

Foundation Separate version — Higher Tier (★) questions removed.

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

[4 marks]

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

[3 marks]

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**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]