

Post Graduate Diploma in Clinical Research & Pharmacovigilance (PCRP)

- 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.
- Examination** : Final Written Exam, Assignments, Exercises & Project work.
- Certification** : To be awarded by Manonmaniam Sundaranar University.
- Course Objectives** : To provide a comprehensive introduction to the clinical research, Pharmacovigilance process. Learn the skills, knowledge and competencies of a candidate for the various job prospects in all aspects of Clinical Research and pharmacovigilance. Become more familiar with roles/jobs as part of the study team of both the disciplines.
Personal Interview and Group Discussion
- Admission Criteria** :
- Placement Support** : 100% Job placement support is provided to the students.
- Evaluation Criteria** : 20% Assignments (Seminars, Assignments, Internal assessment)
80% External Examinations (Viva, Dissertation and Final exam)

Program Details :

Semester – 1				
Code	Subject	Total Marks	External Examinations	Assignments
CRP101	Introduction to Clinical Research	100	80	20
CRP102	Principles of Pharmacology & Drug Discovery	100	80	20
CRP103	Roles & Responsibilities of Key Stakeholders	100	80	20
CRP104	Laws, Ethics & Regulatory Requirements	100	80	20
CRP105	Planning for Clinical Trials	100	80	20
CRP106	Essential Documentation in Clinical Research	100	80	20
Semester – 2				
CRP201	Overview of Pharmacovigilance	100	80	20

CRP202	Regulatory Aspects of Pharmacovigilance	100	80	20
CRP203	MedDRA – Medical dictionary for Drug Regulatory Activities	100	80	20
CRP204	Quality System in Phramacovigilance	100	80	20
CRP205	Signal Detection; Risk Assessment, Evaluation & Management	100	80	20
CRP206	PSURs – Periodic Safety Updated Reports	100	80	20

- Recommended Books :**
- ✓ “A Practical Guide on Pharmacovigilance for Beginners”. Dr. S. Gunasakaran and R. Satheesh Kumar, First Edition
 - ✓ Manual of Drug Safety And Pharmacovigilance. Barton L. Cobert
 - ✓ Practical Drug Safety From A to Z (Paperback) Barton Cobert , Pierre Biron
 - ✓ <http://www.pharmacovigilance.co.in>
 - ✓ ‘Cliniminds & University Course Material’