

# SHORT COURSE IN CLINICAL RESEARCH AND EVIDENCE-BASED MEDICINE (SCREM) AND FUNDAMENTALS OF CLINICAL STUDIES (GCP)

(Course leader: Johan van Griensven)

SCREM is a blended training targeting professionals who are responsible for clinical research and local guidelines/algorithm development. Clinical research in low to middle income countries is often implemented by specialised institutions. Clinicians in national, regional and district hospitals are aware that there is much information they could use to perform “low-scale” research to enhance their own decision-making. While academically oriented clinicians develop their research through doctoral study programs, the others often miss training opportunities. The SCREM aims at filling this gap, targeting professionals who are responsible for clinical quality assurance, for local guideline and/or algorithm development and for coaching junior staff in clinical research.

## NUMBER OF CREDITS

10 ECTS

## MODE OF STUDY

This course (component) is organized :

- Distance learning (Online)
- Face-to-face (Antwerpen)

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10 ECTS

## LEARNING OBJECTIVES

At the end of the course the student should be able to:

- Retrieve relevant published articles related to a research question;
- Evaluate relevance of clinical research results in relation to a concrete low resource setting;
- Design a research project in the field of etiology of health problems, or effectiveness and efficiency of diagnostics, or clinical management and disease prevention in low resource settings;
- Apply principles of evidence-based medicine (EBM). This includes the ability to use gathered evidence in guideline and algorithm development, and the ability to evaluate guidelines;
- Set-up, conduct and follow-up clinical studies, following Good Clinical Practice (ICH-GCP) guidelines as reference;
- Communicate research results to both professional and scientific communities in a written and oral way.

## CONTENT

Starting from a practical question participants encountered in their clinical work (draft personal project as mentioned below under selection criteria), a critical analysis of literature is done and an applied

research protocol is identified at the start of the course. The following contents will be contextualized individually and/or in small groups (2-3 participants).

1. Protocol development: from observation to hypothesis, from hypothesis to study methodology and sampling populations;
2. Presenting medical statistics: how to present statistical information for a proposal, a paper or a report;
3. Presentation of results in a written (Executive Summary) and oral (power point presentation) way;
4. Critical reading: pitfalls in research (bias in hypothesis, in inclusion, in analysis, in interpretation, in applicability);
5. Literature Search: how to run a literature search, levels and types of evidence of published research;
6. Principles of EBM and introduction to constructing and evaluating guidelines and algorithms;
7. IT skills: Excel, Word, Reference Manager;
8. Learning to use statistical software ("R");
9. Seminars:
  - Standard Operating Procedures (SOP);
  - Ethical aspects of research;
  - Research funding;
  - Fundamentals of Clinical Studies: GCP & Beyond.

## TEACHING AND LEARNING METHODS

The course mainly uses adult learning methods, based on problem oriented Socratic approach (problem-based inductive methodology) with assignments in small groups (2-3 participants) coached by a tutor, with regular plenary sessions.

Consultants will be invited to discuss specific problems such as ethics, statistical methods, funding etc. based on the different protocols developed by participants, taking them as field examples.

Except for 4 seminars there will be no classical ex-cathedra teaching.

Moodle is used as Learning Management System (LMS) for the distance learning phase and for the F2F in house management of the students.

The online lectures, for the distance learning component of the course, have embedded:

- Self-assessments;
- MCQ quizzes\*;
- Compulsory discussion forum participation;

\*for online pre-/post-test and GCP certification.

## ASSESSMENT

Portfolio assessment with written weekly assignments from distance learning component (30% of the final mark), formulation of Executive Summary (20% of the final mark) and oral presentation of personal project (50% of final mark). For participants who wish to obtain a GCP certificate, a formal examination (multiple choice quiz, covering aspects of all course sessions) will be held at the end of the Fundamentals of Clinical Studies: GCP & Beyond week. In order to receive a certification, an overall score of at least 70% should be achieved.

## LITERATURE USED

Clinical epidemiology prerequisite knowledge for SCREM<sup>1</sup>

Clinical trials - Regulation EU No 536/2014, European Commission, "Live, work, travel in the EU", available at [https://ec.europa.eu/health/human-use/clinical-trials/regulation\\_en](https://ec.europa.eu/health/human-use/clinical-trials/regulation_en) (last accessed 29 April 2019)

Efficacy Guidelines, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guidelines, available at <http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html> (last accessed 29 April 2019)

Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, World Medical Association (WMA), 2018, available at <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> (last accessed 29 April 2019)

International Ethical Guidelines for Health-related Research Involving Humans, Council for International Organizations of Medical Sciences (CIOMS), available at <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf> (last accessed 29 April 2019)

## STAFF INVOLVED

- Manu Bottieau, Institute of Tropical Medicine Antwerp, Department of Clinical Sciences
- Lut Lynen, Institute of Tropical Medicine Antwerp, Department of Clinical Sciences
- Johan van Griensven, Institute of Tropical Medicine Antwerp, Department of Clinical Sciences
- Jozefien Buyze, Institute of Tropical Medicine Antwerp, Department of Clinical Sciences
- Ermias Diro, University of Gondar, Gondar, Ethiopia
- Rodrigo Henriquez, Universidad de Las Américas (UDLA), Quito, Ecuador
- CTU: Yven Van Herrewege, Bart Smekens, Natacha Herssens, Harry Van Loen, Diana Arango, Hanne Landuyt, Jozefien Buyze
- Irith De Baetselier, ARL at CSDepartment, Raffaella Ravinetto/Anne Buvé, PH Department, Jef Verellen, ITM Quality Assurance

[Archive online phase 2019](#)

[Archive Phase to Phase 2019](#)

[Study Guide](#)

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<sup>1</sup> Text developed by the Unit of Epidemiology & Disease Control at ITM: Marleen Boelaert, Greet Dieltiens, Marie- Laurence Lambert, Francine Matthys, Bart Ostyn, Jo Robays, Patrick Van der Stuyft and Veerle Vanlerberghe; material written by Zeno Bisoffi, Juan Moreira and Jef Van den Ende