



Development of Statistical Scientists for Pharmaceutical Drug Development at India Global Capability Centres

Suresh Chenji

Director of Global Statistics and Data Sciences

Disclaimer

The views presented are the views of the presenter, not necessarily those of Teva
This presentation is based on publicly available information

Abstract

Statistical scientists play a critical role throughout the clinical development lifecycle of pharmaceutical products. Their responsibilities include trial design, sample size calculation, statistical issues, protocol development, randomization, data analysis planning, data cleaning, clinical database lock and finalizing outputs for study reports, right clinical/statistical interpretations, publications, integrated analyses, and regulatory submissions. They collaborate extensively with physicians, data managers, project managers, statistical programmers, medical writers, service providers and regulatory agencies, requiring not only strong statistical expertise but also excellent communication and collaboration skills. Statistical innovations are evolved to address modern development challenges and decision making

Growing opportunities for India based statisticians contribute to global drug development by working virtually require continued focus on professional development in areas like, Therapeutic/clinical science understanding, regulatory guidance& requirement, innovative trial design methodology, modern appropriate statistical methods and applications, proficiency in statistical computing/software and collaborative skills (communication and genuine feedback intent). We will discuss statistician's roles& responsibilities, accountability, and experiences

Agenda

- 01 Statistician Responsibilities
- 02 Essential Skills
- 03 Innovations in Statistics Methodology & Applications
- 04 Evolving Specialized Statistical Roles Across Drug Development
- 05 Role in AI/ML Evolution in Drug Development
- 06 Unique Opportunities
- 07 Emerging Statistics Leadership
- 08 Resources

Statistician Responsibilities (1)

As a statistical Lead be part of core Clinical Trial Team, discuss and provide input to trial design and protocol development including statistical sections for various therapeutic indications and clinical development phases trials

- Choice of control group
- Primary and key secondary clinical endpoints (continuous, binary/count, time-to-event)
- Hypothesis testing (Non-inferiority, Superiority or equivalence)
- Sample Size and Power calculations
- Treatment and Study duration
- Primary Endpoint(s) statistical analysis
- Confirmatory trials with multiple testing endpoints (phase 3)
- Clinical pharmacology trials with PK/PD endpoints/objectives for a dose range/schedule (phase 1)
- Dose Finding/Optimization Trials including safety and tolerability (Oncology Ph1/2)
- Dose-Response trials (Phase 2, across therapeutic indications)
- Non-interventional/observational/phase 4 PMR/C trials

Statistician Responsibilities (2)

Review and provide input to trial startup activities

- confirm the CRF and eCOA
- review Data Management Plan
- Input to critical data edit checks and data transfer specifications
- Input and review to Randomization schedule

Develop Statistical analysis plan and Tables, figures and Listings(TFL) mock shells for CSR

Review SDTM & ADaM standard specifications and provide input to trial specific analysis specifications (mainly efficacy)

Plan and review dry-run TFL output before key milestones like, interim, primary outcome and final data base lock

Clarify analysis and TFL reporting specifications and review and confirm on key issues from P21

Review, discuss and confirm the data quality for various analysis milestones

Confirm the trial database lock

Prepare and release topline results for the internal clinical development leadership

Review and finalize TFL output for CSR

Review CSR drafts and provide input to trial results and conclusions

Review and contribute to trial publications

Review and confirm trial data review submission packages (define, reviewers guide and CRT xpt for FDA)

Develop and support integrated (pooled) analysis dataset specifications, plan and TFL shells and review analysis output & reports for regulatory submissions and response to health authority questions

Essential Skills

Good understanding in clinical development life cycle (Clinical development plans)

Therapeutic knowledge and regulatory guidance & requirements

Get the basics right: Correct statistical methods & analysis approaches and data presentation

Clearly communicate complex data and results and provide right clinical and statistical interpretations

Good understanding of CDISC (SDTM & ADaM) and regulatory submission requirement

Programming proficiency is necessary, SAS and R, software user knowledge: PASS/nQuery/EAST and user knowledge in cloud/distributed computing environments

Communication skills, project management skills and outsourcing/vendor management

Cross-functional collaboration skills are most important (Medical directors, Clinical Pharmacology, clinical project managers, regulatory, medical writing, data management and statistical programming colleagues)

Innovations in Statistical Methodology & Applications

Trial Design & Decision Making

- Clear estimands and robust sensitivity analyses to handle intercurrent events, missing data, and model assumptions
- Probability of Study Success (PoS) to guide phase transitions, portfolio prioritization, and investment decisions
- Clinical trial simulations and Model-Informed Drug Development (MIDD) to optimize design, dosing, and execution

Advanced Designs & Frameworks

- Adaptive designs (sample size re-estimation, futility, arm modifications) with strict type-I error control
- Master protocols: basket, umbrella, and platform trials enabling efficient multi-drug, multi-population evaluation
- Use of Bayesian methods for dose-finding, interim decisions, and dynamic borrowing from historical/external data

Precision, Causal & Real-World Evidence

- Covariate adjustment and subgroup identification to estimate true and personalized treatment effects
- Biomarker-driven personalized medicine (predictive vs prognostic biomarkers) with multiplicity control
- Causal inference & RWE integration to complement RCTs, especially in rare diseases

These developments are not just statistical methods to plan and implement but address modern drug development strategies & challenges and drive optimum decision-making, which require statistical leadership, close partnership and ongoing dialogue with core clinical team (physicians, regulatory, commercial etc.,) and regulatory agency

Statistician role is not only limited to implement complex statistical methods and analyze trial data but also getting involved into the decision-making process to drive strategic business decisions

Evolving Specialized Statistical Roles Across Drug Development

Real-World Evidence & Causal Methods

- Analyze observational data (EHR, registries, claims) to support approvals, especially in rare diseases
- Address bias/confounding using Propensity Scores, IPTW, IV methods, MSMs, and target trial emulation
- RWE increasingly used as external control arms and for long-term effectiveness

Health Technology Assessment (HTA) & Access

- Generate evidence for value, cost-effectiveness, and reimbursement decisions
- Economic modeling (ICER, QALY), meta-analysis/NMA, and advanced survival methods (RMST, parametric models)
- Alignment of regulatory and HTA evidence (e.g., EU HTA Regulation, India HTA)

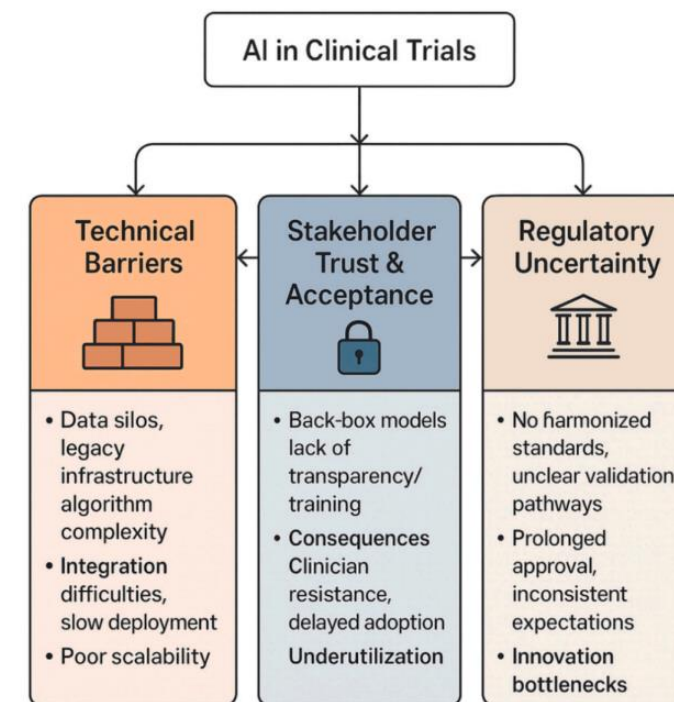
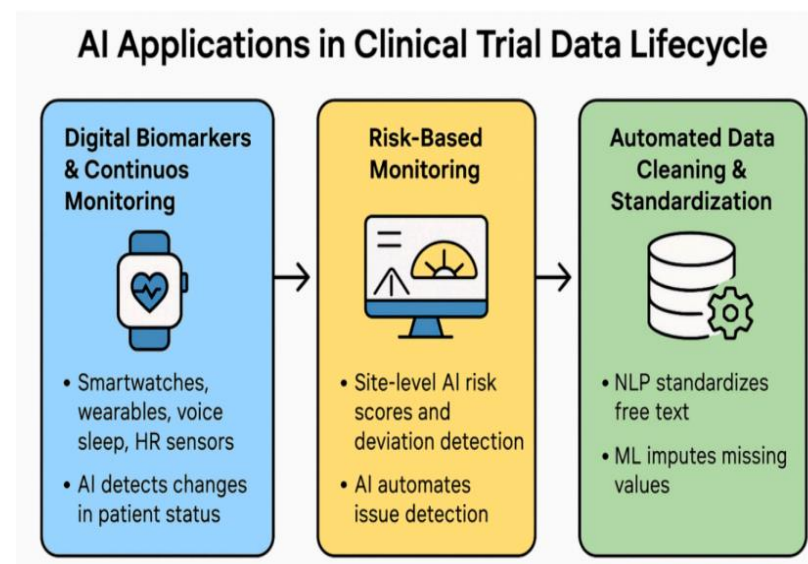
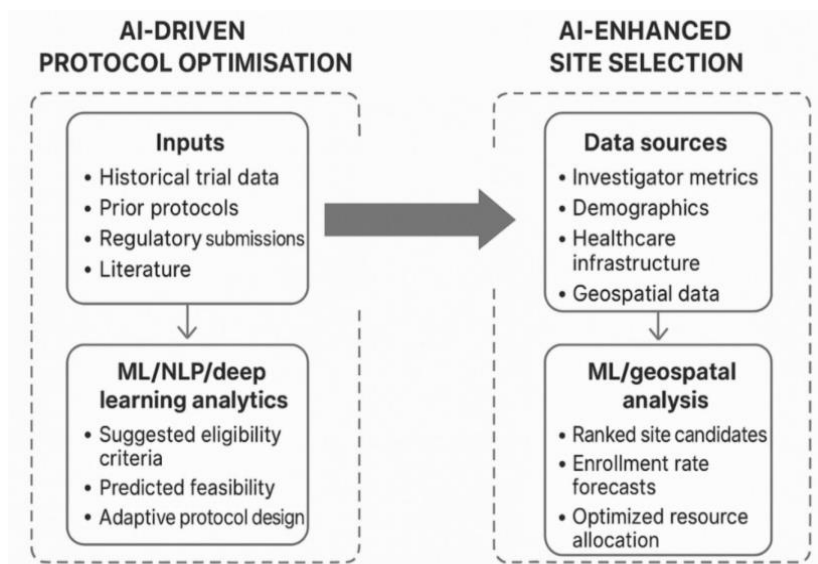
Non-Clinical & Early Development Statistics

- Statistical support across discovery, toxicology, CMC, aligned with ICH & GLP guidance
- Dose–response modeling, ranking & selection, DoE, assay validation, and stability/shelf-life estimation
- Enable safer dose selection, robust manufacturing, and reduction of animal use (3Rs)

Clinical Trial Quality & Oversight

- Risk-Based Quality Management / Centralized Statistical Monitoring as regulatory expectation (ICH E6 R2)
- Detect fraud, safety under-reporting, protocol deviations, and site performance issues
- Use univariate + multivariate analytics (PCA, distance metrics) with risk prioritization dashboards

Role in AI/ML Evolution in Drug Development



Validation of AI systems in a regulated industry is critical, as algorithmic bias or model failures are measured in patient lives

Machine learning algorithms can identify patterns in complex datasets that would be impossible to detect using traditional statistical methods. Statisticians can validate predictive modelling-based AI tools with the pattern recognition capabilities, uncertainty quantification and right interpretability that require by regulators and clinicians

Interconnected barriers to AI implementation in clinical trials

Statisticians bring a unique perspective to AI development and validation, understanding both the mathematical foundations of machine learning and the clinical context

Statisticians are to emerge as essential partners in ensuring that AI systems are reliable, interpretable, and compliant with regulatory standards

Unique Opportunities (1)

Over two decades global pharmaceutical companies have setup GCCs and through CRO FSP teams in India, statistician roles moved here to actively take part in global clinical trial teams and support clinical development portfolio deliverables

With increased visibility in contributions and capabilities, there is raise in capacity building and expectations

Continue to focus on learning latest/relevant statistical methodology and applications, including software coding and advances in drug development & regulatory requirements

Higher focus on soft skill development for statisticians career progression

- Effective communication skills

- Negotiation and Influencing skills

- Cross-functional collaboration and leadership

- Conflict resolution

- Adaptability and resilience

- Strategic/critical thinking

- Problem solving skills

- Storytelling and data visualization

- Awareness of cultural differences

- Understand the audience and business priorities

Unique Opportunities (2)

Develop strategic competencies: regulatory requirements, commercial implications of statistical decisions, innovative statistical methodology and implementation, market access considerations and competitive dynamics

Statisticians should be able to translate complex statistical findings into clear, actionable insights to key stakeholders

Increasing complexity of drug development, regulatory focus on evidence-based decision making and integration of new technologies, create opportunities for statisticians who embrace this evolution and develop the skills needed for the future

Pharmaceutical Statistics has bright future, require continued scientific learning, cross-functional collaboration across regions and growth mindset

Statisticians to develop as strategic influencers

Emerging Statistical Leadership

Promote Innovative clinical trial methodologies and their adoption through knowledge sharing sessions and workshops

Plan for junior statisticians to gain diverse experiences early

Develop young Statisticians through a structured coaching and mentorship

Bridge academia and industry for mutual benefit, Statistical leaders to effectively interact with universities in shaping education programs and strengthen collaborations, to attract future talent to pharma industry

- Experts from industry as guest teachers
- Provide internship programs during last semester
- Motivate to pursue PhD/research topics relevant to pharmaceutical industry statistics applications

Promote innovation in drug development, methodologies, processes and technologies, and bridge the gap between innovation and implementation

Identify development opportunities through collaboration across companies, working groups and inter-region professional organizations

Leaders need to keep abreast of the dynamic nature of how skills and capabilities are changing over time

Leaders need to be both relevant and authentic, what strategies could help us maintain our curiosity and enable continued learning

Resources

Few relevant journals with focus on biostatistics, clinical trials, and industry applications:

- Statistics in Medicine

- Pharmaceutical Statistics

- Journal of Biopharmaceutical Statistics

- DIA Therapeutic Innovation & Regulatory Science

- Clinical Pharmacology & Therapeutics

- other therapeutic medical journals.

ICH, FDA, EMA and other regions regulatory guidance documents

Collaborative open-source initiatives [Openstatsware](#) and [Pharmaverse](#) foster innovation and efficiency in statistical methodologies and clinical reporting

Professional Organizations and Industry working groups workshops and conferences

- American Statistical Association(ASA) Biopharmaceutical Section

- European Federation of Statisticians in the Pharmaceutical Industry (EFSPI)

- Statisticians in the Pharmaceutical Industry (PSI)

- Indian Association for Statistics in Clinical Trials (IASCT)

- Pharmaceutical Users Software Exchange (PHUSE)



Thank you

About Author



Suresh Chenji is a statistics leader with over two decades of experience in pharmaceutical industry. He provides statistics leadership for new medicines clinical development projects that are optimally strategized, scientifically designed, analyzed, and well documented the data and results for regulatory submissions in multiple therapeutic areas (Oncology, Endocrine and Metabolism, Autoimmune, Biosimilars etc.,) and support the maintenance and growth of established products. He has set up high performing statistics teams at various pharma/CRO organizations, and he coaches and develop statisticians and experienced statistical programmers on strategic drug development roles. He currently serves as the Head of Global Statistics and Data Sciences for the India team, providing strategic and operational leadership for the medical writing, data sciences and statistics functions at Teva Pharmaceuticals, Bangalore.