

Post Graduate Diploma in Clinical Trials Management (PCTM)

- Duration** : One Year
- Eligibility** : Graduates / Post graduates degree in medicine, dental, homoeopathy, ayurvedic, life sciences, Pharmacology, Pharmacy, Medical Laboratory, Biochemistry, Microbiology, Biotechnology and all professionals working with Pharmaceutical companies, CROs and hospitals.
- Methodology** : Distance, Face to Face Contact Sessions, Online Study Material, Printed Training Modules and Practical Hands on Training.
- Admission Criteria** : Personal Interview and Group Discussion
- Examination** : Final Written Exam, Assignments, Exercises & Project work.
- Course objectives** : To provide a comprehensive introduction to the clinical research and allied areas in Clinical Research. Learn the skills, knowledge and competencies of a candidate for the various job prospects in all aspects of Clinical Operations , CDM, Pharmacovigilance, Medical Writing etc Become more familiar with roles/jobs as part of the study team of both the disciplines.
- Evaluation Criteria** : 20% (Assignments) + 80% (External Examinations)
- Certification** : To be awarded by Manonmaniam Sundaranar University.
- Placement Support** : 100% Job placement support is provided to the students.
- Program Details** :

Semester – 1				
Code	Subject	Total Marks	External Examinations	Assignments
CTM101	Introduction to Clinical Research	100	80	20
CTM102	Principles of Pharmacology & Drug Discovery	100	80	20
CTM103	Roles & Responsibilities of Key Stakeholders	100	80	20
CTM104	Laws, Ethics & Regulatory Requirements	100	80	20
CTM105	Planning for Clinical Trials	100	80	20
CTM106	Essential Documentation in Clinical Research	100	80	20
Semester – 2				
CTM201	Clinical Trials Monitoring Essentials	100	80	20

CTM202	Compliance, Auditing & Quality Control in Clinical Research	100	80	20
CTM203	Overview of Clinical Data Management & Biostatistics	100	80	20
CTM204	Overview of Phramacovigilance	100	80	20
CTM205	Special Clinical Trials	100	80	20
CTM206	Communication Skills & Organisational Behaviour	100	80	20

- Recommended Books :**
- ✓ "A Practical Guide on Pharmacovigilance for Beginners". Dr. S. Gunasakaran and R. Satheesh Kumar, First Edition
 - ✓ Basic principles of clinical research and methodology: Dr. S.K. Gupta
 - ✓ Elements of Pharmacovigilance by Raman Sehgal, Dr. Rajat Sethi and Dr. Shobha Rani Hiremath
 - ✓ Practical guide to clinical data management By Susanne Prokscha
 - ✓ 'Cliniminds & University Course Material'