ICMR-NIRT INTEGRATED DEGREE COURSE

Bachelor of Science in

“Clinical Trial and Clinical Data Management”

Department of Statistics
National Institute for Research in Tuberculosis
Indian Council of Medical Research
CHENNAI-600031

SHORT TITLE AND COMMENCEMENT:-

These regulations shall be called as **"UNDER GRADUATE INTEGRATED COURSE IN CLINICAL TRIAL AND CLINICAL DATA MANAGEMENT (B.Sc. - INTEGRATED)"** of the Tamil Nadu Dr. MGR Medical University, Chennai. They shall come into force from the academic year "B.Sc. Integrated Course in Clinical Trial and Clinical Data Management". The regulations and the Syllabus framed are subject to modification by the Standing Academic board from time to time.

OVER ALL OBJECTIVES

The **B.Sc. DEGREE in CLINICAL TRIAL AND CLINICAL DATA MANAGEMENT** is aiming to provide Graduate with updated exposure by understanding of the basic principles of clinical trial with respect to statistics and handling of quality data management in areas of clinical specialty in the hospital and community level.

1. ELIGIBILITY FOR ADMISSION

A pass in 10+2 with Physics, Chemistry, Mathematics & Biology subject or an equivalent with 12 years of Schooling from a recognized Board of University with minimum 35% marks in each subjects separately including English for all categories.

2. AGE LIMIT FOR ADMISSION:

A candidate should have completed the age of 17 years at the time of admission or would complete the said age on or before 31st December of the year of admission to the **B.Sc. DEGREE in CLINICAL TRIAL AND CLINICAL DATA MANAGEMENT.**

3. ELIGIBILITY CERTIFICATE:

No Eligibility Certificate is required to submit. However the candidate who has passed any qualifying examinations other than the Higher Secondary Course Examination conducted by the Government of Tamil Nadu, before seeking admission shall obtain an Eligibility Certificate from this University by remitting the prescribed fees along with application form which shall be downloaded from the University website (www.tnmgrmu.ac.in).

4. REGISTRATION:

A Candidate admitted in the "**B.Sc. DEGREE in CLINICAL TRIAL AND CLINICAL DATA MANAGEMENT**" in the affiliated institutions of this University shall register his / her name with this university by submitting the prescribed application form for registration duly filled, along with the prescribed fee and a declaration in the format to the University through the affiliated institution within 30 days from the cut-off date prescribed for the course for admission. The applications should have the date of admission of the course.

5. MIGRATION/TRANSFER OF CANDIDATE :

a) A student studying in any one of the **B.Sc. DEGREE in CLINICAL TRIAL AND CLINICAL DATA MANAGEMENT** can be allowed to migrate/transfer to another institution of Allied Health Science under the same University.
b) Migration / Transfer can be allowed to another affiliated institutions under extraordinary circumstances. All migration/transfer are subject to the approval of the Vice-chancellor.

6. COMMENCEMENT OF THE COURSE:

The course shall commence from 1st August of the academic year.

7. MEDIUM OF INSTRUCTION:

English shall be the Medium of Instruction for all the Subjects of study and for examinations of the **B.Sc. DEGREE in CLINICAL TRIAL AND CLINICAL DATA MANAGEMENT**

8. CURRICULUM :

The Curriculum and the syllabus for the course shall be as prescribed in these regulations are subject to modifications by the Standing Academic Board from time to time.

9. DURATION OF THE COURSE :

The duration of certified study for this **B.Sc. DEGREE in CLINICAL TRIAL AND CLINICAL DATA MANAGEMENT** shall extend over a period of four academic years including one year internship (3+1).

10. RE-ADMISSION AFTER BREAK OF STUDY:

The regulations for re-admission are as per the University Common Regulation for Re-admission after break of study for all courses.

11. WORKING DAYS IN THE ACADEMIC YEAR:

Each academic year shall consist of not less than 240 working days

12. ATTENDANCE REQUIRED FOR ADMISSION TO EXAMINATION

a) No candidate shall be permitted to appear in any one of the parts of this **B.Sc. DEGREE in CLINICAL TRIAL AND CLINICAL DATA MANAGEMENT** Examinations unless he/she has attended the course in the subject for the prescribed period in an affiliated institution recognized by this University and produce the necessary certificate of study, attendance and satisfactory conduct from the Head of the institution.

b) A candidate is required to put in a minimum of 85% of attendance out of 240 working days in theory in each subject before admission to the examinations except for 1st year candidate where attendance will be counted for the date of joining. **The academic year should consist of not less than 240 working days**.

c) A candidate must have 100% attendance in each of the Practical/Clinical areas before the award of Degree.

13. CONDONATION OF LACK OF ATTENDANCE:

There shall be no condonation of lack of attendance.

14. VACATION:

There is no vacation

15. INTERNAL ASSESSMENT MARKS:

The Internal Assessment should consist of the following points for evaluation:-

i Theory
ii Practical
iii Viva

iv A minimum of three written examinations shall be conducted in each subject during a year and the average marks of the three performances shall be taken into consideration for the award of Internal Assessment marks.

v A minimum of one practical examination shall be conducted in each subject (wherever practical has been included in the curriculum) and grades of ongoing clinical evaluation to be considered for the award of Internal Assessment marks.

16. CUT-OFF DATES FOR ADMISSION TO EXAMINATIONS :

(i) 30th September of the academic year concerned

(ii) The candidates admitted up to 30th September of the academic year shall be registered to take up the 1st year examination during August of the next year.

(iii) All kinds of admission shall be completed on or before 30th September of the academic year. There shall not be any admission after 30th September even if seats are vacant.

17. COMMENCEMENT OF THE EXAMINAITONS:

1st August / 1st February

If the date of commencement of examination falls on Saturdays / Sundays or declared Public Holidays, the examination shall begin on the next working day.

18. MARKS QUALIFYING FOR PASS:

50% of marks in the University Theory Examinations

50% of marks in the University Practical Examinations

50% of marks in the subject where internal evaluation alone is conducted

50% of marks in aggregate in Theory, Practical I.A. & Oral taken together

19. CARRY OVER OF FAILED SUBJECTS:

1) A candidate has to pass in theory and practical examinations separately in each of the paper
2) If a candidate fails either in theory or practical examinations, he/she has to reappear for both (theory and practical)

This will be implemented from the Academic Year 2020-21 onwards.

20. PRACTICAL EXAMINATION

Maximum number of candidates for practical examination should not exceed 20 per day. An examiner should be a lecturer or above in any of the affiliated institutions of Allied Health Sciences.

21. NUMBER OF EXAMINERS

One internal and one external examiner should jointly conduct practical/ oral examination for each student

22. REVALUATION/RETOTALLING OF ANSWER PAPERS:

Revaluation / Retotaling of answer papers is not permitted.

23. LATERAL ENTRY

Lateral entry is applicable for this U.G Degree course "**B.Sc. DEGREE in CLINICAL TRIAL AND CLINICAL DATA MANAGEMENT"** in the concerned specialty. The duration of internship is 1 year for this degree course including Lateral Entry Admissions.

SCHEME OF EXAMINATIONS FOR UNDERGRADUATE INTEGRATED COURSE

"CLINICAL TRIAL AND CLINICAL DATA MANAGEMENT (B.Sc. - INTEGRATED)"

YEAR 1

S.No	Subject/Papers	University Examinations						Internal Examinations		Total	Hours per week
		Theory		Practical's		Viva					
		Max	Min	Max	Min	Max	Min	Max	Min		
1	Paper 1: Basic concepts in Clinical Research	100	50	*	*	*	*	50	25	150	6
2	Paper 2: Clinical Trial Designs	100	50	*	*	*	*	50	25	150	5
3	Paper 3: Descriptive Statistics and Basics of Clinical Data Management	100	50	50	25	50	25	100	50	300	5
4	Paper 4: Introduction to software handling and EPI Data	100	50	50	25	50	25	100	50	300	5
5	Paper 5: Communication English	*	*	*	*	*	*	100(IA)	50(IA)	100	4

INTERNAL ASSESSMENT

Sl.No	Subject/Papers	Internal Assessment		Total
		Max	Min	
5	Paper 5: Communication English	100	50	100
6	Paper 6: Computer Science	100	50	100

YEAR 2

Sl.No	Subject/Papers	University Examinations						Internal Examinations		Total	Hours per week
		Theory		Practical's		Viva					
		Max	Min	Max	Min	Max	Min	Max	Min		
1	Paper 1: Importance of Ethics in Clinical Research	100	50	*	*	50	25	50	25	200	5
2	Paper 2: Pharmacology and drug Development in Clinical Research	100	50	*	*	50	25	50	25	200	5
3	Paper 3: Inferential Statistics	100	50	50	25	50	25	100	50	300	7
4	Paper 4: Software Handling part I: SPSS, EPI INFO, RED Cap and Open Clinica	100	50	50	25	50	25	100	50	300	8

YEAR- 3

Sl.No	Subject/Papers	University Examinations						Internal Examinations		Total	Hours per week
		Theory		Practical's		Viva					
		Max	Min	Max	Min	Max	Min	Max	Min		
1	Paper 1: Regulations In Clinical Research	100	50	*	*	50	25	50	25	200	5
2	Paper 2: Data Safety Monitoring Board and Clinical Trial Management	100	50	*	*	50	25	50	25	200	5
3	Paper 3:Advanced Statistical Methods	100	50	50	25	50	25	100	50	300	7
4	Paper 4: Software Handling Part II: SAS, R	100	50	50	25	50	25	100	50	300	8

Year 1

Paper 1: Basic Concepts in Clinical Research

UNIT I

Basics of epidemiology, Definition, scope, and uses of epidemiology Measures of disease and death frequency, Mortality and morbidity, epidemiological study designs, Observational studies, descriptive studies, experimental studies, Ecological studies , cross sectional studies, cohort studies, case control studies, incidence, prevalence, odds ratio, relative risk.

UNIT II

Basics of Clinical Trials: Who can be in clinical trials? need clinical trials, Brief History of Clinical Trials, Glossary of Common Terms in clinical Trials: Clinical Research, Healthy Volunteer, Inclusion/Exclusion Criteria, Informed Consent, Patient Volunteer, Phases of Clinical Trials, Placebo, Protocol, Principal Investigator, Randomization, Single- or Double-Blind, Studies, Types of Clinical Trials. - Diagnostic trials, Natural history studies, Prevention trials, Quality of life trials, Screening trials, Treatment trials. Clinical Trial Protocol and its components. Type of analyses: ITT, mITT and PP.

UNIT II

Randomized Controlled Trial (RCT): what is a randomized controlled trial? Reasons for randomization, Features of RCT. Who sponsors and runs clinical trials? How should an RCT be designed?, How should an RCT be conducted?: Random allocation, Allocation concealment, Blinding, Conduct, Outcome ascertainment, Sample size, Power of a study. How should an RCT be reported? Randomization and Masking, Overview of Clinical Study Design

UNIT III

Clinical Trials Metrics Collection, Clinical Data Management, Data Processing – Database -Definition of Data Management and its benefits -Types of data:, data collection methods, raw, physical collection, models, images etc. –Data entry - File naming – Data assurance : quality control and assurance of data, Medical coding, dictionary management and maintenance of quality documents

UNIT IV

Missing data , Submitting data , Metadata: Metadata standards , submitting Data , File formats ,Preserve: Backup of data , Migration: Transformation of data , Discovering data ,Integrate: Merging of multiple data sets , Data Citation , Data retrieval, Archiving , Double data entry and checking , Quality control and Data Cleaning

References

Leon Gordis (2014). EPIDEMILOGY. Elsevier
Lawrence MF, Curt DF, David LD (2010) Fundamentals of clinical trials

Paper2: Clinical Trial Designs

Unit 1: Comparison Structure: Parallel, Crossover, and Group Allocation Designs

Unit 2: Extensions of the Parallel Design: Factorial and Large Simple Designs

Unit 3: Superiority, Equivalency and Non-Inferiority Designs

Unit 4: Adaptive Design

Reference

Lawrence MF, Curt DF, David LD (2010) Fundamentals of clinical trials
Tom Brody (2016). Clinical trials. Elsevier

Paper 3: Descriptive Statistics and Clinical Data Management

UNIT I

Statistical Methods: Definition and scope of Statistics, concepts of statistical population and sample. Data: quantitative and qualitative, attributes, variables, scales of measurement nominal, ordinal, interval and ratio. Presentation of data: tabular and graphical, including histogram and ogives.

UNIT II

Measures of Central Tendency: arithmetic mean, geometric mean, harmonic mean, median, mode, weighted mean. Measures of Dispersion: range, quartile deviation, mean deviation, standard deviation, coefficient of variation, Moments, absolute moments, factorial moments, skewness and kurtosis, Sheppard's corrections.

UNIT III

Probability: Introduction, random experiments, sample space, events and algebra of events. Definitions of Probability – classical, statistical and axiomatic. Conditional Probability, laws of addition and multiplication, independent events, theorem of total probability, Bayes' theorem and its applications. Bernoulli distribution, Uniform distribution, Binomial distribution, Poisson distribution, Normal distribution.

UNIT IV

SAMPLING DISTRIBUTIONS: Limit Theorems: Chebychev's inequality, Weak Law of Large Numbers, Central Limit Theorems. De Moivre-Laplace and Levy-Lindberg theorems. Proofs and applications- Concepts of statistic, parameter, pivotal quantity, sampling distribution and standard error. Chi-square, t and F distributions, their properties and interrelationships. Independence of sample mean and variance in random sampling from Normal distribution. Sampling distribution of the standard statistics-sample mean, sample variance, student's t and F statistics

UNIT V

Excel for data management, Basic data analysis and visualization in Excel

References

Goon AM, Gupta MK, Dasgupta B (2008). Fundamentals of Statistics, Published by Prentice Hall, 2nd edition. 2.

Gupta SC, Kapoor VK (2000). Fundamentals of Mathematical Statistics, Sultan Chand Sons. 10th edition.

Pagano M, Gauvreau K (2007). Principles of Biostatistics. Duxbury Press.

Rohatgi VK, Saleh AK(2001). An Introduction to Probability and Statistics, John Wiley & Sons.

Bernard R (2010). Fundamentals of Biostatistics. Cengage Learning

William GC (1997). Sampling Techniques. John Wiley & sons 3rd edition.

Paper 4: Introduction to Software Handling and EPI Data

UNIT I:

Introduction to Computers, Concepts of computing, data and information, Data entry, Transcribing data, Clinical Data coding, Database creation, Logical checks, Importing and exporting files, Merging database, Data Review, Data Validation, Discrepancy Management, Data privacy, Database Quality Control, Cleaning data, Missing list, Electronic data capture, CRF form design, Database design, Edit Check and Edit Check Testing, Publishing and sharing data

UNIT II:

EpiData software: Overview of the software, data documentation sheet and creation of documentation sheet, QES, REC, CHK triplet, CHK commands unrelated to a specific field, creating derived fields and concept of temporary variables, Double Data Entry and Validation, use an external file for creating a label block and use it in EpiData, capture data entry time, Exporting Data to other Analysis Software, Data Safety and Security

References

Steve B, Mark M, Damien J, Andrzej R (2001). Data Management for Surveys and Trials . A practical premier using epidata. The Epidata Association

INTERNAL PAPER

Paper 5: Communication English

UNIT I:

Communication: Role of communication, Defining Communication, Classification of communication, Purpose of communication, Major difficulties in communication, Barriers to communication, Characteristics of successful communication, The seven Cs, Communication at the work place, Human needs and communication “Mind mapping”, Information communication

UNIT II:

Comprehension passage: Reading purposefully**,** Understanding what is read**,** Drawing conclusion**,** Finding and analysis

UNIT III:

Explaining: How to explain clearly**,** Defining and giving reasons**,** Explaining differences**,** Explaining procedures**,** Giving directions

UNIT IV:

Writing business letters: How to construct correctly, Formal language, Address, Salutation, Body, Conclusion

UNIT V:

Report writing: Reporting an accident, Reporting what happened at a session, Reporting what happened at a meeting

References

Amit G (2018). English communication. SBPD publications

Elizabeth TR, Deborah B, Lori LH, Jill M, Sarah VH (2011), Communications Handbook for Clinical Trials. Family Health International

YEAR 2

Paper 1: Importance of Ethics in Clinical Research

UNIT I

General ethical issues in clinical trials, General principles, Historical guidelines in Clinical Research: Nuremberg code-Declaration of Helsink-Belmont report

UNIT II:

International Conference on Harmonization (ICH)-Brief history of ICH-Structure of ICH- ICH Harmonization Process, Responsible conduct of research, Ethical review procedures, Informed consent process, Vulnerability

UNIT III:

Guidelines for Good Clinical Practice-Glossary-The Principles of ICH GCP-Institutional Review Board/ Independent Ethics Committee-Investigator-Sponsor-Clinical Trial Protocol and Protocol Amendment(S)-Investigator's Brochure-Essential Documents for the conduct of a Clinical Trial, Biological materials, biobanking and datasets, Research during humanitarian emergencies and disasters

References

Roli M (2017). National ethical guidelines for biomedical and health research involving human participants. ICMR

Declaration of Helsinki: ethical principles for medical research involving human subjects. Fortaleza: World Medical Association. 2013

Federal Policy for the Protection of Human Subjects ('Common Rule'). U.S. Department of Health and Human Services; (1991); 2001, 2017

International ethical guidelines for health-related research involving humans. Geneva: Council for International Organizations of Medical Sciences; 2016.

WHO (2011) Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants

Paper 2: Pharmacology and drug development in clinical Research

UNIT I

Introduction to Pharmacology - Introduction to Drug Discovery and Development - Sources of Drugs -Approaches to Drug Discovery - Evolutionary Classification of the strategies for Drug Discovery -

UNIT II

Concept of Essential Drugs - Routes of Drug Administration Pharmacokinetics, Pharmacodynamics

UNIT III

Investigational New Drug Application and Approval - Preclinical Testing - Phases of Clinical trials - - Pharmacokinetics – Pharmacodynamics - Drug assay - Pharmacogenomics and Protein-based therapies, - Recent advances

References

Gupta SK (2011). Drug discovery and clinical research. Jaypee Brothers Medical Publishers

Turner, JR (2010). New Drug Development: An Introduction to Clinical Trials. Springer

Paper 3: Inferential statistics

UNIT I:

Point Estimation: Concepts of parameter, random sample and its likelihood. Properties of estimators- Unbiasedness, Efficiency, Consistency and sufficient condition for consistency. Sufficiency, Factorization theorem, Minimum variance unbiased estimator, Rao Cramer lower bound of variance and related results. Methods of estimation-maximum likelihood and method of moments

UNIT II:

Test of significance: Statistical hypotheses-Simple and composite, Statistical tests, Critical region, Type I and Type II errors, power of a test Interval estimation: Concepts of confidence interval and confidence coefficient, the confidence interval for mean, difference between means, variance and ratio of variances under normality. The large sample confidence interval for proportions and correlation coefficients

UNIT III:

Testing of Hypothesis: Definition of Most Powerful (MP), Uniformly Most Powerful(UMP), Neyman Pearson Lemma, Monotone Likelihood Ratio Property, Statement of the theorem which gives UMP tests for testing one-sided hypothesis for distribution with MLR property, Likelihood Ratio test, LRT for single mean for normal case (large and small samples), for equality of two means for unknown but equal variances. LRT for single variance and equality of two variances

UNIT IV:

Test for the mean, equality of two means, ANOVA, variance and equality of two variances (large and small samples), large sample tests for proportions, test for correlation coefficients-simple, multiple and partial. Test for regression coefficients. Fisher's Z transformation and its applications.

UNIT V:

Non-Parametric Tests: Need for non-parametric tests, Sign test for one sample and two samples, Wilcoxon signed-rank test, Median test, Wald Wolfowitz run test, Mann Whitney U test, Run test for randomness, test for independence based on Spearman's rank correlation coefficient(small and large samples),. Chi-square test, goodness of fit, independence of attributes in the contingency table, and equality of many proportions. Kruskal Wallis Test.-Sequential Probability Ratio Test: Need for sequential test, Wald's SPRT, Sequential-test for the mean of Normal population when variance is known and for the proportion.-Derivation of expressions for OC and ASN functions in Bernoulli and Normal distributions.

UNIT VI

Bivariate data: Definition, scatter diagram, simple, partial and multiple correlations (3 variables only), rank correlation. Simple linear regression

Principle of least squares and fitting of polynomials and exponential curves. Theory of attributes: Independence and association of attributes, consistency of data, measures of association and contingency, Yule's coefficient of colligation.

References

Hogg RV, Tanis EA (2001). Probability and Statistical Inference, Prentice Hall International Inc.

Kale BK (1999). A first Course on Parametric Inference, Narosa Publishing House.

Goon AM, Gupta M. K., Dasgupta B (2008): Fundamentals of Statistics, Published by Prentice Hall, 2nd edition. 2.

Gupta SC, Kapoor VK (2000): Fundamentals of Mathematical Statistics, Sultan Chand Sons 10th edition.

Pagano M Gauvreau K (2007). Principles of Biostatistics. Duxbury Press

Rohatgi VK, Saleh AK (2001). An Introduction to Probability and Statistics, John Wiley & Sons.

Beth D, Robert GT (2004). Basic & Clinical Biostatistics. Lange Medical Books

Douglas C M, Elizabeth A P, Vining GG (2006). Introduction to Linear Regression Analysis. Wiley India Pvt Ltd

Paper 4: Software handling part I: SPSS, EPI INFO, Red cap and Open Clinica

UNIT I.

Getting acquainted with the SPSS program

Review of terminology: Basic categories of research, What is a variable, Categorical versus continuous, Independent versus dependent variables, Non repeated versus repeated measures variables, Measurement scale, Common statistical programs, Orientation to SPSS program, What is under each menu, Getting data into SPSS: Creating a new data set, Valid variable names, Variable view, Adding value labels, Reading in an existing data set (Excel)

Data management and descriptive statistics

Data entry in SPSS

SPSS techniques for cleaning data- Univariate statistics, creating, modifying, and copying charts/graphs for categorical variables-Creating histograms and boxplots for continuous variables.

Merging and restructuring datasets: Why not to use cut-and-paste-Add variables, Consistency of subject identifiers, Add cases, Consistency of variable types-Restructuring datasets, Long/thin/vertical-Short/wide/horizontal

Data analysis using SPSS: Summarization of data, bivariate correlations, Interpreting correlation coefficients, Pearson, spearman, and point biserial correlations, Scatterplots, Adding a linear regression line, Caution: outliers and non, linear relationships, Scatterplots to demonstrate time trends, Phi coefficient, Crosstabs, Bivariate associations with continuous variables: Correlations using values, _Time Corrected Scatterplots, Adding a line of best fit, scatterplots using for continuous values ,Parametric and non, parametric methods, multivariable regression methods

UNIT II: EPI INFO

Form Designer – Create the questionnaire, form, or form to collect and view data.
Enter – Enter data and show existing records in the form.
Classic Analysis – Run statistical analyses, lists, tables, graphs, charts, etc.
Map – Create maps from Map-Server or Shape Files.
Options – User custom configuration of Epi Info.

UNIT III: RED CAP

Building a Project: Introduction to Project Development- Online Designer- Data Dictionary

- Project Field Types

Basic Features & Modules: Applications Overview- The Calendar- Scheduling Module- Data Access Groups for multi-site projects

Types of REDCap Projects: Types of Projects- Traditional Project (classic model with data entry forms) Single Survey Project- Longitudinal Project (multi-use data entry forms,abstract time-points), Longitudinal Project+ Scheduling (multi-use data entry forms,defined time points), Operations(use case for non-study/non-trial)

Special Features within REDCap Projects: Defining Events in Longitudinal Projects, Designating Instruments for Events in Longitudinal Projects, Repeatable instruments and events, RED Cap Mobile App, Locking Records, Data Resolution, Workflow

References

Beth MS, Janie HW, Dennis MG (2018). An Easy Guide to Research Design & SPSS. Sage publication
IBM (2016). Programming and Data Management for IBM SPSS Statistics 24: A Guide for IBM SPSS Statistics and SAS Users Andrew GD, Kevin MS, Minn MS (2010). Epi Info and Open Epi in Epidemiology and Clinical Medicine: Health Applications of Free Software. Creates pace Independent Pub.
Vanderbilt University (2015). REDCap Beginner's Guide

Paper 5: Computer Science

UNIT I: INTRODUCTION TO COMPUTERS AND OPERATION SYSTEMS

Evolution of Computers, Generation of Computers, Cassification of computes Analog Digital and Hybrid Computers Classification of Computers according to size, types of OS

UNIT II: INTRODUCTION TO PROGRAMMING CONCEPTS

Types of Programming Languages, software, Classification of software

UNIT III: INTRODUCTION TO DATA BASE MANAGEMENT SYSTEMS

Need of DBMS, Storage of data and retrieval of data, file system and DBMS Architecture

UNIT IV: DISCRETE MATHEMATICS

Logic and Boolen algebra, set theory, relations and functions. Mathematical reasoning and Graphs

UNIT V: INTRODUCTION TO ARTIFICIAL INTELLIGENE AND MACHINE LEARNING

Background on Artificial intelligence and Machine Learning Types of Machine Learning, deep learning, Supervised Learning, Unsupervised Learning and Reinforcement Learning.

UNIT IV: DISCRETE MATHEMATICS

Logic and Boolen algebra, set theory, relations and functions. Mathematical reasoning and Graphs

YEAR 3:

Paper 1: Regulations in Clinical Research

UNIT I

Introduction of Clinical Trial Regulation, Aims and Key benefits of the regulations, regulatory and data strategy, Evolution of regulatory changes in India, Regulatory requirements for the conduct of clinical trials in India, Regulatory Bodies, Framework and Procedures (INDIA), Regulatory Bodies, Framework and Procedures (Foreign), Central Drugs Standard Control Organization (CDSCO), Initiatives and Priorities of CDSCO

UNIT II

Food and Drug Administration (US FDA), advances the FDA's mission, Drug and cosmetic act- Schedule Y- ICMR Guideline- data Safety monitoring board Regulations: Roles and Responsibilities, Membership, Meetings, Study Reports for DSMB Meetings, Reports from the DSMB, Relationship Between DSMBs and IRBs, Reimbursement,

References

WHO (2002). Handbook for good clinical research practice: Guidance for implementation. WHO Library Cataloguing-in-Publication Data

Josef K, Paul M, Graeme S (2000). Good Clinical Practice: Standard Operating Procedures for Clinical Researchers. Wiley

Paper 2: Data Safety Monitoring Board and Clinical Trial Management

UNIT I

Project Management, Protocol development in Clinical Research, Informed Consent, Case Report Form, Investigator's Brochure (IB), Selection of an Investigator and Site

UNIT II

Clinical Trial Stakeholders ,Contract Research Organization (CRO) ,Site management organizations (SMO), Ethical and Regulatory Submissions ,Recruitment Techniques ,Retention of Clinical Trial Subjects

UNIT III

Monitoring Visits, Investigator Meeting, Documentation in Clinical Trials, Regulatory Binder, Record Retention – Pharmacovigilance, Training in clinical Research, Project Auditing, Inspection, Fraud and Misconduct, Roles and Responsibilities of Clinical Research Professionals

References

JoAnn P, Cris W (2017). A Practical Guide to Managing Clinical Trials. CRC Press

Alexey L (2017). Project Management in Clinical Trials

Paper 3: Advanced Statistical Methods

Logistic regression, life table construction, log rank test, survival analysis, Kaplan Meir curve, parametric and non-parametric methods, Weibull regression, cox regression, exponential regression, nonlinear regression methods, Poisson regression, Negative binomial regression, Ridge regression

References

David C(2015). Modelling Survival Data in Medical Research. Chapman and Hall

Long JS (1997). Regression Models for Categorical and Limited Dependent Variables. Sage publications

Paper 4: Software Handling Part II: SAS, R and Python

UNIT-I : SAS

Introduction to SAS program , SAS Data types and Libraries , Data Steps and Proc Steps , Format & In format , Creating Output Proc Print, Proc Contents , Output Delivery System (ODS) ,Reading Raw data , Column input , Understanding Data step processing , Formatted Input and List input , Reading date and Time format , Reading Instream data , Creation of raw data file from dataset ,Managing Variables in dataset , Assignment and Cumulative statement , Sub setting data, drop and keep option , If - else, if- else with do statement, Select When, Do, loop Statement , Managing SAS Dataset using set statement , SAS functions Overview , String Functions , Conversion Functions , Date Functions , Mathematical Functions, Descriptive statistics, Proc means and proc freq , Proc report, column, define, headline, head skip, compute, order and group , Proc tabulate Proc transpose, Combining data set, one to one reading, concatenation and merge , Array, single and multi, dimensional array , Proc print, proc import and proc export

UNIT II : R

Installation and Initialization ,Basic Linux Commands ,Package Management and process Monitoring., Important Files, Directories and Utilities ,Advance Shell Programming ,System Services ,User Administration ,File System Security & Advanced File System Management ,Server Configuration & Virtualization ,Samba and Mail Services Virtualization ,Advance Security & Networking Concepts. ,Concept of Data Analytics & ,Data Manipulation in R ,Data Import Techniques, Exploratory Data Analysis, Data Visualization, Data Mining: Clustering Technique, Data Mining: Association Rule Mining and Sentiment Analysis, ANOVA, Predictive Analysis & Simulation, Implementation of Decision tree, Introductory Concepts, Database Design, Relational Model and SQL, Database design using the relational model, Storage and Indexing Structures, Transaction Processing and Concurrency Control (OLTP & OLAP),Database recovery techniques, Query Processing and Optimization, Database Security and Authorization, Enhanced Data Models for specific applications, Enhanced Data Models for specific applications, Distributed databases and issues

UNIT III:

Basic Java ,Arrays, Objects and Classes, Control Flow Statements, Inheritance and Interfaces, Exception Handling & Serialization, Collections, Reading and Writing files, Python Basics, OOPs concept in Python, Exception Handling in Python, Python for Data Science an Introduction, Pre Processing of Data, Visualizing the Data, Exploratory Data Analysis, Clustering and identification of Outliers using Python, DS Performing Cross, Validation, Selection, and Optimization using Python, Learning from Data using Python

References

Lorda DD, Susan JS (2012). The Little SAS Book: A Primer. SAS Institute

Ron C (2015). An Introduction to SAS University Edition. SAS Institute

Venables WN, Smith DM, The R Core Team (2019). An Introduction to R. R Core Team

Norman M (2011).The Art of R Programming – A Tour of Statistical Software Design. No Starch Press

Winston C (2012). R Graphics Cookbook. O'Reilly Media

Jack V (2016). Python Data Science Handbook: Essential Tools for Working with Data. O′Reilly

Eric M(2015). Python Crash Course. No Starch Press

POSTINGS FOR INTERNSHIP:- (12 Months)

v) Clinical Trial Data Monitoring Unit-I (Department of STATISTICS, ICMR-NIRT) : 3 Months
   i Monitoring Screening Activities with respect to Patient enrolment
   ii Checking eligibility criteria
   iii Randomization / Treatment Allocation
   iv Monthly monitoring / investigation or schedule of protocol checking
   v Identifying Discrepancies and resolve queries
   vi Periodical manual data posting and data extraction in a structured format
   vii Treatment Adherence Checking

2. Clinical Data Management Unit (*e-source Wing*, Department of STATISTICS, ICMR-NIRT*)*: 3 Months
   - Form Design, Database Creation and platform checking, identifying deficiency, resolve queries and related modification
   - Database CRF checking, Reviewing CRFs, Documentation Analysis and Deficiency Checking, Export, File conversion and Data transfer mode for analysis Stage)
   - Quality Checking and Quality Assurance
   - Data cleaning, Decoding and creating data definition

3. Clinical Trial Data Monitoring Unit-II (Department of STATISTICS, ICMR-NIRT): 3 Months
   - Clinical Trial Data CONSORT preparation Stage 1 Analysis
   - ITT and mITT analysis, Number Needed to Treat Analysis
   - per Protocol Analysis, sample size re-estimation, power analysis

4. Industrial Training and Report Submission: 3 Months
   - Hospitals and Research Centres
   - Pharmaceutical Companies and Healthcare Industries