AO PEER self-directed online course—Principles of Clinical Research

Start: any time (self-paced learning)

Learning management system: Totara Learn
Mission
The AO’s mission is promoting excellence in patient care and outcomes in trauma and musculoskeletal disorders.

The AO principles of fracture management
1. Fracture reduction and fixation to restore anatomical relationships.
2. Fracture fixation providing absolute or relative stability, as required by the “personality” of the fracture, the patient, and the injury.
3. Preservation of the blood supply to soft tissues and bone by gentle reduction techniques and careful handling.
4. Early and safe mobilization and rehabilitation of the injured part and the patient as a whole.

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
- AO PEER self-directed online course—Principles of Clinical Research
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Level 1
Principles of clinical research course
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• Importance of research
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Level 2
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Level 3
Research mentorship program
Course description

This accredited online course addresses the importance of research and evidence-based medicine (EBM), the relevant ethical considerations and guidelines for Good Clinical Practice (GCP).

Participants will learn how to formulate a clinical research question as well as practicing skills related to critical literature review, working with a statistician, and navigating the AO Program for Education and Excellence in Research (AO PEER), all with the aim of making their research project a success.

Participants will be guided through eight consecutive modules in a self-directed manner. There will be the opportunity to exchange thoughts and challenges in an interactive forum.

Course mentor

Participants of this self-directed online course will be encouraged to involve a mentor (i.e, a person from their network/university/institution etc. for support and advice throughout this course and beyond). The mentor is important for several tasks during this course. There are no specific prerequisites for a person to act as a mentor but we recommend the following:

- Several years of experience in clinical research and publishing
- Several years of experience in mentoring

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 aimed at individuals who want to learn or improve the skills in 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

Duration

- The course is structured in eight modules
- Each module comprises a sequence of learning activities, of altogether 2–5 hours duration to be completed at participants’ own pace
- Total course learning time: 20 hours
- Participants have a time frame of five weeks to complete one module
- Access to the course material: one year
Welcome
Dear AO PEER course participant,

It is our distinct pleasure to welcome you to the AO PEER online learning 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 self-directed online course - Principles of Clinical Research is designed to take your clinical research skills to the next level.

Over this 20 hours self-directed online course, we will introduce you to evidence-based medicine, ethical imperatives, critical appraisal of the literature, statistics, and publication writing. We look forward to providing you with a memorable, online learning experience that will serve you for a lifetime.

Sincerely yours,
AO PEER Taskforce

Asdrubal Falavigna
AO Spine

Risto Kontio
AO CMF

Frankie Leung
AO Trauma

Matthew Allen
AO Vet
Chairs

Asdrubal Falavigna
Professor and Chair of the Neurosurgical Department, Caxias do Sul University, Caxias do Sul, Brazil

Risto Kontio
Professor and Chair of the department of Oral and Maxillofacial Surgery, Helsinki University Hospital, Helsinki, Finland

Matthew Allen
Professor of Small Animal Surgery, Cambridge University, UK

Frankie Leung
Professor and Chief of Division of Orthopaedic Trauma, Queen Mary Hospital, Hong Kong
Module 1

Why is research important?

Learning objectives:
- Explain the reasons for performing clinical research
- Explain the importance of evidence-based medicine
- Define how evidence-based medicine can be beneficial for you and contribute to your practice

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>00:03</td>
<td>Introduction to Module 1</td>
</tr>
<tr>
<td>01:15</td>
<td>Why is research important in your daily practice?</td>
</tr>
<tr>
<td>00:30</td>
<td>Evidence Based Medicine (EBM)</td>
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<tr>
<td>00:03</td>
<td>Wrap up Module 1</td>
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<td>00:10</td>
<td>Quiz at end of Module 1, feedback</td>
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Module 2

Does your study follow the ethical guidelines?

Learning objectives:
- Apply ethical principles when planning and conducting clinical research
- Recognize that clinical research is performed within a strict regulatory framework
- Recognize potential issues and obstacles when submitting a research project to the ethics committee

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<tr>
<th>Time</th>
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<tbody>
<tr>
<td>00:05</td>
<td>Introduction to Module 2</td>
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<tr>
<td>00:40</td>
<td>Ethical imperatives</td>
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<tr>
<td>00:10</td>
<td>Guidelines of GCP</td>
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<td>00:45</td>
<td>Importance of ethics committees</td>
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<tr>
<td>00:35</td>
<td>Informed consent introduction and practical aspects</td>
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<tr>
<td>00:30</td>
<td>Ethical approval case studies</td>
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<tr>
<td>00:05</td>
<td>Wrap up Module 2</td>
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<tr>
<td>00:10</td>
<td>Quiz at end of Module 2, feedback</td>
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Module 3a

Step-by-step to your research question

Learning objectives:

- Recognize the value of deliberate initial planning for a high quality and relevant research study
- Evaluate if a clinical problem is suitable for research
- Formulate a structured and specific clinical research question by applying the PICOT concept

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<tr>
<th>Time</th>
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<tbody>
<tr>
<td>00:05</td>
<td>Introduction to Module 3</td>
</tr>
<tr>
<td>00:05</td>
<td>How to identify a clinical problem for research</td>
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<tr>
<td>00:30</td>
<td>Starting point of a clinical study</td>
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<tr>
<td>02:10</td>
<td>PICOT and formulating a study question</td>
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<tr>
<td>00:10</td>
<td>Quiz at end of Module 3a, feedback</td>
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Module 3b

Selecting the optimal study design for your research question

Learning objectives:

- Recognize the value of initial evaluation to select the appropriate study design to answer your research question
- Describe the different study designs in clinical research and their pros and cons
- Differentiate between observational and interventional studies; as well as descriptive and analytical studies

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<tr>
<th>Time</th>
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<tbody>
<tr>
<td>01:35</td>
<td>Study designs</td>
</tr>
<tr>
<td>00:05</td>
<td>Wrap up Module 3</td>
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<tr>
<td>00:20</td>
<td>Quiz at end of Module 3b, feedback</td>
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### Module 4

**Literature search and critical appraisal: reading between the lines**

**Learning objectives:**
- Explain the different purposes of literature searches
- Special focus: PubMed: Apply different types of searches
- Implement a systematic process to read, synthesize, and critically appraise the literature

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<tbody>
<tr>
<td>00:05</td>
<td>Introduction to Module 4</td>
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<tr>
<td>00:45</td>
<td>Literature Search</td>
</tr>
<tr>
<td>01:00</td>
<td>Critical Appraisal of scientific literature</td>
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<tr>
<td>00:05</td>
<td>Wrap up Module 4</td>
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<td>00:10</td>
<td>Quiz at end of Module 4, feedback</td>
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### Module 5

**How to navigate your research environment**

**Learning objectives:**
- Describe the most important responsibilities of a principal investigator
- Outline the elements of a good research environment
- Recognize the value of mentorship and teamwork from the first idea through to publication

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<th>Time</th>
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<tbody>
<tr>
<td>00:05</td>
<td>Introduction to Module 5</td>
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<tr>
<td>00:17</td>
<td>Roles of research team</td>
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<td>00:30</td>
<td>Accessing &amp; finding your way in a research environment</td>
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<tr>
<td>00:03</td>
<td>Wrap up Module 5</td>
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<td>00:10</td>
<td>Quiz at end of Module 5, feedback</td>
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## Module 6

**Give your study statistical power**

**Learning objectives:**

- Involve the statistician during study planning
- Explain the most important statistical terms (P value, confidence interval, numerical vs categorical variables, descriptive vs inferential statistics)
- Apply the most important statistical tools

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<tr>
<th>Time</th>
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<tbody>
<tr>
<td>00:05</td>
<td>Introduction to Module 6</td>
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<tr>
<td>00:05</td>
<td>How to work with a statistician</td>
</tr>
<tr>
<td>00:15</td>
<td>Intro to statistical thinking</td>
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<tr>
<td>00:40</td>
<td>Basics of statistics: mean, median, boxplot, histogram</td>
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<tr>
<td>01:00</td>
<td>Sample size calculation and statistical analysis</td>
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<tr>
<td>00:35</td>
<td>Introduction to data management</td>
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<tr>
<td>00:12</td>
<td>Most typical flaws in statistics</td>
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<tr>
<td>00:03</td>
<td>Wrap up Module 6</td>
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<td>00:10</td>
<td>Quiz at end of Module 6, feedback</td>
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Module 7

Getting ready to publish

Learning objectives:
- Recognize the importance of adhering to ethical guidelines in a clinical study through to publication
- Recognize the structure of a manuscript and use the “Manuscript Maker”
- Explain why reference management systems should be used

00:05  Introduction to Module 7
01:00  Avoiding bad practice in publishing
00:51  Manuscript structure
00:20  Getting ready to publish
00:15  Medical writing tips: Manuscript maker
00:15  Reference management systems introduction
00:04  Wrap up Module 7
00:10  Quiz at end of Module 7, feedback

Module 8

Make your research a success

Learning objectives:
- Navigate through the AO PEER platform to look for resources for self-directed learning
- Describe the opportunities of continuing research education
- Explain the structure of the AO PEER curriculum

00:05  Introduction to Module 8
00:10  Use the AO PEER platform
00:15  What is next for your research education
00:05  Quiz at end of Module 8
00:30  Conclusions and feedback

End of the course
Course organizer

AO Education Institute
Stettbachstrasse 6
8600 Duebendorf
Switzerland
Event information

Event fee
CHF 350 for non-AO members
CHF 280 for AO members
CHF 315 for SwAPP members

Your registration fee includes:
Access to all course material for one year

European CME Accreditation
An application has been made to the UEMS EACCME for CME accreditation of this course.

Course certificate
The course certificates will be available at the end of the course.

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
Course 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.

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