AO | PEER

AO PEER Course—
Study Management and Good Clinical Practice (GCP)

Date
Place, Country

Lecture room:
xxx

EVENT PROGRAM

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 for by surgeons, for surgeons, and the AO PEER Level II Study Management and Good Clinical Practice (GCP) course is designed to take your clinical research skills to the next level.

In this course you will get practical tips and tricks on how to conduct your research and how to find your way around the regulatory environment of clinical research.
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,

Name
Job, Work place

Course description

This two-day course is organized in eight modules and includes lectures, interactive workshops as well as panel and group discussions, preceded by online preparation activities.

The course explains the importance of Good Clinical Practice (GCP) guidelines and the ISO 14155 standard for the conduct of clinical studies as well as presenting the basic ethical principles according to the Declaration of Helsinki.

The focus will be on the requirements specific to the conduct of clinical studies in orthopedic surgery and traumatology. Participants will be introduced to useful project management tools to be applied in clinical studies.

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

Goal of the course

The aim of this course is to contribute to the quality of conducting clinical studies at an investigational site by training the investigators about the applicable guidelines and providing practical tips on how to conduct a study including examples and project management tools.

Target participants

This course is targeted toward certified orthopedic and trauma surgeons, residents, and other medical doctors acting as investigators and/or subinvestigators. This course is also open for study coordinators and any other specialists involved or interested in clinical research.

Learning objectives

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

- Recognize the importance of conducting research involving human participants.
- Explain the importance of protecting human participants in the design, conduct and follow- up of research projects involving human beings.
- Describe the principles of human research participant protection.
- Identify and describe the basic documents of reference in research ethics
- Explain how conflicts of interest, fraud, and science misconduct can impact design, conduct, and follow up and the measures to counter them.
- Apply the basic rules of research ethics to assess risks,
  - Obtain informed consent, respecting the participant privacy, obtain ethical clearance
  - Obtaining ethical clearance from the competent Research Ethics Committee (REC)
- Describe the responsibilities of investigators in the protection of human participants and how they have the capacity to face them.
- Apply the most relevant project management tools in a clinical study.

Chairperson(s)

Name
Job, Work place

Teacher

Mandatory precourse activities for participants

- Watch a recorded lecture about Good Clinical Practice and Ethical Imperatives, and look for any other examples where clinical research was performed incorrectly
- Complete eLearning module “Outcome Measures”
- Read the documents related to the informed consent process
- Listen to the audio about informed consent

Course prerequisite

AOPEER Principles of Clinical Research course (or similar education on the principles of clinical research)

Day

Date

Location: xxx

Module 1
Basis of clinical research

10	Welcome	Teacher
70	**Introduction** • Homework: historical examples • History of clinical research • Ethical imperatives / Declaration of Helsinki • Aim and history of the International Conference of Harmonization (ICH) • Overview on content of Good Clinical Practice (GCP) guideline: ICH-GCP E6 • Influence of ICH-GCP on regulations and laws • ISO 14155: Focus on medical devices • Other ICH guidelines	
30	**Scientific background of clinical studies** • Measures to avoid bias and confounding: blinding, unblinding, randomization • Scientific accuracy	

Module 2 Regulatory and ethics		
130	**Roles and responsibilities** Investigators, subinvestigators and study coordinators Sponsors and Contract Research Organizations (CRO)	
15	Break	
20	**Essential documents for the study conduct** • Overview and importance of essential documents • Investigator Site File (ISF) • Delegation log	
40	**Workshop „Team Management“**	
20	**Essential documents for the study conduct (cont.)** • Patient Information (PI) / Informed Consent Form (ICF): Content and structure • Document and change management • Hospital documentation • Definition and importance of source documents / source data	
40	**Specific laws and ethics committees** • Overview of relevant regulations • Example local regulations in Switzerland • Data protection regulations • Additional regulations (X-ray exposure, nanoparticles etc.) • Liability and patient insurance • Ethics Committees: Responsibilities, composition, function, submissions • Reports to Ethics Committees and Competent Authorities	
	End of Day 1	

Day

Date

Location: xxx

Module 2
Regulatory and ethics

15	**Fundamental principles and normative framework** • Societal, religious and cultural factors • Local Conditions	
45	**Workshop Ethics regulations**	
20	**Clinical Investigation Plan (CIP)** • CIP development, content and structure according to ICH-GCP E6 • Importance of consistency and comprehensibility of information • Protocol adherence • Risk-benefit analysis • Good Practice of handling CIP amendments	

Module 3
Study conduct

10	**Study initiation** • Site selection • Conflict of interest • Site Initiation Visits (SIVs)	
15	Break	
10	**Informing and consenting patients: Part I** • Definitions • Detailed requirements for content and structure • Process of obtaining the consent • Rights of participants • Autonomy of the participant to decide • Justice / risk-benefit ratio • Confidentiality and privacy • Responsibilities and duties of research personnel • Impact of wording on understandability and recruitment • Re-consent	
20	**Informing and consenting patients: Part II** • Importance of equipoise • Issues in offering incentives • Consenting in retrospective studies • Informed consent for vulnerable patients • Clinical Studies in emergency situations	
60	**Informing and consenting patients: Part III** • Workshop „Informing and consenting patients “	
30	**Monitoring: Part I** • Aim of monitoring as part of quality control • Monitoring visits (MVs) • Source data verification • Monitoring plans and reports • Risk based monitoring • Adherence to CIP • Audits and inspections • Misconduct and fraud	
50	**Monitoring: Part II** • Workshop „Monitoring “	
60	Lunch break	

Module 4
Management of data and samples

15	**Data collection** • Data collection on-site • Case Report Forms (CRF): Paper CRFs / eCRF • Audit trail • De-identification • Good Documentation Practice (GDP) • Data corrections • Data queries and reply • Data protection	
15	**Sample collection and handling** • Sample handling and protection regulations • Anonymization vs encoded / non-encoded (before called de-identification) • Shipment • Storage, handling and archiving requirements of samples	

Module 5
Investigational product and safety

10	**Market application** • Definition medicinal product / medical device • CE Marking • Phases of clinical studies • Approval of new interventions • Common Technical Document (CTD)	
25	**Safety: Part I** • Definitions (Pharma vs. device) • Requirements for documenting and reporting Adverse Events • Liability	
40	**Safety: Part II** • Workshop „Adverse Events “	
30	**Investigational product** • Investigator’s Brochure (IB) • Handling, storage and documentation • Product accountability • Good Manufacturing Practice (GMP) • Importance of correct labelling • Drug/device accountability • Product shipment records • Patient and investigator compliance	
15	Break	

Day

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Module 6 **Study termination and publishing**		
10	**Study termination** • Site close-out visits (SCVs) • Storage and archiving requirements of data. • Final investigation report	
10	**Publishing** • Study registration and obligation to publish • Writing a manuscript • Dealing with intellectual property rights	
Module 7 **Quality control**		
20	**Quality control and quality assurance** • Aim and concept • Standard Operating Procedures (SOPs)	
Module 8 **Budgeting and resource management**		
20	**Introduction to project management** • Project budgeting	
60	**Workshop Project budgeting** • Workshop in budgeting a project	
10	Summary of GCP and project management aspects	
	End of course	

Course organization

Course venue

Event information

Event fee
CHF xxx for non-AO members
CHF xxx for 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

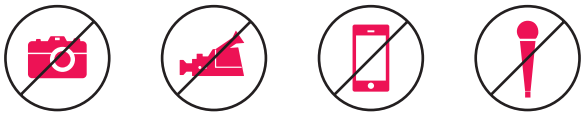
European CME Accreditation
If applicable

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 questionnaires. 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
If applicable

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
Business casual

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 high-quality 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.

Notes

Notes

Upcoming AO PEER courses

For 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

www.aofoundation.org