Track 11 | Statistics

This track will focus on topics related to the practice and application of statistical methods in medical product development throughout their lifecycle. Sessions will explore topics related to current statistical thinking which inform policy, regulation, development, review, and lifecycle management of medical products in the context of the current scientific and regulatory environments. A new aspect of the track is data science, a multidimensional area with the two major dimensions of curation and analysis. This track is focused on the **analysis dimension**, including analytics and predictive analytics.

DIA recommends this track for: biostatisticians, data scientists (analytics), statistical programmers, clinical pharmacologists, health economists, epidemiologists, regulatory scientists, physicians, project leaders, and other clinical development practitioners.

Included Topic Areas

Statistics, biostatistics, Bayesian statistics, novel statistical tools, data standards, analysis and analysis sets, data interpretation, data visualization, trial planning and design, adaptive designs, innovative designs, model-informed drug development, data monitoring committees, precision medicine and subpopulation analysis, biomarkers, multi-regional clinical trials, endpoint assessment, real-world evidence, pragmatic trials, use of historical control, pediatric/rare disease drug development. Topics related to bioethical issues are also welcome and may be considered for a special track in the meeting.

Priority Topics

1. **Complex Innovative Designs**
   a. Practical experiences and lessons learned from the CID Pilot Program
   b. Applications and experiences with master protocols and platform trials
   c. Leveraging external information
2. **Safety and Benefit-Risk**
   a. Applications of appropriate statistical methodologies to properly interpret safety data
   b. Towards improved planning in the design of clinical development programs to evaluate risks and benefit-risk assessment
   c. Applications of quantitative benefit-risk methods
   d. Statistical methodologies for signal detection in randomized clinical trials
3. **Application of Bayesian Methods in Drug Development**
   a. Bayesian design and analysis of randomized clinical trials
   b. Rare diseases
   c. Pediatric trials
   d. Synthetic controls
4. **Estimands**
   a. Practical applications and lessons learned working with non-statisticians
   b. Applications of estimands beyond the RCT (Randomized Clinical Trials)
   c. Estimands for safety and benefit-risk
5. **Machine Learning and Use of Artificial Intelligence in Drug Development**
   a. Opportunities for applications in early clinical development to post-market applications
   b. Application in signal detection (safety, non-compliance)
   c. Machine / Targeted learning
   d. Natural language processing
6. **Patient-Focused Drug Development**
   a. PRO validation
   b. Digital endpoints
   c. Pragmatic trials
   d. Real-world evidence
   e. Decentralized Trials
7. **Causal Inference in Medical Product Development**
   a. Applications to establish clinical evidence in real-world evidence and clinical trials
   b. Applications in rare disease settings
   c. Bridging causal inference and clinical trials
   d. Leveraging external control data in randomized clinical trials
8. **Communication and Collaboration**
   a. Explain commonly used complex statistical methods (e.g., MMRM, estimands, logistic regression, Bayesian Statistics) to non-statisticians
   b. Use of data visualization to augment/enhance data presentation
   c. Use of dynamic data analysis and visualization and experiences with submissions to regulatory agencies