Track 3 | Data and Technology

Innovative technologies are improving efficiency in the collection of data from clinical trials through the product development lifecycle to patients. This track focuses on recent developments in clinical data curation, data development, and harnessing data across the product lifecycle which includes the structure, organization, validation, storage, extraction, and delivery of diverse types of patient data to facilitate review, analysis, and reporting in regulatory submissions. Specifically, the track will have the following as focal points:

- Structured and unstructured data sources
- Data Quality
- Blockchain technology and cloud computing
- Data Standards
- Real-World Data / Real-World Evidence
- Mobile / wearable technologies
- Informatic solutions and machine learning
- Data visualization
- Endpoints: evolving data requirements to support new endpoints
- Diversity, Equity, and Inclusion– strategies to ensure representative and unbiased data?

DIA recommends this track and associated sessions to professionals involved in: informatics (bio and medical), data standards and quality control (and regulatory standards implementation specialists), data quality, clinical data management, clinical trial design, clinical operations, electronic health records, submissions, and global submissions, health economics outcomes research, biostatistics, medical writing, real-world evidence roles, epidemiology, post-market studies, regulatory affairs and operations, and statistics.

Included Topic Areas

The broad range of data that is generated during biopharmaceutical development, approval, and post-market will be covered in this track including: clinical (including data from electronic health records, wearables, and other mobile apps), and real-world data from large data sets (including registries and national datasets, claims data, and prescription fulfillment. Topics related to bioethical issues in data and technology are also welcome and may be considered for a special track in the meeting.

Priority Topics

1. **Harnessing Real-World Data and Real-World Evidence**
   a. Data standards
   b. Data quality/fitness for use
   c. Study designs
   d. Regulatory guidance considerations
   e. Data exchange using common data standards
   f. Case studies and examples of employing real-world evidence relative to data standards
2. **Transformation of the Data Manager to the Data Scientist and Steward**
   a. Evolution of clinical data management: merging or separating roles of data manager and data scientist
   b. Enhanced collaboration of data sharing across partner organizations and health authorities
   c. Workforce readiness: processes, skills, and experience
   d. Knowledge to amplify your career
3. **Technology and Emerging Data Sources**
   a. Effective integration in clinical study process
      i. Artificial intelligence, machine learning, automation
   b. Applications of Natural Language Generation/Processing Techniques/Tools
      i. Blockchain technology
      ii. Deriving endpoints from wearables, sensors, and novel technology
      iii. Managing and ensuring data validation, quality, and integrity
      iv. eSource opportunities and challenges integrating with clinical trials
   c. Digital solutions for remote monitoring including SaMD
      i. Impact on standard processes
   d. Decentralized trials: collection sharing and standardization of data
4. **Data Source Agility and Risk-Based Approaches**
   a. Case studies demonstrating novel techniques and strategies
   b. Analytical tools and technologies to support and enable new study models; how to apply risk-based monitoring (RBM) techniques
   c. How do virtual trials change data management standards and processes?
5. **New and Emerging Standards, Guidance, and Regulations Impacting Data, Data Standards, and Technology**
   a. ICH M11: Data standards related to standardized protocol template
   b. GDPR impact on data management practices and processes
   c. cHL7 FHIR (Fast Healthcare Interoperability Resources) Vulcan: Bridging the gaps between clinical care and clinical research data standards
   d. Modernizing FDA Data Strategy/ EMA (European Medicines Agency) Data Guidance
   e. Cloud-based regulatory submissions and collaboration
   f. Structured Data Submissions
   g. EMA Guideline on computerized systems and electronic data in clinical trials: EMA/226170/2021