



# Module Catalogue

for the Subject

# Clinical Research and Epidemiology

as a Master's with 1 major  
with the degree "Master of Science"  
(90 ECTS credits)

Examination regulations version: 2015  
Responsible: Faculty of Medicine

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## The subject is divided into

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## Content and Objectives of the Programme

The Clinical Research and Epidemiology programme leading to the degree of Master of Science (MSc) is offered by the Faculty of Medicine of JMU as a research-based course in the framework of a consecutive Bachelor's/Master's model. The successful completion of a programme in medicine takes the place of the successful completion of a Bachelor's programme with 210 ECTS credits mentioned in Section 6 (1) Sentence 1 ASPO (General Academic and Examination Regulations). The Master of Science degree is a further professional and research-oriented university degree.

### Graduates from Clinical Research and Epidemiology

- have gained a grounding in clinical and epidemiological research.
- have learned some essential methods used to plan and implement patient-centred projects.
- have developed a high level of proficiency in the analysis of clinical and epidemiological data.
- have developed practical skills and experience in the reading and writing of scientific publications.

## Abbreviations used

Course types: **E** = field trip, **K** = colloquium, **O** = conversatorium, **P** = placement/lab course, **R** = project, **S** = seminar, **T** = tutorial, **Ü** = exercise, **V** = lecture

Term: **SS** = summer semester, **WS** = winter semester

Methods of grading: **NUM** = numerical grade, **B/NB** = (not) successfully completed

Regulations: **(L)ASPO** = general academic and examination regulations (for teaching-degree programmes), **FSB** = subject-specific provisions, **SFB** = list of modules

Other: **A** = thesis, **LV** = course(s), **PL** = assessment(s), **TN** = participants, **VL** = prerequisite(s)

## Conventions

Unless otherwise stated, courses and assessments will be held in German, assessments will be offered every semester and modules are not creditable for bonus.

## Notes

Should there be the option to choose between several methods of assessment, the lecturer will agree with the module coordinator on the method of assessment to be used in the current semester by two weeks after the start of the course at the latest and will communicate this in the customary manner.

Should the module comprise more than one graded assessment, all assessments will be equally weighted, unless otherwise stated below.

Should the assessment comprise several individual assessments, successful completion of the module will require successful completion of all individual assessments.

## In accordance with

the general regulations governing the degree subject described in this module catalogue:

**ASPO2015**

associated official publications (FSB (subject-specific provisions)/SFB (list of modules)):

**13-Jul-2015 (2015-14)**

This module handbook seeks to render, as accurately as possible, the data that is of statutory relevance according to the examination regulations of the degree subject. However, only the FSB (subject-specific provisions) and SFB (list of modules) in their officially published versions shall be legally binding. In the case of doubt, the provisions on, in particular, module assessments specified in the FSB/SFB shall prevail.

## Compulsory Courses

(60 ECTS credits)

## **Compulsory Courses I: Basics of Epidemiology and Biometry**

(22 ECTS credits)

<b>Module title</b>		<b>Abbreviation</b>
Introduction into epidemiology and biometry		03-KFE-01-152-m01
<b>Module coordinator</b>		<b>Module offered by</b>
Institute of Clinical Epidemiology and Biometry (ICE-B)		Faculty of Medicine
<b>ECTS</b>	<b>Method of grading</b>	<b>Only after succ. compl. of module(s)</b>
5	numerical grade	--
<b>Duration</b>	<b>Module level</b>	<b>Other prerequisites</b>
1 semester	graduate	--
<b>Contents</b>		
Foundations of clinical and epidemiological research; fundamental concepts of diagnostics and their application; meaning and computation of epidemiological risk measures.		
<b>Intended learning outcomes</b>		
The students have developed a fundamental knowledge on questions of clinical research and epidemiology, on study designs as well as potential sources of and measures against bias of study results. They are familiar with performance parameters of diagnostic tests and are able to provide quantitative interpretations of diagnostic test results. They are also familiar with fundamental epidemiological risk measures and are able to compute them from data.		
<b>Courses</b> (type, number of weekly contact hours, language – if other than German)		
V (2) + S (4)		
<b>Method of assessment</b> (type, scope, language – if other than German, examination offered – if not every semester, information on whether module is creditable for bonus)		
oral examination of one candidate each (approx. 30 minutes) creditable for bonus		
<b>Allocation of places</b>		
--		
<b>Additional information</b>		
--		
<b>Workload</b>		
150 h		
<b>Teaching cycle</b>		
--		
<b>Referred to in LPO I</b> (examination regulations for teaching-degree programmes)		
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<b>Module appears in</b>		
Master's degree (1 major) Clinical Research and Epidemiology (2015)		



<b>Module title</b>		<b>Abbreviation</b>
Biometrical methods		03-KFE-02-152-m01
<b>Module coordinator</b>		<b>Module offered by</b>
Institute of Clinical Epidemiology and Biometry (ICE-B)		Faculty of Medicine
<b>ECTS</b>	<b>Method of grading</b>	<b>Only after succ. compl. of module(s)</b>
6	numerical grade	--
<b>Duration</b>	<b>Module level</b>	<b>Other prerequisites</b>
1 semester	graduate	--
<b>Contents</b>		
Basics of the statistical software SPSS; data preparation; descriptive statistics; basic methods of inference statistics. Advanced part: statistical modelling by multiple regression for metric, binary, ordinal and survival data.		
<b>Intended learning outcomes</b>		
The students are able to create data tables, to import and export data, to pool and merge as well as to transform and recode data. They have learned to describe data numerically by statistical measures and to represent it graphically. They are familiar with significance tests and confidence estimates as well as fundamental methods for one and two-sample problems. Advanced part: The students perform multiple regression analyses by the general linear model, binary and ordinal logistic regression as well as Cox regression (including time-dependent covariates) and are able to test for interaction effects.		
<b>Courses</b> (type, number of weekly contact hours, language – if other than German)		
V (4) + Ü (2)		
<b>Method of assessment</b> (type, scope, language – if other than German, examination offered – if not every semester, information on whether module is creditable for bonus)		
oral examination in groups (approx. 30 minutes per candidate) creditable for bonus		
<b>Allocation of places</b>		
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<b>Additional information</b>		
--		
<b>Workload</b>		
180 h		
<b>Teaching cycle</b>		
--		
<b>Referred to in LPO I</b> (examination regulations for teaching-degree programmes)		
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<b>Module appears in</b>		
Master's degree (1 major) Clinical Research and Epidemiology (2015)		

<b>Module title</b>		<b>Abbreviation</b>
Applied biometry		03-KFE-03-152-m01
<b>Module coordinator</b>		<b>Module offered by</b>
Institute of Clinical Epidemiology and Biometry (ICE-B)		Faculty of Medicine
<b>ECTS</b>	<b>Method of grading</b>	<b>Only after succ. compl. of module(s)</b>
5	numerical grade	--
<b>Duration</b>	<b>Module level</b>	<b>Other prerequisites</b>
1 semester	graduate	--
<b>Contents</b>		
Complex analyses of larger data sets to solve topical research questions; creation of tables and figures suitable for presentation in a scientific publication; additional statistical methods will be taught as needed for the specific task.		
<b>Intended learning outcomes</b>		
The students become familiar with a topical research question and the related data set. They perform all statistical analyses to answer the questions and learn to present the results in tables and figures. They also contribute to presenting the statistical methods and results, aiming at a co-authorship of a scientific publication in a peer-reviewed journal.		
<b>Courses</b> (type, number of weekly contact hours, language – if other than German)		
S (1.5) + Ü (3.5)		
<b>Method of assessment</b> (type, scope, language – if other than German, examination offered – if not every semester, information on whether module is creditable for bonus)		
Belegarbeit (thesis; approx. 15 pages)		
<b>Allocation of places</b>		
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<b>Additional information</b>		
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<b>Workload</b>		
150 h		
<b>Teaching cycle</b>		
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<b>Referred to in LPO I</b> (examination regulations for teaching-degree programmes)		
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<b>Module appears in</b>		
Master's degree (1 major) Clinical Research and Epidemiology (2015)		

<b>Module title</b>		<b>Abbreviation</b>
Epidemiological methods and evidence-based medicine		03-KFE-04-152-m01
<b>Module coordinator</b>		<b>Module offered by</b>
Institute of Clinical Epidemiology and Biometry (ICE-B)		Faculty of Medicine
<b>ECTS</b>	<b>Method of grading</b>	<b>Only after succ. compl. of module(s)</b>
6	numerical grade	--
<b>Duration</b>	<b>Module level</b>	<b>Other prerequisites</b>
1 semester	graduate	--
<b>Contents</b>		
Further aspects of study design; analysis of the relationship between risk factors and outcome; fundamental concept of evidence-based medicine; systematic reviews and meta-analyses; aims of clinical guidelines.		
<b>Intended learning outcomes</b>		
In further discussions of design aspects, the students learn how to purposefully use methodological elements to answer research questions and to assure the quality of study data. They perform numerical analyses to quantify the relationship between risk factor and outcome in the given study context and assess the evidence arising from the data. The students assess evidence from several sources. They are familiar with methods of systematic review of existing evidence and meta-analysis. They have developed a background knowledge about the development of clinical guidelines.		
<b>Courses</b> (type, number of weekly contact hours, language – if other than German)		
V (2) + S (4)		
<b>Method of assessment</b> (type, scope, language – if other than German, examination offered – if not every semester, information on whether module is creditable for bonus)		
oral examination of one candidate each (approx. 45 minutes) creditable for bonus		
<b>Allocation of places</b>		
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<b>Additional information</b>		
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<b>Workload</b>		
180 h		
<b>Teaching cycle</b>		
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<b>Referred to in LPO I</b> (examination regulations for teaching-degree programmes)		
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<b>Module appears in</b>		
Master's degree (1 major) Clinical Research and Epidemiology (2015)		

## **Compulsory Courses II: Clinical and Epidemiological Research**

(18 ECTS credits)

<b>Module title</b>		<b>Abbreviation</b>
Topical clinical research questions and interpretation of clinical trials		03-KFE-05-152-m01
<b>Module coordinator</b>		<b>Module offered by</b>
Institute of Clinical Epidemiology and Biometry (ICE-B)		Faculty of Medicine
<b>ECTS</b>	<b>Method of grading</b>	<b>Only after succ. compl. of module(s)</b>
6	numerical grade	--
<b>Duration</b>	<b>Module level</b>	<b>Other prerequisites</b>
1 semester	graduate	--
<b>Contents</b>		
Attendance of the course "How to read a paper"; seminar paper in the form of a paper review; regular attendance of the research seminar of the Institute of Clinical Epidemiology and Biometry (ICE-B) and/or a co-operating institution; delivering a talk.		
<b>Intended learning outcomes</b>		
The students know the requirements regarding the structure and content of publications in the context of various study designs. They also know typical pitfalls for authors and readers. By writing a review on a published paper, they have practised to critically reflect strengths and shortcomings of scientific work. The students actively participate in the discussion of topical (internationally relevant) research. Delivering a presentation on a topic of their choice, students have learned to select relevant sources, to prepare them for presentation and to develop a critical view on published material.		
<b>Courses</b> (type, number of weekly contact hours, language – if other than German)		
S (4) + K (2) Module taught in: usually English		
<b>Method of assessment</b> (type, scope, language – if other than German, examination offered – if not every semester, information on whether module is creditable for bonus)		
oral examination of one candidate each (approx. 45 minutes) Language of assessment: German or English creditable for bonus		
<b>Allocation of places</b>		
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<b>Additional information</b>		
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<b>Workload</b>		
180 h		
<b>Teaching cycle</b>		
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<b>Referred to in LPO I</b> (examination regulations for teaching-degree programmes)		
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<b>Module appears in</b>		
Master's degree (1 major) Clinical Research and Epidemiology (2015)		

<b>Module title</b>		<b>Abbreviation</b>
Disease-specific epidemiology and prognostic modelling		03-KFE-06-152-m01
<b>Module coordinator</b>		<b>Module offered by</b>
Institute of Clinical Epidemiology and Biometry (ICE-B)		Faculty of Medicine
<b>ECTS</b>	<b>Method of grading</b>	<b>Only after succ. compl. of module(s)</b>
6	numerical grade	--
<b>Duration</b>	<b>Module level</b>	<b>Other prerequisites</b>
1 semester	graduate	--
<b>Contents</b>		
Attendance of two courses of the Winter School in Epidemiology; selected topics of disease-specific research are presented in lectures and discussed in seminars; during the semester: examples of prognostic modelling from literature are studied in seminars; practical exercises.		
<b>Intended learning outcomes</b>		
The students develop an understanding of the specific implementation of general methods and techniques in the context of disease-specific research. In the joint sessions of students, young clinicians and scientists as well as academic teachers, they practise the interdisciplinary exchange of thoughts and knowledge in a workshop atmosphere. The students practise performing prognostic analyses and developing prognostic scores. They are familiar with common and distinct characteristics of prognostic questions and analyses in comparison to diagnostic and aetiologic research.		
<b>Courses</b> (type, number of weekly contact hours, language – if other than German)		
V (3) + S (3)		
<b>Method of assessment</b> (type, scope, language – if other than German, examination offered – if not every semester, information on whether module is creditable for bonus)		
oral examination of one candidate each (approx. 30 minutes) creditable for bonus		
<b>Allocation of places</b>		
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<b>Additional information</b>		
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<b>Workload</b>		
180 h		
<b>Teaching cycle</b>		
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<b>Referred to in LPO I</b> (examination regulations for teaching-degree programmes)		
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<b>Module appears in</b>		
Master's degree (1 major) Clinical Research and Epidemiology (2015)		

<b>Module title</b>		<b>Abbreviation</b>
<b>Research methodology (I: Clinical trial methodology, II: Transferable skills training)</b>		03-KFE-07-152-m01
<b>Module coordinator</b>		<b>Module offered by</b>
Institute of Clinical Epidemiology and Biometry (ICE-B)		Faculty of Medicine
<b>ECTS</b>	<b>Method of grading</b>	<b>Only after succ. compl. of module(s)</b>
6	numerical grade	--
<b>Duration</b>	<b>Module level</b>	<b>Other prerequisites</b>
1 semester	graduate	--
<b>Contents</b>		
Attendance of the certified course for clinical investigators offered by the Clinical Trial Centre Würzburg; attendance of three courses of the participant's choice offered by the GSLS.		
<b>Intended learning outcomes</b>		
Participants are familiar with the fundamental principles of good clinical practice, legal requirements for drug and medical device studies and other regulatory aspects. They are also familiar with requirements regarding the study protocol, the conduct of a study, data management and quality assurance. The students acquire and extend their technical skills in scientific work such as writing papers, giving talks, professional poster design, literature search etc.		
<b>Courses</b> (type, number of weekly contact hours, language – if other than German)		
S (3) + V (3)		
<b>Method of assessment</b> (type, scope, language – if other than German, examination offered – if not every semester, information on whether module is creditable for bonus)		
report (5 to 10 pages)		
<b>Allocation of places</b>		
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<b>Additional information</b>		
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<b>Workload</b>		
180 h		
<b>Teaching cycle</b>		
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<b>Referred to in LPO I</b> (examination regulations for teaching-degree programmes)		
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<b>Module appears in</b>		
Master's degree (1 major) Clinical Research and Epidemiology (2015)		

## **Compulsory Courses III: Research Placement**

(20 ECTS credits)



<b>Module title</b>		<b>Abbreviation</b>
Practical training I		03-KFE-08-152-m01
<b>Module coordinator</b>		<b>Module offered by</b>
Institute of Clinical Epidemiology and Biometry (ICE-B)		Faculty of Medicine
<b>ECTS</b>	<b>Method of grading</b>	<b>Only after succ. compl. of module(s)</b>
10	numerical grade	--
<b>Duration</b>	<b>Module level</b>	<b>Other prerequisites</b>
1 semester	graduate	--
<b>Contents</b>		
<p>Four-week practical training in a clinical or epidemiological research unit; written summary of research topics the participant was involved in, of experiences and newly acquired knowledge and skills, and critical reflection of the practical training; regular attendance of the colloquium and contribution to the discussion; presentation of the participant's own practical training in a talk.</p>		
<b>Intended learning outcomes</b>		
<p>The students acquire practical experience in all domains of the real world of studies. This includes preparation of studies and study documents, data acquisition (including examination of study participants), data management, data checks, study logistics etc. In the summary report, students relate their newly acquired experience to the theoretical matter studied so far and learn about the practical meaning of theoretical issues. The colloquium talk provides students with an opportunity to review what they have learned in the practical course. During the talk and discussion with their classmates, students will be able to practise their communication skills. The presentation of the individual topics will provide all participants with more in-depth insights into the real world of studies.</p>		
<b>Courses</b> (type, number of weekly contact hours, language – if other than German)		
P (7) + K (3)		
<b>Method of assessment</b> (type, scope, language – if other than German, examination offered – if not every semester, information on whether module is creditable for bonus)		
oral examination of one candidate each (approx. 45 minutes) creditable for bonus		
<b>Allocation of places</b>		
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<b>Additional information</b>		
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<b>Workload</b>		
300 h		
<b>Teaching cycle</b>		
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<b>Referred to in LPO I</b> (examination regulations for teaching-degree programmes)		
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<b>Module appears in</b>		
Master's degree (1 major) Clinical Research and Epidemiology (2015)		

<b>Module title</b>		<b>Abbreviation</b>
Practical training II		03-KFE-09-152-m01
<b>Module coordinator</b>		<b>Module offered by</b>
Institute of Clinical Epidemiology and Biometry (ICE-B)		Faculty of Medicine
<b>ECTS</b>	<b>Method of grading</b>	<b>Only after succ. compl. of module(s)</b>
10	numerical grade	--
<b>Duration</b>	<b>Module level</b>	<b>Other prerequisites</b>
1 semester	graduate	--
<b>Contents</b>		
<p>Four-week practical training in a clinical or epidemiological research unit; written summary of research topics the participant was involved in, of experiences and newly acquired knowledge and skills, and critical reflection of the practical training; regular attendance of the colloquium and contribution to the discussion; presentation of the participant's own practical training in a talk.</p>		
<b>Intended learning outcomes</b>		
<p>The students acquire practical experience in all domains of the real world of studies. This includes preparation of studies and study documents, data acquisition (including examination of study participants), data management, data checks, study logistics etc. In the summary report, students relate their newly acquired experience to the theoretical matter studied so far and learn about the practical meaning of theoretical issues. The colloquium talk provides students with an opportunity to review what they have learned in the practical course. During the talk and discussion with their classmates, students will be able to practise their communication skills. The presentation of the individual topics will provide all participants with more in-depth insights into the real world of studies.</p>		
<b>Courses</b> (type, number of weekly contact hours, language – if other than German)		
P (7) + K (3)		
<b>Method of assessment</b> (type, scope, language – if other than German, examination offered – if not every semester, information on whether module is creditable for bonus)		
oral examination of one candidate each (approx. 45 minutes) creditable for bonus		
<b>Allocation of places</b>		
--		
<b>Additional information</b>		
--		
<b>Workload</b>		
300 h		
<b>Teaching cycle</b>		
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<b>Referred to in LPO I</b> (examination regulations for teaching-degree programmes)		
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<b>Module appears in</b>		
Master's degree (1 major) Clinical Research and Epidemiology (2015)		

## Thesis

(30 ECTS credits)

<b>Module title</b>		<b>Abbreviation</b>
Master Thesis Clinical Research and Epidemiology		03-KFE-10-152-m01
<b>Module coordinator</b>		<b>Module offered by</b>
Institute of Clinical Epidemiology and Biometry (ICE-B)		Faculty of Medicine
<b>ECTS</b>	<b>Method of grading</b>	<b>Only after succ. compl. of module(s)</b>
27	numerical grade	--
<b>Duration</b>	<b>Module level</b>	<b>Other prerequisites</b>
1 semester	graduate	--
<b>Contents</b>		
Writing a Master's thesis.		
<b>Intended learning outcomes</b>		
Comprehensive exploration of a research question, including literature search, data analysis, interpretation and presentation in a scientific paper.		
<b>Courses</b> (type, number of weekly contact hours, language — if other than German)		
No courses assigned to module Module taught in: German or English		
<b>Method of assessment</b> (type, scope, language — if other than German, examination offered — if not every semester, information on whether module is creditable for bonus)		
written thesis (40 to 60 pages) Language of assessment: German or English		
<b>Allocation of places</b>		
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<b>Additional information</b>		
Time to complete: 6 months.		
<b>Workload</b>		
810 h		
<b>Teaching cycle</b>		
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<b>Referred to in LPO I</b> (examination regulations for teaching-degree programmes)		
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<b>Module appears in</b>		
Master's degree (1 major) Clinical Research and Epidemiology (2015)		

<b>Module title</b>		<b>Abbreviation</b>
Colloquium Master Thesis		03-KFE-11-152-m01
<b>Module coordinator</b>		<b>Module offered by</b>
Institute of Clinical Epidemiology and Biometry (ICE-B)		Faculty of Medicine
<b>ECTS</b>	<b>Method of grading</b>	<b>Only after succ. compl. of module(s)</b>
3	numerical grade	03-KFE-10
<b>Duration</b>	<b>Module level</b>	<b>Other prerequisites</b>
1 semester	graduate	--
<b>Contents</b>		
Defence of the Master's thesis in a public colloquium.		
<b>Intended learning outcomes</b>		
Students will deliver a scientific talk on the results of their own research and will spontaneously respond to questions from the audience.		
<b>Courses</b> (type, number of weekly contact hours, language — if other than German)		
K (o) Module taught in: German or English		
<b>Method of assessment</b> (type, scope, language — if other than German, examination offered — if not every semester, information on whether module is creditable for bonus)		
oral examination of one candidate each (approx. 30 minutes) Language of assessment: German or English		
<b>Allocation of places</b>		
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<b>Additional information</b>		
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<b>Workload</b>		
90 h		
<b>Teaching cycle</b>		
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<b>Referred to in LPO I</b> (examination regulations for teaching-degree programmes)		
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<b>Module appears in</b>		
Master's degree (1 major) Clinical Research and Epidemiology (2015)		