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

Date
Place, Country

Lecture room:
xxx

EVENT PROGRAM
Mission
Purpose statement
AO PEER offerings

Welcome

Course description
Goal of the course
Target participants
Learning objectives

Chairperson(s) and Teacher

Date

Event organization
Event venue

Event information

Principles of AO educational events

Upcoming AO PEER courses
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)

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## Day

Date

**Location: xxx**

### Module 1

**Basis of clinical research**

<table>
<thead>
<tr>
<th></th>
<th>Welcome</th>
<th>Teacher</th>
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<tbody>
<tr>
<td>10</td>
<td><strong>Introduction</strong></td>
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<tr>
<td></td>
<td>• Homework: historical examples</td>
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<td></td>
<td>• History of clinical research</td>
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<td></td>
<td>• Ethical imperatives / Declaration of Helsinki</td>
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<td></td>
<td>• Aim and history of the International Conference of Harmonization (ICH)</td>
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<td>• Overview on content of Good Clinical Practice (GCP) guideline: ICH-GCP E6</td>
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<td></td>
<td>• Influence of ICH-GCP on regulations and laws</td>
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<td></td>
<td>• ISO 14155: Focus on medical devices</td>
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<tr>
<td></td>
<td>• Other ICH guidelines</td>
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</tr>
<tr>
<td>70</td>
<td><strong>Scientific background of clinical studies</strong></td>
<td></td>
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<tr>
<td></td>
<td>• Measures to avoid bias and confounding: blinding, unblinding, randomization</td>
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<tr>
<td></td>
<td>• Scientific accuracy</td>
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</table>
Module 2  
Regulatory and ethics

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
</table>
| 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
### Module 2
#### Regulatory and ethics

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
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</table>
| 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

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
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</table>
| 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  

### Module 6: Study termination and publishing

<table>
<thead>
<tr>
<th>Study termination</th>
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<tr>
<td><strong>Site close-out visits (SCVs)</strong></td>
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<td><strong>Storage and archiving requirements of data.</strong></td>
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<td><strong>Final investigation report</strong></td>
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<table>
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<tr>
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<td><strong>Study registration and obligation to publish</strong></td>
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<tr>
<td><strong>Writing a manuscript</strong></td>
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<td><strong>Dealing with intellectual property rights</strong></td>
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### Module 7: Quality control

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<th>Quality control and quality assurance</th>
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<td><strong>Aim and concept</strong></td>
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<td><strong>Standard Operating Procedures (SOPs)</strong></td>
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### Module 8: Budgeting and resource management

<table>
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<tr>
<th>Introduction to project management</th>
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<td><strong>Project budgeting</strong></td>
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<tr>
<th>Workshop Project budgeting</th>
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<td><strong>Workshop in budgeting a project</strong></td>
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<tr>
<th>Summary of GCP and project management aspects</th>
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<tr>
<th>End of course</th>
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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

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.

European CME Accreditation
If applicable

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

Security
If applicable

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.

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.
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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.