

## 课程详述

### COURSE SPECIFICATION

以下课程信息可能根据实际授课需要或在课程检讨之后产生变动。如对课程有任何疑问，请联系授课教师。

The course information as follows may be subject to change, either during the session because of unforeseen circumstances, or following review of the course at the end of the session. Queries about the course should be directed to the course instructor.

1.	<b>课程名称 Course Title</b>	循证医学研究方法与临床试验 Evidence based medicine methodology and clinical trial
2.	<b>授课院系 Originating Department</b>	医学院 School of Medicine
3.	<b>课程编号 Course Code</b>	MED217
4.	<b>课程学分 Credit Value</b>	2
5.	<b>课程类别 Course Type</b>	专业选修课/ Major Elective Courses
6.	<b>授课学期 Semester</b>	春季/ Spring
7.	<b>授课语言 Teaching Language</b>	中英双语 English & Chinese
8.	<b>授课教师、所属学系、联系方式 Instructor(s), Affiliation &amp; Contact</b> (For team teaching, please list all instructors)	杜长征, 医学院, ducz@sustech.edu.cn; Changzhen Du, School of Medicine, ducz@sustech.edu.cn
9.	<b>实验员/助教、所属学系、联系方式 Tutor/TA(s), Contact</b>	
10.	<b>选课人数限额(可不填) Maximum Enrolment (Optional)</b>	

11. 授课方式 Delivery Method	讲授 Lectures	习题/辅导/讨论 Tutorials	实验/实习 Lab/Practical	其它(请具体注明) Other (Please specify)	总学时 Total
学时数 Credit Hours	32				32
12. 先修课程、其它学习要求 Pre-requisites or Other Academic Requirements	无/NA				
13. 后续课程、其它学习规划 Courses for which this course is a pre-requisite	待定/To be determined				
14. 其它要求修读本课程的学系 Cross-listing Dept.	待定/To be determined				

### 教学大纲及教学日历 SYLLABUS

#### 15. 教学目标 Course Objectives

本课程是面向临床专业本科生的选修课，综合《临床流行病学》与《循证医学》的知识点，侧重于培养学生掌握临床研究的基本原则、方法和规范，能够用循证医学的研究方法指导今后可能的临床工作，具备开展临床试验和人体研究相关的业务能力和专业技术；从本科教育开始，培养学生逐步成长为研究型医生和医生科学家。

The elective course is for clinical medical students, which contains comprehensive knowledge of clinical epidemiology and evidence-based medicine (EBM), focusing on teaching the students the basic principle and rule of clinical research, and to be capable to use the methodology of evidence-based medicine in their coming clinical practice and research. The course is helpful to train the medical students to become researcher-doctors and physician-scientists.

#### 16. 预达学习成果 Learning Outcomes

1. 了解循证医学的基本原理和方法;
2. 掌握临床试验的基本原则;
3. 能够运用循证医学的方法设计并开展临床研究

1. Understand the basic principle and methodology of Evidence based medicine;
2. Grasp the basic principles of clinical trials;
3. Be capable to design and administrate clinical research based on EBM methodology

#### 17. 课程内容及教学日历 (如授课语言以英文为主, 则课程内容介绍可以用英文; 如团队教学或模块教学, 教学日历须注明主讲人)

**Course Contents (in Parts/Chapters/Sections/Weeks. Please notify name of instructor for course section(s), if this is a team teaching or module course.)**

##### 1. 导论 PREFACE AND INTRODUCTION

介绍课程的授课目的、授课安排、授课方式以及讲者等基本信息, 总体上介绍课程的基本内容, 并了解学生方面的需求。

Introducing the basic information of the course, including the objective, schedule and basic contents. Communicating with students to know their requirements.

## 2. 临床试验与循证医学的历史 HISTORY OF CLINICAL TRIAL AND EVIDENCE BASED MEDICINE

介绍人类临床试验的历史和循证医学的发展历史。

Introducing the history of human clinical research and the development of Evidence based medicine.

## 3. 临床研究的分类和特点 CLASSIFICATION AND CHARACTERISTICS OF CLINICAL RESEARCH

了解临床研究的分类以及每种临床研究的特点。了解每种临床研究的优点和局限性。

To learn the classification of clinical research and the characteristics of each type. To understand the superiority and limitation of each kind of clinical research.

## 4. 临床研究的评价与偏倚 EVALUATION AND BIAS OF CLINICAL RESEARCH

了解临床研究的评价方法和评价指标，明确各个评价指标的含义和基本的统计过程；了解研究过程中的偏倚；以及如何控制偏倚提高研究质量。

To learn the evaluation method and indexes of clinical research; and to understand the meaning and statistic algorithm of each index, as well as the bias during investigation. To learn how to control the bias to improve the study quality.

## 5. 临床试验的患者招募与质量控制 PATIENT RECRUITMENT AND QUALITY ASSURENCE OF CLINICAL TRIAL

了解临床试验的患者招募的基本原理和过程，学习掌握质量保障与质量控制的基本知识。

To understand the basic principle and process of patient recruitment; to learn the knowledge of quality assurance and quality control.

## 6. 循证医学指导下的临床试验的证据等级与 Meta 分析 EBM BASED EVIDENCE GRADE OF CLINICAL TRIAL AND META ANALYSIS

了解循证医学体系下的临床试验的证据等级以及在临床决策中的意义，学会 Meta 分析的基本原理和过程。

To understand the EBM based grading system of clinical evidence and its significance in clinical decision; to learn the basic principle and process of Meta analysis.

## 7. 临床试验的卫生经济学评价 HEALTH ECONOMIC EVALUATION OF CLINICAL TRIAL

了解临床试验的基本的卫生经济学评价方法和指标。

To learn the basic principle method of health economic evaluation for clinical trials.

## 8. 实例分析与讨论 1 CASE ANALYSIS AND DISCUSSION 1

通过阅读文献评价一个已经发表的临床试验，从循证医学的角度分析该临床试验的科学性、结果的可靠性与可能存在的偏倚，评价临床证据的等级，给出可能的改进意见。

To evaluate a published clinical trial by reading a literature, analyze the reliability and possible bias of the the clinical trial results from the perspective of evidence-based medicine, evaluating the level of clinical evidence, and giving possible suggestions for improvement.

## 9. 循证医学指导下的新药研发 DRUG RESEARCH BASED ON EBM

了解如何在循证医学的原则下开展新药研究和临床试验。

To learn how to deliver a new drug study and clinical trial based on EBM principle.

## 10. 循证医学与医疗新技术的应用 APPLICATION OF NOVEL MEDICAL TECHNOLOGY AND EBM

学会如何以循证医学原则为指导将新技术应用于临床实践。

To learn how to translate the new medical techniques into clinical practice based on EBM principle.

## 11. 生物信息学与临床试验 BIOINFORMATICS AND CLINICAL TRIAL

了解生物信息学的基本知识，学会如何在临床研究与临床试验中充分利用生物信息学的知识和工具。

To learn basic knowledge of bioinformatics, and to learn how to use the bioinformatics knowledge and tools in the clinical research and clinical trials.

## 12. 精准医疗与临床试验 PRECISION MEDICINE AND CLINICAL TRIAL

了解精准医学的历史，了解精准医学在临床研究与临床试验中的发展。

To learn the background and history of precision medicine, and to understand its development in clinical study and clinical trials.

### 13. 实例分析与讨论 2 CASE ANALYSIS AND DISCUSSION 2

通过阅读文献评价一个已经发表的临床试验，从循证医学的角度分析该临床试验的科学性、结果的可靠性与可能存在的偏倚，评价临床证据的等级，并结合前几讲内容给出可能的改进意见。

To evaluate a published clinical trial by reading a literature, analyze the reliability and possible bias of the the clinical trial results from the perspective of evidence-based medicine, evaluating the level of clinical evidence, and giving possible suggestions for improvement according to what they learned from recent classes.

### 14. 循证医学与临床研究常用平台工具 PLATFORM AND TOOLS IN EBM AND CLINICAL RESEARCH

介绍循证医学与临床研究常用平台和网站，为学生今后的研究提供有用的工具。

Introducing some websites and platforms of EBM and clinical trials, providing some useful tools for students.

### 15. 临床试验中的伦理学问题 ETHICS IN CLINICAL TRIAL

了解伦理学的重要性，掌握临床试验基本的伦理学要求。

To learn the importance of ethics, to understand the basic ethic demands of clinical trials.

### 16. 如何运用循证医学方法开展临床试验 HOW TO DELIVER A CLINICAL TRIAL BASED ON EBM PRINCIPLE

对本门课程进行全方位总结，归纳循证医学与临床试验的要领，介绍临床试验的经验。

Summarizing the course comprehensively, summarizing the essentials of evidence-based medicine and clinical trial, and introducing the experience of clinical trial.

Section	Topic	Hours
1	导论 PREFACE AND INTRODUCTION	1
2	临床试验与循证医学的历史 HISTORY OF CLINICAL TRIAL AND EVIDENCE BASED MEDICINE	1
3	临床研究的分类和特点 CLASSIFICATION AND CHARACTERISTICS OF CLINICAL RESEARCH	2

4	临床研究的评价与偏倚 EVALUATION AND BIAS OF CLINICAL RESEARCH (两次课)	4
5	临床试验的患者招募与质量控制 PATIENT RECRUITMENT AND QUALITY ASSURENCE OF CLINICAL TRIAL	2
6	循证医学指导下的临床试验的证据等级与Meta分析 EBM BASED EVIDENCE GRADE OF CLINICAL TRIAL AND META ANALYSIS	2
7	临床试验的卫生经济学评价 HEALTH ECONOMIC EVALUATION OF CLINICAL TRIAL	2
8	实例分析与讨论1 CASE ANALYSIS AND DISCUSSION 1	2
9	循证医学指导下的新药研发 DRUG RESEARCH BASED ON EBM	2
10	循证医学与医疗新技术的应用 APPLICATION OF NOVEL MEDICAL TECHNOLOGY AND EBM	2
11	生物信息学与临床试验 BIOINFORMATICS AND CLINICAL TRIAL	2
12	精准医疗与临床试验 PRECISION MEDICINE AND CLINICAL TRIAL	2
13	实例分析与讨论2 CASE ANALYSIS AND DISCUSSION 2	2
14	循证医学与临床研究常用平台工具 PLATFORM AND TOOLS IN EBM AND CLINICAL RESEARCH	2
15	临床试验中的伦理学问题 ETHICS IN CLINICAL TRIAL	2
16	如何运用循证医学方法开展临床试验 HOW TO DELIVER A CLINICAL TRIAL BASED ON EBM PRINCIPLE	2

#### 教材及其它参考资料 Textbook and Supplementary Readings

教材:

1. Textbook of Clinical Trials, David Machin, WILEY, 2004
2. 《临床流行病学》，王家良主编，上海科学技术出版社，2009.
3. 《循证医学》第3版，王家良主编，人民卫生出版社，2015.

#### 课程评估 ASSESSMENT

19. 评估形式 Type of Assessment	评估时间 Time	占考试总成绩百分比 % of final score	违纪处罚 Penalty	备注 Notes
出勤 Attendance				
课堂表现 Class Performance		10		
小测验 Quiz				
课程项目 Projects				
平时作业 Assignments		30		
期中考试				

Mid-Term Test				
期末考试 Final Exam				
期末报告 Final Presentation		60		
其它（可根据需要 改写以上评估方 式） Others (The above may be modified as necessary)				

20. 记分方式 GRADING SYSTEM

- A. 十三级等级制 Letter Grading  
 B. 二级记分制（通过/不通过） Pass/Fail Grading

课程审批 REVIEW AND APPROVAL

21. 本课程设置已经过以下责任人/委员会审议通过  
 This Course has been approved by the following person or committee of authority

本课程已经医学院教学副院长张文勇教授审核通过。