



# Indian Society for Clinical Research

## 13th ANNUAL CONFERENCE

Track IV – Biostatistics and Statistical programming  
24<sup>th</sup> – 25<sup>th</sup> January 2020

### Speaker Profiles



#### Overview of Adaptive Designs and Regulatory Perspective

**Pinakin R. Jani, Associate Director, Biostatistics, IQVIA**

Pinakin Jani is a biostatistician in healthcare and has nearly 14 years of industry experience. He has worked in pharma companies, CROs and BPO setups in health care, he has worked for several top pharmaceutical sponsors. Currently, he is working as Associate Director at IQVIA, located in Ahmedabad and he works with IQVIA Biostatistics and Programming team. He is responsible for handling FSP accounts operations, project management, oversight for India region and works as a subject matter expert. His interest includes reading, teaching and travelling.



#### Drilling Down the Design Dilemma – A Story of Choosing the Right Design for Phase II Oncology Trial

**Dr. Parasar Pal, Associate Director, Early Development Biostatistics (EDB), Novartis**

Dr. Parasar Pal has obtained Doctor of Philosophy from University of Kalyani, West Bengal in Business Administration. Prior to that he completed Masters in Statistics from University of Calcutta. He has more than fourteen years of experience in providing statistical support to various early development clinical trials including Proof of Concept and Pharmacodynamics. He provided project level statistical support to some key products during submission. He also worked in late phase clinical trial and provided statistical support in one of the Neuroscience projects. Currently working with Novartis as a Group Head in Early Development Biostatistics and leading a group of statisticians working in early development projects in General Medicine and Oncology in India and Basel (Switzerland). In addition, he is also leading an Immuno-oncology program in Phase II as project statistician.





### Designing Non-inferiority Study

**Dr. Neeraj Pandey, DGM Digital Ops - LS Delivery, Cognizant**

Dr. Neeraj Pandey has more than 15 years of experience in research and analysis of data as Statistician spanning across Pharma, CROs/ITeS and Academic Institutes. Dr. Neeraj is currently working with Cognizant Technology Solutions India Pvt. Ltd as Engagement lead, for multiple global clinical studies. He has supported many global trails in role of lead/Study statistician from different TAs e.g. Oncology, Infection and Immunology.



### Application of Multi-State Reliability Theory to a Cancer Related Study

**Dr. Sanjeev Sabnis, Indian Institute of Technology, Bombay**

Sanjeev Sabnis is a faculty member in Department of Mathematics at IIT Bombay. He obtained B.Sc. and M.Sc. from University of Pune and Ph.D. from Old Dominion University, Norfolk, Virginia, USA. His research areas are Reliability Theory and Industrial Statistics, He has so far guided more than 60 M.Sc. projects (of two semester duration) and 3 Ph.D. students. He is presently guiding 1 Ph.D. student. He offers consulting services to industries in and around Mumbai and Pune and conducts in-house workshops on 'Statistical Modelling' for them. Sanjeev was facilitated Excellence in Teaching award of IIT Bombay in 2011 and 2019.



### Old Wine in New Bottle

**Jayapandian N., Head, Statistical Programming – India (Group Lead), Bayer**

Jayapandian N has over 16 years of Statistical Programming experience in different roles and capacities. He is currently associated with Bayer Pharma as Head Statistical Programming – India (Group Lead) and site lead for Data Sciences and Analytics. His past experiences are with Novartis, GSK, Target and Standard Chartered Bank with various domains of Credit Card analytics, Retail Analytics, Epidemiology and Clinical trials. He played various roles technically, functionally and at leadership level in Statistical Programming. He is six-sigma green belt certified. He leads PhUSE-India Single Day (SDE) events. He was member of Scientific Program Committee (SPC) of IASCT-ConSPIC 2019. He is passionate about developing people through strength-based approach. Keep the team as role model with the balance of opportunity, motivation, career growth, and recognition by aligning with business need.



### AI Use Cases in Clinical Trials

**Lakshmikanthan Santhanakumar, Director, Statistical Programming, Parexel**

Lakshmikanthan Santhanakumar is a Director, Statistical Programming at Parexel International, heading Statistical Programming team in India. In his current role he is responsible for strategizing India operations and ensuring timeliness and quality deliverable. He provides expertise and consultation, facilitate metrics collection and develop action plans. He also maintains positive, results orientated work environment, building partnerships and modeling teamwork, communicating to the team and stakeholders in an open, balanced and objective manner. Lakshmikanthan has been with Parexel for about 7 years and managed Database Programming, SDTM and Statistical Programming teams. Lakshmikanthan has been in the industry for the last 16 years with experience working in Data Management, Database Programming, SDTM and Statistical Programming in various Therapeutic areas. Lakshmikanthan has done his M.Sc., from Bharathidasan University. Before joining Parexel, he worked for organizations like Accenture, Jubilant Clinsys and Take Solutions.



**Verender Kumar, Senior Director, RTSM, Parexel**

Verender Kumar is working as Senior Director with PAREXEL managing the delivery of IRT services. He is a Computer Science engineer with over 25 years of experience in clinical research domain. He is currently pursuing M.Sc. in AI/ML and exploring relevant use cases within clinical research area.



### How AI & Technologies Leading the Drug Development Process for the Future and its Uses in Real Time

**Moovendhan Devaraj, Operations Lead, SDTM and Data Base Programming process, Accenture**

Moovendhan Devaraj is currently working as Operations Lead for SDTM and Data Base Programming process in Accenture Services Private Ltd. He earned Masters in Bioinformatics from Bharathiyar University, Coimbatore, Tamil Nadu, India. He is associated with programming in clinical trials for 12+ years with experience on study build, SDTM, ADaM and TLF across multiple therapeutic areas, has great knowledge on E2E of a clinical trials. In his current role, he leads two statistical processes with multiple SAS resources within group and oversees top pharma clients, coordinates on the deliverables. Also, he has served as subject matter expert in complex integrated summary analysis. He coordinates to Initiatives related to statistical programming capabilities, hiring and resourcing, innovation, etc. He has been associated with various conferences, attended multiple workshops and chaired the sessions.



### [SDTM Programs Before First Patient in \(FPI\) Using Robotics Process Automation \(RPA\)](#)

**Bhaskar Subramanian, Senior Director, Clinical Programming, Covance FSPx**

Bhaskar heads India clinical programming team for Covance FSPx based in Bangalore along with heads the India FSPx Innovation team for in-house tools development. He has more than 19+ years of experience in Clinical Research ranging from collection to statistical analysis and submission. He has worked in GSK, Quintiles, Octagon, Accenture at various positions, leading/building clinical programming teams. He holds the Masters in Computer Applications (MCA) and Masters in Business Administration (MBA) and living in Bengaluru, Karnataka, India.



### [CDISC Standards for BA / BE Studies - US FDA Perspective](#)

**Partha Chakraborty, Vice President, Global Delivery, CliniOps**

Partha has more than 25 years of experience working across USA, Europe, Hong Kong, New Zealand and India, in leading global delivery in life sciences & healthcare industry. Prior to joining CliniOps, he has worked in Cognizant as Global Delivery Head of Life Sciences R&D Practice and at Zensar (formerly Fujitsu ICIM). He has led initiatives of transforming pharmaceutical organizations in the area of clinical development & drug safety and providing them comprehensive end-to-end business process and IT solutions using state of the art technology services. Partha was former Chair of CDISC AP3C (Asia Pacific Coordination Committee), a key industry forum working on data standard. He has also presented his views on transformations in clinical development and pharmacovigilance in FDA science congress, DIA, ISPE, CDISC and several conferences and seminars in past. Partha has published chapters in books on methods & technology of pharmacovigilance, digital security (Software Development Techniques for Constructive Information Systems Design, Pharmacoinformatics and Drug Discovery Technologies and Elements of Pharmacovigilance). His latest book on *Modern Approaches in Software innovations in Clinical and Medical Technologies* was published in 2015. Partha holds a B. Tech (Honors) from IIT Kharagpur.



[Sample Size Calculation for Planning a Non-Inferiority Study](#)  
[Understanding FDA Guidance for Industry and its Related Challenges](#)

**Anadya Prakash Tripathi, Sr. Manager, Principal Biostatistician, EPD- (Established Pharmaceutical Division) Clinical Development and Medical affairs, Abbott**

Anadya Prakash Tripathi is a Masters in Biostatistics from Banaras Hindu University. He is a first rank holder and gold medalist in M.Sc. He has over 13 years' experience as biostatistician in pharmaceutical research and public health research. He has served many pharmaceutical companies, CRO and public health research organizations. He has started his career as a biostatistician and is now taking care of biostatistical and programming requirement of Abbott India operation locally and globally. He is very friendly in nature and easily approachable. He likes to connect people and talk. He is a good mentor and adviser. Anadya believes knowledge sharing is one of the key assets for every one's success and growth. He likes coaching people and developing them.



[Applied Statistics in Drug Development: Powering Decisions under Uncertainty](#)

**Ajay Sathe, CEO – India, Cytel**

Ajay Sathe heads the Indian operation of Cytel Inc. spread across five cities. Additionally, he is involved in Cytel's global initiatives in Automation, Innovation and Upskilling. CliPLab arose out of his initiative in Biometrics and Data Sciences training that is contributing to overall talent pool enhancement. He is co-founder and Director on the board of UpThink EduTech Services Pvt Ltd which is in the business of delivering online tutoring in STEM and soft skills to global undergraduate university students. Ajay was formerly (2014-2015) on the board of directors of PhUSE, as Events Director – Asia. He also served as (2016-2018) Vice President on the Governing Council of Indian Association for Statistics in Clinical Trials. Prior to joining Cytel, Ajay was Co-founder and Technical Director at Spectrum Business Support Ltd., where he led teams building WordMiner, an information retrieval library, and Jurix, a law information service. Ajay is an occasional guest speaker at IIM Ahmedabad and other business schools on Data Sciences, Analytics and Quantitative Methods; and at numerous colleges and educational departments on careers in contemporary services businesses. Ajay obtained B.Tech. in Electronics Engineering at IIT (BHU), Varanasi, India, and an MBA from IIM Ahmedabad, India. At both institutes, he ranked in the top 10% of his class and won various academic accolades.



### [A Class of Covariate-Adjusted Response-Adaptive Allocation Designs for Multi-treatment Binary Response Trials](#)

**Dr. Atanu Biswas, Professor, Indian Statistical Institute, Kolkata**

Dr. Atanu Biswas has obtained Doctor of Philosophy from Calcutta University (1998). He has nearly 200 research publications. He has authored following books: (1) *Randomized Response-Adaptive Designs in Clinical Trial* (2014), Anthony C Atkinson, Atanu Biswas (CRC Press). (2) *Statistical Advances in the Biomedical Sciences: Clinical Trials, Epidemiology, Survival Analysis, and Bioinformatics* (2007), Atanu Biswas, Sujay Datta, Jason P. Fine, Mark R. Segal Wiley). He is Associate Editor for Statistics and Probability Letters, Communications in Statistics.



### [Landscape of Clinical Submission Today](#)

**Krishnendu Biswas, Director, GDO, Data Operations, Statistical Programming, Novartis**

Krishnendu has over 15 years of experience working for number of major pharmaceutical companies as well as Clinical Research Organizations. He is currently a Senior Group Head in Novartis and leads a global team of statistical programmers. He also has experience of leading multi discipline teams and managing end-to-end projects. He has been a part of project transformation and had played a key role in organizational restructuring. He is statistician by training and holds a management degree as well. Krishnendu has led major non-clinical initiatives in the field of metrics, training and process improvement. Krishnendu has been associated with leading industry forums such as PhUSE, ISCR, and IASCT over the years as presenter and session chairs.



### [The Hustle and Bustle of CRT Preparations](#)

**Shubhangi Manjrekar, Delivery Manager, Biostatistics and Programming,  
Tata Consultancy Services**

Shubhangi Manjrekar is a statistician by qualification and has over 17 years industry experience in application of statistical methods for analysis and interpretation of clinical trial data. Shubhangi holds Master's degree in Applied Statistics from the University of Mumbai. In her association with different companies like SIRO Clinpharm, Cognizant Technology Solutions and currently at TCS, she got opportunities to work on various clinical trials of world's top pharmaceutical companies for analysis and reporting of data to regulatory authorities. She has been leading team of statisticians and statistical programmers. Shubhangi believes in building strong process base and in leading process improvement initiatives.



### [External Control Arm Studies – The Beginning of an End to the Placebo Trials](#)

**Sangeet Kumar, Director – Operations, SymphonyAI (Concerto HealthAI)**

Sangeet is an Engineering graduate and had CCDM Certification from SCDM, US. He comes up with 13 years of experience in Clinical Data Services that includes Clinical Data Management, Clinical Database Programming, Medical Coding, Biostats & SAS Programming functions. Currently part of India Leadership sand working as Director - Operations for Symphony AI (Concerto HealthAI) providing oversight to the Real World Evidence Data products, Data Curation Software & Outcome Science (HEOR) Biostatistics & Programming teams in India. Have chaired sessions in SCDM Global conference 3 Times (2016, 2018 and 2019) and regularly speaks, contributes and provide Thought Leadership in DIA, SCDM, PhUSE conferences both nationally and internationally. Handled end-to-end CDM studies from draft Protocol to regulatory submission across phase I-IV of clinical trials in variety of TAs such as Oncology, Infectious Diseases, Neurosciences, Critical care and Cardiovascular Diseases and have managed large operations team of 150+ associates spread across locations/roles and project management for over 100 clinical trial protocols. Prior associations were with IQVIA, Parexel, TCS, Cytel and Cognizant with increasing responsibilities within CDM, Biostatistics and SAS Programming functions.



### [Introduction to Clinical Trial Feasibility](#)

**Gaurab Chakraborty, Senior Director, Statistical Programming, Covance FSPx**

Gaurab brings over 15 years' experience in a variety of roles within Biostatistics and Programming teams. Gaurab holds Bachelor degree in Statistics and Masters in Computers. He joined Covance in early 2010; prior to joining Covance, he was working with GlaxoSmithKline Pharmaceuticals. In his current role, Gaurab is responsible for statistical programming in Covance FSPx group in India. Gaurab is a CDISC enthusiast and one of the founding members of Asia-Pacific Coordination Committee of CDISC (AP3C). He has made several presentations in industry and academia including few at CDISC Asia-Pacific & Japan Interchanges, and PhUSE SDEs. He is also actively involved in training people on data standard.



### [Technology Transformation in the Data Processing and Analytics](#)

**Inder Sachdeva, Delivery Leader, Cognizant**

Inder Sachdeva is an industry veteran with 17+ years of industry experience spanning across Pharma, CROs and IT/ITeS. Inder has been leading multifunctional engagements across Biostatistics, Statistical Programming, CDM, PV & Regulatory functions and through this wide range of experience, he's been able to see the impact of technology across the complete spectrum of clinical trials. Inder is currently working with Cognizant Technology Solutions India Pvt. Ltd. as Delivery Leader for multiple international accounts. Inder has a personal interest in tracking how the clinical domain is going through transformation and is also collaborating with his clients in planning and implementation many of these initiatives.





## Using Real World Data to Optimize Clinical Trial Conduct

### **Dr. Chitra Lele, Covance**

Chitra is founding team member of Sciformix, a Covance company; responsible for strategy, business development, quality and general management of the company for over 12 years, with focus on Safety and Risk Management, Clinical Development, Scientific Writing & Regulatory Affairs, and Real World Evidence and Market Access. Prior to Sciformix, Chitra was Executive Director, Development Operations India, Pfizer Global R&D. During 9+ years at Pfizer, she was responsible for establishing the first offshore Clinical Data Management centre in India, and then growing it to a size of over 400, including captive and contract resources. Prior to Pfizer, she worked as a biostatistician in Medical schools in the US (Stanford University and University of San Francisco), and as a faculty member in US & in India (University of Minnesota, IIT Bombay). Chitra is Instrumental in setting up Academy for Clinical Excellence (ACE) at the Bombay College of Pharmacy (BCP), a governing council member and a course developer and faculty member. She is founding member of the Indian Association for Statistics in Clinical Trials. She served as visiting faculty at University of Pune and at IIT Bombay for several years, involved in teaching and research activities. She is Instrumental in creating awareness about applications of statistics in clinical trials in India and in developing M.Sc. courses on this topic. Chitra holds Ph.D. (Statistics) from Stanford University, USA and is Associate, Society of Actuaries, USA. She has over twenty publications in reputed Statistics journals and other medical journals.