PHARMA-STATS
knowledge change the power

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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 Techniques in Drug Development

Current Activities

March 2013-Current

Consultant Biostatistician & Trainer, PHARMA-STATS
Corporate Training Center & Independent Statistical Consultancy Services, Ahmedabad, India

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 of Statistics) for pharmaceuticals & CROs

- 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

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, EMA, TGA Australia, ANVISA, MCC-South Africa, BPFK-Malaysia, HSA-Singapore, MHSD-Russia, HPFB-Canada

Experience of Regulatory audit: ANVISA, USFDA, EMA, 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, MINITAB
Microsoft office: Excel, Word, PowerPoint, Access
Languages: 'C'

Language skills

Fluent in spoken and written Gujarati, Hindi & English.

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

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	1. Data Integrity in Bioequivalence study 2. Handling of Drug concentration data before PK analysis 3. Bioequivalence statistical analysis in 3-steps 4. Discussion on Outlier from Regulatory aspects
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} Septembe, 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 & 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	20^{th}-21^{st} June, 2016	1. Basic statistical concept 2. Bioequivalence analysis & Interpretation with case study of failed bioequivalence 3. Reference scaled Difference between US & EU criteria

Trainings & Presentations		Subject
		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 Regulatory affairs team (of USA, Ukraine, Russia, China, India, South Africa, UK and other foreign countries) 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) & 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)	25-26th January, 2014	Understanding the outcome of BE studies with Biostatistical concepts