

		ECTS/Hours
Module: Scientific Work and Empirical Research - Theory and Practice in Science and Research.		30/750
SM1 Scientific Working and Writing (1)	<ul style="list-style-type: none"> - Basics of cognition and science theory - Historical development of scientific writing - Evidence-based medicine - Basics of scientific writing and presenting 	1
SM2 Study and publication types (1)	<ul style="list-style-type: none"> - Categorization of different types of sources - Primary sources: Experimental study types <ul style="list-style-type: none"> - In vitro studies - Animal studies - Clinical studies - Secondary sources: reviews and guidelines <ul style="list-style-type: none"> - Narrative Review - Systematic review - Meta-analysis - Guideline - Tertiary sources: books - Prerequisites, limits, advantages, disadvantages, and possible applications of publication types 	1
SM3 Quality of Studies and Publications (1)	<ul style="list-style-type: none"> - Different bias types and options to minimize bias, i. e. randomization, blinding, etc. - Evaluation criteria of quality of <ul style="list-style-type: none"> - Randomised clinical trials - Observational studies - Case-type studies - Reviews - Guidelines - Common mistakes and deficiencies in published studies 	1
SM4 Literature search 1: Search strategies (1)	<ul style="list-style-type: none"> - Scientific question - PICO questions - Searches - Review: inclusion and exclusion criteria - Review: Setting Outcome Parameters 	1

SM5 Literature Search 2: Bibliographic Databases and Citation Programs (1)	<ul style="list-style-type: none"> - Introduction to various bibliographic databases (ie PubMed, Cochrane) - Database search - Deduplicating results - Search: expand and limit - Introduction to citation programs (Endnote, Mendeley, Citavi) - Applications 	1
SM6 Literature search 3: Analysis of homework for UM2-UM5 (1)	<ul style="list-style-type: none"> - Independently developing of a scientific question - elaboration of the search terms - database search - Effective results limitation - Assessment of work quality 	1
SM7 Ethical Aspects of Research (1)	<ul style="list-style-type: none"> - Social aspects - Basics of research ethics - Good scientific practice - Animal testing - Clinical research - Data Management 	1
SM8 Statistics - Definitions and Basic Knowledge (2)	<p>Motivation for statistical considerations in clinical research</p> <ul style="list-style-type: none"> - Basic concepts in descriptive statistics: <ul style="list-style-type: none"> - Features, random variables (discrete and continuous random variables) - Tabular and graphical representation of the data of a qualitative feature - Tabular and graphical representation of the data of a quantitative feature - Frequencies; Histograms and empirical distributions - (Normal distribution, skewed distributions, multimodal distributions, logarithmic transformation) - Standardization of the normal distribution - Random samples 	2

	<ul style="list-style-type: none"> - Statistical figures - Measures (mean value, median) - Scatter measures (standard deviation, range, interquartile distances) - Inferential statistics <ul style="list-style-type: none"> - Quantiles of the normal distribution, t-distribution - Point estimate - Interval estimation (confidence intervals) 	
<p>SM9 Statistical testing and special statistical tests (2)</p>	<ul style="list-style-type: none"> - Overview of parametric and non-parametric tests - Error (α, β error) \diamond Sensitivity and specificity - Null hypothesis, alternative hypothesis - One-sided and two-sided alternative - Connected and unconnected samples - Repetition quantiles of the normal distribution - Phases of statistical testing - Conceptual explanation: degrees of freedom, test statistics and critical values, p-value - Detailed test procedure based on two typical tests (t-test, χ-test) - t-test: <ul style="list-style-type: none"> - Repeating quantiles of normal distribution, introduction t-distribution, degrees of freedom - Description of the phases by means of a concrete example, - Application of statistical programs: <ul style="list-style-type: none"> - Possibilities with Excel, SPSS, online calculators - χ test: 	<p>2</p>

	<ul style="list-style-type: none"> - Procedure, calculation of observed and expected frequencies - Distribution test, independence test, homogeneity test - Description of the phases using a concrete example - Calculation of an example using Excel 	
SM10 Design of clinical studies (self-study for refresher with script and own research) (1)	<ul style="list-style-type: none"> - Observational studies vs. experimental studies - Cohort studies, case-control studies, cross-sectional studies - Randomized and non-randomized controlled clinical trials - Advantages and disadvantages of the study designs - Bias and confounder 	1
SM11 Statistics in clinical trials (2)	<ul style="list-style-type: none"> - Prevalence and incidence - Risk Ratio and odds ratio - Survival after Kaplan Meyer - Regression - Correlation 	2
SM12 Introduction to Meta-analysis (2)	<ul style="list-style-type: none"> - Overview - Importance of summary analysis of individual studies - Factors influencing the outcome of meta-analyzes - Methods for improving quality in meta-analyzes and systematic reviews: - QUORUM and PRISMA guidelines - Cochrane collaboration and Cochrane reviews - Inherent pitfalls (publication bias, heterogeneity, lack of robustness) - Assessment of bias and confounders in clinical trials - Presentation of recognized rating schemes to assess the risk of bias - Newcastle-Ottawa Scale for observational studies 	2

	<ul style="list-style-type: none"> - Recommendation of the Cochrane Collaboration for RCTs 	
SM13 Meta-analysis: Basics & Calculations (2)	<ul style="list-style-type: none"> - Homogeneity tests (Qhet, I2 H2M) - Choice of the right model depending on the result of the homogeneity test <ul style="list-style-type: none"> - Fixed effects - Random effects - Calculation of the weighted average - Cochran Coat Haenszel Estimator for Risk and Odds Ratio - Presentation and interpretation of forest plots - Calculation of a concrete example - RevMan presentation of the Cochrane Collaboration <ul style="list-style-type: none"> - Data extraction from published studies - Data input and calculations - Data output - Dealing with misleading data or parameters 	2
SM14 Homework Analysis for UM1-UM6 (1)	<ul style="list-style-type: none"> - Questionnaire on basic terms of descriptive statistics - Perform statistical tests and critically interpretation of the results for applied clinical situations - Questionnaire on basic terms and statistical measures in clinical trials - Assessment of bias risk for selected published studies - Carrying out a meta-analysis, presentation and interpretation of the results 	1
SM15 Design of clinical trials and interpretation of results (1)	<ul style="list-style-type: none"> - Study planning and phases of clinical trials - Study protocol, study documents (Trial Master File) - Regulatory aspects of study planning and implementation, regulations and legal requirements (ICH-GCP, 	1

	<p>Declaration of Helsinki, AMG), implementation requirements (SOP)</p> <ul style="list-style-type: none"> - Data collection and quality control, SOPs, monitoring, audits, data management, data checks and corrections (audit trail), database requirements, data sharing - Dose determination / dose selection, randomized and nonrandomized dose determination methods, case number and evaluation aspects - Randomization, recruitment (Informed Consent, data protection), documentation - Case number planning, case number planning software (NQuery, SAS, Addplan) - Evaluation of a clinical study, analysis groups (intention to treat ITT, per protocol PP), definitions of drop-outs 	
<p>SM16 Scientific Writing 1: Question (1)</p>	<p>Reviews</p> <ul style="list-style-type: none"> - Thesis question - Material and methods <p>Experimental work</p> <ul style="list-style-type: none"> - Hypothesis - Material and methods 	1
<p>SM17 Scientific Writing 2: Data Extraction and Analysis (2)</p>	<p>Reviews</p> <ul style="list-style-type: none"> - Data Extraction - Comparability of the data - Reviews and experimental work - Presentation: Tables and graphs - Analysis approaches - Database and statistics - what is required? - Understandable writing of result texts - Avoiding plagiarism and using correct citation 	2
<p>SM18 Scientific Writing 3: Data Interpretation and Discussion (2)</p>	<ul style="list-style-type: none"> - Writing structured discussions - Correctly recapitulating and interpreting the results - Placing results into a literature context - Critical analysis of the limitations of the work 	2

	<ul style="list-style-type: none"> - Conclusions and recommendations 	
SM19 Scientific Writing 4: Editing and Finishing (1)	<ul style="list-style-type: none"> - Main Word functions for text and tables - Main Excel functions for tables and graphics - Strategies for editing and revising - Correct formatting - Linguistic rules in scientific writing - Using attachments 	1
SM20 homework analysis for UM15-UM18 (1)	<ul style="list-style-type: none"> - Introduction - Thesis question - Material and methods - Data extraction and analysis - Interpretation and discussion - Citation and bibliography 	1
SM21 Presentations, Publications and Application (1)	<ul style="list-style-type: none"> - Rules and guidelines for presentations - Main PowerPoint features for presentations - Rules and guidelines for publishing - Copyright rules - Privacy issues - Preparing the manuscript - Submission and response to reviewers - Rules and guidelines for the application 	1
SM22 Presentation of an independent literature research and analysis on an individual question (final seminar) (2)		2