Medical Writing in Clinical Trials

(Медицинская документация в клинических исследованиях)

Elective course in English

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Abstract

Medical Writing plays a major role in clinical trials. Clinical trials are essential for new drugs to come into the market for various therapeutic areas; similarly Medical Writing plays a vital role in presentation of the research data in a clear, precise and concise fashion. The aim of this course is to give students basic knowledges and skills in writing significant documents for clinical research.

Thematic Plan (1 h = 45 min)

1. Lecture 1. A writer’s role in drug development (2 h)
2. Lecture 2. Good Clinical Practice (2 h)
3. Lecture 3. Clinical trial designs. Statistical principles for clinical trials (2 h)
4. Workshop 1. Making clinical trial design (4 h)
5. Lecture 4. How to write clinical trial protocols and reports (2 h)
6. Workshop 2. Creating clinical trial protocol and clinical study report (4 h)
7. Lecture 5. How to write Investigator’s Brochure (IB) (2 h)
8. Workshop 3. Updating IB (4 h)
10. Workshop 4. Working with CTD modules (4 h)
11. Lecture 7. Medical writing for patients (2 h)
12. Workshop 5. Developing Questionnaires and Informed Consent Documents for patients (4 h)
13. Final Workshop. Presenting your CRFs (4 h)

Home Project: Creating Case Report Form (CRF) and Clinical Trial Protocol for your clinical study (34 h)

Lectures 7 (14 h), Workshops 6 (24 h), Homework (34 h)

Total: 72 h, 2 credits