Faculty	Natural Sciences		
Home Department	School of Pharmacy		
Module Topic	Statistics and Clinical Trial Management		
Generic Module Name	Clinical Trials and its Statistics 820		
Alpha-numeric Code	**PAR820**		
NQF Level	9		
NQF Credit Value	20		
Duration	Semester		
Proposed semester to be offered.	First Semester		
Programmes in which the module will be offered	MSc (Pharmacy Administration and Policy Regulation) (3859)		
Year level	1		
Main Outcomes	On completion of this module, students should be able to: **Statistics and Clinical Trial Management** • Critically appraise the principle steps in the clinical trial phases that can often be based on incomplete and sometimes contradictory data and objectives • Evaluate the suitability of research methodologies for the purpose of undertaking clinical trials as adaptive as possible • Critically review the issues (including legal, ethical, clinical and/or commercial) involved when undertaking clinical trials • Demonstrate the ability to plan and develop clinical trials in accordance with legislative requirements and Good Clinical Practice (GCP) procedures • Critically interpret and manage statistical data used in clinical development and discriminate between relevant and non-relevant data and be able to justify such decisions		
Main Content	• The Clinical Trial Management module covers the practical management of the development of a medicinal product from Phase I to IV using the latest flexible and adaptive research techniques to optimise efficiency in the development process. It also teaches participants how to critically review and evaluate statistical data and to leverage the information and knowledge created to contribute to the competitive advantage of their organisation. • It is a practical course on how to plan and manage clinical trials cognizant of the pharmacoeconomic conditions and leadership challenges the participant will need to address when leading clinical development programs. • Practical exercises are presented on how to plan and manage clinical trials cognizant of the pharmacoeconomic conditions and leadership challenges the participant will need to address when leading clinical development programs.		
Pre-requisite modules	None		
Co-requisite modules	None		
Prohibited module Combination	None		
Breakdown of Learning Time	**Hours**	**Timetable Requirement per**	**Other teaching modes that does not require**

		week		time-table
Contact with lecturer: / tutor:	40	*Lectures p.w.*	0	
Assignments & tasks:	70	*Practicals p.w.*	0	
Practicals:	0	*Tutorials p.w.*	0	
Tutorials:	20			
Tests & Examinations:	0			
Selfstudy:	70			
Other:	0			
Total Learning Time	**200**			
Methods of Student Assessment	Continuous Assessment (CA): 50% Final Assessment (FA): 50%			
Assessment Module type	Continuous and Final Assessment			