Research School in Medical Science MEFMV2F, 13.5 hp

Examiner: Jan Lexell

1. Introduction

Welcome to the Research School in Medical Science at the Faculty of Medicine, Lund University! We offer a course package to provide the basics in scientific theory, methods, statistics, and ethics, as well as skills for communicating science. Together the aim of the research school is to help you achieve the learning outcomes of the PhD program and provide tools for all stages throughout your research project.

Approximately 160 PhD students (a third are full-time PhD students, two thirds part-time) per year are admitted to the Faculty of Medicine at Lund University. The group is heterogeneous, with 70-75% clinical and 20-25 % pre-clinical students. Additionally, the PhD program hosts a significant number of international students with limited proficiency in Swedish and admission to the program is continuous throughout the year.

This research school is designed to secure timely participation, align students of different backgrounds, build professional networks across the Faculty, and improve the impact of the compulsory courses for each individual PhD student. The Research School in Medical Science offers all compulsory PhD courses during one semester together with a fixed class of students from various research topics across all disciplines at the Faculty. Students are offered admission to and are expected to attend the research school during the first year of their PhD program. The courses are taught in English using Canvas as the digital learning environment.

Two of the most important concepts when initiating the Research School were early access to compulsory courses as well as the idea of building networks across the various subjects of the Faculty. Therefore students and supervisors are expected to prioritize the course and respect that active participation is compulsory throughout.

2. Learning objectives

The overall aim of the Research School in Medical Science is to provide a foundation based on the theory of science, methodology and ethics for scientific work in all steps of the research process.

Specific learning outcomes

Knowledge and understanding

- 1. Describe the PhD program's learning outcomes and define the function of the individual study plan (ISP).
- 2. Identify roles and division of responsibilities between the PhD student, supervisor and others involved in the education process.
- 3. Identify and summarize key concepts and theories that are of importance for the student's own thesis.
- 4. Identify ethical considerations and problems in various research contexts and in the student's own research.
- 5. Compare perspectives on evidence and explain epistemological differences.

6. Identify differences in quantitative and qualitative study designs and discuss the level of evidence and generalizability.

Competence and skills

- 1. Apply ethical guidelines and legal rules in the student's own research and in that of others.
- 2. Analyze and present the student's own research and others from an ethical perspective.
- 3. Analyse, discuss and present differences in study design, method and data handling in relation to research questions and research paradigms.
- 4. Independently select, justify, examine and evaluate a statistical method of relevance for the student's own research or a specific research question.
- 5. Problematize perceptions on gender, diversity, sustainability and equal rights in relation to the student's own research field.
- 6. Communicate, orally and in writing, the student's own research in a manner that is relevant in relation to the selected target group, situation and context.
- 7. Develop and argue for search strategies for the student's own research in relevant databases and explain the research publication process.

Judgment and approach

- 1. Justify the need for the student's continued personal competencies development in relation to their professional development as a researcher.
- 2. Critically reflect on the ethical challenges and standpoints through the various steps of the research process, as well as on the shortcomings and merits of ethical guidelines and legal rules in research.

3. Modules

The research school consists of the following course modules:

- Introduction to PhD studies (the module runs digitally and "on-demand" you take it immediately after admission to PhD studies and it has to be completed before you start the other Research School courses)
- Introduction to Research Methodology, 3 hp/credits
- Theory and practice of scientific communication, 1.5 hp/credits
- Applied statistics I, 1.5 hp/credits
- Research ethics, 3 hp/credits
- Applied statistics II, 3 hp/credits, (you choose one of the three possible level II-modules: (Clinical Research; Biomedicine and Laboratory medicine; Epidemiology and Health Sciences)
- Oral communication, 1.5 hp/credits

Module 1 (2100). Introduction to PhD studies

Course leader Jan Lexell (jan.lexell@med.lu.se)

Contents and format

The module is fully digital and all documents and lectures can be viewed at any time-point in <u>www.canvas.education.lu.se</u>.

To complete the course, you will need to read and view the compulsory material and also pass a test with multiple choice questions (MCQ). You will also need to complete an individual reflection and together with your supervisor discuss your reflection.

This digital introductory module will give you a glimpse of what modules to come and learning goals for the different modules, including Introduction to research methodology, Scientific communication, Statistics and choice of statistical software, Research ethics and Oral communication. Useful information to facilitate your academic writing will also be provided. In this module you will learn about your individual study plan (ISP) and be introduced to the portfolio, which will be a reflection document you will work with throughout your PhD education.

Furthermore, you will get information from the post-graduate studies office, and the human resource department related to the working environment describing your and the employer's responsibility at the University and available support. You will get to know the role of the doctoral student ombudsman (DOMB), how to benefit from the Medical doctoral student council (MDR), and how Lund University Innovation can help you to utilize your research. Career Centre, will provide the perspective of what possibilities you have when you have obtained a PhD.

Aims

To get an overview of the research studies at the Medical Faculty in Lund, including courses, learning goals, the individual study plan (ISP) and the portfolio.

To provide information about the post-graduate studies office, the human resource department, the doctoral student ombudsman (DOMB), the Medical doctoral student council (MDR), and Lund University Innovation, and the Career Centre.

Learning objectives

- Describe the learning outcomes and content for the PhD program in its local context as well as the national aims and policies for doctoral studies.
- Define the function of the individual study plan and how it can become a significant instrument in the learning process.
- Identify the value of self-reflection and how the portfolio system can be of support in the learning process.
- Identify various roles and clarify the distribution of responsibility between doctoral students, supervisors and others involved in the educational process.

Assignments

- Read and view the compulsory material;
- Pass a Multiple Choice Questions (MCQ) examination online;
- Complete an individual reflection and together with your supervisor discuss your reflection.

References

The Handbook for PhD Students http://www.med.lu.se/english/intramed/teaching research/phd students supervisors

Module 2 (2101). Introduction to Research Methodology (3hp/credits)

Course leaders Helena Jernström(helena.jernstrom@med.lu.se)and Johan Mårtensson (johan.martensson@med.lu.se)

Contents and format

The module consists of lectures, group work, case-based demonstrations, practical exercises, guizzes, discussions and presentations. Attendance is compulsory for all components. The course focuses on the different methods relevant in research at the Medical Faculty, Lund University. The course introduces the research process and scientific reasoning. It includes the following research methodology:

- Experimental designs and methodological pre-clinical studies
- Quantitative methods: clinical research & design and epidemiology
- Health economics
- Qualitative methods
- Systematic review technique
- Mixed designs and methods

Aims

The course aims to enable the participants to develop an understanding of the research process, research design and methodology.

Learning objectives

- To gain the ability to put into perspective why and why not a certain design/research method for a specific purpose/a specific hypothesis should or should not be used
- Identify differences in quantitative and qualitative study designs and discuss the level of evidence and generalizability.
- Analyse, discuss and present differences in study design, method and data handling in relation to research questions and research paradigms.

Assessment

The assessment is based on active participation in all the components of the course.

- Written individual report on own research process
- Multiple Choice Questions (MCQ)

References

Recommended reading is listed in Canvas and available from the start of the module.

Module 3 (2102). Theory and practice of scientific communication (1.5hp/credits)

Course leaders Aprile Clark (<u>aprile.clark@med.lu.se</u>) and Matthias Bank (<u>matthias.bank@med.lu.se</u>)

Contents and format

The module consists of lectures, group work, demonstrations of and practical exercises in information management, group discussions, and presentations. Attendance is compulsory for all components.

Aim

The module aims to enable the participants to develop an understanding of the different stages of the process of scientific communication.

Learning objectives

- Explain the process of research publication including examples from your own research area and different publication models.
- Develop a search strategy for your own research in relevant databases and reflect on this strategy.
- Formulate your own research in writing in a clear and accessible way for a target group in a popular science forum.
- Formulate your own research in writing in a scientific forum.
- Provide constructive oral peer review of scientific and popular science texts.
- Apply different functions/tools for evaluation of research quality, identify strengths and weaknesses and discuss these.

Assessment

The assessment is based on active participation in all the components of the module and a number of assignments:

- Written assignment on the publication process
- Written assignment on your own research for the general public
- Written assignment on your own research for researchers
- Providing and receiving constructive feedback on texts with a fellow student
- Written assignment on search strategies for information related to their own projects

References

Recommended reading is listed in Canvas and available from the start of the module.

Module 4 (2103). Applied statistics I (1.5 hp/credits)

Course leader Mahnaz Moghaddassi (mahnaz.moghaddassi@med.lu.se)

Contents and format

The module includes the following three blocks:

1. Introduction to medical statistics

- Study design
- Generalizability
- Basic statistical concepts
- Descriptive statistics
- 2. Parameter estimates and hypothesis testing
 - Basic principles
 - P-value, confidence intervals and statistical power
 - Common statistical tests for comparing two groups
- 3. Data management
 - Create and validate datasets
 - Documentation
 - Basic knowledge in a statistical package (R, SPSS, Stata or equivalent)
 - Reproducible analyses (script-based)

This module discusses questions that can be studied through quantitative methods. The module touches upon common study designs and basic statistical concepts, principles, and methods. The module introduces concepts like variable, distribution, parameter, random variability and variance. The concepts are illustrated by examples from medical science. The module will also include and discuss different measures of dispersions and proper graphical techniques to visualize and study the characteristics of the collected data. The module will also introduce concepts like parameter estimation, and uncertainty will be discussed and described through standard errors and confidence intervals. Additionally, hypothesis testing, p-values and statistical power are introduced. The module will also cover basic tests for comparing two groups e.g., t-test, Mann-Whitney, Chi-square and Fisher's exact test. The focus will be on interpretation and on which conclusions can be drawn from the results based on statistical significance, evidence, effect size and generalizability.

The module also includes a practical introduction to a statistical package. This session focuses on principles for data management but the participants will also get the opportunity to conduct the statistical analyses covered in the module.

The module includes lectures and group sessions and one day with data management and analyses. This day will be given separately for the programs R, SPSS and Stata. The participants are expected to choose one of these packages (or an equivalent) and then use this when participating in statistical courses on a higher level at the Faculty.

Learning objectives

On completion of the course, the student shall able to propose, perform, interpret, and critically review basic statistical analyses within each of the four different themes of the course: binary outcomes, correlation and regression, management of confounding effects and studies of reliability.

References

Kirkwood B and Sterne J. Essential Medical Statistics. Blackwell Science, 2nd edition, 2003. Chapter 2-8, 14, 15 and 17.

Available as e-book at Lund University (www.lub.lu.se)

The module requires access to a laptop with an installed statistical package. More information will be provided before the module.

Module 5a (2104). Applied statistics II - Clinical Research (3hp/credits)

Course leaders Pär-Ola Bendahl (<u>par-ola.bendahl@med.lu.se</u>) and Anton Nilsson (<u>Anton.Nilsson@med.lu.se</u>)

Contents and format

The target group is PhD students at the Faculty of Medicine with a research project within clinical research.

The module includes the following four blocks:

1. Design and analysis of studies with a focus on binary outcomes

- Cohort and case-control studies
- Incidence and risk measures
- Measures of association: Odds ratio, absolute and relative associations
- Basic survival problems (time-to-event)
- Power
- 2. Introduction to correlation and regression analysis
 - Spearman's and Pearson's correlation coefficients
 - Simple linear regression
 - Simple logistic regression
- 3. Regression analysis advanced
 - Introduction to Cox regression
 - Multivariable modelling
 - Interaction
- 4. Randomized Controlled Trials (RCT) and diagnostic studies
 - Design and analysis of randomized controlled trials
 - Diagnostic measures: sensitivity, specificity, predictive values
 - ROC-analysis

This module for clinical researchers focuses on regression methods, especially linear regression models for a continuous outcome variable and one or more independent variables: in what situations they can be used and how the results should be interpreted.

The module will also cover how regression methods can be used to assess and handle confounding and interaction. Further, other types of regression models such as binary outcomes (logistic regression) and survival analysis (Cox regression) will be introduced. Additionally, statistical methods for diagnostic tests will be covered by introducing sensitivity, specificity, positive and negative predictive value, as well as a choice of cut off with ROC-analysis. The module also introduces theories and regulations around randomized controlled trials.

Aims

The course will provide students with practical knowledge of the best way to manage and analyze empirical data in clinical research projects. The course will also prepare the participants for understanding and critically examining other empirical research in medical science, including outside their own field of research.

Learning objectives

On completion of the course, the student shall be able to propose, perform, interpret, and critically review basic statistical analyses within each of the four different themes of the course: binary outcomes, correlation and regression, advanced regression, and randomised clinical trials/diagnostic testing.

Assessment

The assessment is based on a take-home exam and a group assignment. A Pass on the course requires a Pass on the take-home exam, as well as a completed group assignment, which involves active participation in the discussions about their own group's work and other groups' work.

References

Kirkwood B and Sterne J. Essential Medical Statistics. Blackwell Science, 2nd edition, 2003. Chapter: 10-16, 18-22, 26-27, 29, 34-38.

Available as an e-book at Lund University Libraries (<u>www.lub.lu.se</u>)

The module will be held in English and requires active participation and access to a laptop with an installed statistical package that you are familiar with from earlier courses (SPSS, STATA or R). More information will be provided before the start of the module.

Module 5b (2105). Applied statistics II – Biomedicine and Laboratory medicine (3hp/credits) Course leader Aleksandra Turkiewicz (<u>Aleksandra.Turkiewicz@med.lu.se</u>)

Contents and format

The target group is PhD students at the Faculty of Medicine with a research project within biomedicine or laboratory medicine.

The module includes four themes:

1) Non-parametric testing for the comparison of two or more groups, for example

- Mann-Whitney test
- Wilcoxon Signed Rank test

2) Introduction to regression and analysis of variance

- Linear regression
- Analysis of variance (ANOVA)
- Relation between t-tests, linear regression and ANOVA
- Multiple testing and its consequences

3) Issues in design of experiments

- Dependent and independent observations
- Randomization, blinding and confounding
- Statistical testing, power and confidence intervals
- Reporting of study design and statistical analyses in basic science papers

4) Reliability

- Correlation versus agreement
- Limits of agreement
- Cohen's kappa for categorical data

This advanced module in applied statistics, specializing in biomedicine and laboratory medicine, provides the participant with an introduction to the necessary tools for designing and analyzing experimental data in biomedicine and laboratory medicine. The module starts with non-parametric testing for group comparisons. The module also provides students with an introduction to regression and analysis of variance, as well as issues in design of experiments. Finally, the module addresses different types of reliability analyses.

The module requires access to a laptop with an installed statistical package that you are familiar with from earlier courses (SPSS, Stata or R). More information will be provided before the start of the module.

Aims

This module provides students with practical knowledge of suitable ways to design experiments, manage and analyze empirical data in research projects within biomedicine and laboratory medicine. The course will also prepare participants for understanding and critically examining other empirical research in medical science, including outside their own field.

Learning objectives

On completion of the module, the student shall be able to propose, perform, interpret, and critically review basic statistical analyses in relation to the four different themes of the course: non-parametric testing, introduction to regression and analysis of variance, issues in design of experiments and reliability.

Assessment

The assessment is based on a take-home exam. A Pass on the module requires a Pass on the take-home exam, as well as a completed individual and group assignments, including active participation in the discussions about own and other's work.

References

Kirkwood B and Sterne J. Essential Medical Statistics. Blackwell Science, 2nd edition, 2003. Other course literature will be given during the course.

<u>Module 5c (2106). Applied statistics II - Epidemiology and Health Sciences (3hp/credits)</u> Course leaders Mahnaz Moghaddassi (<u>Mahnaz.Moghaddassi@med.lu.se</u>) and Jonas Björk (Jonas.Bjork@med.lu.se)

Contents and format

The module provides general knowledge about common statistical methods that are applicable in epidemiological and health sciences research. The target group is all PhD students at the Faculty of Medicine who have epidemiology or health sciences as an essential part of their thesis work.

The module contains four content areas:

- 1) Design and analysis of studies of binary outcomes
 - Cohort and case-control studies
 - Incidence and risk calculations
 - The measure of association, odds ratios, absolute and relative comparisons
 - Simple survival analysis (time to event)
 - Power calculation

2) Introduction to correlation and regression analysis

- Spearman rank and Pearson's correlation coefficient
- Simple linear regression
- Simple logistic regression
- 3) How to control for confounding effects
 - Overview of the different approaches
 - Overview of common regression models
 - Using multiple logistic regression
- 4) Reliability analysis
 - Association vs consistency
 - Bland-Altman
 - Limits of agreement
 - ICC for continuous data
 - Kappa calculations for categorical data, Introduction to more advanced methods

This module in applied statistics with a specialization in Epidemiology (Public Health) and Health Sciences provides participants with the necessary tools to plan, analyze, and evaluate common types of observational studies in these research fields. Emphasis is placed on the use of regression methods as a way to manage confounding effects.

The module provides an overview of commonly used regression models in this context, but with a primary focus on logistic regression analysis of case-control data. The module addresses the difference between correlation, association, and consistency, and also provides an introduction to reliability analysis of both quantitative measurements and qualitative assessment instruments.

Aim

The module will provide practical knowledge concerning the management and analysis of empirical data in the chosen epidemiological and health research project. The module will also help the participants to be able to critically examine various types of empirical research in medical science, also outside their own field of research.

Learning objectives

On completion of the course, the student shall able to propose, perform, interpret, and critically review basic statistical analyses within each of the four different themes of the course: binary outcomes, correlation and regression, management of confounding effects and studies of reliability.

Assessment

Take-home examination. To pass the module it is not only required to have a passing grade on the examination but also to have completed the group assignment, including active participation in the discussions concerning both their own group work as well as the work of other groups.

References

Vittinghoff E, Glidden DV, Shiboski SC, McCulloch CE. Regression methods in biostatistics.
Springer, 2nd edition, 2012. Chapters 3.1-3.5, 4.1–4.4 & 5.1-5.4.
(The book is available as an e-book at Lund University)
As a reference to the section on the design and analysis of binary outcomes (theme No. 1) the same book is used as in the module.
Epidemiology I – Introduction till epidemiology:
Rothman KJ. Epidemiology – an introduction. Oxford University Press, 2nd edition, 2012.
The articles that deal with the topic of reliability analysis (theme No. 4) will be handed out at

the start of the module.

Module 6 (2107). Research Ethics (3hp/credits) Course leader

Kristina Hug (<u>kristina.hug@med.lu.se</u>)

Contents and format

Codes, rules, and principles in different parts of research ethics, including an introduction to The Act on Ethical Review of Research Involving Humans. Ethical considerations on research on human subjects. Research integrity, including research misconduct, publication ethics, and researchers' relation to society.

Aims

The course aims to strengthen the participants' competence in research ethics and encourage a critical approach to their own research and that of others.

Learning objectives

After completion of the course, doctoral students should be able to identify ethical problems in different types of biomedical research, including the one conducted for his/her own doctoral studies; to analyze such problems in an independent and informed way as well as apply laws, rules and recommendations about research that involves human subjects and personal data. Students should also be able to apply current provisions and guidelines regarding research misconduct and good research practice in an informed and independent way.

Assessment

Active participation in discussion exercises and group-work, and completion of an individual assignment on the ethical aspects of the research conducted as part of student's own research studies.

References

Will be handed out at the start of the module or with the welcome letter.

Module 7 (2108). Oral Communication (1.5 hp/credits).

Course leaders Karin Öjehagen (Karin.Ojehagen@med.lu.se) and Kristina Lundholm Fors (Kristina.Lundholm_fors@med.lu.se)

Contents and format

The course covers different aspects of oral communication of scientific content. The focus is on various ways to audience-adapt, structure and visualize the content of an oral presentation, the use of voice and body language, and stress management strategies. The main emphasis is on research presentations to research colleagues, but adaptation to other target groups is also covered. The course content relates to rhetoric and theories of communication and adult learning. There is a considerable emphasis on the role of feedback in the learning process and how feedback from research colleagues contributes usefully and meaningfully to developing oral presentation skills.

The course is based on different types of practical exercises and builds on the participants' own material. The structure of the module is based on the participants' involvement and exchange of feedback in all activities. The structure is intended to boost the participants, so that they can take on and perform oral presentations with an increased awareness of their own resources and a feeling of security.

Aim

The aim of the module is that participants shall develop their ability to orally communicate and visualize research to different target groups in different contexts. Another aim is to inspire participants to explore different ways of orally presenting research in a safe learning climate.

Learning objectives

After completing the module, participants should be able to structure, visualize and orally communicate a scientific content taking into consideration the audience's needs, the situation and the context; to provide feedback that aims to support development of oral communication skills; and to analyze and discuss, based on the relevant literature, how an oral research presentation can be audience-adapted, structured, and performed.

Assessment

Active participation in the learning activities, two oral presentations and an analysis of presentation forms based on relevant literature.

References

Literature and resources will be made available with the welcome letter and/or through Canvas at the start of the module.