Track 2 | Clinical Trials and Clinical Operations

This comprehensive track covers the latest advances in clinical research and operations. Sessions cover innovative design strategies, establishing efficiencies in operations, and effective integration of patient outcomes in clinical trial design.

This track covers clinical research development and operations. Sessions explore:

- current and innovative methods to evaluate technology advances and systems to support clinical research programs cross-functional management integration, clinical utility, and endpoint development with the use of mobile/digital technology;
- optimizing clinical trial enrollment and reviewing technological advances in clinical research operations;
- optimal clinical operations management structures in small, medium, and large companies;
- program challenges and solutions in global clinical and multi-regional clinical trials;
- advances in Sponsor and CRO collaborations; vendor oversight; and the evolving value of real-world data.

DIA recommends this track and associated sessions to professionals involved in clinical operations, clinical research, safety and pharmacovigilance, project management, patient centricity, and statistics. Also, potentially: medical affairs, regulatory affairs, vendor management/alliance management, data management, and quality assurance.

Included Topic Areas

Unique challenges on clinical study execution for innovative drugs e.g., personalized medicine, gene editing, stem cells, regenerative therapies, gene therapies, etc.; clinical trial recruitment and retention; patient engagement, site management; specific therapeutic areas; endpoints/COAs, [patient-reported outcome (PRO) measures, clinician-reported outcome (ClinRO) measures, observer-reported outcome (ObsRO) measures, and performance outcome (PerfO) measures; COA (Clinical Outcome Assessments) Compendium]; specific therapeutic areas; telemedicine, eHealth, mobile health, wearables, EHR (Electronic Health Record), clinical trial diversity, collaborations; ICH(E); GCP (Good Clinical Practice), audit/inspection, global study execution, and management.

Priority Topics

Topics related to bioethical issues in clinical operations and clinical trial designs are also welcome and may be considered for a special track in the meeting.

1. **The Evolution of Study Endpoints**
   a. Endpoint science (how to select, validate, and measure endpoints)
   b. Deriving endpoints from wearables, sensors, and novel technology
   c. eCOA/ PRO
2. **Clinical Study/Research Management**
   a. Managing research in emerging global regions
   b. Making accurate assessments of protocol complexity and participant burden
   c. Planning for and managing mid-study disruption (natural, political, etc.)
   d. Incorporating change management strategy into clinical trial planning (DCT (Decentralized Clinical Trials) adoption, etc.)
   e. Making clinical trials more accessible to more participants
   f. Data-driven feasibility assessment and modeling for trial planning, optimization, and execution
   g. Applications of artificial intelligence, natural language processing, and machine learning in clinical trial conduct: beyond theory and into practice
   h. Considerations for supply chain integrity for decentralized trials and in times of disruption
3. **Innovation in Clinical Trial Designs**
   a. Pragmatic Trials
   b. Decentralized Trials
   c. Master Protocols
      i. Umbrella Trials
      ii. Basket Trials
      iii. Platform Trials
   d. Applications of real-world data in clinical trial design (including synthetic control arms)
   e. Lessons learned as “novel” designs become more common
4. **Innovation in Partnerships and Collaboration**
   a. Data sharing across pharmaceutical sponsors, regulators, CROs, and academia
   b. Integrating collaborators from those traditionally outside healthcare/ research
   c. Designing and managing multi-sponsor trials (e.g., platform studies)
   d. Real world data collaborations in external control arms, market access studies, and pragmatic trial designs
   e. Using real-world data to enhance understanding of the patient’s journey
   f. Leveraging industry consortia
5. **Clinical Development Program Planning**
   a. Planning for clinical development programs rather than individual studies
   b. Strategies to save time and reduce costs in end-to-end clinical development
   c. Best practices for working with patients and patient advocates on drug development programs
   d. Biomarker selection, development, and implementation strategies
   e. Begin with the end in mind: Obtaining and considering stakeholder needs throughout Evidence Generation Planning
6. **Next Generation Site/Investigator Collaboration**
   a. Implementation of decentralized trials at the ground level
   b. System integration best practices
   c. Strategies to influence diversity, equity and inclusion in trial enrollment and patient engagement
   d. Managing modern site delivery needs (resourcing, compensation, system overload)
   e. Site network/consortia engagement strategies
   f. Identifying, training, and initiating sites in underserved regions