

B6- Organisation and the digestive system Exam Practice 2

Name:

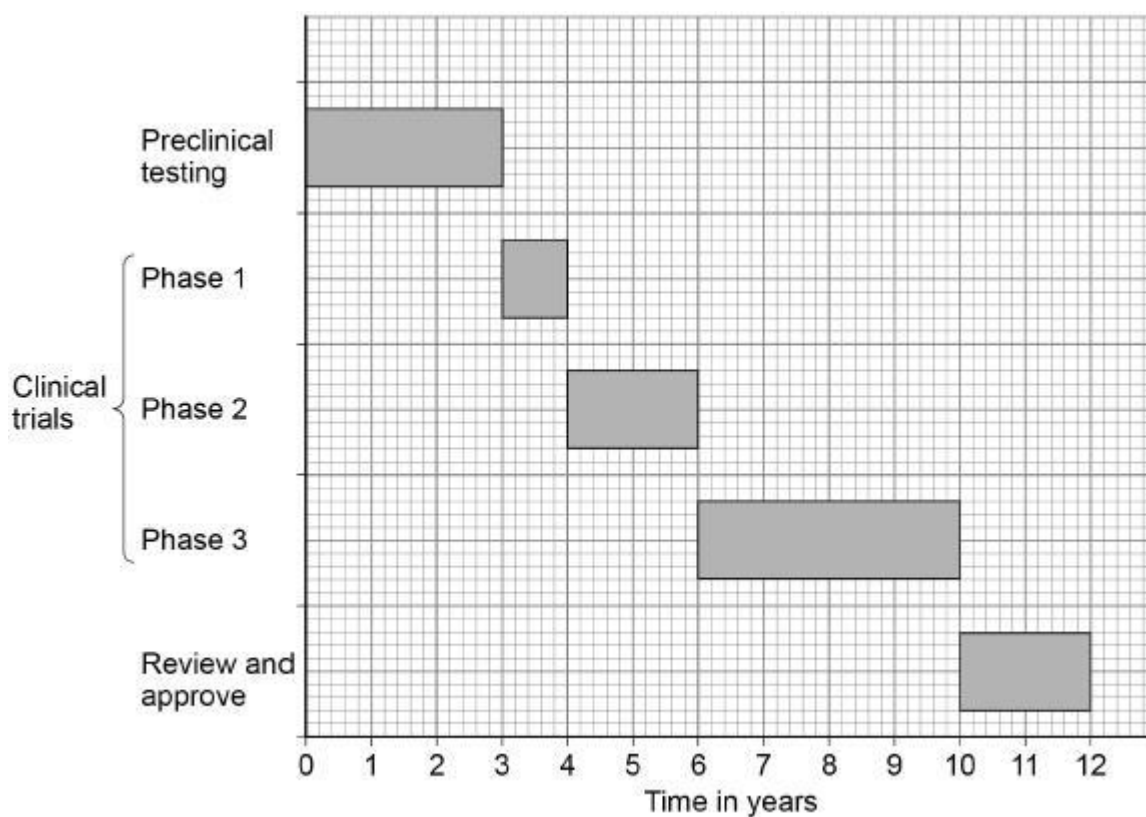
Score:

Q1.

New drugs are tested before they can be licensed for use with patients.

Figure 1 shows how much time the different stages of testing took for one new drug.

Figure 1



(a) Preclinical testing is done in a laboratory.

What is the drug tested on in a laboratory?

Give **one** example.

(1)

(b) How many years did the clinical trials take for the drug in **Figure 1**?

Time for clinical trials = _____ years

(1)

- (c) During Phase 1 clinical trials, the drug is tested on **healthy** volunteers using **low** doses.

What is the main purpose of Phase 1 testing?

Tick (✓) **one** box.

To find the best dose to use.

To see if the drug is safe to use.

To see if the drug works.

(1)

During clinical trials, half of the patients are given a placebo in a double blind trial.

- (d) What is a placebo?

(1)

- (e) Who knows which patients are given the placebo and which patients are given the drug in a double blind trial?

Tick (✓) **one** box.

Not the patients or the doctors

The patients and the doctors

The patients but not the doctors

(1)

Paracetamol and ibuprofen are two medicines used to reduce a high body temperature.

Doctors investigated which medicine was more effective at reducing high body temperature in 200 children who were ill.

The children were put into two groups, which were matched for:

- age
- gender
- body mass.

Each group had 100 children.

This is the method used.

1. Measure the body temperature of each child before any medicine is given.
2. Give children in Group 1 paracetamol.
3. Give children in Group 2 ibuprofen.
4. Measure the body temperature of each child every hour after the medicine is given.

(f) Give **two** control variables in this investigation.

1. _____
2. _____

(2)

(g) None of the children was given a placebo.

Suggest **one** reason why.

(1)

Figure 2 shows the results.

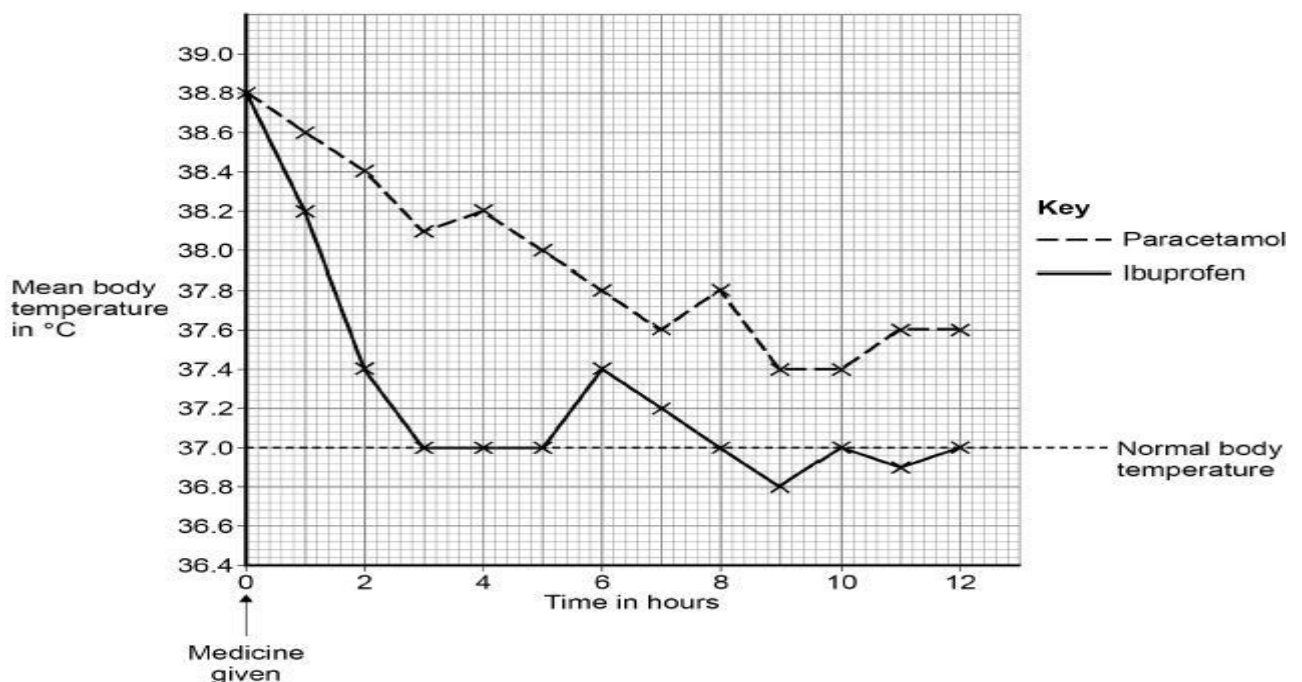


Figure 2

- (h) What was the mean body temperature after 6 hours for the children given ibuprofen?

Mean body temperature = _____ °C

(1)

- (i) The doctors concluded that children with a high body temperature should be given ibuprofen and not paracetamol.

Give **two** reasons for the doctors' conclusion.

Use **Figure 2**.

1. _____

2. _____

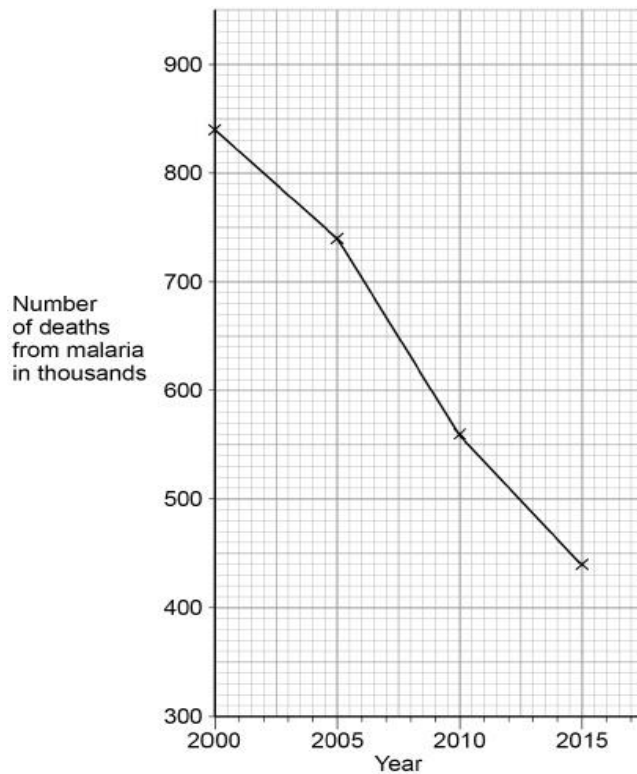
(2)

(Total 11 marks)

Q2.

Malaria is a disease transmitted by mosquitos.

The graph shows information about the number of deaths from malaria.



- (a) Calculate the decrease in the number of deaths between 2000 and 2015.

Decrease in number of deaths = _____

(2)

- (b) Which time period shows the greatest decrease in the number of deaths?

Tick (✓) **one** box.

2000 to 2005

2005 to 2010

2010 to 2015

(1)

- (c) A student looked at the graph above and concluded that there were 800 000 deaths from malaria in 2002.

Suggest **one** reason why this conclusion might **not** be correct.

(1)

- (d) What type of pathogen causes malaria?

Tick (✓) **one** box.

Bacterium

Fungus

Protist

Virus

(1)

(e) Scientists are developing a vaccine against malaria.

Suggest how a vaccine against malaria could reduce the spread of the disease.

(2)

(f) Give **one** way of controlling the spread of malaria.

Do **not** refer to a vaccine in your answer.

(1)

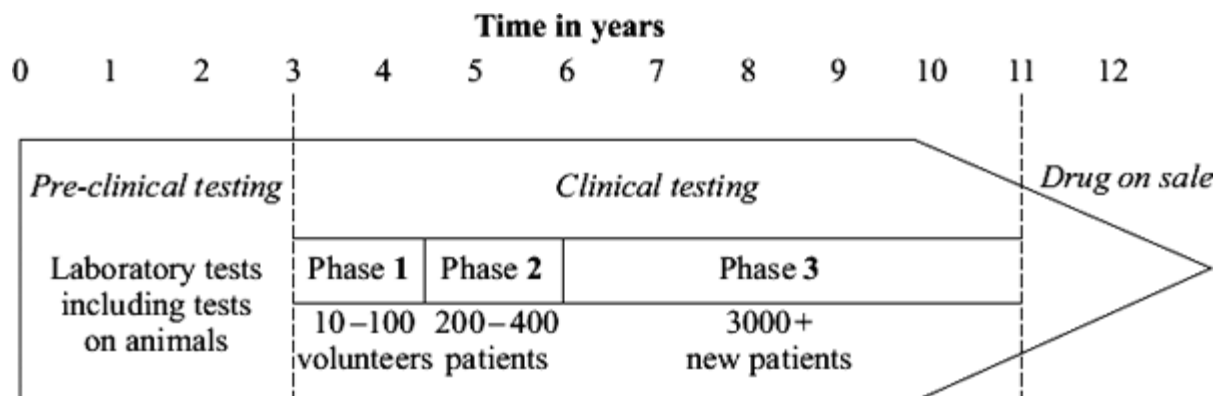
(Total 8 marks)

Higher Tier Questions

Q3.

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)

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

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

(1)

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

Suggest **one** reason for this.

(1)

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

(1)

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

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

(1)

(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

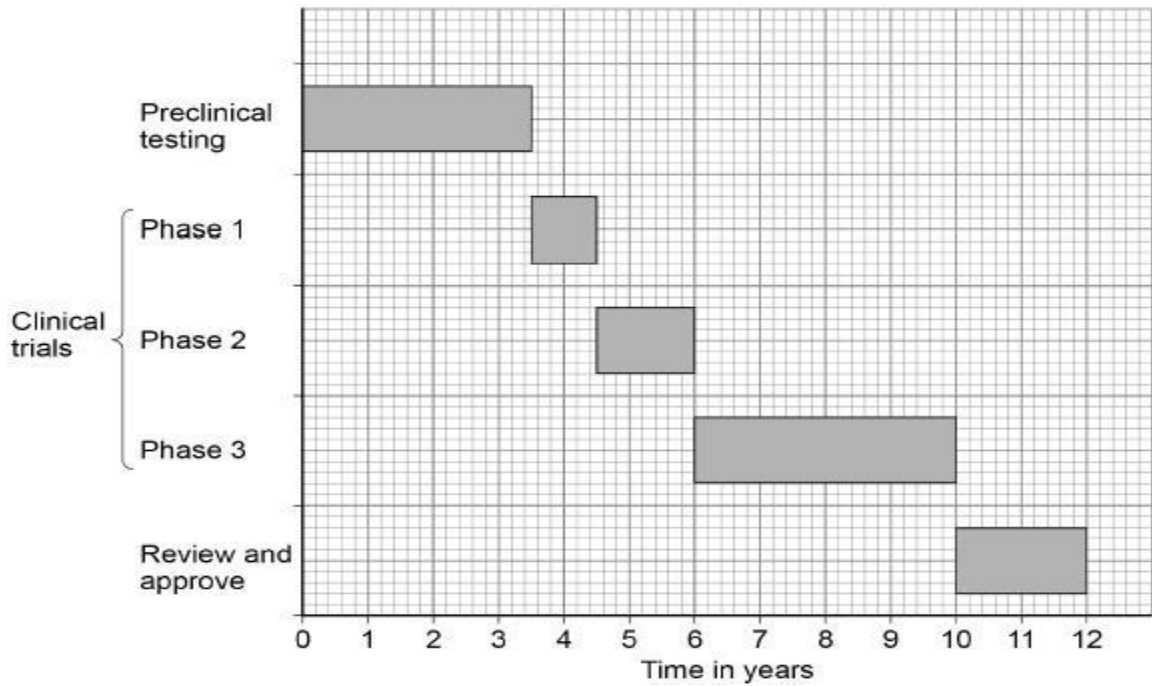
(1)

(Total 6 marks)

Q4.

New drugs are tested and trialled before they can be licensed to treat patients.

The graph below shows how much time the different stages of testing took for one new drug.



- (a) How much more time did the clinical trials take compared with the preclinical testing?

Tick (✓) **one** box.

3 years

3.5 years

5 years

6.5 years

(1)

During Phase 1 clinical trials low doses of the drug are tested on healthy volunteers.

- (b) Suggest **one** reason why **low doses** of the drug are used in Phase 1 clinical trials.

(1)

(c) Suggest **two** reasons why **healthy** volunteers are used in Phase 1 clinical trials.

1. _____

2. _____

(2)

(d) The results of clinical trials can only be published after peer review by other scientists.

Suggest **one** reason why the results must be reviewed by other scientists.

(1)

(e) A drug is only licensed for the medical conditions it was tested to treat in the clinical trials.

Drug regulations:

- control what drugs a doctor can prescribe
- ensure doctors can prescribe a drug with confidence
- protect patients.

AMD is an eye condition that can result in very poor vision.

Doctors treat approximately 40 000 new cases of AMD each year.

Two drugs licensed to treat AMD in the UK are drug **A** and drug **B**.

In many other countries drug **C** is used to treat AMD. Drug **C** is only licensed in the UK to treat cancer.

The cost per injection for each drug is:

- drug **A** £561
- drug **B** £800
- drug **C** £28

The number of injections required to treat AMD is the same for each drug.

In 2018 the High Court in the UK gave permission for drug **C** to be used to treat AMD.

Mark schemes

Q1.

- (a) any **one** from:
- (live) cells
 - (live) tissues
 - (live) animals
- allow examples , eg mice / rats*
- 1
- (b) 7 / seven (years)
- 1
- (c) to see if the drug is safe to use
- 1
- (d) tablet that does not contain the drug / active ingredient
- allow a sugar pill*
allow a fake drug
- 1
- (e) not the patients or the doctors
- 1
- (f) any **two** from:
- age
 - gender
 - body mass
 - number of children (in group)
- or**
- 100 in group
 - time (after taking medicine) when temperature was measured
- allow all (children had a) high body temperature (at the start)*
allow dose of drug / medicine
ignore temperature unqualified
- 2
- (g) any **one** from:
- unethical not to treat ill children
 - children were ill so had to be treated
 - children may become more ill if no drug given
- 1
- (h) 37.4 (°C)
- 1
- (i) any **two** from:
- reduced (body) temperature faster
allow converse arguments
 - decreased (body) temperature more
 - reduced (body) temperature to normal / 37 °C

*allow paracetamol did **not** reduce (body) temperature to normal*

- maintained normal (body) temperature / 37 °C for longer **or** for several hours

2

[11]

Q2.

(a)

an answer of 400 000 scores 2 marks

840 000 – 440 000

allow tolerance of +/- half a small square

allow 840 – 440 = 400

1

400 000

1

(b) 2005 to 2010

1

(c) any **one** from:

- data not collected (for 2002)
- only shows a trend line
- not all deaths reported / recorded

allow no data plotted for 2002

1

(d) protist

1

(e) makes people immune

or

they do not develop the disease

allow ecf from part (d)

allow correct description of immunity

1

(so) fewer (infected) people to pass pathogen on (to mosquitos)

allow idea of disrupting life cycle of parasite

1

(f) any **one** from:

- (mosquito) nets / long clothing
- prevent mosquitos breeding

- insect repellents
- anti-malarial tablets

- kill mosquitos

allow specific method e.g. drain swamps, release GM mosquitos

allow DEET / mosquito band

allow names e.g. Larium / Malarone
allow antibiotics

1

[8]

Higher Tier Mark Scheme

Q3.

- (a) testing for toxicity / see if it is safe / see if it is dangerous / to see if it works
ignore side effects unqualified 1
- (b) (i) testing for side effects / testing for reactions (to drug)
ignore to see if it works
*do **not** accept dosage* 1
- (ii) any **one** from
ignore immune system
- dose too low to help patient
 - higher risk for patient
 - might conflict with patient's treatment / patient on other drug
 - effect might be masked by patient's symptoms / side effects clearer 1
- (c) to find optimum dose
*allow testing on larger sample **or** it makes results more reliable*
allow to find out if drug is effective / find out if drug works on ill people (not just if drug works) 1
- (d) (i) (tablet / drug / injection) that does not contain drug
allow control / fake / false
allow tablet / injection that does not affect body
*do **not** accept drug that does not affect body* 1
- (ii) neither patients nor doctors 1

[6]

Q4.

- (a) 3 years 1
- (b) any **one** from:
- to reduce any risk
allow idea (if it is unsafe) less harm will be

*caused with a lower dose
ignore that it may be unsafe / dangerous
unqualified*

- to look for side effects
ignore unknown side effects unqualified

1

- (c) too great a risk for ill person / patient
*allow may make their condition worse
allow less risk to healthy person
ignore references to immune system*

1

patient might be taking another drug
*allow unhealthy person might be taking another
drug*

or
side effects of drug are easier to identify
ignore to see side effects unqualified

1

- (d) any **one** from:
- to prevent false claims
 - to make sure the results / conclusions are correct / valid
*ignore references to accuracy, reliability or
precision*
 - to avoid bias

1

- (e) **Level 3:** A judgement, strongly linked and logically supported by a sufficient range of correct reasons, is given.

5-6

Level 2: Some logically linked reasons are given. There may also be a simple judgement.

3-4

Level 1: Relevant points are made. They are not logically linked.

1-2

No relevant content

0

Indicative content

arguments for use:

- will save the NHS money
- (approximately) 20 times as many people or 19 more people can be treated compared to Drug A
- (approximately) 29 times as many people can be treated compared to Drug B (allow 28 times **or** 28 / 27 more people)
- more people can be treated for the same cost
- patients will be treated sooner
- improves patient choice
- used in other countries so likely to be effective
- used in other countries so likely to be safe

- likely to have been tested in other countries

arguments against use:

- injections of drug not tested (in UK)
- cannot be sure it is as effective as Drug A / Drug B
- cannot be sure if it is safe to use
- may have unknown side effects
- doctors cannot be confident in prescribing Drug C
- goes against regulations / laws regulating drug development / use
- might set a precedent for other drugs not to be fully tested
- might set a precedent for other non- approved / unlicensed drugs to be used

Need advantages and disadvantages for Level 2

[11]