



Diploma in Pharmaceutical Medicine Part 2

21 October 2025 – Short Answer Question Paper

QUESTION 1

- a) Briefly describe 5 limitations or issues with using animals in the non-clinical testing of pharmaceuticals. (5 marks)
- b) ICH references the '3Rs' principles (Replacement, Reduction and Refinement) when considering the non-clinical testing of pharmaceuticals. Based on these three principles, briefly outline 5 different approaches to minimise the impact on animals in non-clinical testing, stating which principle each approach addresses (to gain full marks you must include at least 1 approach for each principle). (5 marks)

QUESTION 2

- a) Briefly describe three different mechanisms by which an investigational drug might cause a drug-drug interaction (DDI) and the potential impact of each. (6 marks)
- b) Describe what is meant by the 'Cocktail approach' for a type of clinical DDI study, and why this might be used. (2 marks)
- c) Give 4 key factors that must be considered when designing DDI studies. (2 marks)

QUESTION 3

You are working in a pharmaceutical company on a new molecular entity for the treatment of Severe Combined Immunodeficiency (SCID).

- a) Briefly describe 4 factors to take into consideration when deciding on the countries/regions to take part in the pivotal registration study. (4 marks)

The company decides to request protocol assistance/scientific advice from the EMA.

- b) What is protocol assistance, and why might this new molecular entity be eligible for this? (2 marks)
- c) List 3 topics that can be addressed by scientific advice. (3 marks)
- d) Explain why following scientific advice does not guarantee marketing authorisation. (1 mark)



QUESTION 4

- a) What is the Child-Pugh classification and how can it be used in clinical trials? (2 marks)
- b) You are responsible for writing a phase 2 clinical trial protocol, testing a new investigational small molecule (Drug X) for a non-liver disease indication. What should the protocol include to ensure the safe conduct of the trial from a liver perspective? (8 marks)

QUESTION 5

- a) State 4 principles of informed consent for a clinical trial. (2 marks)
- b) With respect to the provision of information, describe the following concepts in lay terms that could be understood by a prospective clinical trial participant. (8 marks)
 - i. Screening
 - ii. Randomisation
 - iii. Experimental Drug
 - iv. Adverse events

QUESTION 6

- a) Relative Risk, Odds Ratio and Hazard Ratios are three commonly used statistical measures in clinical research. A more junior colleague has asked you to explain what these are. Provide your answer by stating for each of these: (6 marks)
 - i. What it is used to measure
 - ii. An example of where it can be used in clinical studies
 - iii. 2 limitations to its use
- b) A randomised clinical trial comparing an active treatment A, with placebo P, included data on how many patients experienced at least one serious adverse event (SAE):

	Number of patients		
	At least one SAE	No SAEs	Total
Treatment A	50	450	500
Placebo P	10	490	500
Total	60	940	1000



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- i. Show how you would calculate the Relative Risk of a patient suffering at least one SAE on treatment A compared to P (1.5 marks)
- ii. Show how you would calculate the Odds Ratio of a patient suffering at least one SAE on treatment A compared to P (1.5 marks)

Note: you only need to show the steps you would do to make the calculations – you do not have to actually perform the calculations to achieve the marks

- c) In which circumstances would the Relative Risk and Odds Ratio give very similar values? (1 mark)

QUESTION 7

- a) As defined by ICH M4, what is the Common Technical Document (CTD)? (1 mark)
- b) List 4 summary documents that are included in the CTD (2 marks)
- c) What is the purpose of the Clinical Overview? (3 marks)
- d) You are developing the European Risk Management Plan (RMP) for a new monoclonal antibody that has infusion-related reactions as an important identified risk. Briefly describe two pharmacovigilance activities, and two risk minimisation measures that you could include in the RMP to address this risk. To gain full marks you should include the objective of each of these. (4 marks)

QUESTION 8

A double-blind randomised placebo-controlled trial of medicine 'X' has just been completed. The safety results show the proportion of patients on 'X' who reported an adverse event of diarrhoea was notably greater than the proportion on placebo who reported the same event.

- a) Briefly describe 5 types of information you would use to assess whether there is a causal relationship between medicine 'X' and diarrhoea. (5 marks)
- b) Briefly describe 5 ways in which you could assess the clinical relevance or importance of this finding (assuming there is an underlying causal relationship). (5 marks)



QUESTION 9

With regards to the United Kingdom's Association of the British Pharmaceutical Industry (ABPI) Code of Practice:

- a) What is the definition of 'Donations and Grants' (1 mark)
- b) What is the difference between a donation and a grant. (1 mark)
- c) What are some of the requirements to consider before approving a donation request. (8 marks)

QUESTION 10

You are a pharmaceutical physician working in Medical Affairs. You have been asked to support the Market Access team in generating the dossier to support pricing for a new medicine currently in development.

- a) Briefly describe 4 pharmaceutical pricing mechanisms. (4 marks)
- b) List 4 important characteristics to consider when choosing pricing analogues. (2 marks)
- c) After licensing, the team decide that to ensure that the widest group of patients who could benefit from this drug are able to access it, additional data on its effectiveness and safety profile would be of value. Provide 2 benefits and 2 limitations of using US insurance claims data to demonstrate the benefit of the drug in the real world. (4 marks)