PTCMA

HTA in Action

Online short course

2021

HTA101:

Intervention Research and Clinical Trials

Study Guide

PHARMACEUTICAL & TECHNOLOGY CLINICAL MANAGEMENT ASSOCIATION

HTA101:

Intervention Research & Clinical Trials

Contents

SUMMARY

Intervention research is research undertaken to develop new or improved healthcare interventions and to evaluate the effectiveness of pharmacologic interventions. This is considered to be the most reliable evidence in healthcare research. In a clinical trial setting, the researcher aims to explore whether a medical strategy, a treatment or a device is safe and effective for humans. Clinical trials produce the best data available for healthcare decision making by utilising stringent scientific standards and protocols in the design and development of intervention research.

LECTURER AND SUPPORT

Meet the Lecturer

Professor Danie van Zyl
Prof van Zyl completed his Master of Medicine in Internal Medicine at the University of Pretoria in 2000 and went on to complete a second Master's degree, this time a Master of Science in Clinical Epidemiology in 2003. He earned his PhD in Internal Medicine in 2012, also from the University of Pretoria.
Prof van Zyl has been a specialist Physician at Kalafong Hospital in the Department of Internal Medicine since June 1999.
His responsibilities include supervision of medical in- and outpatients care in his firm, training 4th to 6th year medical students and doing postgraduate training.

Support

For all technical and administrative questions, please contact our support team via email to education@ptcma.org.za.

COURSE STRUCTURE

Contact times

This course will not have any contact times. Should you have any questions, please post them in the online forum or send it via email and we will get back to you.

Admin

The course will be presented on an online Moodle platform found at http://education.ptcma.org.za/. You will be registered and enrolled to the module for which registration details will be sent via email.

Once enrolled you will have access to the Orientation Module to familiarise yourself with the platform. You will also receive access to the material for the first study unit. This will include a lecture presentation with a voice-over and any additional reading the lecturer might deem necessary.

Once you have completed the content for the study unit, you will have access to complete the assessment. Once the assessment has been successfully completed, you will gain access to the next study unit.

There is no time limit for completing a study unit, but the **advised guideline is one week per study unit**. You will have **90 days from enrolment** to complete the course.

Should you neglect to complete the course in 90 days, your enrolment will terminate, and you will need to re-register and repay to access the course again.

All administrative questions can be directed to Janine at education@ptcma.org.za.

DESCRIPTION OF THE MODULE

This is the first course of the PTCMA online HTA in Action short course category. All professionals registered with the HPCSA will receive **30 CPD points** upon the successful completion of the Module. This relates to at least **30 study hours** for this Module.

The emphasis in the course is on the comprehension and development of insight into intervention research and to evaluate the effectiveness of pharmacologic interventions.

The better part of this module will be self-study with an online forum available to ask questions to which your fellow students or the lecturer can respond.

ASSESSMENT

Assessments

There will be online assessments consisting of 5 multiple choice questions for each study unit on the scope of that unit's material. You will have 60 minutes to complete the questionnaire. These assessments will be made available once all the content has been viewed. In order to access the next unit's material, you will be required to achieve a minimum of 70%. Should you not achieve this, you will need to review all the material again and wait 2 days until you will be able to re-attempt the assessment.

To qualify for the final assignment, all assessments need to be successfully completed with an average grade of 70%. Should this minimum requirement not be met, you will be deregistered from the course with the opportunity to re-register in 6 months' time.

Final Assignment

The final assignment will comprise of practical questions that should be answered and summarised in one or two short paragraphs to indicate understanding of the topic.
The final assignment will be made available upon completion of the final assessment, provided the required grade was met.

The final assignment is due upon the end of the 90-day enrolment. No late submissions will be accepted.

Final Marks

The final marks for the module will be calculated as follows:

- Weekly assessments = 20%

- Final assignment = 80%

The pass rate is 50%. Should you not achieve this, but you received at least 35% for the **final assignment**, you will have the opportunity to do a rewrite at a cost of R350. The minimum required pass rate for the rewrite will be 50%.

Extensions and enrolment suspension

- As the course was created as an 8-week (56 day) programme, no extensions will be granted. Participants will need to manage their pace to submit the final assignment within the time of enrolment.
- Should a participant find their workload does not permit them to work on the course, they may request a temporary suspension. This will block all access to the course for the set time, but the participant will regain access after the suspension period.
- Maximum suspension allowed is 3 months.
- Suspension is only allowed up until the 5th study unit and only within the first 60 days of enrolment.

OVERVIEW OF THE MODULE

Schedule	Topics
Study unit 1 Suggest 1 week for completion	• Why RCT (Randomised Controlled Trials) • Phases of clinical trials • Good Clinical Practice (GCP)
Study unit 2 Suggest 1 week for completion	• Erroneous results • Types of RCT designs
Study unit 3 Suggest 1 week for completion	• Endpoints • Validity issues
Study unit 4 Suggest 1 week for completion	• Interpreting RCT results • NNT's
Study unit 5 Suggest 1 week for completion	• Power • Subgroup analysis (Multiplicity) • Interim analysis and stopping rules
Study unit 6 Suggest 1 week for completion	• Revision
Final assignment Suggest 2 weeks for completion	

LEARNING OUTCOMES

In this module you will be able to develop tools to evaluate the most current medical research findings, use the skills developed to apply specific research findings to your own setting or patient population by calculating and interpreting the results.

- Understand the crucial issues regarding validity requirements for designing and developing protocols for intervention research as well as deciding on the appropriate outcome measures and their interpretation. This includes the following:
    - Understanding RCT (randomised controlled trials) and other trial design and clinical endpoints,
    - Validity issues: Randomisation, allocation concealment, blinding and completeness of follow-up
    - Clinical trial result interpretation: Risk, Rate, Relative Risk Reduction, Absolute Risk Reduction, NNT and NNH, p-values, Confidence Interval (CI) and power
    - Superiority, Non-inferiority, Equivalence and Bioequivalence studies

There will be assignments to complete which will assist in competence evaluation.