1. Fungal allergens are carried mainly on fungal spores. Air samples taken in late summer and autumn (July to October) have the highest levels of fungal spores.

As part of a study, hospital admissions for asthma in different seasons for people in two different age groups were investigated.

The results are shown in Fig. 1.2.

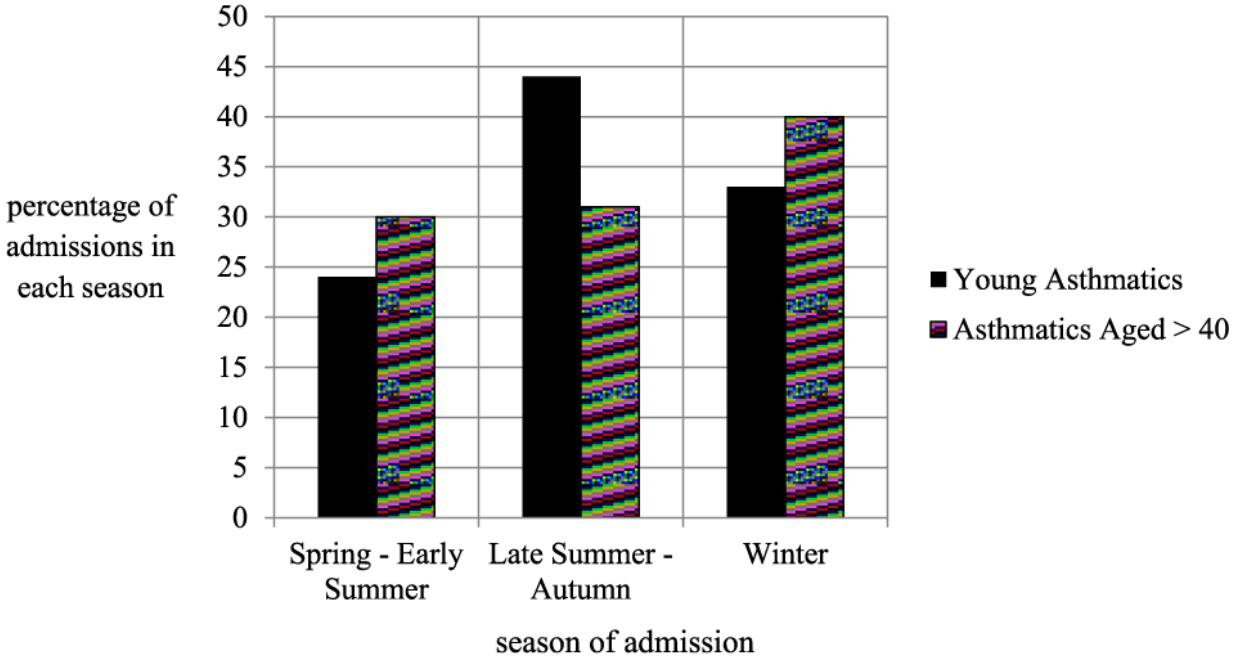


Fig. 1.2

(i) Asthma attacks are not only caused by fungal allergens. Severe asthma attacks during winter months, for example, are frequently associated with respiratory tract infections.

Suggest what other allergen might be responsible for severe asthma attacks during spring and early summer.

---

[1]

(ii) By analysing the information in Fig. 1.2, what can you conclude about the effects of different allergens on asthma attacks in different age groups at different times of the year?

---

[4]

2. Asthma is a chronic respiratory condition that causes approximately 250 000 deaths per year worldwide.

Different types of medication are used to treat asthma:

- fast-acting medication treats asthma attacks
- slow-acting medication controls asthma in the long-term.

Name **one** type of fast-acting and **one** type of slow-acting medication used for treating asthma and explain how each medication helps to relieve the symptoms of asthma.

fast-acting medication _____

explanation _____

slow-acting medication _____

explanation _____

[4]

3. Chronic myeloid leukemia (CML) is a type of blood cancer.

What is a chronic disease?

[1]

4(a). Kartagener syndrome is a genetic disorder that affects the respiratory system.

Children born with Kartagener syndrome commonly have the following symptoms:

- mucus retention
- recurrent infections of the respiratory system
- respiratory distress.

Suggest **one** reason why children with Kartagener syndrome may have '*mucus retention*' and **one** reason why they may have '*recurrent infections of the respiratory system*'.

reason for '*mucus retention*' _____

reason for '*recurrent infections of the respiratory system*' _____

[2]

(b). Spirometry measurements can be used to monitor respiratory disorders such as Kartagener syndrome.

Fig. 5.2 shows spirometry measurements taken during exhalation for a normal person and for a person with a respiratory disorder.

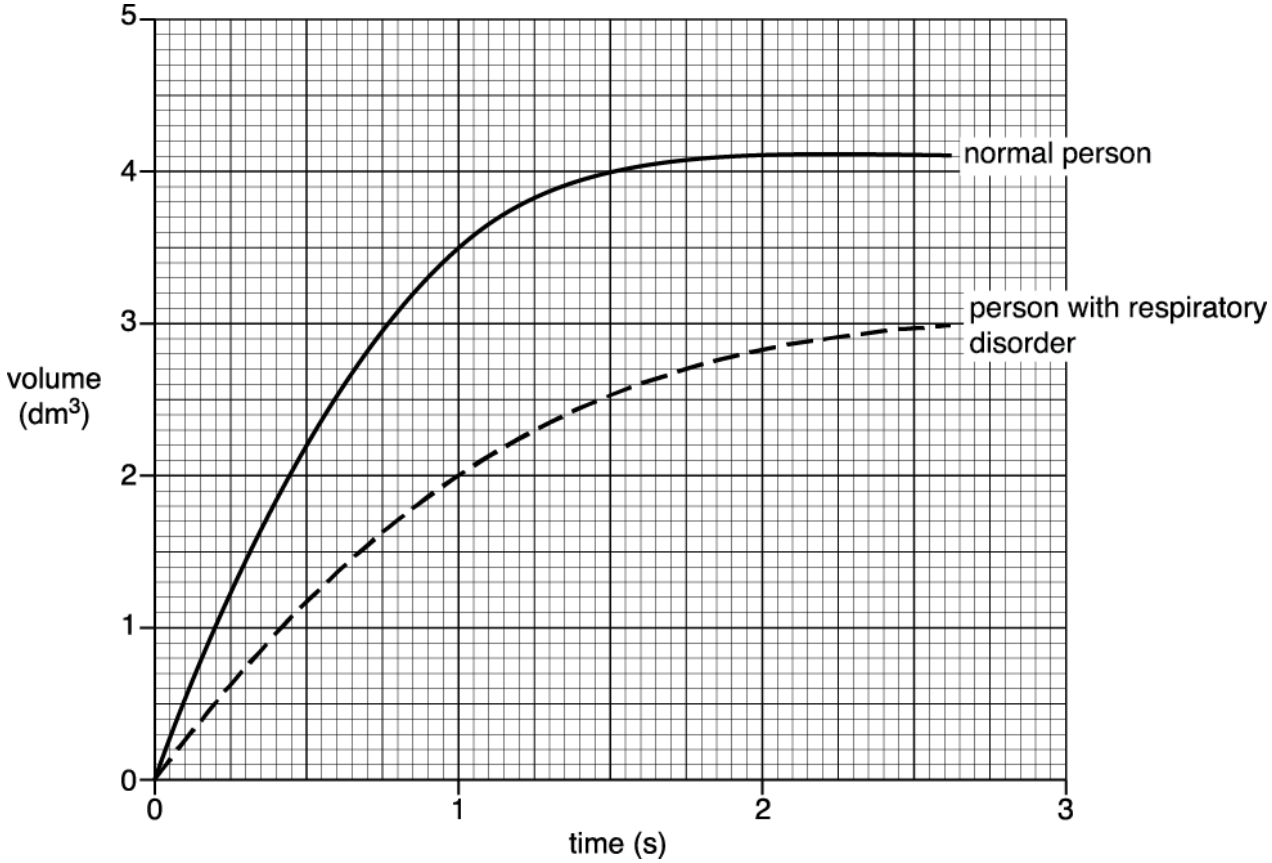


Fig. 5.2

(i) Using the information shown in Fig. 5.2, state the FEV^1 measurement for each person.

Explain the reason for the difference between the two FEV^1 measurements.

FEV^1 normal person _____ $dm^3\ s^{-1}$

FEV^1 person with respiratory disorder _____ $dm^3\ s^{-1}$

Explanation _____

_____

---

[2]

(ii) Suggest why FEV^1 measurements should be taken at least four times per year for people with respiratory disorders such as Kartagener syndrome.

---

[1]

5. Plants are used in traditional medicine in many countries.

The Hausa and Fulani tribes of West Africa use the leaves of the shrub *Vismia guianensis* in their traditional folk medicine. Recent research indicates that *Vismia guianensis* may have antimicrobial properties.

Suggest **two** advantages of researching plants already known to work in traditional folk medicine when attempting to find sources of medicinal drugs.

---

[2]

6(a). Tobacco smoking is the cause of approximately 25% of all deaths from cancer in the UK and has killed millions of people over the last 50 years.

Table 3.1 shows the relative risk of lung cancer based on two variables:

- the number of years a person has smoked cigarettes
- the number of cigarettes smoked per day.

Number of years smoking	Relative risk of lung cancer		
	<10 cigarettes smoked	10–19 cigarettes smoked	20+ cigarettes smoked
<20	0.9	2.6	1.3
20–29	1.4	2.3	2.8
30–39	4.3	6.0	10.9
40–49	5.7	16.2	12.6
50+	17.6	22.6	41.0

Table 3.1

(i) Using the information in Table 3.1, calculate the percentage increase in relative risk of lung cancer when smoking 20+ cigarettes per day for 30–39 years compared to smoking fewer than 10 cigarettes per day for 30–39 years.

Show your working.

Answer = _____ %

[2]

(ii) Suggest an explanation for the trends shown in Table 3.1.

_____

_____

_____

_____

---

[3]

(iii) A student examining the data in Table 3.1 made the following statement:

"*The number of cigarettes you smoke per day doesn't affect your risk of developing lung cancer*."

Suggest one piece of evidence that supports the statement **and** one piece of evidence that does not support the statement.

evidence supporting the statement

---

evidence not supporting the statement

---

[2]

(b). Chronic bronchitis is another lung disease that can be caused by smoking cigarettes.

Describe how cigarette smoke leads to the development of chronic bronchitis **and** how this reduces the rate of gas exchange in the lungs.

In your answer you should give a balanced account of the development of bronchitis and its effect on gas exchange.

[8]

7. TIC10 is a promising anti-cancer drug that has been tested on mice.

It may be years before TIC10 can be used to treat cancer in humans.
The drug will first need to undergo clinical trials.

(i) Outline the role of NICE (National Institute for Health and Clinical Excellence) after a drug has undergone clinical trials.

---

[2]

(ii) TIC10 causes apoptosis in cancerous cells but not in healthy cells.

Complete the following passage, which describes how apoptosis works.

Apoptosis is triggered by extracellular and intracellular signals. Enzymes break down the cell's cytoskeleton.

The _____ condenses in a process known as pyknosis and then it fragments. The

_____ forms bulges called blebs. The cell breaks into vesicles. Macrophages

recognise and engulf the vesicles by _____.

[3]

8(a). Asthma and asbestosis are both chronic inflammatory diseases that affect the respiratory system.

(i) Name **two** cells other than macrophages that are responsible for the inflammatory response occurring in diseases such as asthma.

1

2

---

[2]

(ii) Explain why asthma could be considered an example of a specific immune response.

---

[1]

(b). Asbestosis occurs when asbestos fibres are engulfed by macrophages. Macrophages then stimulate an inflammatory response and the production of fibrous tissues in the region.

Other diseases associated with asbestos fibres are lung cancer and mesothelioma. Mesothelioma is a cancer of the tissue covering the surface of the lungs.

Table 5.1 shows the length of fibres in different types of asbestos.

Type of asbestos	Length of fibre (μm)
White	< 5
Blue	5–10
Brown	5–10

Table 5.1

Table 5.2 shows the relationship between the size of asbestos fibres and the disease caused.

Disease induced by asbestos	Length of fibre (μm)	Width of fibre (μm)
Asbestosis	> 2 μm	> 0.15 μm
Mesothelioma	> 5 μm	< 0.1 μm
Lung cancer	> 10 μm	< 0.15 μm

Table 5.2

White asbestos fibres can have diameters up to 1 μm and tend to be wider than blue or brown asbestos fibres.

What do you conclude about the relationship between the type of asbestos and the risk of an asbestos-induced disease? Justify your conclusion.

---

[2]

9. The passage below describes some of the research into the use of beetroot products for the treatment of obesity.

> Chronic inflammation is often associated with obesity.
>
> Beetroot extracts have been investigated as potential anti-inflammatory agents. Some of their effects seem to be in interfering with the cell signalling cascades that initiate, regulate and amplify the inflammatory response.
>
> In particular betalain pigments, such as betanin, in beetroot have been shown to interfere with the action of cytokines.

(i) Describe the inflammatory response.

---

[3]

(ii) Using your knowledge, suggest how betalain pigments could interfere with the action of cytokines.

---

[1]

10. The symptoms of asthma can be triggered by allergens.

The table below shows information about two types of drug that are used in inhalers to treat the symptoms of asthma.

Complete the table by inserting a tick (✓) or a cross (×) as appropriate for each drug.

Drug	Reduce inflammation of the bronchi	Widen the lumen of the bronchi	Can be used during an acute asthma attack
Corticosteroids			
Beta-agonists			

[2]

11(a). Quinine is a drug that occurs naturally in the bark of cinchona trees. It is used to treat malaria caused by the parasite, *Plasmodium falciparum*, which infects human erythrocytes.

- The medicinal properties of cinchona bark were first realised by the Quechua people of South America
- The use of cinchona bark in treating fever was documented in Europe during the 17th century.
- In the 1800s, researchers isolated quinine from cinchona bark and identified it as the medicinally active compound.

(i) Suggest why researchers concentrated on studying cinchona bark when looking for a treatment for malaria.

---

[2]

(ii) Quinine interferes with the ability of *P. falciparum* to completely digest haemoglobin resulting in the death of the parasite.

Suggest how incomplete digestion of haemoglobin results in the death of *P. falciparum.*

---

[2]

(b). Quinine has been used to treat muscle cramps associated with a neurological condition known as restless leg syndrome. A clinical trial to assess the effectiveness of quinine in treating restless leg syndrome was carried out on a large number of volunteers divided into two groups. One group was given oral quinine and the other group was given a placebo.

(i) Explain what is meant by a placebo in this context.

---

[1]

(ii) Describe how the volunteers could have been allocated to each group for this trial.

---

[2]

(c). The dose required to treat a patient with malaria using oral quinine is 10 mg kg^{-1} every eight hours.

Calculate the mass of quinine required in the first four days of treatment for a patient who weighs 75 kg.

---

g **[2]**

12(a). Drugs must be evaluated for safety and effectiveness in clinical trials before they are licensed for the treatment of specific diseases.

A clinical trial was conducted to investigate the effect of a drug on blood glucose levels in patients with type 2 diabetes. Blood glucose levels can be monitored by measuring glycosylated (or glycated) haemoglobin (HbA_{1C}).

- Sixty patients with untreated type 2 diabetes were recruited.
- HbA_{1C} levels were measured before the trial began.
- The patients were divided into two groups.
- One group received daily drug treatment and the other group received a daily placebo.
- After three months, HbA_{1C} levels were measured and changes from pre-trial measurements were calculated.

Fig. 35 shows the results of the trial. The boxes show the mean change in HbA_{1C} levels after three months and the error bars represent standard deviations.

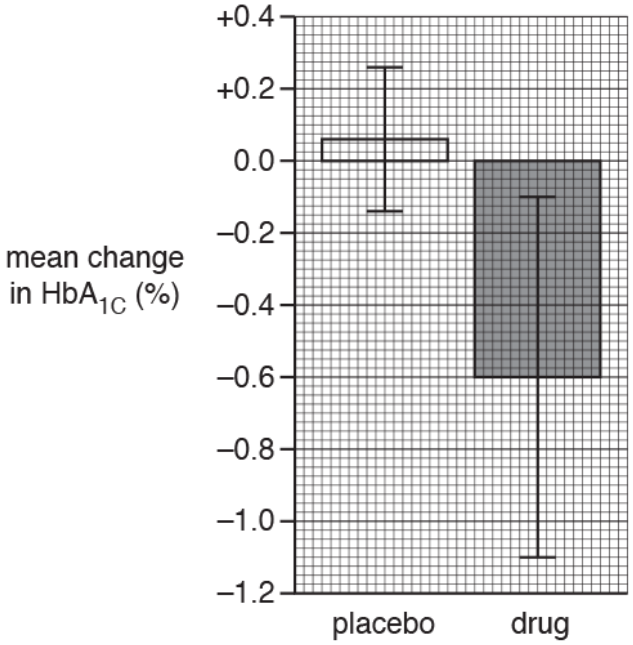


Fig. 35

(i) State the **phase** of the clinical trial in which the data in Fig. 35 were obtained.

---

[1]

(ii) Describe what a placebo is **and** explain why it was used.

---

[2]

(iii) Compare the results shown in Fig. 35 for the group receiving the placebo with the group receiving the drug.

---

[3]

(iv) Suggest **two** reasons why this trial does **not** support the use of the drug in the treatment of type 2 diabetes.

1 ---

---

2 ---

---

[2]

(b). This question is about the development of medicines.

(i) What are the features of a chronic disease?

---

[1]

(ii) Over half of commonly-used drugs are similar or identical to chemicals found in plants.

Name **one** such drug and state its medical use.

Drug ---

Medical use ---

[1]

13. In 2015, a trial was conducted in Guinea, Africa to test the effectiveness of the vaccine rVSV-ZEBOV against the Ebola virus.

- Researchers wanted to save as many lives as possible, so ring vaccination was used during the trial instead of a placebo.
- In communities where at least one new case of the disease had been reported, 7651 participants were randomly assigned to one of two groups.
- Group one were vaccinated immediately after Ebola was reported.
- Group two were vaccinated ten days after group one.
- The incubation time for the Ebola virus is ten days.

Results showed that there were no new cases of Ebola among the 4123 people in group one and 16 cases among the 3528 people in group two.

(i) What was the purpose of **group two** in this trial?

____ [1]

(ii) Discuss the ethical issues related to this trial.

____

____

____

____ [2]

(iii) Using the information, evaluate the effectiveness of the rVSV-ZEBOV vaccine.

____

____

____

____ [2]

14(a). During a clinical trial, the number of abnormal white blood cells (blasts) was recorded over a period of time for two patients, **F** and **G**, who were being treated with Imatinib. Both patients had received alternative therapies before starting treatment with Imatinib.

Fig. 24.2(a) and Fig. 24.2(b) show the results of the clinical trial

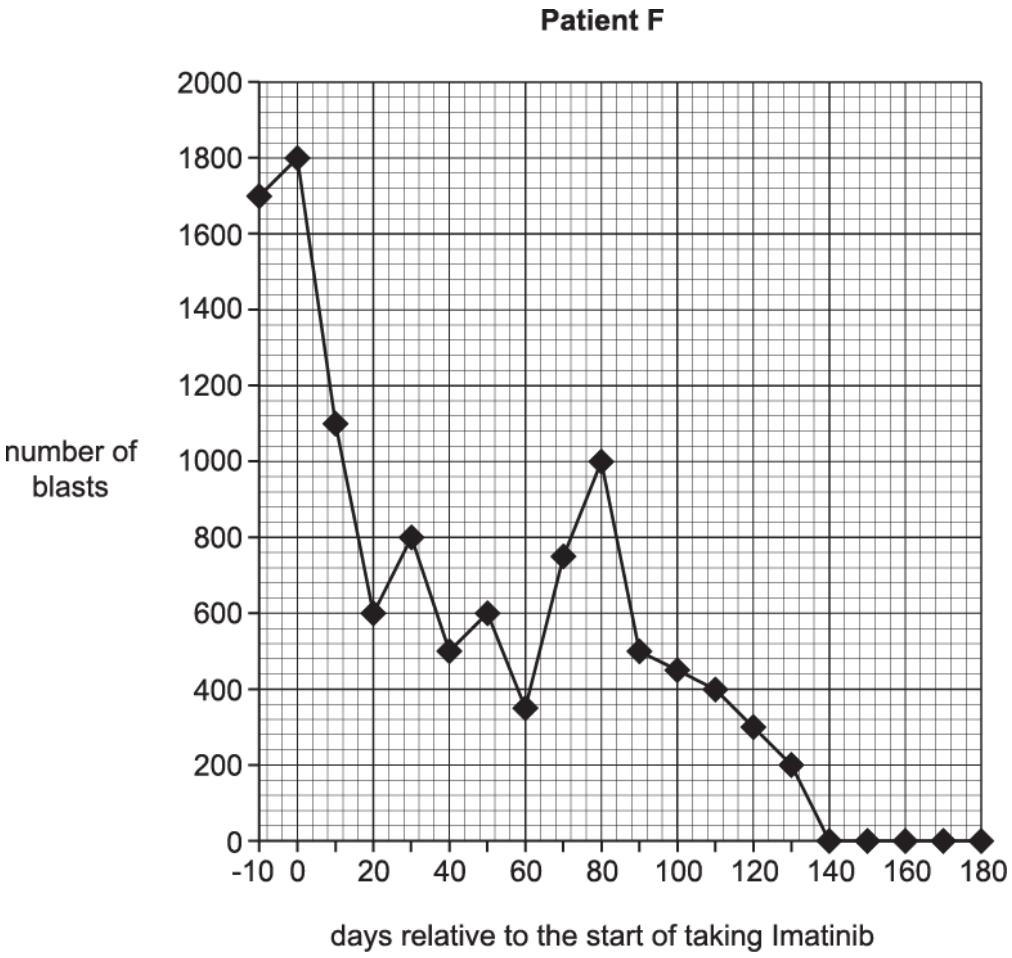


Fig. 24.2(a)

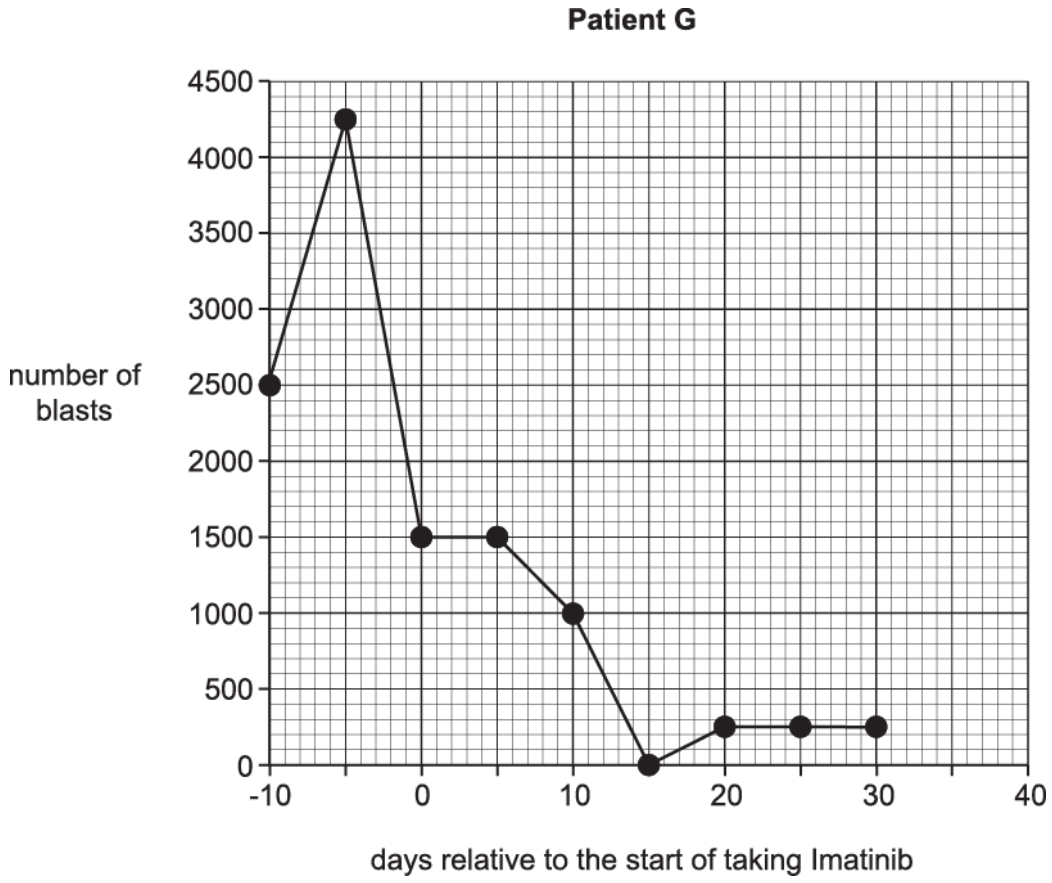


Fig. 24.2(b)

(i) Calculate the percentage reduction in blasts for patient G from the day treatment with Imatinib **started** to the end of the trial.

Show your working. Give your answer to **three significant figures**.

Answer = _____ **% [2]**

(ii) Suggest why different scales were used on **both** axes for the two patients.

_____

_____

_____

_____ **[1]**

(b). Chronic myeloid leukemia (CML) is a type of blood cancer.

CML can be treated using the targeted therapy drug Imatinib, also known as Glivec®.

During clinical tests, a phase 3 trial found that almost 90% of CML patients treated with Imatinib showed no further progression of the disease.

What is meant by a phase 3 trial?

---

[2]

15. Alzheimer's is a neurological disorder. A potential new drug treatment for Alzheimer's has entered clinical trials. The drug has passed the phase 2 trial in which it was tested on 50 patients.

A brief summary of the plan for phase 3 of the trial is as follows:

- The new drug is compared to the best treatment currently available.
- 70 patients receive the new drug in total, 35 from hospital A and 35 from hospital B.
- A placebo is not used.
- Blind trials are used.

(i) Discuss aspects of the planned phase 3 clinical trial and explain how each aspect is likely to affect the validity of the results.

---[3]

(ii) State **two** possible causes of Alzheimer's.

1

2

---[2]

END OF QUESTION PAPER

Question			Answer/Indicative content	Marks	Guidance
1		i	(Allergy to) pollen (1)	1	
		ii	*idea that* more asthma attacks in young people in late summer / autumn (1) *idea that* main trigger in young people is fungal spores (1) *idea that* asthma in adults higher in winter and spring (1) due to (more) infections (winter) or pollen (spring) (1) ref other allergens / named allergens not being seasonal (1)	3	ALLOW references to dust mites
		ii	Manipulation of data in support of any point (1)	1	
			Total	**5**	
2			*Fast-acting*: beta agonists; *Explanation*: relax muscles in the airways / (act as) bronchodilators; *Slow-acting*: steroids; *Explanation*: reduce inflammation (in the airways);	4	IGNORE prompt lines ACCEPT correct examples of named beta-agonists ACCEPT correct examples of named steroid(s) ECF for mp2 and mp4 Examiner's Comments This was well answered although a number of candidates mixed up the slow-acting and fast-acting medications. Many candidates referred to brown and blue inhalers in the context of the medication but clearly related this to the correct explanation. Some candidates confused the term bronchodilator with vasodilator.
			Total	**4**	

Question			Answer/Indicative content	Marks	Guidance
3			a disease that, has a slow onset / has symptoms that worsen over time / lasts a long time ✓	1	IGNORE caused by pathogens or may be incurable Examiner's Comments This question addressed mainly AO1 and AO2. Candidates were required to demonstrate their mathematical skills by performing a percentage decrease calculation. The diagram was well answered and many candidates were able to describe the meaning of the term *'chronic disease'*.
			Total	1	
4	a		*reason for mucus retention* cilia not functioning correctly / AW OR goblet cells producing too much mucus; *reason for recurrent infections of respiratory system* bacteria / pathogens / viruses / microorganisms are not removed;	2	e.g. ciliated cells damaged / cilia missing / fewer cilia / fewer or no ciliated cells Examiner's Comments Most candidates were able to answer this part in terms of changes to the ciliated epithelial cells.
	b	i	FEV_1 for normal person is 3.5 AND FEV_1 for person with a respiratory disorder is 2.0; *idea that* blocked / damaged , airways reduce flow of air out of lungs;	2	BOTH FEV_1 values needed for 1 mark Examiner's Comments Part (i) was a good discriminator with only more able candidates getting the calculation correct and explaining their findings. Common misconceptions referred to changes to tidal volume or vital capacity.
		ii	to check if medication is working; to monitor the condition / AW; AVP;	1 max	e.g. to see if it is getting any worse e.g. this is the NICE recommendations for this condition Examiner's Comments Part (ii) was straightforward for the majority of candidates.
			Total	5	

Question			Answer/Indicative content	Marks	Guidance
5			*idea of* quicker / cheaper / easier (to find, plants / active chemicals); *idea of* known side effects / interaction; *idea* that known dosage;	2	Examiner's Comments This question was based on the pre-release material, and tested a range of abilities. Candidates achieved higher marks if they had thoroughly researched the material provided. This question assessed AO1, AO2 and AO3 skills. Most candidates restated the information in the stem of the question that the folk medicine was known to have an effect, and then failed to develop their answer to give a consequence of this. Some felt that the fact they had been used already made them completely safe, rather than knowing what the possible side effects were, or that they needed no further testing.
			Total	2	

Question			Answer/Indicative content	Marks	Guidance
6	a	i	153 / 153.49 / 153.5 (%);;	2	2 marks for correct answer If answer incorrect, award 1 mark for correct working i.e. $\frac{10.9 - 4.3}{(?)} \times 100$ Where (?) = 10.9 or 4.3 **Examiner's Comments** This question equally addressed **AO1** and **AO2**, and had some elements of **AO3**. Very few candidates knew how to correctly calculate % increase. Some candidates could correctly work out the difference in risk, but then often divided by the incorrect denominator.
		ii	*Idea of* (people who have smoked, more cigarettes / for longer have) more exposure to (named) carcinogens (in tobacco smoke); (the more a person smokes) the more likely they are to have a mutation; increase in (number of) mutations increases the risk of cancer; lung cancer takes a long time to develop;	3	**IGNORE** 'chronic' disease without qualification **Examiner's Comments** This question equally addressed **AO1** and **AO2**, and had some elements of **AO3**. Candidates who focussed on the command word 'explain' in the question scored well in this question, explaining how increased smoking led to more exposure to carcinogens, leading to the increased mutation risk. Some candidates just gave a description of the trend which failed to gain credit.

Question			Answer/Indicative content	Marks	Guidance
		iii	*supports* In the less than 20 years of smoking group, there is a higher (relative) risk (of lung cancer) if 10-19 cigarettes are smoked than if 20+ are smoked; In the 40-49 years of smoking group, the (relative) risk (of lung cancer) when smoking 20+ is less than the risk when smoking 10-19 cigarettes; *does not support* *Idea that* 20 –29 / 30 – 39 / 50+ years of smoking, the higher the number of cigarettes smoked per day the higher the risk of lung cancer;	2	**Number of years smoking** / **Relative risk of lung cancer**: <10 cigarettes smoked; 10-19 cigarettes smoked; 20+ cigarettes smoked <20: 0.9; 2.6; 1.3 20-29: 1.4; 2.3; 2.8 30-39: 4.3; 6.0; 10.9 40-49: 5.7; 16.2; 12.6 50+: 17.6; 22.6; 41.0 **Examiner's Comments** This question equally addressed **AO1** and **AO2**, and had some elements of **AO3**. Candidates who carefully considered the data and its meaning often scored both marks, recognising that the data for those smoking less than 20 years, or for 40 - 49 years, did not support the statement, whereas the data for those who smoked for 50+ years (for example) did.

Question			Answer/Indicative content	Marks	Guidance
	b		*development of chronic bronchitis* 1 tar, deposited in / coats / sticks to, bronchi / bronchioles; 2 (causes) more / build up of, mucus (in respiratory tract); 3 (causes) cilia to, stop working / become paralysed; 4 microorganisms / pathogens, not removed (from respiratory system); 5 a, persistent / AW, cough develops (to get rid of mucus); 6 scar tissue forms / AW; 7 tar / allergens / pathogens, cause inflammation; *effect on gas exchange* 8 diameter / lumen of, airways / bronchi / bronchioles, narrows; 9 reduces rate of air, reaching alveoli; 10 (volume of) air in, alveoli / (named) airway(s) / lungs, reduced; 11 *idea that* concentration gradient is reduced; 12 mucus / scar tissue, increases (length of) diffusion pathway;	7	IGNORE ref alveoli elasticity, surface area, emphysema IGNORE alveoli and lungs CREDIT EITHER more produced (by goblet cells) OR mucus not removed ACCEPT 'oxygen' instead of air

Question			Answer/Indicative content	Marks	Guidance
			max 7 QWC for balanced account	1	AWARD QWC mark for: 2 marks from mp 1 – 7 AND 1 mark from mp 8 – 12 Examiner's Comments This question equally addressed AO1 and AO2, and had some elements of AO3. Candidates' answers about the development of chronic bronchitis were good, but several failed to develop their ideas to explain the effect of the symptoms on gas exchange. Some candidates incorrectly referred to a reduced diffusion gradient rather than a reduced concentration gradient. Some candidates also answered in terms of carbon monoxide and nicotine which were not relevant here. Imprecise answers failed to credit, eg talking about a reduction in the bronchi, rather than a reduction in the diameter of the bronchi. Several candidates went on to describe the symptoms and effects of emphysema, which was not relevant here.
			Total	15	

Question			Answer/Indicative content	Marks	Guidance
7		i	*idea of* evaluating effectiveness of (new) drugs (compared to existing drugs); *idea of* setting (NHS) guidelines for drug use; *idea of* ensuring treatment is, cost-effective / value for money;	2 max	IGNORE reference to side effects, and safety (as this would have been done during trials and licenced) Examiner's Comments Many candidates had a good understanding of the role of NICE, although several candidates incorrectly stated that they were involved in clinical trial work, rather than the pharmaceutical company developing the drug. NICE considers evidence on efficacy and provides guidelines based on all available treatment options, they do not test drugs themselves. Where dosage is concerned, they produce guidance on which dosages should be used and when, but they do not determine dosages or safe dosages as these are determined during trial work.
		ii	nucleus / DNA / chromosome / chromatin; plasma / cell surface, membrane; phagocytosis / endocytosis;	3	Examiner's Comments Nearly all candidates correctly identified that macrophages use phagocytosis or endocytosis, however, most candidates did not correctly name the plasma membrane or cell surface membrane forming blebs, merely calling it the 'cell membrane' or 'membrane'.
			Total	5	

Question			Answer/Indicative content	Marks	Guidance
8	a	i	B lymphocyte / plasma cell ✓ Mast cell ✓ T-helper lymphocytes ✓	max 2	
		ii	*idea that* an antigen / allergen triggers the production of an antibody / IgE (antibody)	1	
	b		*idea that* white asbestos less carcinogenic / blue and brown asbestos more carcinogenic ✓ j*ustification* fibre length is shorter in white asbestos / fibre length is longer in blue and brown asbestos / fibres are wider in white asbestos / fibres are narrower in blue and brown asbestos AND *idea that* longer / narrower, fibres are more carcinogenic ✓ *idea that* white asbestos linked more to asbestosis / blue and brown asbestos less likely to cause asbestosis ✓ OR shorter / thicker, fibres that cause asbestosis more likely in white asbestos AND data in support ✓	max 2	One mark for conclusion and one for justification Justification must be linked to the conclusion ALLOW white asbestos less likely to cause mesothelioma / lung cancer
			Total	5	

Question			Answer/Indicative content	Marks	Guidance
9		i	*idea that* it is triggered by , damaged cells / entry of pathogens ✓ mast cells release histamine ✓ (histamine causes) vasodilation ✓ (so) increases blood flow to area ✓ capillary walls become more permeable ✓ (so) easier for phagocytes to leave the blood ✓	3 max	ALLOW dilation of , blood vessels / arterioles **Examiner's Comments** The most commonly seen correct responses for **Q22(d)(i)** involved references to vasodilation and increased blood flow, with few candidates referring to mast cells releasing histamine or increased permeability of the capillary walls. Some good responses that included betalain binding to receptor sites or to cytokines were seen in **Q22(d)(ii)** but some suggestions linked to enzyme inhibition were too vague to gain credit.
		ii	*idea that* betanin prevents cytokines binding to cell surface receptors of target cells ✓	1	IGNORE reference to enzyme / active site / inhibition e.g. betanin binds to cytokines betanin binds to cell surface receptors betanin competes with cytokines for receptor binding site **Examiner's Comments** The most commonly seen correct responses for **Q22(d)(i)** involved references to vasodilation and increased blood flow, with few candidates referring to mast cells releasing histamine or increased permeability of the capillary walls. Some good responses that included betalain binding to receptor sites or to cytokines were seen in **Q22(d) (ii)** but some suggestions linked to enzyme inhibition were too vague to gain credit.
			Total	**4**	

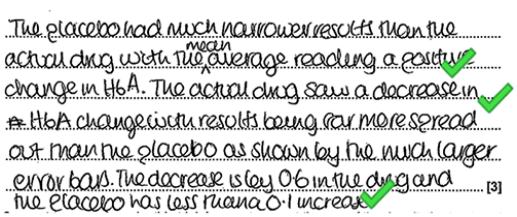
<table>
<tr><th colspan="3">Question</th><th>Answer/Indicative content</th><th>Marks</th><th>Guidance</th></tr>
<tr><td>10</td><td></td><td></td><td>
<table>
<tr><th>Drug</th><th>Reduce inflammation of the bronchi</th><th>Widen the lumen of the bronchi</th><th>Can be used during an acute asthma attack</th></tr>
<tr><td>Corticosteroids</td><td>✓</td><td>×</td><td>×</td></tr>
<tr><td>Beta-agonists</td><td>×</td><td>✓</td><td>✓</td></tr>
</table>
✓✓
</td><td>2</td><td>ONE mark per row

<u>Examiner's Comments</u>

There were few correct responses for this question which was assessing AO1. Candidates that had learned this and could recall the information did gain both marks. It is important that candidates follow instructions for tick box style questions. Responses where ticks and crosses had been omitted or where a tick had been made to look like a cross (or vice-versa) could not be credited due to their ambiguity.</td></tr>
<tr><td></td><td></td><td></td><td>Total</td><td>2</td><td></td></tr>
</table>

Question			Answer/Indicative content	Marks	Guidance
11	a	i	already known to have some medicinal properties ✓ some side effects were known ✓ reduced time in finding , drug / quinine , to treat malaria / AW ✓	Max 2	ALLOW already used to treat fever Examiner's Comments Candidates usually scored one mark for reference to the previously known medicinal use of the bark without developing the answer to explain why this was an advantage.
		ii	*idea that* the parasite starves ✓ *idea that* (host) haemoglobin not hydrolysed to amino acids ✓ amino acids needed for making (parasite) proteins ✓ *idea that* the incomplete breakdown of haemoglobin is toxic ✓	Max 2	Examiner's Comments Many candidates identified that the malarial parasite would starve. Although quite a few candidates identified that the parasite would die due to lack of oxygen because of the incomplete digestion of haemoglobin, a high proportion thought that the parasite was a virus. Key Misconception
	b	i	looks / tastes the same, without the active ingredient ✓	1	Examiner's Comments Candidates who didn't receive credit often lacked the idea that a placebo either looks and/or tastes the same as the tested drug. An answer such as 'a drug that has no effect' was common and the term 'no effect' is far too vague and incorrect for candidates to be using at this level.

Question			Answer/Indicative content	Marks	Guidance
		ii	random method / random selection explained ✓ use of double-blind trial / AW ✓ gender ✓ age ✓ similar , stage / severity , of , condition / syndrome ✓	Max 2	
	c		9 (g) ✓ ✓	2	ALLOW one mark for 9000 mg provided units are stated Examiner's Comments The most common error for those candidates that gained one mark for this question was being unable to convert 'mg' into 'g'. It is clear that candidates need to practice and become confident in using and converting the different units required on the course.
			Total	9	

Question			Answer/Indicative content	Marks	Guidance
12	a	i	2 / two ✓	1	ALLOW II
		ii	drug with, same / similar, appearance to real drug but with no effect ✓ to compare with treatment group /to see effect of treatment ✓	2	IGNORE references to psychological effect
		iii	any 3 from: mean decrease in drug group and mean increase in placebo ✓ mean change (in HbA_{1C}) greater with drug than placebo ✓ 0.65% difference in means ✓ more variable changes (in HbA_{1C}) in treatment group ✓	2	needs to be comparative statement DO NOT ALLOW greater range Examiner's Comments Some candidates interpreted the boxes on the graph as the range of data rather than the mean change in glycosylated haemoglobin. Few candidates achieved the full three marks. Exemplar 10  The placebo had much narrower results than the actual drug with the mean average reading a positive change in HbA. The actual drug saw a decrease in HbA change with results being far more spread out than the placebo as shown by the much larger error bars. The decrease is by 0.6 in the drug and the placebo has less than a 0.1 increase [3] A comparative answer including the scale and direction of differences and a statement about the more varied data in the treatment group.

Question			Answer/Indicative content	Marks	Guidance
		iv	**any 2 from:** error bars overlap ✓ no evidence of permanent drug effect / 3 months not long enough ✓ group size too small / need more participants ✓ disease severity may be different among patients / example of other variables to control ✓ idea that uncertainty as to whether reduction (in HbA_{1C}) in treatment group is great enough ✓	max 2	**AW**
	b	i	long duration **AND** gradual development / worsening, of symptoms over time ✓	1	**ALLOW** slow onset
		ii	**any 1 from:** drug theophylline medical use (treat) COPD / asthma ✓ drug topotecan medical use (treat) (lung) cancer ✓ drug (treat) medical use cancer ✓ drug reduce/relieve, fever medical use / inflammation / pain / anti-thrombotic ✓ drug (treat) malaria ✓ medical use	max 1	correct drug **and** correct medical use = 1 mark **ALLOW** other correct examples of drugs and medical uses e.g. morphine/opiates pain relief
			Total	**10**	

Question			Answer/Indicative content	Marks	Guidance
13		i	*idea that* group two could be used as a comparison **OR** control group ✓	1	**Examiner's Comments** Good responses showed an understanding that the other group in the trial was used as a comparison or a control. There were some misconceptions with a few candidates thinking that it was to see if the patients already had the virus.
		ii	*idea that* healthy participants were being given untested vaccine ✓☐ *idea that* group 2 were being given the vaccine later than group 1✓☐ *idea that* group 2 were given the vaccine after known incubation time for the Ebola virus ✓☐ *idea that* only communities with new cases of Ebola could participate in the trial ✓☐ *idea that* group 2 may think that they , would be immune to / wouldn't become infected with , Ebola ✓☐	2max	**IGNORE** participants not having a choice e.g. healthy people may suffer side effects e.g. unethical to split into two groups as group 2 still exposed to Ebola **Examiner's Comments** Many candidates gained one mark, usually for reference to group 2 having to wait ten days for the vaccination and some went on to gain both marking points with excellent ideas relating to the vaccine being untested or for comments such *as 'the long term effects of the vaccine are unknown'*.
		iii	100% effective if given immediately / AW ✓ *idea that* it is still effective after incubation period ✓☐	2max	**ALLOW** data processing for mp 2 e.g. only 0.5% new cases in group 2 **Examiner's Comments** At the end of the paper, **Q25(b) (iii)** proved challenging. Candidates were required to evaluate the data provided in the trial and there were vague responses which referred to the vaccine as being 'fairly' effective or 'quite' effective which were not credited. Examiners were looking for the idea that the vaccine was totally or 100% effective if given immediately as shown by the data for group 1.
			Total	5	

Question			Answer/Indicative content	Marks	Guidance
14	a	i	83.3 % ✓✓	2	ALLOW for 1 mark 1250 / 1500 × 100 OR 83.3333… Examiner's Comments This question addressed mainly AO1 and AO2. Candidates were required to demonstrate their mathematical skills by performing a percentage decrease calculation. Most candidates attempted the calculation in there were few 'no responses'. It was noted that candidates who correctly performed the calculation also gave their response to three significant figures as requested.
		ii	(y axis) patient G had a much higher blast count (at the start of the trial) AND (x axis) patient G was being given a higher dose OR (x axis) *idea that* patient G did not continue with the treatment ✓	1	CREDIT ORA for patient F ACCEPT very different blast counts e.g. patient G had much less time on the drug e.g. patient G decided to opt out of the trial e.g. blast count of patient G had reduced sufficiently e.g. patient G had stabilised Examiner's Comments This question addressed mainly AO1 and AO2. Candidates were required to demonstrate their mathematical skills by performing a percentage decrease calculation. To gain credit it was important for candidates to comment on the scales for both x and y axes. It was also important for candidates to have the idea that the different scales were needed to present all the data because of large differences between the two patients e.g. patient G had a *much* higher blast count.

Question			Answer/Indicative content	Marks	Guidance
	b		drug is tested on people with the disease ✓ tests how effective the drug is against the disease ✓ gathers information about dosage of the drug ✓ determines if the drug is, more effective / better than, existing drugs ✓ *idea that* more people participate than in previous phases ✓ qualified reference to placebo ✓	2 max	disease only needs to be referred to once if awarding both **mps 1** and **2** e.g. *the drug is given to people with the disease to see how effective it is* gets **mps 1** and **2**. **IGNORE** references to side effects **ACCEPT** compares effectiveness with existing drug **ACCEPT** larger scale than previous trials e.g. don't usually have placebo because it would be unethical to give to a person with the disease **Examiner's Comments** This question addressed mainly **AO1** and **AO2**. Candidates were required to demonstrate their mathematical skills by performing a percentage decrease calculation. Good responses demonstrated an understanding that a phase 3 trial would need a larger number of participants and that these participants would have the disease thereby gaining both marks.
			Total	**5**	

Question			Answer/Indicative content	Marks	Guidance
15		i	**Any 3 from:** *idea that* 70 people is too low for a phase 3 trial (therefore reducing validity) / phase 3 trial should involve, hundreds / thousands, of people *idea that* (sample size of 70 people is) unlikely to differentiate new drug's performance from current drug (therefore reducing validity) blind trials (improve validity by), reducing / removing, bias (of patients) double blind trials (would be), improvement / AW, by removing bias of scientists *idea that* placebo cannot be used because it would be unethical in a phase 3 trial	3	
		ii	**Any 2 from:** genetics head injuries age smoking	2	
			Total	**5**	