



**Nirali Mehta, M.Sc., M.Phil.**

Founder & Consultant Biostatistician

Ahmedabad, Gujarat, India.

M +91 9377060504

E [nirali.mehta@pharma-stats.in](mailto:nirali.mehta@pharma-stats.in)

W [www.pharma-stats.in](http://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., Some Statistical Models in Pharmaceutical Statistics

**Current Activities**

**Consultant Biostatistician & Trainer, PHARMA-STATS**

Corporate Training Center & Independent Statistical Consultancy Services, Ahmedabad

**Single point statistical solution:**

- 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) for clinical and pre-clinical studies.
- Post study statistical evaluation. It helps manufacturer to better understand their formulations from statistical point of view
- System audit from statistical point of view.
- Biostatistics department set up: SOP, validations, organogram
- Independent statistical consultant for Data Safety & Monitoring Board (DSMB), advisory biostatistician for pre-stage study design

**Training to Non-statisticians:**

- Customized 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 (BE) and pre-clinical studies from statistical point of view.

**Training to Statisticians- Advance Post Graduate in Pharmaceutical Statistics (APGPS):**

- Unique concept to train Statisticians (Masters in Statistics) for pharmaceuticals & CROs

March 2013-Current

- Complete industry oriented curriculum, designed by industry experts
- Specific areas of training: Bioequivalence, Clinical Trial (phase II/III/IV/PMS), Pharmacovigilance, DOE by QbD, SAS programming, CDISC, MINITAB and other statistical tools with hands on approach.
- Training statisticians to read-interpret-conclude clinical and statistical data and results.
- Placement of trained statisticians

**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

Aug 2005-Feb 2013

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

**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

Sept 2004 to Aug 2005

June 2004 to Aug 2004	<b>SAL Hospital, Ahmedabad</b> Research Assistant, Cardiology department
Dec 2003 to Mar 2004	<b>Sterling Hospital, Ahmedabad</b> Research Assistant, Cardiology department
Aug 2003 to Aug 2004	<b>GCRI –Gujarat Cancer &amp; Research Institute, Civil hospital, Ahmedabad</b> Volunteer Biostatistician Key area: Research projects regarding Cancer Risk Assessment (software: SPSS)
July 2003 to Dec 2003	<b>St.Xavier college, Ahmedabad</b> 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
Speaker and Silver partner at “Recent trends and challenges in Bioanalysis and Scientific writing- BIOANALYTICA 2017” conducted by ABC Biologics at Taj Banjara hotel, Hyderabad, India.	June 2017	<ol style="list-style-type: none"> <li>1.Data Integrity in Bioequivalence study</li> <li>2. Handling of Drug concentration data before PK analysis</li> <li>3.Bioequivalence statistical analysis in 3-steps</li> <li>4. Discussion on Outlier from Regulatory aspects</li> </ol>
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	<ol style="list-style-type: none"> <li>1.CDISC Introduction</li> <li>2.SDTM</li> <li>3.ADaM Datasets</li> <li>4.Validation process</li> <li>5.Define.xml</li> <li>6.SDRG &amp; ADRG</li> </ol>

Trainings & Presentations		Subject
		<ul style="list-style-type: none"> <li>7. Case Study</li> <li>8. Regulatory guidelines &amp; requirements etc.</li> </ul>
Conducted 2-days workshop on “Statistical Concepts in Bioequivalence Studies” organized by Alembic Pharmaceuticals Ltd., at Alembic Research Centre, Vadodara	9 <sup>th</sup> -10 <sup>th</sup> September, 2016	<ul style="list-style-type: none"> <li>1. Basic statistical concepts</li> <li>2. Bioequivalence analysis &amp; Interpretation</li> <li>3. Importance of Sample size calculation and its reference data</li> <li>4. Reference scaled difference between US &amp; EU Criteria</li> <li>5. Individual case studies on failed bioequivalence</li> <li>6. Statistical Outlier &amp; submission</li> </ul>
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	20 <sup>th</sup> -21 <sup>st</sup> June, 2016	<ul style="list-style-type: none"> <li>1. Basic statistical concept</li> <li>2. Bioequivalence analysis &amp; Interpretation with case study of failed bioequivalence</li> <li>3. Reference scaled Difference between US &amp; EU criteria</li> <li>4. ISCV Comparison for Replicate designs</li> <li>5. Two stage Design</li> <li>6. Bootstrapping Method</li> </ul>
Presenter & trainer at International Clinical Trials Workshop (ICTW) during 34 <sup>th</sup> ICON, by American Society of Clinical Oncology (ASCO) at Hotel NOVOTEL, Hyderabad	12 <sup>th</sup> March, 2016	<ul style="list-style-type: none"> <li>1. Statistical considerations from clinical point of view</li> </ul>
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.	28 <sup>th</sup> April, 2015	<ul style="list-style-type: none"> <li>1. Basic Statistical Concepts</li> <li>2. Sample size calculation</li> <li>3. Bioequivalence analysis in 3-steps with case study</li> <li>4. Clinical trials &amp; designs</li> <li>5. Importance of Adaptive design</li> <li>6. Discussion on various regulatory queries</li> </ul>

Trainings & Presentations		Subject
<p>PHARMA-STATS had arranged one day workshop on “Concepts of Bioequivalence from Statistical Point of View” for non-statisticians at Ahmedabad</p>	<p>9<sup>th</sup> March, 2014</p>	<ol style="list-style-type: none"> <li>1. Basic statistical concepts</li> <li>2. Sample size calculation</li> <li>3. Bioequivalence analysis with case study</li> <li>4. Bioequivalence criteria of US-EU on Replicate design</li> <li>5. Importance of ‘Cleaned’ Data in Bioequivalence</li> </ol>
<p>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) &amp; 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)</p>	<p>25-26<sup>th</sup> January, 2014</p>	<p>Understanding the outcome of BE studies with Biostatistical concepts</p>
<p>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</p>	<p>27-29<sup>th</sup> January, 2012</p>	<p>In vitro-in vivo correlation (IVIVC), Biowaivers &amp; Statistical aspects of Bioequivalence in Drug Product Development</p>
<p>Presented a talk in the seminar “Statistical analysis for drug discovery and design” conducted by Pharmacy Department, Faculty of Technology &amp; Engineering, The M. S. University of Baroda, Gujarat</p>	<p>20-21<sup>st</sup> January, 2012</p>	<p>Bioequivalence by Clinical &amp; Statistical point of view</p>
<p>Presented a talk in the workshop “Medical Pharmaceutical statistics” conducted by Dept. of Statistics, Sardar Patel University, Vallabh Vidyanagar, Gujarat</p>	<p>25-28<sup>th</sup> February, 2010</p>	<p>Fundamental of Biostatistics and its Opportunities in Pharmaceutical and CRO</p>

## 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