

Question 1

Multiple answers possible

Criteria for the evaluation of medical devices (MD) are:

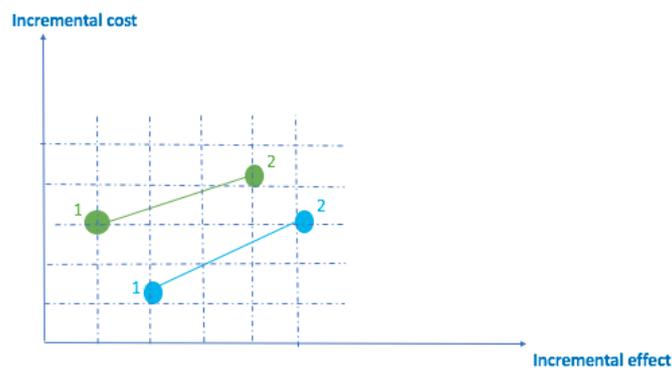
- a. **performance** of the MD
- b. definition of the MD **risk** (safety)
- c. **impact** of the cost of the MD **on the health budget** (affordability)
- d. **cost-effectiveness** (acceptability)
- e. **safety, quality and efficacy**

FEEDBACK

a and b are correct

Question 2

Only one answer is correct



Based on the figure here above, please decide what drugs would be the better option in terms of cost-effectiveness?

- a. The green line (1→2)
- b. The blue line (1→2)
- c. None of the lines provide information, because we don't know the comparator
- d. Both lines show equal improvement in terms of cost-effectiveness
- e. We have too little information to decide which drugs is most cost-effective

FEEDBACK

Correct answer is a.

Economic evaluation is the comparative analysis of alternative courses of actions in terms of both their costs and consequences. The incremental cost-effectiveness ratio (ICER) is a tool helping you decide which alternative best suits the current situation based on the cost and benefits of the proposed alternative.

The green line (a.) is the correct choice since the incremental cost is lower than the one of the blue line with a same incremental benefit.

Question 3

Fill in the missing words (drag and drop):

The is the increase in medical errors occurring when
Community advisory boards (CABs) rely on CABs can bring a lot to medical R&D such as which might improve the recruitment strategy and improve to alleviate the burden on patients involved in clinical trials.

WORDS:

Patients – study procedures – failure increase – traineeship phenomenon – July effect – ‘I just got started’ excuse – holiday effect – traineeship shifts last too long (shifts up to 24h) – too many physicians and nurses take their holidays, even if the hospital does not have this capacity – information dissemination – diseases – new residents start working in the hospitals – just graduated doctors arrive too late at work after a night at the bar – patient experts – communities – guidelines – health laws

FEEDBACK

The July effect is the increase in medical errors occurring when new residents start working in the hospitals.

Community advisory boards (CABs) rely on patient experts. CABs can bring a lot to medical R&D such as information dissemination which might improve the recruitment strategy and improve study procedures to alleviate the burden on patients involved in clinical trials.

Question 4

Please indicate if the following statements are true or false

- 4.1. Clinical studies must be first approved by an Ethics Committee before the first patient can be screened and/or included in the study.
- 4.2. Phase IV of the clinical trial is conducted after the marketing authorisation, and records data that will enable the measurement of the effectiveness of the newly approved drug.
- 4.3. Collaboration between hospitals members is key for the right conduct of a trial, whereas the collaboration between sponsor and competent authorities and between sponsor and centers are only conducted at the beginning of the study.
- 4.4. A clinical trial is a prospective, interventional study without IMP.
- 4.5. All clinical studies are clinical trials.
- 4.6. During a phase I study, the drug is tested on healthy volunteers in order to measure the dose efficacy.

FEEDBACK

Correct answer is

- 4.1. TRUE - Patients can only be included in a trial if the Ethics Committee has reviewed and approved the study protocol.
- 4.2. TRUE

- 4.3. FALSE - Collaboration is key at all stages and between all actors!
- 4.4. FALSE - A clinical trial is a prospective, interventional study WITH!!! IMP.
- 4.5. FALSE - All clinical trials are clinical studies but the reverse is not correct.
- 4.6. FALSE - Phase I studies are done with healthy volunteers to measure the safety, side effects and the formulation and best dose to give to future patients, by a dose escalation scheme.

Question 5

Only one answer is correct

Why is research in the field of 'Microbiome, nutrition & health' gaining importance ?

- a. Because the number of bacterial cells in and on our body at least equals the number of eucaryotic cells in our body, meaning that studying this relationship (host-microbiome) is very important
- b. Because there are hundreds of metabolites, most with an unknown effect on the health of their host
- c. Because there are more genes present in the microbiome than in the human genome
- d. Because knowing which components of the microbiome might be potentially harmful for humans could improve our health
- e. Because researchers want to know the importance of the gut barrier to keep the microbial balance safe
- f. Because the microbiome interacts with endocrine cells (secreting hormones) in our intestines, meaning that the microbiome may have an effect at distance from the gut (e.g. on our lungs)
- g. Because the environment (incl. our nutrients) has an impact on our microbiome and hence our health

Answer :

- a. 3 out of 7 answers are correct
- b. None of the answers are correct
- c. All the answers are correct
- d. Less than 3 answers are correct
- e. 4-6 answers are correct

FEEDBACK

Correct answer is c.