


18BP105 CLINICAL DATA MANAGEMENT

UNIT – I

INTRODUCTION: Process, work flow, steps in CDM, Data entry, data tracking, code of ethics

UNIT – II

STANDARD OPERATING PROCEDURES: Study set-up, data entry, CRF tracking and corrections, laboratory management, ADR data, guidelines

UNIT – III

DATA MANAGEMENT PLANNING: Data coding (significance, quality, dictionaries, symbols, problems, adverse effect), software handling, overcoming challenges

UNIT –IV

DATA COLLECTION AND PROCESSING : Types of data collection procedures (capture) i.e. paper and electronic, data flow procedures, data capture tools, advantages and disadvantages, data processing methods

UNIT – V

AUDIT AND VALIDATION: Design validation, process validation, system validation, Discrepancy management system, edit check specifications, query management, cleaning data checklist, SAE reconciliation, managing laboratory data, data locking/freezing