



Department of Life science
Clinical Research Program
Ph.D Syllabus

CLINICAL RESEARCH OVERVIEW

Definition of Clinical research, Terminologies & definitions used in Clinical Research, Types of Clinical research and Phases of Clinical Research, Features of Clinical Trials - Advantages and Disadvantages, Role players in the Clinical Research, The stand of Clinical Research in Scientific Arena, Basics of Bioavailability, Bioequivalence Studies, Drug discovery

INTRODUCTION TO CLINICAL PHARMACOLOGY

Drug, Pharmacology Pharmacokinetics, Pharmacodynamics, Therapeutics, Toxicology, Chemotherapy, Pharmacoepidemiology and Pharmacoeconomics. Bioavailability & Bioequivalence (Definitions, Types of Factors affecting in Bioavailability, Significance of BA-BE studies in Clinical Trial

ETHICS COMMITTEE & ETHICAL ISSUES IN CLINICAL RESEARCH

Ethical review committee, Informed Consent Process, Ethical Submission and Approval Process

CLINICAL TRIAL REGULATIONS

Indian Regulatory Authority Frame Work: CDSCO. Schedule Y: Rules 122A, 122B, 122D, 122DA, 122DAA and 122E, Application for permission, Approval for Clinical Trial, Studies in Special Populations, Latest DCGI rules, Sugam portal Application

INTRODUCTION TO SITE MANAGEMENT ORGANIZATION & STAKEHOLDERS IN CT

Site Management Services, Roles and Responsibilities of a Clinical Research Coordinator (CRC), SMO Business scenario, Concept of stake holders in a clinical trial project

BASICS OF PHARMACOVIGILANCE

Introduction to Pharmacovigilance, Key Definitions in Pharmacovigilance, Pharmacovigilance Historical Perspective, Pharmacovigilance need and Objectives, Pharmacovigilance and Pharmacogenetics, Current methods in Pharmacovigilance. Adverse drug reactions and SAE criteria, Post Marketing Surveillance

CLINICAL TRIAL MANAGEMENT

defining project management in general, different models of project management, concept of clinical Trial Management flow; Essential

Document preparation, clinical trial management: service providers/vendor's perspective

INTRODUCTION TO CLINICAL DATA MANAGEMENT

Introduction to CDM, Basic terminologies, definitions and Glossary, Importance of CDM, Data privacy, Data Management standards in clinical research, Design and development of data collection instruments, electronic data capture.

CENTRAL LAB AND MEDICAL THERAPEUTIC AREA

Introduction to Laboratory management and planning, Over view of Medical therapeutics area

QUALITY MANAGEMENT IN CLINICAL TRIAL

Quality management and clinical trial documents, Misconduct and frauds in clinical trial, FDA inspections, DCGI audits and inspections, NABH audits of ethics committee

CASE STUDIES