PHARMA-STATS
knowledge change the power

Nirali Mehta, M.Sc., M.Phil.
Founder & Consultant Biostatistician
Ahmedabad, Gujarat, India.
M +91 9737043778
E nirali.mehta@pharma-stats.in
W www.pharma-stats.in

Education

1998-2001	Bachelor of Science (B.Sc.) – Statistics (Mathematics) Gujarat University
2001-2003	Masters of Science (M.Sc.) – Statistics, Gujarat University
2003-2005	Masters of Philosophy (M.Phil.), Some Mathematical Models in Medical Research, Gujarat University
2014-ongoing	Pursuing Ph.D., Statistics in Drug Development

Current Activities

March 2013-Current

Advisory Biostatistician, PHARMA-STATS
Corporate Training Center & Independent Statistical Consultancy Services, Ahmedabad

Single point statistical solution:
- Post study statistical evaluation. It helps manufacturer to better understand their formulations from statistical point of view
- Expert statistical solutions at planning stage to get precise results like sample size calculation, SAP-Statistical Analysis Plan, protocol inputs, SAS Programming, Bioequivalence CDISC submissions to FDA (with SAS macro codes)
- Independent statistical consultant for Data Safety & Monitoring Board (DSMB), advisory biostatistician for pre-stage study design

Training for Non-statisticians:
- Statistical training as per client requirements
- Specially designed structure of training for non-statistician employees working in pharmacokinetics, clinical research, quality assurance, medical writing, dissolution Similarity, regulatory affairs, formulation development, project management & IVIVC, Complete hands on training for CDISC - BE submission
- It helps in better understanding of clinical studies (BE) from statistical point of view.

Pharmaceutical Statistics:
- Unique design to train Statisticians (Masters in Statistics) for pharmaceuticals & CROs
- Specific areas of training: Bioequivalence, Clinical Trial (phase II/III/IV/PMS), Pharmacovigilance, DOE by QbD with SAS programming, MINITAB and other statistical tools with hands on approach.

- Training statisticians to read-interpret-conclude clinical and statistical data and results.

Aug 2005-Feb 2013

Torrent Pharmaceuticals Ltd., Torrent Research Centre, Ahmedabad

Biostatistician – Clinical Research

Clinical Trials, Bioavailability, Bioequivalence

Protocol Design:

- Study design
- Sample size & Randomization
- Statistical Analysis Plan (SAP)
- Prepare & Review SAP according to study design and regulatory requirement
- Discuss with sponsor/study-investigator/respective clinical group regarding statistical aspects and inputs of planned study

Data Management:

- Database designing, data verification and query resolutions.

Statistical Analyses:

- Perform & review the statistical analysis
- Data Presentation- Tables, charts

Statistical Write up (Report):

- Describe statistical methodology
- Conclude the results of efficacy and safety parameters
- Discuss the results and conclusion of the study with sponsor/ study-investigator/respective clinical group/FND

Statistical Tool:

- Statistical and Pharmacokinetic analysis using the SAS®programming & WinNonlin®
- Prepare and review SAS programs

Query resolution:

- Response to regulatory/customer queries

Regulatory/Customer audit:

- Responsible for inclusive statistical phase

SOPs:

- Prepare & review the SOPs of Clinical trial, BA/BE studies, Statistical software and data management

Software validation & Documentation:

- Validation and documentation of SAS programs, WinNonlin procedures and other software applications.
- Documentation of software licenses and system access permits.

Training & seminars:

- Provide statistical training and seminars to statisticians and non-statisticians within company and University.

Other Areas

Simulation:

- Extrapolation of single dose data to the multiple dose

Stability data analysis:

- Extrapolation of impurities, dissolution, assay and water content stability data.
- Calculate confidence interval and expiry date for the same using SAS programming.
- Identification of Out Of Trend(OOT) Stability

In vitro-In vivo Relation (IVIVR):

- Calculation of point-A correlation

Patent:

- Review and support regulatory issues related to Patent of the drug

Pharmacovigilance:

- Signal detection/Risk assessment

Work for the Regulatory: USFDA, EU, ANVISA, Canada, ROW

Experience of Regulatory audit: ANVISA, USA, France, Denmark, Austria

Sept 2004 to Aug 2005

Wockhardt Ltd., HO, BKC, Mumbai

Medical Statistician-Clinical Research

Key area: Clinical Trials

- Protocol designing
- Statistical Analysis Plan
- Data Management (Data verifications, Query resolutions)
- Site Monitoring
- SAS programming
- Statistical analyses
- Report writing
- Data Presentation
- SOP preparations
- Query resolutions
- Project management
- Co-ordination with clinical team

June 2004 to Aug 2004

SAL Hospital, Ahmedabad

Research Assistant, Cardiology department

Dec 2003 to Mar 2004

Sterling Hospital, Ahmedabad

Research Assistant, Cardiology department

Aug 2003 to Aug 2004 — **GCRI –Gujarat Cancer & Research Institute, Civil hospital, Ahmedabad**
Volunteer Biostatistician
Key area: Research projects regarding Cancer Risk Assessment (software: SPSS)

July 2003 to Dec 2003 — **St.Xavier college, Ahmedabad**
Visiting lecturer- Bachelor of Science & Bachelor of Arts
Key area: Design and analyses, Statistical Quality Control, Modeling

Computer skills

Software and Tools: SAS Programming, WinNonlin, SPSS, Data management (Clinical trials), MINITAB
Microsoft office: Excel, Word, PowerPoint, Access
Languages: FORTRAN, C

Language skills

Fluent in spoken and written Gujarati, Hindi & English.

TRAININGS & SEMINARS

Trainings & Presentations		**Subject**
Conducted 6-days workshop on "CDISC Standards: Implementation, Regulatory Requirements and Application in Bioequivalence Studies", organized by Sun Pharmaceutical Industries Ltd. (Vadodara), at PHARMA-STATS, Ahmedabad	March 2017	1.CDISC Introduction 2.SDTM 3.ADaM Datasets 4.Validation process 5.Define.xml 6.SDRG & ADRG 7.Case Study 8.Regulatory guidelines & requirements etc.
Conducted 2-days workshop on "Statistical Concepts in Bioequivalence Studies" organized by Alembic Pharmaceuticals Ltd., at Alembic Research Centre, Vadodara	9^{th}-10^{th} September, 2016	1. Basic statistical concepts 2. Bioequivalence analysis & Interpretation 3. Importance of Sample size calculation and its reference data 4. Reference scaled difference between US & EU Criteria 5. Individual case studies on failed bioequivalence 6. Statistical Outlier &

Trainings & Presentations		Subject
		submission
Delivered 2-days workshop on "Concepts of Bioequivalence from statistical point of view" for non-statisticians organized by Cadila Healthcare Ltd., at Hotel Aloft, Ahmedabad	20th-21st June, 2016	1. Basic statistical concept 2. Bioequivalence analysis & Interpretation with case study of failed bioequivalence 3. Reference scaled Difference between US & EU criteria 4. ISCV Comparison for Replicate designs 5. Two stage Design 6. Bootstrapping Method
Presenter & trainer at International Clinical Trials Workshop(ICTW) during 34th ICON, by American Society of Clinical Oncology(ASCO) at Hotel NOVOTEL, Hyderabad	12th March, 2016	1. Statistical considerations from clinical point of view
Presented a full day talk in the fellowship program conducted by Dr. Reddy's on Clinical Research for international clinical and marketing team at Hotel AVASA, Hyderabad.	28th April, 2015	1. Basic Statistical Concepts 2. Sample size calculation 3. Bioequivalence analysis in 3-steps with case study 4. Clinical trials & designs 5. Importance of Adaptive design 6. Discussion on various regulatory queries
PHARMA-STATS had arranged one day workshop on "Concepts of Bioequivalence from Statistical Point of View'" for non-statisticians at Ahmedabad	9th March, 2014	1. Basic statistical concepts 2. Sample size calculation 3. Bioequivalence analysis with case study 4. Bioequivalence criteria of US-EU on Replicate design 5. Importance of 'Cleaned' Data in Bioequivalence
Presented a talk in 2-days workshop conducted by Pharma Edge Centre (I) Pvt. Ltd. at Mumbai on "Use of Biowaivers as in-vivo surrogate, basic concepts of in vitro-in vivo correlation (ivivc) &	25-26th January, 2014	Understanding the outcome of BE studies with Biostatistical concepts

Trainings & Presentations		Subject
Understanding statistical outcome of BE studies through examples for non-statisticians." Speakers: 1) Ms. Nirali Mehta (PHARMA-STATS) 2) Dr. J-M. Cardot Faculté de Pharmacie Laboratoire de Biopharmacie, FRANCE 3)Dr. Vinay Shedbalkar (Pharma Edge)		
Attended the 3-days workshop conducted by PharmaEdge Centre (I) Pvt. Ltd. at Mumbai. Speakers:1) Mr. Helmut Schütz, BEBAC - Consultancy Services for Bioequivalence and Bioavailability Studies; 2) Dr. J-M. Cardot Faculté de Pharmacie Laboratoire de Biopharmacie, FRANCE	27-29th January, 2012	In vitro-in vivo correlation (IVIVC), Biowaivers & Statistical aspects of Bioequivalence in Drug Product Development
Presented a talk in the seminar "Statistical analysis for drug discovery and design" conducted by Pharmacy Department, Faculty of Technology & Engineering, The M. S. University of Baroda, Gujarat	20-21st January, 2012	Bioequivalence by Clinical & Statistical point of view
Presented a talk in the workshop "Medical Pharmaceutical statistics" conducted by Dept. of Statistics, Sardar Patel University, Vallabh Vidyanagar, Gujarat	25-28th February, 2010	Fundamental of Biostatistics and its Opportunities in Pharmaceutical and CRO

PUBLICATIONS

1	Bioequivalence Study Of FDC Of Two Different Formulations Of Fixed Dose Combination Of Ramipril And Hydrochlorothiazide (5+12.5)mg Tablet In Healthy Human Volunteers Under Fasting Condition IJPI's Journal of Hospital and Clinical Pharmacy 2010, Vol. 1(1) 1-8.
2	Bioequivalence Study Of Two Oral Extended Release Formulations Of Felodipine 10 mg Tablets In Healthy Human Volunteers Under Fed Condition International Journal Of Pharmaceutical Sciences 2010 456-467
3	Bioequivalence study of two Fixed Dose Combination formulations of Perindopril and Indapamide (4 + 1.25) mg tablet in healthy human volunteers under fasting condition IJPI's Journal of Pharmacology and Toxicology 2011, Vol. 1(3) 16-24