Course No.: CDM	**Course Title:** Clinical Data Management	**Hours Total:** 150 h
		Credit Points: 5 ECTS
Course Type: Pflicht **Course Availability:** WS, SS **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 covers key elements of the data management process, such as CRF design, data entry, data validation, and medical coding as well as exploring the relevant regulatory requirements.

The course also provides an overview on different technologies used in clinical trials, and enables students to assess criteria for selection based on the requirements of a study.

Course Objectives and Outcome:

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

- understand the essential elements of data management and related processes and work collaboratively with the other group members to compile an appropriate process flow
- develop criteria for good CRF design and identify the crucial parts of the study protocol, evaluate and compare different design examples, exchange conclusions within a group discussion, and work out sample criteria for best practice
- distinguish between and compare different technologies and assess their pros and cons, analyze a given project synopsis by critically evaluating and synthesizing information, develop and present a proposal for the deployment of technologies, and identify and communicate critical information gaps
- recognize and justify the needs of regulatory requirements and their impact on clinical data processing
- understand the validation plan as a key document for the data cleaning process, critically evaluate one CRF example, and outline an appropriate validation plan for the different categories of edit checks
- analyze and assess the purpose and benefits of a clinical coding system, and determine, categorize, and order investigational terms based on medical coding dictionaries
- explain and assess key tools for study closeout optimization

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 Role of a Clinical Data Manager

2 Data Management Process

3 Technologies in Data Management

4 Flowchart and CRF Design

5 Data Entry and Final Database Quality Control

6 Data Validation Plan

7 Discrepancy Management and Query Processing

8 Medical Coding

9 Database Lock

10 Regulatory Requirements and SOP Development

11 Electronic Data Capture in Practice

Literature:

• Prokscha, S. (2011). A practical guide to clinical data management (3rd ed.). Boca Raton, FL: CRC Press, 2011
• Society for Clinical Data Management. (2013). Good clinical data management practices (GCDMP).
• Rondel, R. K., Varley, S. A., & Webb, C. F. (2000). Clinical data management (2nd ed.). Chicester: John Wiley and Sons.

Prerequisites to Qualify for Assessment:

• Course evaluation

Assessment:

• 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-testing: 30