**Study coordinators course: Agenda**

**Training program 3 days (17 h),**

**Venue: University Trauma Hospital 'Sisters of Mercy' Zagreb**

**Day 1: 15 October 2015**

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| **Part 1: Introduction to clinical research** |  | **3h 20min** |
| 1. **Introduction – Part 1: Vide?, Andreas Fäh** | 12.00-12:40 | 40 min |
| Welcome |  |  |
| Introduction of course participants (including small lunch) |  |  |
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| 1. **Introduction – Part 2: Marina Meuwly** | 12.40-12.55 | 15 min |
| Short introduction of AO Foundation and AOCID |  |  |
| Qualified AO Clinical Study Center (AOCSC) concept |  |  |
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| 1. **Basis of clinical research: Andreas Fäh** | 12.55-13.35 | 40 min |
| History of clinical research |  |  |
| Ethical imperatives / Declaration of Helsinki |  |  |
| Good Clinical Practice (GCP) guideline / ISO 14155 |  |  |
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| ***Coffee break (10 min)*** | *13.35-1345* |  |
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| 1. **Practical exercise: Joffrey Baczkowski** | 13.45-14.05 | 20 min |
| Clinical research obstacles course |  |  |
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| 1. **Scientific aspects of clinical studies: Andreas Fäh** | 14.05-14.25 | 20 min |
| Principles of clinical research |  |  |
| Different designs and phases of clinical studies |  |  |
| Practical aspects of blinded and randomized studies |  |  |
| Clinical Investigation Plan: relevant sections | 14.25-14.45 | 20 min |
| *Workshop "Clinical Investigation Plan and study synopsis"* | 145.45-15.25 | *40 min* |
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| * **Please complete your reflection sheet!** | **15.25-15.30** | **5 min** |
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| ***Coffee break (10 min)*** | ***15.30-15.40*** |  |

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| **Part 2: Documentation** |  | **1h 40min** |
| 1. **Essential documents: Joffrey Baczkowski** | 15.40-16.15 | 35 min |
| Importance of essential documents |  |  |
| Investigator Site File (ISF) |  |  |
| Delegation log |  |  |
| Hospital documentation (patient records, medical history etc.) |  |  |
| Importance of source documents / source data |  |  |
| Contract handling |  |  |
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| 1. **Data management: Marina Meuwly** | 16.15-16.30 | 15 min |
| Data collection on-site |  |  |
| De-identification of data |  |  |
| Data clarifications and corrections |  |  |
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| *Workshop "Data clarifications"* | *16.30-16.40* | *10 min* |
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| 1. **Imaging: Marina Meuwly** | 16.40-16.55 | 15 min |
| Imaging (radiographs etc.) |  |  |
| Sample handling |  |  |
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| *Workshop "Principles of data entry":* **Marina Meuwly** | *16.55-17.15* | *20 min* |
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| * **Please complete your reflection sheet!** | **17.15-17.20** | **5 min** |
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**Day 2: 16 October 2015**

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| **Part 3: Study initiation** |  | **5h 05min** | |
| 1. **International regulations: Andreas Fäh** | 08.30-08.50 | 20 min | |
| Data protection |  |  | |
| Liability and patient insurance |  |  | |
| Trends in regulations |  |  | |
| *Workshop "International regulations"* | *08.50-09.10* | *20 min* | |
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| 1. **EC / IRBs: Joffrey Baczkowski** | 09.10-09.20 | 10 min | |
| EC/IRB submissions |  |  | |
| EC/IRB communication |  |  | |
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| 1. **Challenges during clinical studies (Part 1): Marina Küng** |  |  | |
| The sponsor's viewpoint (Discussion round) | 09.20-10.05 | 45 min | |
| ***Coffee break (20 min)*** | 10.05-10.25 |  | |
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| 1. **Study initiation: Joffrey Baczkowski** |  |  | |
| Site selection | *10.25-10.35* | 10 min | |
| Site initiation visit |  |  | |
| *Workshop "Imaging"* **Marina Küng** | *10.35-11.10* | *35 min* | |
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| 1. **Research team and project management: Marina Küng** | |  | |
| Set-up of research team | 11.10-12.05 | 55 min | |
| Roles and responsibilities of investigators / subinvestigators |  |  | |
| Roles and responsibilities study coordinators |  |  | |
| Project management tools |  |  | |
| *Workshop "Research team, delegation log and PM"* **Joffrey Baczkowski** | |  | |
|  | 12.05-13.05 | *60 min* | |
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| * **Please complete your reflection sheet!** | **13.05-13.10** | **5 min** | |
| ***Lunch (50 min)*** | **13.10-14.00** |  | |
| **6. Introduction to local clinic facilities:** |  | |  |
|  | 14:15 - 16:15 | | 30 min |
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| **7. Challenges during clinical studies (Part 2): Joffrey Baczkowski** | 16:20 - 17:05 | 45 min | |
| The study coordinator's viewpoint (Discussion round) |  |  | |
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| Wrap-up of tour and discussion round | 17:05 - 17:20 | 15 min | |

**Day 3: 17 October 2015**

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| **Part 4: Study conduct** |  | **3h 40min** |
| 1. **Informing and consenting patients- Part 1: Marina Meuwly** | 08.30-09.10 | 40 min |
| Definition of informed consent |  |  |
| Content and structure of patient information |  |  |
| Process of obtaining the consent |  |  |
| Impact of wording on understandability and recruitment |  |  |
| **Informing and consenting patients- Part 2: Joffrey Baczkowski** |  |  |
| Issues in offering incentives  Informed consent for vulnerable patients |  |  |
| Emergency situations |  |  |
| * **Please complete your reflection sheet!** | ***09.10-09.15*** | ***5 min*** |
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| 1. **Communication: Marina Meuwly** |  |  |
| Communication with patients / investigators | 09.15-09.35 | 20 min |
| Communication with sponsors |  |  |
| Cultural differences awareness |  |  |
| *Workshop: Role plays communication:*  **Andreas Fäh** | *09.35.-10.25* | *50 min* |
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| ***Coffee break (10 min)*** | ***10.25-10.35*** |  |
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| 1. **Study conduct and monitoring: Joffrey Baczkowski** |  |  |
| *Workshop: Study conduct* | *10.35-10.55* | *20 min* |
| Aim of monitoring | 10.55-11.15 | 20 min |
| On-site visits |  |  |
| Misconduct and fraud |  |  |
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| 1. **Investigational product: Andreas Fäh** | 11.15-11.35 | 20 min |
| Investigational product handling, storage, documentation |  |  |
| Patient and investigator compliance |  |  |
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| 1. **Adverse events: Andreas Fäh** |  |  |
| Definitions and reporting | 11.35-11.55 | 20 min |
| *Workshop: Adverse events:* | *11.55-12.15* | *20 min* |
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| * **Please complete your reflection sheet!** | ***12.15-12.20*** | ***5 min*** |

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| **Part 5: Study termination** |  | **45 min** |
| 1. **Study termination: Marina Meuwly** | 12.20-12.30 | 10 min |
| Site close-out visit |  |  |
| Archiving |  |  |
| Final study report |  |  |
| Premature study termination |  |  |
| ***Coffee break (10 min)*** | 12.30-12.40 |  |
| 1. **Wrap-up and outlook: Andreas Fäh** | 12.40-13.10 | 30 min |
| Summary of aspects discussed |  |  |
| Feedback and outlook |  |  |
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| * **Please complete your reflection sheet!** | ***13.10-13.15*** | ***5 min*** |
| **End of course: 13.15** |  |  |

**Glossary**

| Term / Abbreviation | Explanation |
| --- | --- |
| AE/SAE | Adverse Event/Serious Adverse Event |
| AO | Arbeitsgemeinschaft für Osteosynthesefragen = Association for the Study of Internal Fixation (ASIF) |
| AOCID | AO Documentation and Publishing Foundation, Clinical Investigation and Documentation |
| AOCSC | AO Clinical Study Center concept |
| CE | European Conformity |
| CIP | Clinical Investigation Plan |
| CRF | Case Report Form |
| CRA | Clinical Research Associate (= Monitor) |
| CRO | Contract Research Organization = Clinical Research Organization |
| DICOM | Digital Imaging and Communications in Medicine |
| DSMB | Data Safety Monitoring Board |
| EC | Ethics Committee |
| eCRF | Electronic Case Report Form |
| EDC | Electronic Data Capture |
| FDA | Food and Drug Administration |
| FU(s) | Follow-up(s), e.g. follow-up visit(s), follow-up procedure(s) |
| GCP | Good Clinical Practice |
| IB | Investigator`s Brochure |
| ICH | International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use |
| ICU | Intensive Care Unit |
| ITT | Intention to treat |
| IMP | Investigational Medicinal Product |
| Informed Consent (written) | Legally binding signature on the Informed Consent Form (i.e. either the patient, legally authorized representative or consultee), whereas the person who signs the Informed Consent Form …  has the ability to understand the content of the patient information  has signed and dated the Ethics Committee (EC)/Institutional Review Board (IRB) approved written informed consent |
| ICF | Informed Consent Form |
| IRB | Institutional Review Board |
| ISF | Investigator Site File |
| ISO | International Organization for Standardization |
| ITT | Intention to treat analysis (statistics) |
| MV | Monitoring Visit |
| PCI | Principal Coordinating Investigator (= Principal Clinical Investigator) |
| PI | Principal Investigator (local, at each study site) |
| PM | Project Manager |
| PP | Per Protocol analysis (statistics) |
| QM(S) | Quality Management (System) |
| QOL | Quality of Life |
| RCT | Randomized Controlled Trial |
| SC | Study Coordinator |
| SD | Standard Deviation |
| SDV | Source Data Verification |
| SI | Sub-Investigator |
| SCV | Site Close-out Visit |
| SIV | Site Initiation Visit |
| SO | Safety Officer |
| SOP | Standard Operating Procedure |
| WHO | World Health Organization |