

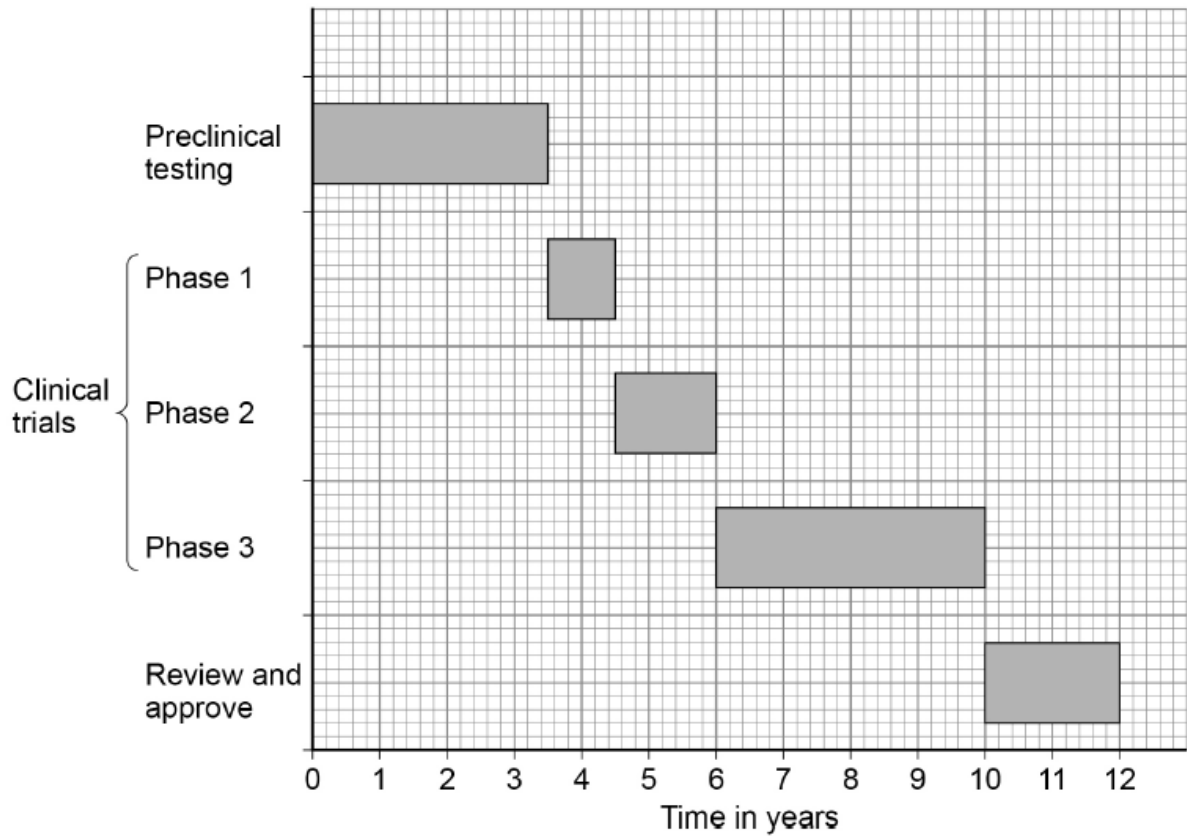
Monoclonal antibodies – GCSE Combine Science Biology

1. No.6

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

Figure 6 shows how much time the different stages of testing took for one new drug.

Figure 6

0 6 . 1

How much more time did the clinical trials take compared with the preclinical testing? [1 mark]

Tick (✓) one box.

3 years

☐

3.5 years

☐

5 years

☐

6.5 years

☐

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

- 0 6 . 2 Suggest **one** reason why **low doses** of the drug are used in Phase 1 clinical trials. [1 mark]

- 0 6 . 3 Suggest **two** reasons why **healthy** volunteers are used in Phase 1 clinical trials. [2 marks]

1

2

- 0 6 . 4 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 mark]

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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.

Evaluate the decision to allow the use of drug **C** to treat AMD in the UK.

[6 marks]
