

Higher Combined version — Higher Tier (★) included; Separate-only (◆) removed.

Q1. Describe the stages of clinical trials. Explain why double-blind design is used.

[4 marks]

Q2. Explain how cancer results from changes in cell division. Distinguish between benign and malignant tumours.

[3 marks]

Total: 7 marks

Q1 (4 marks)

Describe the stages of clinical trials. Explain why double-blind design is used.

- Phase 1: healthy volunteers — safety and dosage [1]
- Phase 2: patients — effectiveness [1]
- Phase 3: large-scale vs placebo or existing treatment [1]
- Double-blind: neither patient nor doctor knows allocation — prevents bias/placebo effect [1]

Q2 (3 marks)

Explain how cancer results from changes in cell division. Distinguish between benign and m...

- Mutations in genes controlling cell cycle → uncontrolled division [1]
- Benign: stays localised, not immediately life-threatening [1]
- Malignant: invades tissue, can metastasise to other organs via blood [1]