



Developed by

Centre for Digital Learning, Manipal Academy of Higher Education
&
Manipal College of Pharmaceutical Sciences, MAHE, Manipal

About the course

Job oriented

Designed with help from industry partners

Online course

> 25 self learning exercises

SDL based Learning

32 hours

28 videos

2 Credits

The course will help you -

1. Understand the organization and conduct of clinical research.
2. Learn clinical trial terminologies (>150 terms discussed).
3. Answer the entry level questions on clinical trials & medical writing during interviews.

Career prospects

Pharmaceutical Industries and *Contract Research Organizations* conducting clinical research and /or offering Medical Writing Services

Course Outline

Module- 1: Clinical Research – Trial Protocol, Principal Investigator, Independent Ethics Committee, Ethics in Clinical Research, ICH-GCP Guidelines, Indian Regulations, Trial Subjects, Trial Profile and End Points, Bias, Confounding, Blinding, Phases of Clinical Trials, Clinical Study Designs, Clinical Trial Subtypes, Randomization etc.

Module-2: Medical Writing – Introduction to Medical Writing, Medical Writing - Regulatory writing and Non-regulatory Writing, The Medical Writing Team, Developing a Regulatory Document, Competencies for Medical Writing, Literature search using PubMed and other online tools, Trial Registry, Good Writing Practices, etc.

Eligibility – Graduates/postgraduates in Pharmacy/Dentistry/Life sciences/allied health sciences

Prerequisites: – Laptop (for videos and assignments), internet connection and basic knowledge of using a web browser

For enrolment, contact

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The course is offered twice in a year, and accordingly, the registration link will be activated. Please contact the course coordinator for more details, or click the link below to check the course activation status.

Online certificate issued by: *Manipal College of Pharmaceutical Sciences & Centre for Digital Learning, Manipal Academy of Higher Education*