Module Title:	**Conducting Clinical Trials**	
Module No.: CCT	**Semester / Term:** --	**Duration:** 1 Semester
Module Type(s): Pflicht		**Regularly offered in:** WS, SS
Workload: 150 h		**Credit Points:** 5
Admission Requirements: None		**Language of Instruction:** Englisch
Contributing Courses to Module: • Conducting Clinical Trials (CCT)		**Workload:** Lectures: 30 h Self-study: 90h Self-examination: 30 h
Course Coordinator(s) / Tutor(s): Dr. Dagmar Peitsch		**Module Director:** Dr. Dagmar Peitsch
References to Other Programs: • N/A		**References to Other Modules in the Program:** • Clinical Data Management
Qualification and Educational Objectives of the Module: This course enables students to deepen insight into Clinical Research, standard trial documentation procedures and more challenging settings during a clinical trial.		
Course Content of the Module:		
• International guidelines and local requirements for the conduct of clinical trials • The Trial Master File • Clinical Monitoring: Types of visits; Special tasks and challenges of each visit type, including Source Data Verification, Case Report Forms (CRF) and queries, Adverse Events and Test article handling procedures • Current trends in monitoring: principles of the Risk-Based-Monitoring approach • Quality Control: Handling of protocol deviations: how to detect and categorize deviations • Quality assurance: Audits and inspections		
Teaching Methods:	See the contributing course outline(s)	
Literature:	See the contributing course outline(s)	

Percentage of the Module Grade Relative to the Final Grade for the Program:	Prerequisites to Qualify for Assessment:	Assessment:
--	See course outline(s)	Exam, 90 minutes (100%)

Course No.: CCT	**Course Title:** Conducting Clinical Trials	**Hours Total:** 150 h
		Credit Points: 5 ECTS
Course Type: Pflicht **Course Availability:** **Course Duration:** 1 Semester		**Admission Requirements:** None
Course Coordinator / Instructor: See current list of tutors in the Learning Management System		**References to Other Modules:** Please see module description

Course Description:

The course focuses on the fundamental aspects of Monitoring an investigational site, and extends the insight in tasks and responsibilities that accompany the work of any functional role involved in site management. Challenges of complex situations will be discussed, and solutions will be presented by the students.

Course Objectives and Outcome:

On successful completion of this module students will be able to:

- describe the purpose of the different types of site visits made by Clinical Monitors to investigators during a trial;
- detect inconsistencies on site and demonstrate ability to take appropriate action;
- illustrate the importance of regulatory safety reporting, distinguish between adverse events and serious adverse events, and demonstrate awareness of SAE Management and reporting procedures and their impact on the trial;
- discuss the purpose of the Trial Master File;
- demonstrate profound knowledge of the handling of test article according to different requirements;
- critically discuss the approach of Risk-Based-Monitoring in clinical trials;
- explain Quality Assurance and Quality Management processes within Clinical Research.

Teaching Methods:

This course is taught in blended format. It consists of 120 h directed, remote learning (via recorded presentations, self-readings, and exercises), followed by 4 days of full-time, face-to-face training in form of lectures, supplemented by class discussions. Class discussions refer to the concepts being introduced and case studies.

Course Content:

1 International guidelines and local requirements for the conduct of clinical trials

2 The Trial Master File

3 Clinical Monitoring: Types of visits; Special tasks and challenges of each visit type, including Source Data Verification, Case Report Forms (CRF) and queries, Adverse Events and Test article handling procedures

4 Current trends in monitoring: principles of the Risk-Based-Monitoring approach

5 Quality Control: Handling of protocol deviations: how to detect and categorize deviations

6 Quality assurance: Audits and inspections

Literature:

• Brock-Utne, J. G. (2015). Clinical Research: Case Studies of Successes and Failures. New York, NY: Springer.
• Brody, T. (2001). Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines (2nd ed.). London et al.: Academic Press.
• Pfeiffer, J., Wells, C. (2017). A Practical Guide to Managing Clinical Trials. Boca Raton (FL): Taylor and Francis.
• Vijay, V., Khandelwal, A. (2012). Investigational Product Management in Clinical Trials: Case studies and Methods of Clinical Trials. Saarbrücken: Lambert Academic Publishing.

Examinations:

• Ongoing self-assessments. Students are expected to develop or evaluate multifaceted scenarios, preferably in group sessions where immediate feedback will be provided.
• Exam, 90 minutes

Student Workload (in hours): 150

Lectures: 30
Self-study: 90
Self-examination: 30

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