- 1. Scientists have developed a drug that could be used to treat Ebola.
  - (i) Which of the statements can be used to complete the sentence about testing a new drug?

Put ticks ( $\checkmark$ ) in the boxes next to the **two** correct statements.

The first stages of testing a new drug include tests on ...

animals	
healthy human volunteers	
human cells grown in a laboratory	
humans with the disease	

(ii) The scientists plan to test the new drug in humans.

The table shows groups that they could include in their plan.

Group	People in group	Treatment the people receive
A	healthy volunteers	the drug
В	people with Ebola	the drug
С	people with Ebola	a placebo

Explain the benefits of including each group and the ethical issues raised by including Group C.

The quality of written communication will be assessed in your answer.

-----

 [6]
·

2(a). Tony has pneumonia.

His doctor prescribes antibiotics.

Suggest why it is important that Tony starts his course of treatment as soon as possible.

[1] The doctor tells Tony to complete the course of treatment

(b). The doctor tells Tony to complete the course of treatment. Explain why this is important.

[2]

### (c). Tony recovers.

Several years later, Tony's friend, Gordon, also catches pneumonia. This time the antibiotic does not work. The doctor decides to give Gordon two other antibiotics at the same time. Gordon recovers.

Suggest why:

- the original antibiotic did not work
- using two other antibiotics was effective.

[3]

3(a). Antidepressants are drugs prescribed by doctors to treat depression.

The table gives information about drugs A, B, C and D that are used to treat depression.

Drug	Information
A	Some people respond to this drug better than other drugs. Do not take if you have high blood pressure.
В	Causes fewer side effects than other drugs. Overdose not likely to be fatal. Do not take if you have epilepsy, diabetes or kidney disease.
С	Unpleasant side effects. Do not take if you have liver disease or heart disease.
D	Need to avoid red wine. Can lead to high blood pressure.

Fiona has depression and high blood pressure.

Her doctor prescribes drug B.

Suggest why her doctor makes this choice.

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(b). Antidepressant drugs usually have side effects.

Which two statements explain why Fiona is willing to risk side effects?

Put ticks ( $\checkmark$ ) in the boxes next to the **two** best explanations.

The drugs are very expensive.

The benefits of taking the antidepressants outweigh the risks.

The risk of serious side effects is low.

All of the side effects are serious.

Overdoses are always fatal.

13 - 23	
int 29	
9 - E	
18 29 29	

[2] [Total: 5] 4(a). Helen is investigating the effect of antibiotics on the growth of bacteria.

Bacteria are grown on nutrient jelly. This makes the jelly look cloudy.

Helen puts a small paper disc into each of three different antibiotic solutions, A, B and C.

She puts another paper disc into water.

She then places all of the paper discs onto the nutrient jelly.

The diagram shows the apparatus she uses for her investigation.



After two days Helen sees clear circular areas around some of the paper discs.

Helen measures the radius (r) as shown in the diagram.



She then calculates the total area of the clear circle (including the paper disc) using the formula:

area =  $?r^2$  (where ? = 3.14).

Here are her results.

	Radius in mm	Total area of the clear circle (including the paper disc) in mm <sup>2</sup>
A	8	
В	14	615.44
С	3	28.26
water	3	28.26

Complete the table by calculating the total area of the clear circle (including the paper disc) for A.

Show your working below.

(b). The clear areas on the nutrient jelly are where the bacteria have been killed by the antibiotic.

Helen makes the following conclusions from her results.

Which of these conclusions are correct?

Put ticks (?) in the boxes next to the three correct conclusions.

The greater the clear area, the more bacteria have died.
The bacteria may be resistant to antibiotic C.
Antibiotic A is the least effective.
Water kills more bacteria than any antibiotic.
Antibiotic C must be water.
Antibiotic B is the most effective.



[2]

(c). Explain why it is important for all the paper discs to be the same size.

[2]

(d). New antibiotics must be tested before they can be made available to the general public.

Write down one reason why.

5. Penicillin was the first antibiotic used by doctors.

Streptomycin is also an antibiotic. It was developed in 1947.

Describe how streptomycin should be used by doctors to treat their patients, including why it is important to regularly discover new antibiotics.

The quality of written communication will be assessed in your answer.

6. A clinical trial investigated the effect of different combinations of chemotherapy drugs on survival rates of cancer patients.

Two groups of cancer patients were given different combinations of drugs.

- Patients in group A were given two drugs: 1 and 2.
- Patients in group **B** were given two drugs: 3 and 4.
- (i) A placebo was not used in the trial.

Explain why.

\_\_\_\_\_[2]

(ii) The results of the trial are shown in the table.

	Group A	Group B
	(Drugs 1 and 2)	(Drugs 3 and 4)
Number of people in the trial	305	314
Number of people still alive two	247	222
years after treatment		

What conclusion could be made from these results?

Tick (✓) one box.

The drugs given to the patients in Group A cured their cancer.

The combination of drugs given to Group B was not effective.

The combination of drugs given to Group A was the most effective.

(iii) New drugs are tested to see how safe they are to use and how well they work (their effectiveness).

Put a tick ( $\checkmark$ ) in **one** box in each row of the table to show what each stage of the drug development process tests for.

Clinical trial stage	Tests for both safety and	Tests only for safety	Tests only for effectiveness
	effectiveness		
Preclinical trial using			
human cells and animals			
Clinical testing – using			
healthy human volunteers			
Clinical trials – using			
humans with the disease			

[3]

7. Amir works in a laboratory. His job is to identify the pathogens that cause plant diseases.

Amir has a sample of bacteria from an infected plant.

He wants to test the effectiveness of different antibiotics against the bacteria.

Amir writes a method for transferring bacteria from the sample onto a Petri dish.



the sample of bacteria

# Petri dish containing agar jelly

## Method:

- 1. Pick up the wire loop from the bench.
- 2. Open the glass bottle containing the sample of bacteria.
- 3. Dip the loop in the sample of bacteria
- 4. Take the lid off the Petri dish.
- 5. Wipe the loop over the agar jelly in the Petri dish to spread bacteria.
- 6. Put the lid back on the Petri dish.
- (i) Suggest **three** improvements Amir could make to his method to reduce the risk of contaminating the Petri dish with unwanted bacteria.



(ii) After transferring bacteria from the sample onto a Petri dish, Amir adds four different paper discs to the agar.

Three of the discs have been soaked in solutions of different antibiotics, A, B and C. One disc has been soaked in sterilised water.

Amir places the dish in an incubator overnight. The bacteria grow to cover the surface of the agar jelly.

The diagram shows what he sees after the dish has been incubated.



The radius (r) of the clear zone around the disc soaked in antibiotic A is 11 mm.

Calculate the area of this clear zone.

Use the equation: area of clear zone =  $3.14 \times r^2$ 

Give your answer to 3 significant figures.

----- mm<sup>2</sup>[3]

(iii) Amir sets up three more Petri dishes in the same way as the first.

		Area of clear zone (mm <sup>2</sup> )				
Disc	Soaked in	Petri dish 1	Petri dish 2	Petri dish 3	Petri dish 4	
1	Antibiotic A		363	346	346	
2	Antibiotic <b>B</b>	227	363	227	214	
3	Antibiotic C	314	283	298	314	
4	Sterilised water	0	0	0	0	

The table shows his results for all four dishes.

Amir thinks one of the discs was soaked in the wrong solution.

Suggest which disc may have been soaked in the wrong solution.

Give a reason for your answer.

Disc \_\_\_\_\_ in Petri dish \_\_\_\_\_

Reason .....

[2]

8. Warfarin is a medicine that helps to prevent the formation of blood clots.

It is given to people who are at risk from a blood clot blocking one of their veins.

Warfarin helps to prevent the formation of blood clots when it is given to a patient in the correct amount.

The amount of medicine given to a patient is called the dose.

However, there is not one correct dose of warfarin that works for everybody. Different patients need a different dose.

(i) Doctors usually start by giving a low dose of warfarin to a patient. They then increase the dose if necessary.

Explain why it is better to start with a low dose of warfarin **and** suggest what could happen if the dose is too high.

\_\_\_\_\_

(ii) Doctors think that different people need a different dose of warfarin because of differences in their genomes.

Explain how differences in the genome could cause a person to need a different dose of warfarin.

[2]

(iii) Explain how gene technology could be used to help a doctor to give the correct dose of warfarin to a patient.

[2]

# END OF QUESTION PAPER

Quest	tion	Answer/Indicative conte	nt	Marks	Guidance
1	i	Animals human cells grown in the laboratory	<ul> <li></li> <li></li> </ul>	1	two correct ticks = 1 mark three or more ticks = 0 marks <b>Examiner's Comments</b> The most common error on this question arose from candidates only ticking one box
		laboratory			arose from candidates only ticking one box instead of two, therefore those candidates were unable to gain the mark. Those candidates that did tick two boxes often correctly identified testing 'animals' as one of the first stages in testing new drugs. The most common incorrect answer was identifying that testing 'humans with the disease' was part of these initial testing stages.

Question	Answer/Indicative content	Marks	Guidance
ii	[Level 3] Answer gives correct reason for three groups AND discusses ethical issues. Quality of written communication does not impede communication of the science at	6	This question is targeted at grades up to C Indicative scientific points may include: Reasons for group A / healthy volunteers + drug:
	this level.		<ul> <li>to test for safety</li> <li>side effects/examples of side effects</li> </ul>
	[Level 2] Answer gives correct reason for two groups OR one group and discusses		Reasons for group B / people with Ebola + drug:
	ethical issues. Quality of written communication partly impedes communication of the science at this level.		<ul> <li>to test for safety</li> <li>side effects/examples of side effects</li> <li>effectiveness/if drug works</li> </ul>
	(3 – 4 marks)		Reasons for group C / people with Ebola + placebo:
	[Level 1] Answer gives general statements for drug testing. Quality of written communication impedes communication of the science at this level. (1 – 2 marks)		<ul> <li>a placebo (is a similar substance that) has no drug in it</li> <li>to show results without drug</li> <li>control group</li> <li>to compare with group</li> <li>placebo (only) used if there is no existing treatment for Ebola</li> </ul>
	Insufficient or irrelevant science. Answer not worthy of credit.		Ethical issues with group C / placebo:
	(0 marks)		<ul> <li>should not knowingly withhold a drug that could help them</li> <li>people in this group likely to die/suffer</li> <li>people in this group will not benefit from the new drug</li> <li>because case fatality rate/death rate for Ebola is high</li> </ul>
			<ul> <li>General statements</li> <li>drug trials test for safety/side effects</li> <li>drug trials test for effectiveness</li> <li>placebos can be used and do not contain active ingredients</li> <li>use a placebo to see if there is a placebo/psychological effect</li> </ul>

Question		Answer/Indicative content	Marks	Guidance
Quest	tion	Answer/Indicative content	Marks	Guidance         • use of blind/double blind trials         Use the L1, L2, L3 annotations in Scoris; do not use ticks.         Examiner's Comments         This was the second of the six-mark extended writing questions. Candidates were asked to consider some information about plans to test a new drug in humans. This question discriminated well between candidates, with marks scored across the 0-6 range. A large proportion scored in Level 2 and it was pleasing to see candidates scoring in Level 3.         The most common correct answers arose from the identification of the use of groups A and B. Many candidates identified that giving healthy volunteers the drug would allow side effects to be identified. Many also identified that giving people with Ebola the drug would allow the scientists to see if the drug actually worked. Many candidates scored in Level 2 for those reasons. It was also common to see candidates discussing the ethical issues of using a placebo with Ebola patients with candidates identifying that the placebo would not help them and as a result they could die. Very few candidates correctly identified the reason for giving common C the placebo. Whilst a
				as a result they could die. Very few candidates correctly identified the reason for giving group C the placebo. Whilst a number of candidates understood that placebos were a "fake drug", very few grasped the reasons for using them in drug trials. Centres should ensure that when teaching about placebos and drug trials they highlight the fact that they provide a control group for the other results to be compared against.
				Common errors made included giving ethical reasons for groups A and B receiving their corresponding treatments.
		Total	7	

Q	Question		Answer/Indicative content	Marks	Guidance
2	а		idea that numbers of bacteria in the body will be much less / less damaged caused;	1	<ul> <li>accept reverse argument that if treatment not commenced the numbers of bacteria will become greater</li> <li>Examiner's Comments</li> <li>Was even better answered than 5b, with the idea that the bacteria were reproducing rapidly being presented in a number of ways.</li> </ul>
	b		some bacteria may not be killed; bacterial resistance to the antibiotic is more likely;	2	Examiner's Comments Was however not so well answered as hardly any used the idea of bacteria developing resistance to the antibiotic; where a mark was scored it was almost always on the idea that remaining bacteria could multiply all over again and make Tony ill again.
	C		idea that bacteria became resistant to the original antibiotic; bacteria that survive one of other antibiotics; will be killed off by the second antibiotic; idea of preventing development of new resistant strain;	3	accept references to "superbug" for idea of resistance Examiner's Comments Revealed that few candidates appreciated the nature of resistance to antibiotics. There were many weak answers along the lines of "the first one was not powerful enough, the other two were stronger" etc. Another major misconception shown here was that Tony or Gordon became resistant to the antibiotics. Some candidates though that the bacteria became immune to the antibiotics and gave imaginative descriptions of how this affected their antibodies. This perhaps indicates a level of confusion about what antibiotics are and how they work.
			Total	6	

Question		n	Answer/Indicative content	Marks	Guidance
3	а		Fewer side effects; Can take with high blood pressure / doesn't cause high blood pressure; C has unpleasant side effects; overdose not likely to be fatal;	3	Ignore NO side effects She can't take drug A / D with high blood pressure. Assume "it" means drug B unless indicates otherwise. Examiner's Comments Most candidates were able to recognise the reasons for prescribing one particular antidepressant in terms of side effects, and commonly scored at least 2 marks out of the 3 available.
	b		The drugs are very expensive.         The benefits of taking the antidepressants outweigh the risks.         The risk of serious side effects is low.         ✓         All of the side effects are serious.         Overdoses are always fatal.	2	remove one mark for each additional incorrect answer Examiner's Comments Most candidates could identify explanations as to why patients are prepared to take the risk of side effects and scored well.
			Total	5	

Question		n	Answer/Indicative content	Marks	Guidance
4	а		200.96 / 201.06 / 201.14 / 201.1 / 201 (2)	2	correct answer = 2 marks $3.14 \times 8 \times 8 / ? \times 8 \times 8 / ? \times 8^2 = 1$ mark <b>Examiner's Comments</b> This mathematical question proved more demanding. Many candidates struggled to use the formula provided to generate a correct answer and failed to identify that r was the radius of the zone of inhibition. Common mistakes observed included ? <sup>2</sup> or r × 2. Candidates who understood the formula gained two marks.
	þ		The greater the clear area, the more bacteria have died.       ✓         The bacteria may be resistant to antibiotic C.       ✓         Antibiotic A is the least effective.       ✓         Water kills more bacteria than any antibiotic.       ✓         Antibiotic C must be water.       ✓         Antibiotic B is the most effective.       ✓	3	if more than 3 ticks, delete one mark for each extra tick Examiner's Comments Candidates were asked to use data to draw conclusions from the results. Candidates who did not score in part a, were not disadvantaged in this question as the correct answers could be identified despite an incorrect answer to part a. A range of marks were observed for this question. A common error made by candidates was the identification that 'water kills more bacteria than any antibiotic' and that 'antibiotic C must be water'.

Question	Answer/Indicative content	Marks	Guidance
C	fair comparison of the antibiotics (1) so there is the same amount of antibiotic (1)	2	allow fair test ora Examiner's Comments This question proved more difficult. Candidates found it difficult to explain why it was important that all the paper discs were the same size. Many candidates scored one mark for using the term 'fair test', but struggled to express what they meant by this term and could not relate it to the investigation. Centres should be encouraged to address this problem. Very few candidates stated that using the same size paper discs allowed a fair comparison of the antibiotics and even fewer candidates were able to relate the size of discs to the same amount of antibiotic used in each test.
d	to check they're safe / in case they are harmful / may have side effects / may cause allergic reactions / to see if they work (1)	1	<ul> <li>do not allow vague statements e.g. 'it might not be good for you' / 'it might have an effect'</li> <li>Examiner's Comments</li> <li>The vast majority of candidates answered this question well. They were able to explain that new antibiotics were tested both for safety and effectiveness. These reasons were expressed in many ways.</li> </ul>
	Total	8	

Question	Answer/Indicative content	Marks	Guidance	
Question	Answer/Indicative content         [Level 3]         Explanation of resistance and how it can be avoided         OR full description using general points.         Quality of written communication does not impede communication of the science at this level.         (5–6 marks)         [Level 2]         Use of idea of resistance and how it can be avoided, from general points.         Quality of written communication partially impedes communication of the science at this level.         (3–4 marks)         [Level 1]         Makes basic points about antibiotics         Quality of written communication impedes communication of the science at this level.         (1–2 marks)         Level 0 (0 marks)         Insufficient or irrelevant science. Answer not worthy of credit.	6	Guidance This question is targeted at grades up to E Indicative scientific points explaining resistance:  some bacteria will be more resistant to the antibiotic than other bacteria due to mutation or variation these will survive and breed non-resistant ones will die out because of rapid reproduction bacteria will soon be all resistant should make sure all bacteria killed (by finishing course or use new antibiotic) Indicative general points: idea that bacteria can become resistant to antibiotics antibiotics do not work on viruses only work against bacteria & fungi only when necessary complete course of treatment new antibiotics are required to replace the ones that bacteria are now resistant to bacteria mutate Indicative basic points:	
			<ul> <li>bacteria can change / evolve</li> <li>(new antibiotics) to avoid side effects eg allergy</li> <li>work against / kill bacteria / fungi</li> <li>different antibiotics needed for different diseases</li> <li>antibiotic stops being effective / stops working</li> <li>beware answers where people become resistant</li> <li>accept microbes or pathogens but ignore reference to viruses ignore immune</li> <li>Use the L1, L2, L3 annotations in Scoris;</li> </ul>	

Question	Answer/Indicative content	Marks	Guidance
			do not use ticks. Examiner's Comments Candidates would be well advised to read the whole question and ensure that they answer all sections of the question in order to maximise their marks. Many candidates knew that antibiotics killed fungi and bacteria and many knew that they do not work on viruses. Some candidates knew that bacteria could become resistant to antibiotics but few were able to link this to the bacteria mutating. It was disappointing to see that many of the candidates who had addressed how streptomycin should be used by doctors had not considered the reasons as to why it is important to
	Total	6	

Question		n	Answer/Indicative content	Marks	Guidance
6		i	Any two from: a placebo contains no active drug (so treatment is effectively witheld) ×	2 (AO 3.2a × 2)	
			cancer would not be treated / disease could get worse ×		DO NOT ALLOW could affect the person's health
			it is not ethical to withhold treatment ×		
					Examiner's Comments
					Candidates found this AO3 question difficult. They did not seem to realise that the lack of active drug in a placebo would mean the cancer would get worse, or that withholding treatment would be unethical. Most answers centred around the idea that the researchers wanted to compare how the pairs of drugs would work (relative to each other) so didn't need to bother with a placebo.
		ii	The combination of drugs given to Group A was the most effective $\checkmark$	1 (AO 3.2b)	
					Examiner's Comments
					Most candidates were able to correctly conclude that the drugs given to Group A were the most effective. This question assessed objective AO3.
		iii	Tests for both ✓	3 (AO 1.1	IGNORE any row containing more than
			Tests for safety ✓		
			Tests for both ✓		Examiner's Comments
					This question assessed AO1. Most candidates scored at least one mark on this question, with the majority scoring two marks for identifying the purpose of preclinical trials and trials involving healthy humans. Candidates were less able to correctly identify why clinical trials on humans with a disease are carried out.
			Total	6	

Question	Answer/Indicative content	Marks	Guidance
7 i	Any three from: use aseptic technique(s) ✓ put on gloves before starting ✓ disinfect/sterilise the bench with alcohol before starting ✓ work next to a Bunsen burner (to create an updraft) ✓ pass the neck of the jar through a flame before dipping wire loop through a flame (and allow to cool) / sterilise the loop before dipping into sample jar ✓ idea of not taking lid fully off Petri dish / putting it back on quickly ✓ secure the Petri dish lid with Sello/sticky tape (following the inoculum spread) ✓	3 (AO 3.3b × 3)	DO NOT ALLOW "clean", as this may not be sterile DO NOT ALLOW "seal the Petri dish" Examiner's Comments Responses to this question suggested that most candidates were familiar with this kind of practical procedure, most likely through having done it themselves in a hands-on practical activity. Many candidates were able to give two or three correct examples of aseptic techniques. Some candidates needed to use scientific language such as 'disinfect' or 'sterilise' to score marks, rather than imprecise and everyday terms such as 'wipe', 'wash' and 'clean'. AfL The word 'clean' (as in "clean the wire loop") was not sufficient to score a mark. When learning about aseptic techniques and about the spread of diseases, there is an important distinction to make between 'clean' and 'sterile', because apparatus, surfaces, water, food, cooking utensils and hands can all look clean but be contaminated with pathogens, as most pathogens are too small to see.

Question	Answer/Indicative content	Marks	Guidance
	Disc 2 in Petri dish 2 ✓ Plus any one from: the area of the clear zone is much higher / outside the range of results for this disc in the other dishes / it is an outlier ✓ the area of the clear zone is in the range of results for disc 1 in the other dishes ✓ the area of the clear zone suggests it was soaked in antibiotic A ✓	2 (AO 3.2b) (AO 3.1b)	ALLOW Disc B in Petri dish 2 ALLOW same as disc 1 in dish 2 Examiner's Comments Many candidates needed to make clear which specific parts of the data they were referring to in order to score the reason mark. Exemplar 3 Amir thinks one of the disc was soaked in the wrong solution. Suggest which disc may have been soaked in the wrong solution. Give a reason for your answer: Disc in Petri dish biggest. He Boottone. Becouve: He biggest. He This candidate has identified the correct disc and dish for 1 mark, but does not get the mark for their reason. The candidate needed to refer to the other results 'for this disc' or 'for this antibiotic', or even 'in this row', rather than referring non-specifically to "the other results".
	Total	8	

Question		n	Answer/Indicative content	Marks	Guidance
8		i	low dose is less risky / reduces the risk / is safer $\checkmark$	3 (AO 2.1 × 3)	
			Plus any two from: (reduces risk of) side-effects from a high dose / high dose could be toxic / overdose / kill ✓ high dose could prevent patient from being able to seal/clot wounds / lead to excess blood loss and/or risk of infection ✓ it is easier to add more warfarin (bit by bit) than it is to take it out of the blood if too high a dose ✓		Examiner's Comments Most candidates were able to make a sensible suggestion about what could happen if the dose was too high, with many scoring a mark for a mention of side effects or overdose. However, this question also draws on ideas about risk from IaS4 in asking candidates to explain why it is better to start with a low dose, and relatively few candidates scored marks for this aspect.
		ii	different people have different genetic variants/alleles/mutations ✓	2 (AO 1.1)	DO NOT ALLOW different genes
			some variants/alleles/mutations will affect how the body reacts to warfarin / how warfarin is broken down in the body / (how well warfarin fits into) blood clotting enzyme active site ✓	(AO 2.1)	

Question	Answer/Indicative content	Marks	Guidance
	genetic testing/test(s) ✓ for variants/alleles/mutations that affect how the body reacts to warfarin / how warfarin is broken down in the body / (how well warfarin fits into) blood clotting enzyme active site OR to develop personalised medicine for the patient ✓	2 (AO 1.1) (AO 2.1)	DO NOT ALLOW genes Examiner's Comments Questions 4 (b) (ii) and 4 (b) (iii) were not well answered. In part (ii), candidates were not able to communicate understanding that differences in the genome are caused by mutations, which create new alleles/genetic variants, or to apply their understanding to suggest that these could affect how the body would interact with warfarin. In part (iii), candidates did not seem to recognise the term 'gene technology', or could not apply their understanding of it to this context to select examples of gene technology that might be helpful. AfL Two examples of gene technology are introduced in Section B1.3 of the specification. These are: • genetic testing for particular alleles/genetic variants and the development of personalised medicine based on test results; • genetic engineering. The first of these would be helpful to doctors in the context described in question <i>4</i> (b)
	Total	7	