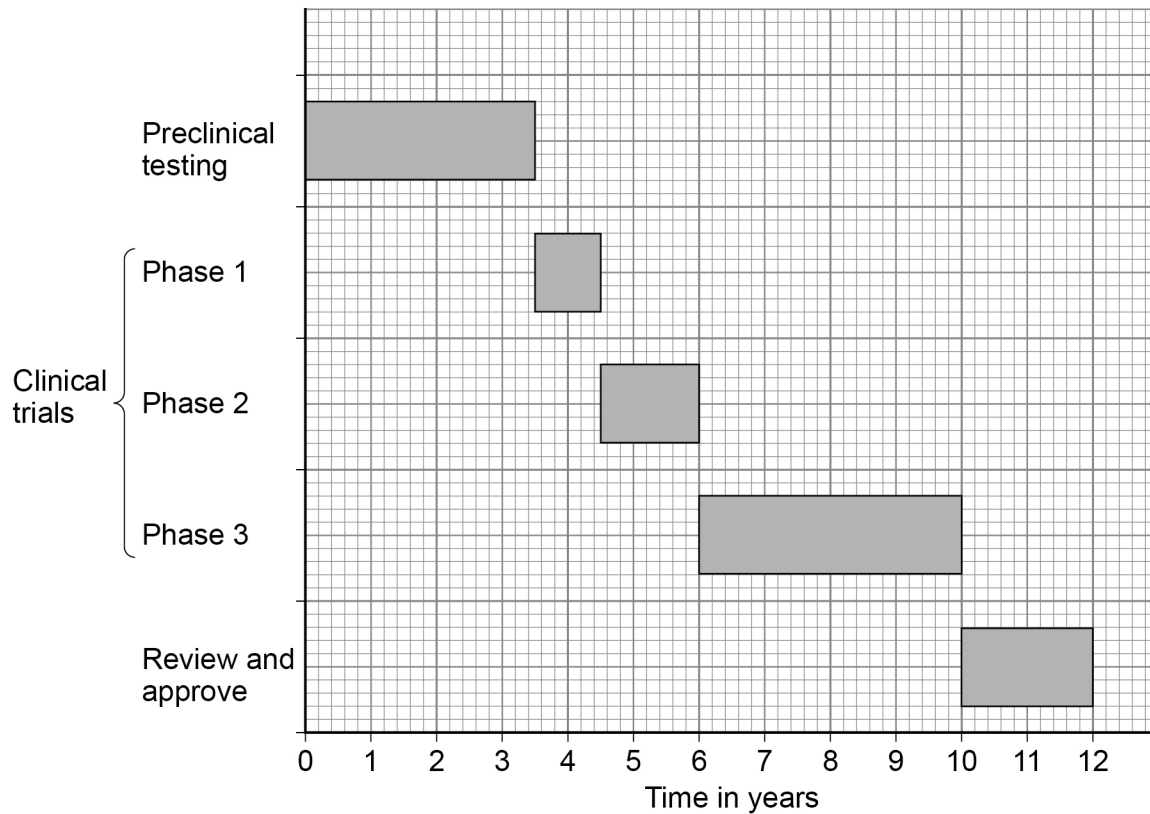


0 6

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]**

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**0 6 . 3** Suggest **two** reasons why **healthy** volunteers are used in Phase 1 clinical trials.

**[2 marks]**

1 

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2 

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**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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**Question 6 continues on the next page**

**Turn over ►**



06.5

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.





Question	Answers	Extra information	Mark	AO / Spec. Ref.
06.1	3 years		1	AO2 4.3.1.9
06.2	any <b>one</b> from: <ul style="list-style-type: none"> <li>• to reduce any risk</li>   <li>• to look for side effects</li> </ul>	allow idea (if it is unsafe) less harm will be caused with a lower dose ignore that it may be unsafe / dangerous unqualified  ignore unknown side effects unqualified	1	AO1 4.3.1.9
06.3	too great a risk for ill person / patient  patient might be taking another drug <b>or</b> side effects of drug are easier to identify	allow may make their condition worse allow less risk to healthy person ignore references to immune system  allow unhealthy person might be taking another drug  ignore to see side effects unqualified	1  1	AO2 4.3.1.9
06.4	any <b>one</b> from: <ul style="list-style-type: none"> <li>• to prevent false claims</li> <li>• to make sure the results / conclusions are correct / valid</li> <li>• to avoid bias</li> </ul>	ignore references to accuracy, reliability or precision	1	AO2 4.3.1.9

Question	Answers	Mark	AO / Spec.
06.5	<b>Level 3:</b> A judgement, strongly linked and logically supported by a sufficient range of correct reasons, is given.	5–6	AO3 4.3.1.9
	<b>Level 2:</b> Some logically linked reasons are given. There may also be a simple judgement.	3–4	
	<b>Level 1:</b> Relevant points are made. They are not logically linked.	1–2	
	<b>No relevant content</b>	0	
	<p><b>Indicative content</b></p> <p><b>arguments for use:</b></p> <ul style="list-style-type: none"> <li>• will save the NHS money</li> <li>• (approximately) 20 times as many people or 19 more people can be treated compared to Drug A</li> <li>• (approximately) 29 times as many people can be treated compared to Drug B (allow 28 times <b>or</b> 28 / 27 more people)</li> <li>• more people can be treated for the same cost</li> <li>• patients will be treated sooner</li> <li>• improves patient choice</li> <li>• used in other countries so likely to be effective</li> <li>• used in other countries so likely to be safe</li> <li>• likely to have been tested in other countries</li> </ul> <p><b>arguments against use:</b></p> <ul style="list-style-type: none"> <li>• injections of drug not tested (in UK)</li> <li>• cannot be sure it is as effective as Drug A / Drug B</li> <li>• cannot be sure if it is safe to use</li> <li>• may have unknown side effects</li> <li>• doctors cannot be confident in prescribing Drug C</li> <li>• goes against regulations / laws regulating drug development / use</li> <li>• might set a precedent for other drugs not to be fully tested</li> <li>• might set a precedent for other non- approved / unlicensed drugs to be used</li> </ul> <p>Need advantages and disadvantages for Level 2</p>		
<b>Total</b>		<b>11</b>	