Preliminary Course program

Good Clinical Practice (GCP) course for surgeons

December 8-9, 2017    Davos, Switzerland

Congress Center Davos
7 Principles of Education

Based on needs
Interactive
Motivates to learn
Promotes reflection
Provides feedback
Relevant
Leads to verifiable outcomes
The first AO Course was held in Davos in 1960—these early courses pioneered psychomotor techniques by teaching practical skills of AO Techniques. Since those early days over 455,000 surgeons and 155,000 ORP from over 110 countries have attended AO Courses.

Dear GCP course participant

It is my pleasure to welcome you to our Good Clinical Practice course for surgeons—an interactive course covering the principles of planning, conducting, and publishing clinical studies in the field of medical devices.

Conducting clinical investigations is a challenging and multifaceted task. We will provide you with practical guides and tips to complete a successful clinical study.

We look forward to welcoming you at our course!

Denise Hess
Manager Clinical Education
AO Clinical Investigation and Documentation

Mandatory prerequisite for participants

The following pre-course activities have to be completed before the start of the GCP course:

- Completing the pre-course evaluation survey
- Watching a recorded lecture about Good Clinical Practice and Ethical Imperatives, and looking for any other examples where clinical research was performed incorrectly
- Reading the documents related to the informed consent process

Content

2 7 Principles of Education
3 Dear GCP course participant
4 Course structure
4 Goal of the course
4 Target participants
4 Learning objectives
4 Course description
5 Chairpersons
5 Faculty
5 Course organization
6 Course prerequisites
6 8 December 2017
8 9 December 2017
10 Course information
10 Course venue
The main objective of the course is to increase 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.

This event is targeted to certified orthopaedic 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.

The course participants will learn to understand and implement the guidelines for Good Clinical Practice (GCP) and the ISO 14155 standard for the conduct of clinical studies. They will also be aware of the basic ethical principles according to the Declaration of Helsinki and the local regulations.

Goal of the course

The main objective of the course is to increase 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.

Target participants

This event is targeted to certified orthopaedic 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.

Course description

The course participants will learn to understand and implement the guidelines for Good Clinical Practice (GCP) and the ISO 14155 standard for the conduct of clinical studies. They will also be aware of the basic ethical principles according to the Declaration of Helsinki and the local regulations.

Furthermore, the participants learn about the requirements specific to the conduct of clinical studies in orthopaedic surgery and traumatology.

For this event, the following educational methods will be used: Lectures, interactive workshops as well as panel and group discussions.

Course structure

2 days course (total 12 h) including interactive workshops and homework.

Learning objectives

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

- Explain the importance of conducting research involving human participants for the advancement of biomedical sciences and in the interest of public health
- Explain the importance of protecting human participants in the design, conduct and follow-up of research projects involving human beings
- Describe the fundamental principles of human research participant protection including autonomy, beneficence, non-maleficence and justice
- Identify and describe the basic documents of reference in research ethics (from Declaration of Helsinki to ISO14155 and ICH-GCP) including the applicable law and regulation in Switzerland
- Describe how conflicts of interest may impact the design, conduct and follow-up of a research project and what are the main measures to limit them
- Explain the negative impact of fraud and science misconduct and name measures to act against them
- Identify the basic rules of research ethics applicable in given situations and apply them to solve simple cases, in particular:
  - Assuring a proper balance of the risks and the benefits in a given research project (defining and assessing the risks)
  - Obtaining a valid informed consent, including in situations where potential participants are legally incompetent (minors/incapacitated adults) or from a vulnerable group
  - Respecting the privacy of the participants as well as the data protection requirements in collecting, processing and storing data/human biological materials
  - 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
Chairperson

Denise Hess
Manager Clinical Education
AO Clinical Investigation and Documentation
denise.hess@aofoundation.org

Faculty

tbd

Course organization

AO Clinical Investigation and Documentation
Marina Meuwly
Clavadelerstrasse 8
7270 Davos, Switzerland
Phone  +41 81-414 25 05
Fax    +41 81-414 22 82
Email  marina.meuwly@aofoundation.org
Course prerequisite:

- Watch recorded lecture about history of clinical research
- Submit information about history in clinical research of your country
- Read the handouts “Study synopsis” and “Patient information sheet”

8 December 2017

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<th>TIME</th>
<th>AGENDA ITEM</th>
<th>WHO</th>
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<td>LOCATION Lecture hall: Forum</td>
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**Part 1:** Basis of clinical research

- Welcome
- 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

**BREAK**

**Part 2:** Regulatory and ethics

- Roles and responsibilities
- Investigators, subinvestigators and study coordinators
- Sponsors and Contract Research Organizations (CRO)
- Essential documents for the study conduct
- Overview and importance of essential documents
- Investigator Site File (ISF)
- Delegation log
- Workshop „Research team and delegation log”
- 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
### 8 December 2017 (cont.)

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<th>TIME</th>
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<td>Specific laws and ethics committees</td>
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<td>Overview of relevant regulations</td>
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<td>Example local regulations in Switzerland</td>
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<td>Data protection regulations</td>
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<td>Additional regulations (x-ray exposure, nanoparticles etc.)</td>
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<td>Liability and patient insurance</td>
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<td>Ethics committees: Responsibilities, composition, function, submissions</td>
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<td>Reports to ethics committees and competent authorities</td>
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<td><strong>Fundamental principles and normative framework</strong></td>
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<td>Societal, religious and cultural factors</td>
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<td>Local Conditions</td>
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<td>Clinical Investigation Plan (CIP)</td>
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<td>CIP development, content and structure according to ICH-GCP E6</td>
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<td>Importance of consistency and comprehensibility of information</td>
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<td>Protocol adherence</td>
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<td>Risk-benefit analysis</td>
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<td>Good Practice of handling CIP amendments</td>
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### Part 3: Study conduct

- Study initiation
- Site selection
- Conflict of interest
- Site Initiation Visits
- 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
- 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

### END OF DAY 1
09 December, 2017

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<td>Informing and consenting patients: Part III</td>
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<td>Workshop „Informing and consenting patients“</td>
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<td>Monitoring: Part I</td>
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<td>Workshop „Monitoring“</td>
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<td>Monitoring: Part II</td>
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<td>Aim of monitoring as part of quality control</td>
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<td>Monitoring visits (MV)</td>
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<td>Source data verification</td>
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<td>Monitoring plans and reports</td>
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<td>Risk based monitoring</td>
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<td>Adherence to CIP</td>
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<td>Audits and inspections</td>
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<td>Misconduct and fraud</td>
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**Part 4:** Management of data and samples

- Data management
- Data collection on-site
- Case Report Forms (CRF): Paper CRF / eCRF
- Audit Trail
- De-identification
- Good Documentation Practice (GDP)
- Data corrections
- Data queries and reply
- Data management by Sponsor

**Statistics**

- Types of variables
- Parameters and distribution
- Hypothesis testing
- Power and sample size calculations
- Confidence intervals

- Sample collection and handling
- Sample handling and protection regulations
- Anonymization vs encoded / non-encoded (before called de-identificaton)
- Shipment
- Storage, handling and archiving requirements of samples

**Part 5:** Investigational product and safety

- Market application
- Definition medicinal product / medical device
- CE Marking
- Phases of clinical studies
- Approval of new interventions
- Common Technical Document (CTD)

**LUNCH BREAK**
### 9 December, 2017

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#### Safety: Part I
- Definitions (Pharma vs. device)
- Requirements for documenting and reporting Adverse Events
- Liability

#### Safety: Part II
- Workshop „Adverse Events“
- 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

#### BREAK

#### Part 6: Study termination and publishing
- Study termination
- Close-out visits (SCV)
- Storage and archiving requirements of data.
- Final investigation report
- Publishing
- Study registration and obligation to publish
- Writing a manuscript
- Dealing with intellectual property rights

#### Part 7: Quality control and wrap-up
- Quality control and quality assurance
- Aim and concept
- Standard Operating Procedures (SOP)
- Summary and outlook
- Summary of GCP aspects

#### END OF COURSE
Course information

Course fee
Good Clinical Practice (GCP) course for surgeons: CHF 500.00

Your registration fee includes
• Attendance of all lectures/practical sessions
• Teaching material for the course
• Coffee breaks and lunch

European CME Accreditation
An application has been made to the UEMS-EACCME® in Brussels for CME accreditation of this event.

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

Evaluation guidelines
All AOCID courses apply the same evaluation process with paper and pencil questionnaires. This will help AOCID to ensure that we continue to meet your training needs.

Intellectual property
Course materials, presentations, and case studies are the intellectual property of the course faculty. All rights are reserved. Check hazards and legal restrictions on www.aofoundation.org/legal.

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

The AO Foundation reserves the right to film, photograph, and audio record during their 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 AO marketing and other purposes, and made available to the public.

Security
Security checks will be conducted at the entrance of the building. Wearing of a name tag is compulsory during lectures, practicals, and discussion groups.

No insurance
The course organization does not take out insurance to cover any individual against accidents, thefts or other risks.

Use of mobile phones
Use of mobile phones is not allowed in the lecture rooms and in any other facilities during educational activities. Please be considerate of others by turning off your mobile phone.

Dress code
Davos: warm clothes and suitable shoes are advisable.

Travel and hotels
Participants are responsible for their own travel and hotel arrangements.

Course venue
Congress Center Davos
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