

Course syllabus

TMCD503 Introduction to Clinical Research

1. **Institute** Mahidol University
- Faculty/Department** Faculty of Tropical Medicine, Department of Clinical Tropical Medicine
2. **Course Name:**
 - a. **Course Code:** TMCD 503
 - b. **Course Title:** Introduction to Clinical Research
3. **Number of credits:** 1 (1-0-2)
4. **Programme use:** Graduate Diploma Programme in Tropical Medicine and Hygiene
Master of Clinical Tropical Medicine
5. **Prerequisite:** None
6. **Type of Course:** Elective subject
7. **Condition: class size:** None
8. **Session/Academics year:** The first semester of each academic year
9. **Course description:**

Basic research methodology and applications in study process including protocol writing, ethical issues and consent form, diagnostic tests, designing case-record form, sampling and allocation under good clinical practice (GCP) and epidemiological and clinical trials including etiologic study, how to conduct the study, data management, publication and presentation

10. **Course expected learning outcomes:**

The students should be able to

- 1) Explain the good clinical research
- 2) Discuss fundamental knowledge using in clinical research, writing of proposal, good clinical research management
- 3) Differentiate the research methodology in clinical research
- 4) Critique research methodology and ethic in clinical research

11. Course outline and constructive alignment

	Topics	Hours			Instructors	Course learning outcomes	Programme ELOs	Learning Activities	Assessment
		Lecture	Lab	Self-study					
1	Introduction to Clinical Research and Clinical Trial Design	1	0	2	Prof Arjen Dondorp/Prof Sasithon/Dr Prakaykaew	1,2,3,4	2.2	Lecture, slide presentation	Student participation, Discussion
2	Research Methodology	1	0	2	Prof Sasithon/Dr Prakaykaew/Dr Natthida	3,4	2.2	Lecture, slide presentation	Student participation, Discussion
3	Grant application	1	0	2	David Gandy/Dr Prakaykaew/Dr Borimas	2,4	2.2	Lecture, slide presentation	Student participation, Discussion
4	Protocol	1	0	2	Prof Punnee	1,2,3,4	1.1,2.2	Lecture, slide presentation	Student participation, Discussion
5	Informed Consent	1	0	2	Asst Prof Supat/Asst Prof Jittima	1,2	1.1,2.2	Lecture, slide presentation	Student participation, Discussion
6	Diagnostic tests	2	0	4	Assoc Prof Varunee/Assoc Prof Vipa	2	3.3	Lecture, slide presentation	Student participation, Discussion
7	Good Clinical Practice (GCP)	2	0	4	Prof Punnee	1,2,4	1.1,2.2	Lecture, slide presentation	Student participation, Discussion
8	Literature search	1	0	2	Ms Duangjai	2	2.2	Lecture, slide, presentation, demonstration, practice	Student participation, Discussion, Practice in class
9	Ethics in Clinical Research	2	0	4	Assoc Prof Yupaporn	1,2,4	1.1	Lecture, slide presentation	Student participation, Discussion
10	How to develop GCP compliant documents	1	0	2	Asst Prof Jittima	1,2,3,4	1.1,2.2	Lecture, slide presentation	Student participation, Discussion
11	Systemic review and Literature Review	2	0	4	Asst Prof Chusak	2,4	3.3	Lecture, slide presentation	Student participation, Discussion
	Total	15	0	30					

12. Teaching and Learning Activities

Lecture, scenario, Discussion

Teaching media

PowerPoint presentation

Discussion

13. Course achievement and evaluation

Attendance	50%
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Discussion and course participation	50%
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Note¹ Students must attend at least 80% of all activities.

14. Course evaluation

Discussion and comments session at the end of the course

Questionnaire for contentment and suggestion for the course

15. References

15.1. Spriet A, Simon P. Methodology of clinical drug trials. Translation of Methodologie des essais cliniques des médicaments by Edelstein R, Weintraub M with a preface by Lasagna L. Basel, New York: Karger, 1985.

15.2. MRC Guidelines for Good Clinical Practice in Clinical Trial

15.3. GCP/ICH Guidelines

15.4. Mandell GL, Bennett JE, Dolin R. Mandell Douglas, and Bennett's Principles and Practice of Infectious Diseases. 6th ed. Philadelphia: Churchill Livingstone; 2005

16. Instructors:

As in course outline

17. Course responsibility:

Prof Punnee Pitisutthithum

Department of Clinical Tropical Medicine, Faculty of Tropical Medicine, Mahidol University