Short Answer Question Paper 2011

1. a) What categories of medicines of medicines can be submitted for approval, using the Centralised Procedure in Europe? (5 marks)
   b) *Ignoring timelines*, briefly list the main differences in procedure and outcome between the Centralised and Decentralised Procedure in Europe (5marks)

2. a)What is meant by the terms absolute bioavailability and relative bioavailability ? (2 marks)
   b) Outline the key elements in the design of a relative bioavailability study. (8 marks)

3. What considerations are relevant to the design and conduct of clinical trials in-patient populations with rare diseases? (10 marks)

4. Briefly explain the following concepts in lay terms that could be understood by a potential trial participant:

   a) Analysis of the Intention To Threat (ITT) population (3 marks)
   b) Cytochrome P450 (3 marks)
   c) Genotoxity (2 marks)
   d) Rescue medication (2 marks)

5. You read an article in a medical journal about Drug X, a new drug developed to treat heart failure, which was tested against placebo in 2000 patients for 1 year. Of the 1000 patients assigned to placebo, 80 patients were hospitalised for heart failure, compared to 40 patients in the Drug X treated group.

   a) Show how you would work out the absolute risk reduction (ARR) with drug X for this event (2 marks)
   b) Show how you would work out the relative risk reduction (RRR) with drug X for this event. (2marks)
   c) What is meant by the Number Needed to Treat (NNT) for this result and show how you would calculate the NNT (2 marks)
   d) Suggest two pieces of further information you would need in order to evaluate the significance of this finding (2 marks)
   e) Why is it important to consider both the ARR and the RRR when Interpreting results? (2 marks)

6. In the context of Phase III clinical development

    a) What are the aims of "superiority" and "non-inferiority" trials? (2 marks)
    b) List the key considerations in the design and analysis of a non Inferiority trial (6 marks)
    c) State one situation where a superiority approach must be used (1 mark)
    d) State one situation where a superiority approach may be used (1 mark)

7. The UK Prescription Medicines Code of Practice Authority (PMCPA) Code of Practice applies to the promotion of medicines to healthcare professionals and to appropriate administrative personnel

    a) Define the term "promotion" as used in the PMCPA Code of Practice (2 marks)
    b) List the activities included under this term "promotion" (8 marks)

8. What types of data should be considered before taking the decision to progress a small molecule into formal (GLP standard) non-clinical development? (10 marks)

9. You receive a spontaneous of QTc prolongation for a newly launched combination product of a novel agent with a long established licensed drug.

    a) List 4 possible causes of this event in relation to this combination product? (2 marks)
    b) What factors should be taken into consideration regarding the likely causality of this event? (2 marks)

10. a) What are the responsibilities of the investigator in the reporting of adverse events in clinical trials? (2 marks)
    b)The EU Directive requires Sponsors to provide safety information during the conduct of clinical trials:
        i) List the types of safety information that a Sponsor must provide (4 marks)
        ii) Briefly outline the key requirements underlying this reporting (4 marks)