

# AO PEER Course– Principles of Clinical Research

Date Place Lecture room: xxx

**EVENT PROGRAM** 



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# Mission

The AO's mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

### **Purpose statement**

In its work to advance the AO's mission, AO PEER's purpose is to support surgeons in their clinical and translational research activities with innovative education and tools.

### **AO PEER offerings**

**Level 1** Principles of clinical research course

### 8 modules

- Importance of research
- Basics of GCP
- Study questions
- Literature review
- Research environment
- Basics of statistical thinking
- Basics of medical writing
- Make your research project a success

**Level 2** Advanced courses

Grant writing

- Study management and GCP
- Publication writing

**Level 3** Research mentorship program

### Welcome Dear AO PEER course participant,

It is our distinct pleasure to welcome you to the AO PEER course. Like you, we understand that research is key to advancing patient outcomes and—like you—we know that initiating, planning and conducting research can be challenging. AO PEER learning opportunities are designed by surgeons, for surgeons, and the AO PEER Principles of Clinical Research course is designed to take your clinical research skills to the next level.

Over the two-day program, we will introduce you to evidence-based medicine, ethical imperatives, critical appraisal of the literature, statistics, and publication writing. We look forward to engaging with you and providing you with a memorable, best-in-class learning experience that will serve you for a lifetime.

Sincerely yours,

**Chairperson** Job title, Work place

## **Course description**

Participants will learn about the importance of research and evidence-based medicine (EBM), the relevant ethical considerations and guidelines for Good Clinical Practice (GCP) with a focus on the formulation of a clinical research question.

In addition to practicing some of the skills related to critical literature review, this course offers support in working with a statistician, and navigating the AO Program for Education and Excellence in Research (AO PEER) to help make their research project a success.

For more information, please visit www.aopeer.org. Access is free for all members of an AO Clinical Division.

## **Goal of the course**

The goal of this course is to introduce the principles of clinical research, including skills and knowledge on why and how to do research, how to build a good research environment, and where to find additional resources, tools, and reference packages to support a research project.

### **Target participants**

This course is targeted at individuals who want to learn or improve the skills for conducting clinical research and publishing results and also at those with a general interest in research and documentation of clinical cases.

## Learning objectives

At the end of this course, participants should be able to:

- Explain the importance of doing research and the link to evidence-based medicine
- Apply the basic principles of literature search and critical appraisal
- Follow GCP guidelines and adhere to ethical requirements, eg, informed consent
- Identify a clinical problem, formulate a clinical research question, and select the study design
- Collaborate with a statistician to perform sample size calculation and basic statistical analyses
- Describe the principles of medical writing
- Utilize available research environment, resources, and tools

## Chairperson(s)

Name Job title, Work place, email address



Name Job title, Work place, email address

### Mandatory precourse activities for participants

- Think of factors that make a clinical problem suitable as a starting point for a clinical study.
- Watch recorded lecture about "study designs" and read through the presentation with specific study design examples.
- Read the article of Guo et al and complete the related tasks.
- Complete 2 eLearning modules "Statistics for surgeons".

### Day

Date

### Location:

#### Module 1 Importance of research

15	Welcome	Teacher Name
15	Why is research important in your daily practice? Plenary discussions	
15	Evidence-based medicine (EBM): Why is it important? Lecture	
30	What can EBM do for you? Small group discussions	

### Module 2 Basics of Good Clinical Practice

30	Ethical imperatives Introduction and plenary discussions	
15	Break	
10	Guidelines of Good Clinical Practice Lecture	
10	Importance of ethics committee Plenary discussions	
20	Informed consent process Lecture	
45	<b>Ethical approval case studies</b> Practical exercise	

Module 3 Study question		
45	How to identify a clinical problem for research Small group discussions (follow-up from homework)	
50	Lunch break	
50	<b>PICOT and formulating a structured clinical research question</b> Introduction and practical exercise	
15	Study designs Lecture	 

### Module 4 Literature view 40 Literature search Introduction / demonstration 50 Critical appraisal Practical exercise

# Module 5 Research environment 10 Roles of research team Lecture 15 Break 30 Accessing and finding your way around a research environment Small group discussions Ind of Day 1

# Day

### Location: xxx

Module 6 Basics of statistical thinking	
10	How to work with a statistician Lecture
20	Basics of statistics Lecture: Confidence intervals, hypothesis testing, P value
20	Sample size calculation Lecture
20	Most typical flaws in statistics Plenary discussion

### Module 7 Basics of medical writing

45	Bad practice in publishing Plenary discussion and lecture	
15	Break	
80	<ul> <li>Review a paper section by section</li> <li>Practical exercise</li> <li>Abstract</li> <li>Introduction: Describe the clinical question</li> <li>Methods: Explain the study design</li> <li>Results: Reporting the findings of the study</li> <li>Discussion: How are the results interpreted?</li> <li>Conclusion: Lessions learned</li> </ul>	
10	Medical writing tips: Manuscript maker Demonstration	
10	Reference management Demonstration	

### Module 8 Make your research project a success

10	Use the AO PEER platform Demonstration
5	What's next for your research education Lecture
10	Conclusions and feedback Plenary discussion
	End of the course

## **Course organizer**

**Course venue** 

### **Event information**

#### Event fee

CHF xxx for non-AO members CHF xxxfor AO members CHF xxx for other non-for-profit organizations and SwAPP members

Your registration fee includes:

- Attendance of all lectures/practical sessions
- Teaching material for the course
- Coffee breaks and lunch

#### **European CME Accreditation**

If applicable

#### **Course certificate**

The course certificates will be available at the end of the event at the general information desk.

#### **Evaluation guidelines**

All AO PEER events apply the same evaluation process, which includes online before and after the event evaluation. This helps AO PEER to ensure that we continue to meet your training needs.

#### Intellectual property

Event materials, presentations, and case studies are the intellectual property of the event faculty. All rights are reserved. For more information, please see: www.aofoundation.org/legal.

Recording, photographing, or copying lectures, practical exercises, case discussions, or any event materials is strictly forbidden. Participants violating intellectual property will be dismissed.



The AO Foundation reserves the right to film, photograph, and audio record during its events. Participants must understand that in this context they may appear in these recorded materials. The AO Foundation assumes participants agree that these recorded materials may be used for the AO's marketing and other purposes, and that they may be made available to the public.

#### Security

XXX

#### Insurance

The event organization does not take out insurance to cover any individual against accident, theft, or other risks.

#### Use of mobile phones

Use of mobile phones is not permitted in the lecture halls or in other rooms during educational activities. Please be considerate of others by turning off your mobile phone.

#### **Dress code**

XXXX

## **Principles of AO educational events**

#### 1. Academic independence

Development of all curricula, design of scientific event programs, and selection of faculty are the sole responsibilities of volunteer AO network surgeons. All education is planned based on needs assessment data, designed and evaluated using concepts and evidence from the most current medical education research, and reflects the expertise of the AO Education Institute (www.aofoundation.org).

Industry participation is not allowed during the entire curriculum development and planning process to ensure academic independence and to keep content free from bias.

#### 2. Compliance to accreditation and industry codes

All planning, organization, and execution of educational activities follow existing codes for accreditation of highquality education:

- Accreditation Criteria of the Accreditation Council for Continuing Medical Education, US (www.accme.org)
- ACCME Standards for Commercial Support: Standards to Ensure Independence in CME Activities (www.accme.org)
- Criteria for Accreditation of Live Educational Events of the European Accreditation Council for Continuing Medical Education (www.uems.eu)

Events that receive direct or indirect unrestricted educational grants or in-kind support from industry also follow the ethical codes of the medical industry, such as:

- Eucomed Guidelines on Interactions with Healthcare Professionals (www.medtecheurope.org)
- AdvaMed Code of Ethics on Interactions with Health Care Professionals (advamed.org)
- Mecomed Guidelines on Interactions with Healthcare
   Professionals (www.mecomed.org)

#### 3. Branding and advertising

No industry logos or advertising (apart from the AO Foundation and its clinical divisions) are permitted in the area where educational activities take place.

Sponsors providing financial or in-kind support are allowed to have a promotional booth or run activities outside the educational area with approval from the event chairperson.

#### 4. Use of technologies and products in simulations

In case simulations are chosen as an educational method to educate skills, we only use technology approved by the AO Technical Commission—a large independent group of volunteer surgeons developing and peer reviewing new technology.

More information about the AO Technical Commission and its development and approval processes can be found on the AO's website: www.aofoundation.org.

#### 5. Personnel

Industry staff members are not permitted to interfere with the educational content or engage in educational activities during the event.

# **Upcoming AO PEER courses**

For further information about upcoming AO PEER courses please visit www.aopeer.org

# Transforming Surgery– Changing Lives



The AO is a medically-guided, not-for-profit organization, a global network of surgeons, and the world's leading education, innovation, and research organization specializing in the surgical treatment of trauma and musculoskeletal disorders. Today the AO has a global community of over 215,000 health care professionals in the fields of trauma, spine, craniomaxillofacial, veterinary, and reconstructive surgery. Each year the AO offers over 830 educational events globally with over 58,000 participants and supported by 9,000 faculty.



AO Foundation | Clavadelerstrasse 8 | CH-7270 Davos Phone +41 81 414 21 11 | Fax +41 81 414 22 80 | info@aofoundation.org AO

www.aofoundation.org