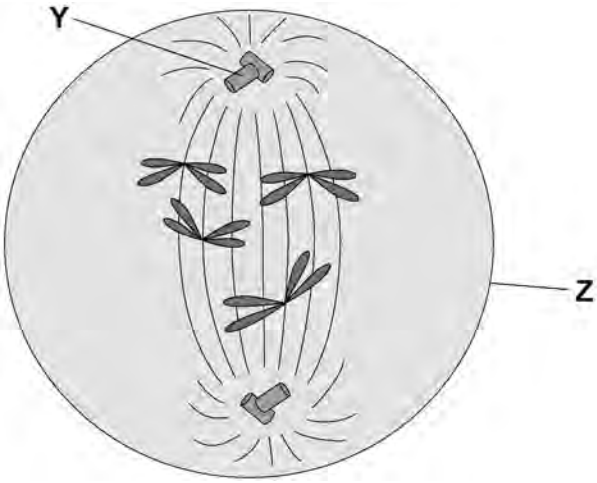
0 8 . 1 Before a cell begins to divide, its DNA replicates to form two copies of each chromosome.

Describe **one other** change that occurs in a cell **before** the cell begins to divide.

[1 mark]

Figure 8 shows a cell during one of the stages of cell division.

Figure 8



0 8 . 2 Name structure **Z** in **Figure 8**.

[1 mark]

4.3.1.9 Discovery and development of drugs

Question 27 · continued

0 8 . 3 Structure **Y** in **Figure 8** is a cylinder.

For structure **Y**:

- real volume = 24 500 000 nm^3
- real radius = 125 nm.

The length of a cylinder is calculated using the equation:

$$\text{length} = \frac{\text{volume}}{\pi \times \text{radius}^2}$$

The length of the image of structure **Y** in **Figure 8** is 4 mm.

Calculate the magnification of structure **Y** in **Figure 8**.

Use $\pi = 3.14$

[6 marks]

Magnification = × _____

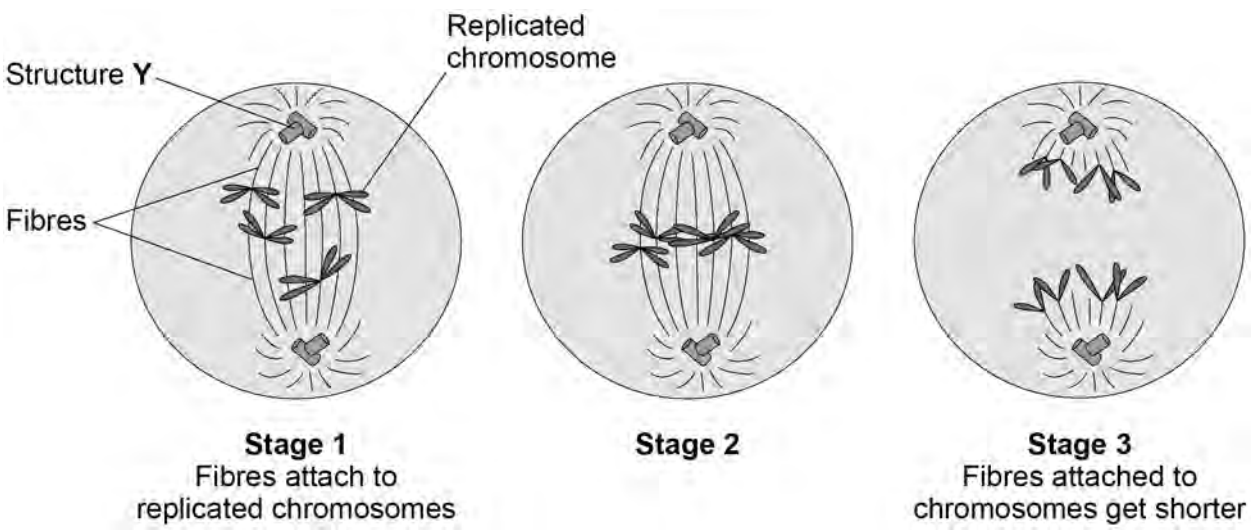
Question 8 continues on the next page

4.3.1.9 Discovery and development of drugs

Question 27 · continued

Figure 9 shows some of the stages of cell division.

Figure 9



Some cancer drugs prevent cell division.

Drug **X** prevents the fibres from attaching to the replicated chromosomes in **stage 1**.

0 8 . 4 Explain why a cell **cannot** complete division when affected by drug **X**.

[2 marks]

4.3.1.9 Discovery and development of drugs

Question 27 · continued

0 8 . 5 Give the reason why a drug that stops cell division helps to treat cancer.

[1 mark]

0 8 . 6 New cancer drugs are tested in clinical trials.

Preclinical testing happens before clinical trials.

What is involved in preclinical testing of drugs?

[1 mark]

Tick (✓) **one** box.

- Testing the drugs for side effects ☐
- Testing the drugs on live tissues in a laboratory ☐
- Testing the drugs to find the optimum dose ☐
- Testing the drugs with chemicals in a laboratory ☐

12

4.3.1.9 Discovery and development of drugs

Question 28

June 2025 | 8461/2H | Original Q9

0 9 Type 2 diabetes is a condition that has become more common in recent years.

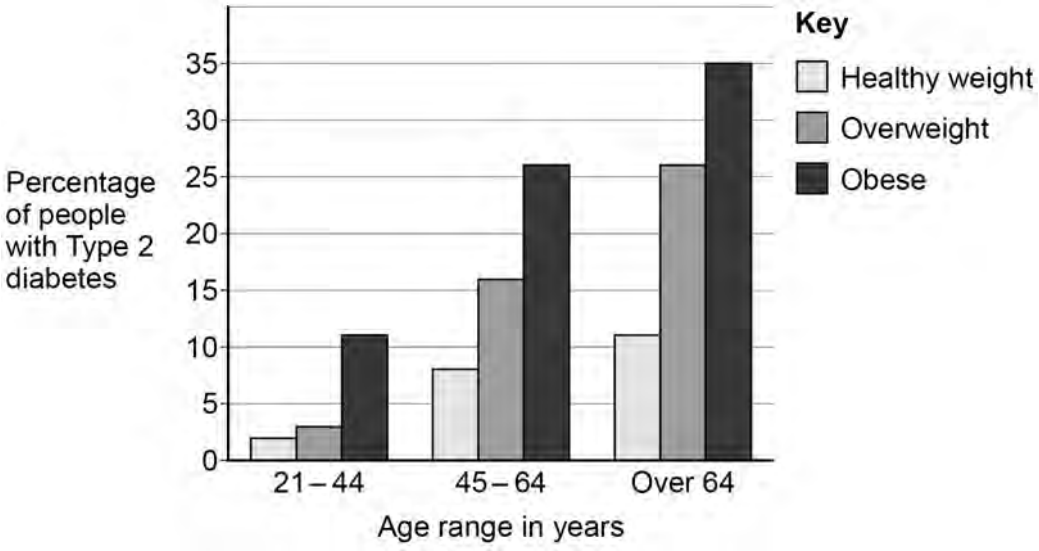
0 9 . 1 Scientists recorded the percentage of people of different ages who had Type 2 diabetes.

The people were in different weight categories:

- healthy weight
- overweight
- obese.

Figure 10 shows the results.

Figure 10



Give **two** conclusions from the results in **Figure 10**.

[2 marks]

1 _____

_____

2 _____

_____

Question 9 continues on the next page

Question 28 · continued

Two groups of scientists investigated the use of different drugs to treat Type 2 diabetes.

In both investigations, the scientists measured the percentage of haemoglobin with glucose attached (Hb-G).
This showed the long-term concentration of glucose in the blood.

Investigation 1:

The scientists injected drug **A** into 175 patients with Type 2 diabetes once each day for 12 weeks.

Table 4 shows the results.

Table 4

	Mean value	
	At start	**At 12 weeks**
Percentage (%) of haemoglobin with glucose attached (Hb-G)	9.2	7.6

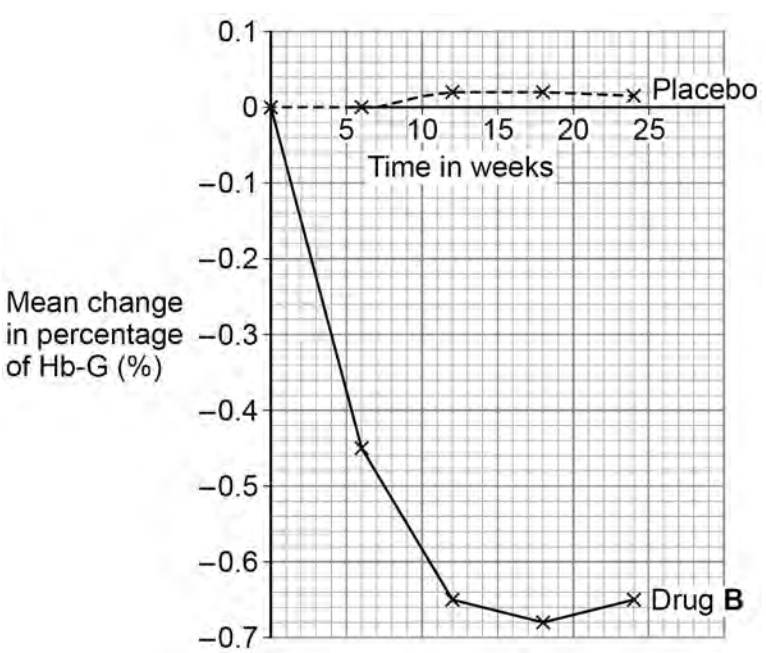
Investigation 2:

631 patients with Type 2 diabetes took one tablet containing drug **B** each day.
A control group of 630 patients took a placebo tablet each day.

The scientists measured the Hb-G in each patient's blood at the start of the investigation and at 6-week intervals up to 24 weeks.

Figure 11 shows the results.

Figure 11



4.3.1.9 Discovery and development of drugs

Question 28 · continued

0 9 . 2 For the patients treated with drug **B** the mean percentage of Hb-G at the start was 8.3%.

What was the mean percentage of Hb-G after 12 weeks for the patients treated with drug **B**?

[1 mark]

Tick (✓) **one** box.

0.65% ☐ 0.75% ☐ 7.65% ☐ 8.95% ☐

0 9 . 3 In a person **without** diabetes, the Hb-G value is between 4.5% and 6%.

When treating patients with Type 2 diabetes, doctors think that an Hb-G value <7% is acceptable.

Evaluate:

- the methods used in the investigations
- the usefulness of drug **A** and drug **B** for controlling Type 2 diabetes.

[6 marks]

Extra space

9