# 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)
9. **Lecture 6.** How to write Common Technical Document (CTD) (2 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: <u>72 h, 2 credits</u>**