MECOR Global Virtual Level 2

Methods in Epidemiologic, Clinical & Operations Research

2025
Course Syllabus
Level 2

Location: Online

(Zoom Platform)

Acknowledgments

The American Thoracic Society is the primary sponsor of the 2025 MECOR Global – Virtual Level 2 course.

Our sincere thanks to all who have shared the vision and support this program.

The American Thoracic Society acknowledges and gratefully thanks

Drs. Özge Yilmaz and Richard Van Zyl - Smit, MECOR Global – Virtual Level 2 Course Directors, and all Faculty Members who generously shared their time and knowledge during the course.

ATS MECOR Program

"Improving global lung health through development of local, country and regional lung disease research capacity"

American Thoracic Society

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WELCOME TO 2025 MECOR Global – Virtual Level 2

COURSE OVERVIEW

Welcome back to MECOR 2.0! During the following weeks you will gain a deeper understanding of research methods and the approaches necessary for operationalizing your study. Level 2 is focused on refining your study protocol and developing a manual of procedures (MOP) and an analysis plan for the study. In developing the MOP you will learn to identify and describe the details of study procedures. In addition you will learn to apply the statistical tests discussed in level 1 in the analysis of data from your study.

Level 2 builds on protocols developed in Level 1 by adding the descriptions of study forms and operational procedures needed to successfully carry out the research. The majority of time will be spent working individually, with regular consultations from a faculty member and others as needed, and minimal time in formal lectures.

The course utilizes a "flipped classroom" approach wherein you will complete readings, view recorded lectures, and complete assignments prior to each day of the course. During the day, key points of the lectures/readings will be summarized in the classroom. Small group and individual work will focus on application of the information learned from the videos and to your research protocols.

The overall organization of the course is as follows:

- Daily check-in: At the start of each day, course faculty will briefly review completion of the prior evening's homework, slide sets and reading, and identify any topics/issues students are struggling with.
- Summary of Key Points and Discussion: A course faculty member will highlight key points from video lectures and readings with examples, and address student questions.
- Small groups: Students will separate into their pre-assigned small groups (3-4 students/group). Each student will present her/his assignment and receive feedback from other students and faculty. Small group sessions are 60-90 minutes in length, allowing for about 15 minutes of discussion for each student's assignment.
- Mentored individual work: Students will work independently to update their research protocol, including a MOP and analysis plan, by incorporating feedback received during small group. All course faculty will be available to answer questions and work 1:1 with students.
- Individual work: Students will work independently to update their research protocol, and to begin assignments (readings, lecture slide sets, homework) for the next day. Faculty will be available to address questions and work 1:1 with students as needed.

LEARNING OBJECTIVES

1) Develop a comprehensive MOP aligned with the research protocol.
2) Design a comprehensive data analysis plan including a data management and quality control plan.
3) Develop and present a Power Point presentation summarizing the student's work during the course.
4) Critique and support one's own research protocol as well as others.

These objectives are designed to enable you to confidently carry out your study with a high likelihood that the results will be valid and publishable.

EXPECTATIONS FROM STUDENTS

Prior to the courses

1) Familiarize yourself with the course syllabus and reference materials that are available in CANVAS.
2) Actively engage with your faculty mentor.
3) Complete all of the pre-course homework that is assigned in CANVAS.
4) Assemble and bring with you any materials (articles, pilot test results, etc.) that you have or can find that are relevant to your study.

During the course

1) Be committed to the course for the entire period. This means regular course hours online plus extra work offline for both students and faculty.
2) Participate fully in all course activities, including check-ins and small group work.
3) Complete assigned homework on a timely basis.
4) Seek help from Level 2 or other faculty when you have problems or need to review your plans/progress.
5) Fully engage in preparing and presenting your research protocol during sessions and at the conclusion of the course.

After the course

1) After you leave the course, make any final additions to your MOP as needed and complete your study prior to coming to Level 3 for assistance in writing up your results.
2) Keep your mentor informed about the progress of your study. Should you need any assistance we will help you trouble shoot and problem-solve.

EXPECTATIONS OF FACULTY?

The Level 2 faculty will provide the structure for the course and will lead discussions on key topics. Lectures will be few, brief, and highly interactive, using illustrations from the L2 students' studies. Faculty will work with each student to help with decisions related to study design and methods, refine/revise plans as necessary, and to review all documentation. Additionally, they will evaluate the students' progress and accomplishments during and at the end of the course. Students can also request appointments with faculty outside of regular online class time. We also welcome the opportunity to discuss your research interests, career plans, and the resources/challenges in your research environment.

RESOURCES

Textbooks

These books are both available in CANVAS.

- **Kirkwood BR & Sterne JAC.** Essential Medical Statistics, 2nd edition. Malden, MA, Blackwell Publishing, 2003
- **Hulley SB, et al.** Designing clinical research: an epidemiologic approach. 4th edition. Philadelphia: Lippincott Williams & Wilkins, 2013. (The 3rd edition is equally helpful.)

Helpful websites

- **Statistics at Square One (British Medical Journal):** http://bmj.bmjjournals.com/collections/statsbk/
  This is an excellent review of basic medical statistics.
- **UCLA:** http://socr.ucla.edu/htmls/SOCR_Analyses.html UCLA's statistical calculators run JAVA applets to estimate sample size needs for two-sample Poisson, ANOVA, Fisher's exact test, correlation/regression, t-test with unequal variances, nonparametric rank sum and sign tests, and other features.
- **Vanderbilt University:** http://biostat.mc.vanderbilt.edu/twiki/bin/view/Main/PowerSampleSize A downloadable free program for Power and Sample Size calculation. Highly recommended. It does several sample and power size calculations for continuous data and offers several capabilities that the Epi Info program does not have.
- **University of California, San Francisco** Web based sample size and power calculator http://www.biostat.ucsf.edu/sampsize.html
- Look also for a free software called **G-Power** (for sample size calculation): http://www.gpower.hhu.de/en.html
- Comprehensive collection of online clinical and statistics calculators. http://vassarstats.net/
- **University of Iowa:** http://www.stat.uiowa.edu/~rlenth/Power/index.html
  Excellent website that covers many ANOVA and regression designs, repeated measures, and a lot more. This is a superb resource with the ability to work out power for contrasts, generate power curves, and so on.

Other helpful resources

- **Gordis L.** Epidemiology. Fifth edition. Elsevier Saunders, Philadelphia, PA 2014.
- **Glantz, S A**. Primer of biostatistics / Stanton A. Glantz. 7th ed. New York: McGraw-Hill Medical Pub. Division, 2011.
- **IUATLD Monograph:** "Research Methods for the Promotion of Lung Health, A Guide to Protocol Development for Low-Income Countries."
  http://www.theunion.org/what-we-do/publications/technical/research-methods-for-the-promotion-of-lung-health-a-guide-to-protocol-development-for-low-income-countries.

LEVEL 2 TASKS AND COMPETENCIES

The intent of Level 2 is to utilize the tasks listed in Table 1 to develop the competencies specified in Table 2. The degree to which we will be able to complete the tasks will depend on how quickly we can move through each of the components of your protocols and produce a final document.

TABLE 1: LEVEL 2 TASKS	
Creating a manual of procedures (MOP)	
MOP vs Protocol	*Develop an understanding of the difference between a Protocol and a Manual of Procedures*
Study Flow Diagram	*Develop a graphic that summarizes study flow, starting with participant selection and recruitment through data collection and analysis*
Sampling /Population Selection	*Develop a strategy for identifying and recruiting study participants*
Questionnaires, Measures and Measurement Procedures	*Develop all data collection instruments and procedures,*
Quality Control	*Develop a quality control plan for all aspects of the study (e.g., recruitment, assessment, intervention/treatment, data management, analysis)*
Research Ethics & Protection of Human Subjects in Research	*Identify any potential conflicts of interest of study investigators; Develop a plan to ensure informed consent and ethical treatment of participants*
Creating a plan for data analysis	
Analysis Plan	*Develop a plan for analysis that addresses both a descriptive presentation of your study data as well as the formal statistical analyses needed to address the research aims and hypothese/s*
Regression Models	*Develop a plan for multivariate analyses (e.g., logistic or linear regression models) to address the research hypotheses, and be able to justify the model chosen.*
Shell tables and figures	*Develop the shell (dummy) figures and tables that you plan to use to summarize your data when you write up your results for publication*
Presentation	
PowerPoint presentation	*Prepare a PowerPoint presentation summarizing your accomplishments during the week.*

TABLE 2: LEVEL 2 COMPETENCIES	
Research Design	*Understand the basis of clinical epidemiology as an approach to diagnosis, prognosis, and treatment of disease*
	Understand the application of study design to clinical studies
Research Question	*Apply and adapt epidemiologic questions to clinical and health services problems*
Population Selection and Sampling	*Develop feasible & valid approaches to sampling*
Measurement Procedures	*Balance precision & accuracy in measurements; Be able to design & pre-test a study questionnaire.*
Quality Control	*Know effective approaches to monitoring quality of data gathering, data entry, and data management*
Choose appropriate statistics for a research question	*Choose how to pick which statistical methods are most appropriate for a research question, taking into account the study design, the outcome and exposure variables, and the sampling.*
Sample Size and Power	*Know basic elements required to determine sufficient sample size for planned study*
Sources of Error	*Bias, confounding chance; type I and II errors. Reliability, validity, accuracy & precision*
Multivariate Analysis	*Understand role of multivariable modeling including logistic regression and survival analysis*
Ethics and Informed Consent	*Know& follow current standards of ethical treatment of human subjects; understand role of IRB.*
Study Outline	*Be able to present research protocol developed in course*

COURSE SCHEDULE AND ASSIGNMENTS

Pre-course

Required videos to watch (combined time about 141 minutes)

1) What is a MOP and Why Do We Need One? (duration 12:32)
2) Basic Biostatistics, part 1 (duration 31:32)
3) Basic Biostatistics, part 2 (duration 16:42)
4) Data Mgmt & QC, pt 2 – Getting To Know Your Data (duration 34:13)
5) Using Charts and Tables (duration 38:09)
6) Developing a Study Flow Diagram (8:32)

Optional videos to watch from ATS Webinar series (combined time about 2 hrs 43 minutes)
1) Preparing slides and posters (duration 12:02)
2) Preparing bar graphs (duration 11:20)
3) Poster preparation (duration 9:30)
4) Creating scatterplots (duration 7:41)
5) Preparing posters and slides for national meetings (duration 59:58)
6) Tips for large group PowerPoint presentations (duration 1:02:14)

Suggested readings
1) Concepts of Data Analysis (brief pdf document)
2) Chapters 1-4 from Kirkwood and Sterne text Essential Medical Statistics

Written and other assignments
1) Upload the current draft of your Protocol
2) Upload any MOP elements that have already been developed
3) Complete analysis of practice dataset and upload results
4) Draft and upload a Study Flow Diagram for your study
5) Draft and upload a shell Characteristics of Sample table for your study
6) Complete and upload the “Day 1 Student PowerPoint Presentation” using template provided

PRELIMINAR COURSE AGENDA

Session 1 - April 11, 2025 FRIDAY			
TIME	**TOPIC**	**FACULTY**	**FORMAT**
10:00 - 10:30 AM (EDT - New York)	Welcome & Introduction to Course and Faculty		
10:30 - 11:30 AM (EDT - New York)	Student Introductions, Overall goals of global online MOP course		
11:30 - 12:15 AM (EDT - New York)	**Summary of key points and discussion:** What is a MOP and how to develop a MOP		

Session 2 - April 12, 2025 SATURDAY			
TIME	**TOPIC**	**FACULTY**	**FORMAT**
8:45 - 9:30 AM (EDT - New York)	**Summary of key points and discussion:** Creating dummy figures and tables aligned with the research		
9:30 - 10:15 AM (EDT - New York)	**Summary of key points and discussion:** Study Flow & CONSORT diagram		
10:15-10:30 AM (EDT - New York)	**BREAK**		
10:30 AM - 11:15 AM (EDT - New York)	**Summary of key points and discussion:** Sampling and recruitment		

Session 3 - April 15, 2025 TUESDAY			
TIME	**TOPIC**	**FACULTY**	**FORMAT**
10:00 - 12:30 AM (EDT - New York) **5:00 - 7:30 PM (EEST - Istanbul)**	**Small Group:** Discuss and refine each student's Study Flow Diagram and Characteristics of the Sample table		

Session 4 - APRIL 22, 2025 TUESDAY			
TIME	**TOPIC**	**FACULTY**	**FORMAT**
10:00 AM - 10:45 AM (EDT - New York)	**Summary of key points and discussion:** Review of basic biostatistics and developing an analysis plan		
10:45 - 11:30 AM (EDT - New York)	**Summary of key points and discussion:** Choosing an analytic model		
Session 5 - APRIL 27, 2025 SUNDAY			

TIME	TOPIC	FACULTY	FORMAT
8:45 - 11:00 AM (EDT - New York)	**Student presentations and discussion:** Finalized dummy tables and analysis plan		

Session 6 - APRIL 29, 2025 TUESDAY			
TIME	**TOPIC**	**FACULTY**	**FORMAT**
10:00 AM - 10:45 AM (EDT - New York)	**Summary of key points and discussion:** Questionnaire design		
10:45 - 11:30 AM (EDT - New York)	**Summary of key points and discussion:** Data management and quality control		

Session 7 - MAY 2, 2025 FRIDAY			
TIME	**TOPIC**	**FACULTY**	**FORMAT**
10:00 AM - 12:30 PM (EDT - New York)	**Student presentations and discussion:** MOP outline, sampling and recruitment strategy		

Session 8 - MAY 4, 2025 SUNDAY			
TIME	**TOPIC**	**FACULTY**	**FORMAT**
9:00 - 11:30 AM (EDT - New York)	Final Student presentations		
11:30 AM - 12:00 PM (EDT - New York)	GRADUATION AND CLOSING CEREMONY		

TEMPLATES AND WORKSHEETS

FINER Criteria for Evaluating Study Questions

Feasible
- Adequate number of subjects
- Adequate technical expertise
- Affordable in time and money
- Manageable in scope

Interesting
- To the investigator

Novel
- Confirms or refutes previous findings
- Extends previous findings, such as to new geographic areas or populations
- Provides new findings

Ethical
- Must go through institutional human subjects review board

Relevant
- To scientific knowledge
- To clinical and health policy (e.g., affects treatment or prevention)
- To future research (e.g., improves understanding of mechanism)
- I.e., what are the implications of finding out the answer to your question?

(Adapted from Hulley et al.: Designing Clinical Research: An Epidemiologic Approach, Table 2.1)

RESEARCH PRESENTATION AND PROTOCOL OUTLINE

(1-2 pages for dissemination and comment by colleagues)

1. **Title**
   Clear and descriptive

2. **Rationale/Background/Significance**
   One to several paragraphs indicating why the question is important

3. **Research Question**
   One sentence concisely stating your question; (answer should be Yes, No, or a number.)

4. **Objective (s)**
   Overall purpose, primary and secondary objectives: statement

5. **Study Design**
   Cross-sectional vs. case-control, vs. cohort, etc. Illustrate with 2x2 table

6. **Participants/Study Population**
   Inclusion and exclusion criteria (location, age, sex, etc.)
   Sampling and recruitment strategies
   Institutional Review Board (IRB) issues: human subjects ethics review, informed consent, etc.

7. **Variables**
   Outcome (dependent variable, response variable)
   Exposure (risk factor, independent variable, predictor, explanatory variable, treatment)
   Covariates and potential confounders and effect modifiers
   Data collection and quality control methods (questionnaire, medical record review, etc.)

8. **Statistical Analysis**
   Hypothesis
   Analytic approach
   Sample size and power

9. **Timeline**
   Phases of research plan, recruitment, screening, data collection, follow up, data analysis, report preparation

10. **Budget**
    Personnel, Equipment, Travel, Materials, Publication Costs

11. **Strengths and Weaknesses**