Track 1 | Clinical Safety and Pharmacovigilance

This track provides an overview of the global regulatory environment in the field of clinical safety and pharmacovigilance for medical products (biopharmaceutical products, advanced therapies, and medical devices), with a focus on pragmatic approaches to protecting patient safety and incorporating the patient voice into the complex and evolving pharmacovigilance ecosystem. Forward-thinking sessions address the application of new technologies and methods to streamline pharmacovigilance systems and processes to enhance protection of patient safety as products become more complex, new data sources drive new analytical techniques, regulatory requirements become more detailed, and medical product development becomes more global.

DIA recommends this track and associated sessions to professionals involved in: drug safety/pharmacovigilance, medical product safety risk assessment, pharmacoepidemiology (including real-world evidence generation), post-market studies (including Large Simple Safety Studies and pragmatic safety studies), statistics, benefit-risk assessment and management, benefit-risk communication (including professional and consumer medical product safety labeling), regulatory affairs, clinical research (including clinical trial design), medical affairs, and health outcomes.

Included Topic Areas

New initiatives, and emerging regulatory requirements and expectations regarding drug safety-related policies, processes and best practices, and quality metrics, especially those relating to patient engagement; data privacy; Good Pharmacovigilance Practices (GVPs), including insights into revised modules; pre- and post-market safety; expansion of ICH (International Council for Harmonisation) "E2" guidelines to developing markets; benefit-risk assessment and management; epidemiologic studies and impact on labeling; safety considerations for combination products, medical devices, generic products (including biosimilars), and advanced therapies; companion diagnostics; pharmacovigilance audits/inspections; use of digital technology for risk identification, minimization, and communication; patient-centric labeling and risk minimization methods; application of artificial intelligence to pharmacovigilance; generating meaningful insights on medical product safety from social media and other new data sources; optimizing the global pharmacovigilance footprint (including local safety offices and partners); and considerations for signal detection and management across the product lifecycle. Topics related to bioethical issues in clinical safety and pharmacovigilance

Priority Topics

1. **Update on Regulations and Cross-Industry PV Initiatives**
   a. FDA Guidances
   b. Updates from CIOMS Working Groups
   c. Updates from ICH, new and ongoing
   d. Updates from other cross-industry working groups (e.g., TransCelerate, IMI, ICMRA (International Coalition of Medicines Regulatory Authorities), etc.), including PHUSE and other initiatives regarding grouping of adverse event terms
   e. Recent impact of COVID-19 of regulatory and industry collaborations/initiatives/strategies
   f. Cross-industry and regulatory: AE (Adverse Events) groupings in safety

2. **Special PV Considerations**
   a. Immuno-oncology
   b. Gene therapy
   c. Pediatrics
   d. Rare diseases
   e. Pregnancy
   f. Biosimilars
   g. Use of Real-World Evidence (RWE) for safety assessments, including for COVID-19 and monkeypox
   h. Personalized treatments
   i. Diversity and inclusion in drug-related research and/or safety assessments: How representative is our safety data?
   j. Vaccine safety
   k. Safety and PV aspects of medical devices, software as a medical device (SaMD), and combination products
   l. Safety monitoring of ongoing blinded studies

3. **Transforming the Drug Safety Organization**
   a. From cost center to strategic value provider
   b. Hot trends and topics in PV audits and inspections
   c. Diversity and Inclusion in drug safety organizations
   d. Increasing representation of safety voices beyond the US and Europe
   e. Building a patient-centered drug safety organization
   f. Qualifications for the new drug safety professional
   g. Maintaining safety and compliance in self-managed organizations
   h. TransCelerate PVA (Personal Values Assessment) agreements survey
   i. Organizational "merger" of drug safety and device safety

4. **Benefit-Risk Assessment and Risk Management**
   a. COVID-19 pandemic
   b. Opioid analgesic abuse
   c. Sharing learnings externally: publishing results of risk minimization studies
   d. Impact of COVID-19 on design, implementation, and evaluation of risk minimization strategies
   e. Integrating risk minimization measures into the healthcare delivery system
   f. Patient voice in benefit-risk assessment and risk management within industry and regulatory agencies
   g. Diversity and inclusion in benefit-risk assessment and/or risk management (e.g., supporting countries with fewer resources to help them in designing and implementing patient-centered PV and RM)
   h. Safety and risk management in rural and underserved areas, for patients in clinical studies and routine medical practice [Note: This topic was submitted by Track 2, not safety specific.]
   i. Risk communication and future pandemics (industry and regulator view): What can we learn and apply for PV risk management? How do we handle misinformation? What is the role of patient engagement? How can it affect vaccine hesitancy?
   j. Use of mixed methods and other novel research designs for risk minimization program evaluation
   k. Digital approaches to risk minimization
   l. Ongoing challenge of more useful and meaningful risk minimization effectiveness measurement generally
   m. Treatment decision support for individual patients using shared decision-making tools that reflect patient preferences regarding risks and benefits: What is new in the research? How can we improve shared decision-making tools?

5. **Artificial Intelligence in Pharmacovigilance**
   a. Practical examples: opportunities, benefits, and limitations
   b. Regulatory challenges and approaches
   c. AI in Software as a Medical Device
   d. Interpretations by regulators and inspectors

6. **Future Directions in Patient Safety**
   a. Dealing with increasing local safety reporting requirements (e.g., SUSAR submission) worldwide including low- and middle-income countries
   b. Challenges in the implementation of local and global risk minimization commitments
   c. Safety surveillance: methods, data sources, etc.
   d. Quantitative systems pharmacology for predicting, modeling, and assessing drug safety
   e. COVID-19 and preparing for future pandemics
   f. Accumulus and PV
   g. Drug safety analysis and visualization serving the needs of industry and regulators
   h. Experience with implementation of a learning healthcare system for PV and safety
   i. Reimagining a safety submission: Rolling integrated safety summary, interactive safety
   j. Wish list for the future of AI use in PV