

Examination MSA620

2018

Examination:

- Closed book written exam and Compulsory computer project
- The written exam is worth 30 scores (pass (G) = 15 scores, excellent (VG) = 24 scores).
- No material is allowed at the exam other than a simple pocket calculator
- Difficult formula as well statistical tables will be provided (cf. sample and old exams)

Chapter 1 Reading instructions

- •1.1 What are clinical trials: Read
- •1.2 History of clinical trials: Less important
- •1.3 Regulatory process and requirements: Read page 14
- •1.4 Investigational new drug application: Read page 17–20
- •1.5 New drug application: Less important
- •1.6 Clinical development plan and practice: Read
- •1.7 Aims and structure of this book: Skip

Chapter 2 Reading instructions

- 2.1 Introduction: Not very important
- 2.2 Uncertainty and probability: Read
- 2.3 Bias and variability: Read
- 2.4 Confounding and interaction: Read
- 2.5 Descriptive and inferential statistics: Repetition
- 2.6 Hypothesis testing and p-values: Repetition*
- 2.7 Clinical significance and clinical equivalence: Read
- 2.8 Reproducibility and generalizability: Read

*) Read extra material

Chapter 4 Reading instructions

- 4.1 Introduction: Read
- 4.2 Randomisation Models: Read
- 4.3 Randomisation Methods: Read
- 4.4 Implementation of Randomisation: Less important
- 4.5 Generalization of Controlled Randomised Trials: Less important
- 4.6 Blinding: Read
- 4.7 Discussion: Less important

Chapter 5 Reading Instructions

- 5.1: Introduction
- 5.2: Parallel Group Designs (read)
- 5.3: Cluster Randomized Designs (less important)
- 5.4: Crossover Designs (read+copies)
- 5.5: Titration Designs (read)
- 5.6: Enrichment Designs (less important)
- 5.7: Group Sequential Designs (read include 10.6)
- 5.8: Placebo-Challenging Designs (less important)
- 5.9: Blinded Reader Designs (less important)
- 5.10: Discussion

Chapter7 Reading instructions

- •7.1 Introduction
- •7.2 Multicenter Trials: Read + extra material
- •7.3 Superiority Trials: Read
- •7.4 Equivalence/Non-inferiorityTrials: Read
- •7.5 DoseResponseTrials: Read
- •7.6 Combination Trials: Read
- •7.7 BridgingTrials: Skip
- •7.8 VaccineTrails: Skip

For the technical chapters you should learn the content of the following chapters

- Chapter 8: 8.1-8.5,
- Chapter 9: 9.1-9.6,
- Chapter 10: 10.1-10.4 and 10.6,
- Chapter 11: 11.1-11.4 (until example 11.4.1) and 11.5-11.7 (until example 11.7.2),
- Chapter 12: 12.6 as well as the lectures notes distributed as handouts.