

PhD Course Work

Total marks: 100

Duration: 3 hrs

Part A – Research Methodology

Introduction to Research

Definition of the term research and anusandhan

Need of research in the field of Ayurveda

General Guidelines and steps in the Research process

- a) Selection of the research problem
- b) Literature review: different methods (including computer database) with their advantages and limitations
- c) Defining research problem and formulation of hypothesis
- d) Defining general and specific objectives
- e) Research design: observational and interventional, descriptive and analytical, preclinical and clinical, qualitative and quantitative
- f) Collection of the data
- g) Clinical trial data management, analysis of data.
- h) Generalization and interpretation, evaluation and assessment of hypothesis.
- i) Ethical aspects related to human and animal experimentation.
- j) Ethical issues in drug development, Nuremberg code, Helsinki declaration, ICMR ethical guidelines for biomedical research on human subjects in india
- k) Informed consent, essential elements of informed consent as per schedule Y, practical issues with ICF, format of informed consent form for subject participating in a research study
- l) Information about Institutional Ethics Committee (IEC) and Animal Ethics Committee (AEC) and their functions. Procedure to obtain clearance from respective committees, including filling up of the consent forms and information sheets and publication ethics.

Bioequivalence studies

Definition, bioavailability, determination of equivalence, types of equivalence studies, exemption from equivalence studies, study designs, study conduct: study protocol, blinding, randomization and allocation of treatments, dosage and sampling schedules, drug assay- bioassays, physico-chemical assays, immunoassays, data analysis, statistical models of bioequivalence

Preparation of Research proposals in different disciplines for submission to funding agencies taking EMR-AYUSH scheme as a model.

Scientific writing and Publication skills.

- a) Familiarization with publication guidelines- Journal specific and CONSORT guidelines.
- b) Different types of referencing and bibliography.
- c) Thesis/Dissertation: contents and structure
- d) Research articles structuring: Introduction, Methods, Results and Discussions (IMRAD)

Clinical research:

- a) Introduction to Clinical Research Methodology identifying the priority areas of Ayurveda
- b) Study design: Observational and Interventional studies Descriptive & Analytical studies Longitudinal & Cross sectional studies Prospective & Retrospectives studies Cohort studies
- c) Randomization: Randomized Controlled Trials (RCT) & their types
- d) Single-case design, case control studies, ethnographic studies, black box design, cross-over design, factorial design.
- e) Blinding
- f) Errors and bias in research.
- g) New concepts in clinical trial- Adaptive clinical trials/ Good clinical practices (GCP), Phases of Clinical studies: 0,1,2,3, and 4.

Survey studies -

Methodology, types, utility and analysis of qualitative research methods.
Concepts of in-depth interview and Focus Group Discussion.

Questionnaires

Definition, surveys vs questionnaire, types of questionnaire, types of questions in questionnaire, examples, demographic questionnaire, psychographic questionnaire, various scales to design questionnaire

Method of Standardization & Validation of questionnaire

Pharmacovigilance for ASU drugs

Need, scope and aims & objectives. National Pharmacovigilance Programme for ASU drugs.

Bioinformatics

Introduction to bioinformatics, scope of bioinformatics, role of computers in biology.
Introduction to Data base- Pub med, Medlar and Scopus. Accession of databases.

Intellectual Property Rights-

Different aspect and steps in patenting, Information of Traditional Knowledge Digital Library (TKDL).

Nadi tarangini instrument

Part B - Biostatistics

Definition of Statistics:

Concepts, relevance and general applications of Biostatistics in Ayurveda

Collection, classification, presentation, analysis and interpretation of data:

Definition, utility and methods

Scales of Measurements:

Nominal, ordinal, interval and ratio scales.

Types of variables:

Continuous, discrete, dependent and independent variables.

Type of series:

Simple, Continuous and Discrete

Measures of Central tendency:

Mean, Median and Mode.

Variability:

Types and measures of variability- Range, Quartile deviation, Percentile, Mean deviation and Standard deviation

Probability:

Definitions, types and laws of probability,

Normal distribution:

Concept and Properties, Sampling distribution, Standard Error, Confidence Interval and its application in interpretation of results and normal probability curve.

Fundamentals of testing of hypotheses:

Null and alternate hypotheses, type I and type 2 errors.

Tests of significance:

Parametric and Non-Parametric tests, level of significance and power of the test, P value and its interpretation, statistical significance and clinical significance

Univariate analysis of categorical data:

Confidence interval of incidence and prevalence, Odds ratio, relative risk and Risk difference, and their confidence intervals

Parametric tests:

Z test, Student's t test: paired and unpaired, F test, Analysis of variance (ANOVA) test, repeated measures analysis of variance

Non parametric methods:

Chi-square test, Fisher's exact test, McNemar's test, Wilcoxon signed rank test, Mann-Whitney U test, Kruskal – Wallis with relevant post hoc tests (Dunn)

Correlation and regression analysis:

Concept, properties, computation and applications of correlation, Simple linear correlation, Karl Pearson's correlation co-efficient, Spearman's rank correlation, Regression- simple and multiple.

Sampling and Sample size computation for Ayurvedic research:

Population and sample, Advantages of sampling, Random (Probability) and non random (Non- probability) sampling, Merits of random sampling, Random sampling methods- simple random, stratified, systematic, cluster and multiphase sampling. Concept, logic and requirement of sample size computation, computation of sample size for comparing two means, two proportions, estimating mean and proportions.

Vital statistics and Demography:

Computation and applications - Rate, Ratio, Proportion, Mortality and fertility rates, Attack rate and hospital-related statistics

Familiarization with the use of Statistical software like SPSS/Graph Pad/Sigma stat**Designing Diagnostic Studies**

Diagnostic Research Design, Phases in Clinical Diagnostic Studies, Diagnostic Accuracy Studies, Index Test, Reference Standards, Examples of Diagnostic Accuracy Study Designs, Observational Studies, Paired Comparative Accuracy Studies, Randomized Comparative Accuracy Studies, Sample Size Calculations, Reporting of Diagnostic Accuracy Studies

Assessing Diagnostic Tests

Technical Accuracy and Precision, Error, Standard Deviation, Confidence Interval, Calculating Reference Intervals, Calculating Sample Size for Reference Interval Estimation, Diagnostic Accuracy and Testing for Accuracy, Sensitivity and Specificity, Predictive Values, Receiver Operating Characteristic Curve, Calculating AUC, Clinical Applicability, Transferability, Feasibility, Cost-Effectiveness Analysis

Critical Appraisal of Diagnostic Studies

Levels of Evidence, Evidence-Based Recommendations, Critical Appraisal of Diagnostic Studies, Systematic Reviews, Meta-analysis, Publication Bias

Validation of New Tests

Test Validation, Defining Analytical Goals, Validation Experiments, Sample Size Calculations, Accuracy Experiment for Qualitative Tests, Precision Experiment for Qualitative Tests, Method Comparison Experiments for Quantitative Tests, F-Test for

Precision, Linearity Experiments for Reportable Range, Allowable Total Error, Detection Limit Experiments

Imputation and Missing Data

Missing Data, Types of Missing Data, Graphical Visualization of Missing Data, Dealing with Missing Data, Robust Statistics, Data Discarding Solutions, Complete-Case Analysis, Available-Case Analysis, Imputation, Single Imputation, Multiple Imputation

Statistical Concepts in Laboratory Quality Control

Control Limits, Levey-Jennings Charts, Westgard Rules, Average of Normals, Delta Check, Moving Patient Averages, Statistical Concepts for External Quality Control

Comparing Sample Means

Continuous Data, Mean and Median, Variance, Skewness, and Kurtosis, Parametric Versus Non-parametric Tests, Outliers, One-Tailed Versus Two-Tailed Testing, Testing for Normality, Parametric Tests, Student's t-Test, One-Way ANOVA, Non-parametric Tests, Mann-Whitney U Test, Kruskal-Wallis Test, Effect Size, Cohen's d, Cohen's f, Ordinal Variables, Kendall's Tau Test, Spearman's Rho Test

Cross Tabulation and Categorical Data Analysis

Categorical Variables, Contingency Table, Hypothesis Testing, Analysis of Risk Ratios, Chi-Squared Tests, Degrees of Freedom, Chi-Squared Distribution, Pearson Chi-Squared Test, McNemar's Test, Cochran-Mantel-Haenszel Test, Fisher's Exact Test, Measures of Agreement, Cohen's Kappa, Fleiss's Kappa

Multivariate Analysis

Generalized Linear Model, Multiple Regression Analysis, Assessing Utility of the Fitted Model, Interaction and Collinearity, Logistic Regression, Binary Logistic Regression, Multinomial Logistic Regression, Ordinal Logistic Regression, Internal and External Validity

Part C - Computer Skills

1. Characteristics of computer, Input & Output Devices, Storage Devices, CPU, System Software, Application Software.
2. Applications of computer in research, Multimedia & presentation devices.
3. Internet, use of internet and www, electronic mail (e-mail), downloading & uploading
4. Access of e-Journals, e- Library
5. Search engines, searching the keywords, advance search, overview of Google application.
6. M.S.-WORD: Toolbars, menu, editing a document, file handling and various format of file, mail merge, reviewing a document, basics of latex, and all the latest features
7. M.S.- EXCEL: Toolbars, menu, creating worksheet, charts, sorting and filtering, use of formulas.
8. M.S. POWERPOINT: Creating presentation & adding effects along with use of all the latest features
9. Plagiarism Software

REFERENCE BOOKS

Medical Statistics:

1. Indrayan. (2008). Basic Methods of Medical Research. AITBS Publishers- India
2. Mahajan B K, Methods in Bio statistics for medical students, 5th Ed. New Delhi, Jaypee Brothers Medical Publishers
3. Introduction to Statistical Methods in Pathology, Amir Momeni • Matthew Pincus Jenny Libien, Springer, ISBN 978-3-319-60542-5 ISBN 978-3-319-60543-2 (eBook)
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7. Bradford Hill – Basic Medical Statistics
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11. Mehdi, B and Prakash A. (2010). Biostatistics in Pharmacology. Practical Manual in experimental and clinical pharmacology. 1stEdition. New-Delhi: Jaypee brothers Medical Publishers
12. Rao, NSN and Murthy, NS. (2008) 2nd Edition. Applied statistics in health sciences. Jaypee Brothers Medical Publishers (P) Ltd.Bengaluru, New Delhi.
13. Rick J Turner and Todd A Durham (2008). Introduction to Statistics in Pharmaceutical Clinical trails. Published by thePharmaceutical Press- An imprint of RPS Publishing,1 Lambeth High Street, London SE1 7JN, UK
14. Symalan, K. (2006). Statistics in Medicine (First Edition) Trivandrum: Global Education Bureau.
15. Sundar Rao, Jesudian Richard - An Introduction to Biostatistics.
16. Suhas Kumar Shetty- Medical statistics made easy

Biotechnology and Bio-informatics:

1. Angela M. Meireles A (2009). Extracting Bioactive compounds for food products. Theory and applications. CRC- PressTaylor and Francis Group.
2. Bergeron BP 2002 Bioinformatics Computing 1st Edition, Prentice Hall
3. Chikhale, N.J. and Virendra Gomase, Bioinformatics- Theory and Practice, Publisher: Himalaya Publication House, India; 1edition (July, 2007) ISBN-13: 978-81-8318-831-9
4. Lesk, A.M. Introduction to Bioinformatics Oxford 2002.
5. Satyanarayana, U.: Biotechnology, Books and Allied (P) Ltd, Kolkata, 2005
6. Setubal J. C and J. Meidanis, Introduction to Computational Molecular Biology, PWS Publishing Company, 1997.
7. <http://www.iitb.ac.in/~crnts>.
8. <http://www.zygogen.com>.
9. <http://www.dsir.nic.in/reports/tifp/database/metallo.pdf>.
10. www.consort-statement.org
11. www.strobe-statement.org
12. www.icmr.nic.in

Clinical research

1. Clinical Research Fundamentals & Practices, Dr Vishal Bansal, Paras Medical Publisher, Hyderabad, New Delhi, 2010
2. CDSCO, Good Clinical Practices For Clinical Research in India, Schedule Y (Amended Version – 2005),<http://cdsco.nic.in/html/GCP1.php>

3. Ethical Guidelines for Biomedical Research on Human subjects. (2000). Indian Council of Medical Research- New Delhi.
4. Gallo P., Chuang-Stein C., Dragalin V., Gaydos B., Krams M., Pinheiro J. Adaptive Designs in Clinical Drug Development—An Executive Summary of the PhRMA Working Group. *Journal of Biopharmaceutical Statistics*. 16: 275–283; 2006
5. Good Clinical Practices- (2001). Guidelines for Clinical Trial on Pharmaceutical Products in India. Central Drugs Standard Control Organization. Directorate General of Health Services. New Delhi. (<http://WWW.cdsc.nic.in.ich.org>)
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9. Petter Laake, Haakon Breien Benestad and Bjørn Reino Olsen. (2007). Research Methodology in the Medical and Biological sciences. Academic Press is an imprint of Elsevier, 84 Theobald's Road, London WC1X 8RR, UK. ISBN: 978-0-12-373874-5
10. William C. Scheffer Introduction to Clinical Researchs

Drug research and development:

1. RICK NG, (2009). DRUGS- from discovery to approval. John Wiley & Sons, Inc., Hoboken, New Jersey
2. Research guidelines for evaluating the safety and efficacy of herbal medicines. (1993). . WHO- (Regional Office for the Western Pacific – Manila) ISBN 92 9061 110 3 (NLM Classification: WB 925).
3. Jagdeesh, Sreekant Murthy, Gupta, YK and Amitabh Prakash Eds. Biomedical Research (From Ideation to Publication) (2010). Wolters Kluwer/ Lippincott Williams and Wilkins.
4. WHO Guidelines on Safety Monitoring of herbal medicines in pharmacovigilance systems. (2004). WHO- Geneva. ISBN 92 41592214.
5. Natural products isolation. (2006) 2nd ed. / edited by Satyajit D. Sarker, Zahid Latif, Alexander I. Gray. (Methods in biotechnology; 20). Includes bibliographical references and index. Humana Press Inc. ISBN 1-58829-447-1 (acid-free paper) – ISBN 1-59259-955-9 (eISBN)
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9. OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring, 1998.http://www.oecd.org/document/63/0,2340,en_2649_34381_2346175_1_1_1_1,00.php
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12. Bombay.\Jaju B.P.: Pharmacological Practical Exercise Book, Jaypee Brothers, New Delhi.
13. Kulkarni S.K.: Hand Book of Experimental Pharmacology, Vallabh Prakashan, New Delhi
14. Ravindran R.: X-Pharm (Software), Indian Journal of Pharmacology, JIPMER, Pondicherry.

Computer skills

1. Basic Of Computer – By Peter Norton
2. Basic Of Computer – By P.K. Sahani
3. Microsoft Office 365-Shelly Cashman Series.
4. Mastering M.S. Office.