CALL FOR ABSTRACTS | Submission Deadline: September 12
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About DIA 2020

About the DIA 2020 Global Annual Meeting

DIA's Global Annual Meeting is the largest, longest-running event in the life sciences industry designed to foster the international exchange of actionable insights to improve health globally through the advancement of lifesaving medicines and technologies. The DIA 2020 Global Annual Meeting (DIA 2020) will bring together industry, regulatory, academia, and patients in one venue, hosting thousands of professionals in the pharmaceutical, biotechnology, and medical device communities from more than 50 countries around the globe. DIA 2020 boasts more than 450 exhibiting companies, over 13+ tracks, and more than 250 sessions.

DIA 2020 provides you with a rare opportunity to build on what you already know in the development of new therapies and accelerate efforts to enhance health and well-being. Where else can you meet with people from around the world, share knowledge, experience cross-functional content with real-world application from top speakers in the industry, and network with peers to build new relationships across multiple disciplines?

Abstract Tip!

Our Track Chairs have highlighted priority topics within their educational tracks to provide direction on content they would like to receive via the Call for Abstracts. You may submit abstracts addressing priority topics and/or topics relevant to the DIA 2020 track descriptions. Both priority topics and track-specific topics will be reviewed and considered by the Annual Meeting Program Committee (AMPC).

What is a Priority Topic?

The AMPC has identified several priority topics they believe to be of significant value to the DIA 2020 program.

What is a Track-Specific Topic?

Track-specific topics are topics that support the overall purpose for the track. For full descriptions of the DIA 2020 tracks click here.

DIA is committed to including the voice of the patient at DIA 2020. DIA’s Patient Partner initiative continues to ensure that the perspectives of patient communities are part of the discourse in all of our content formats. We encourage patients and patient representatives to submit abstract proposals, not only into the Patient Engagement track, but to all relevant tracks. The AMPC will be looking for these during the abstract selection process.

Submission Deadline - Thursday, September 12
Types of Abstracts

There are five types of abstracts you can submit for the Global Annual Meeting, including a session, forum, presentation, workshop, or half- and full-day short courses. Each abstract type is defined herein and has its own format and structure and cannot be altered. You may submit more than one abstract.

SESSION
A 60- or 75-minute session concept delivered lecture-style from the podium.
*Helpful hint! Plan your submission separately and in advance by using this session abstract template. Read a sample session abstract.

FORUM
A 60- or 75-minute concept designed for panel interaction and attendee engagement.
*Helpful hint! Plan your submission separately and in advance by using this forum abstract template. Read a sample forum abstract.

PRESENTATION
A 20-minute presentation abstract addressing a specific topic. If selected, this abstract will be combined with other abstracts to create a session. Please note: co-presenters are not allowed.
*Helpful hint! Plan your submission separately and in advance by using this presentation abstract template. Read a sample presentation abstract.

WORKSHOP
A 60- or 75-minute workshop delivered in an interactive/simulation or role-playing format.
*Helpful hint! Plan your submission separately and in advance by using this workshop abstract template. Read a sample workshop abstract.

SHORT COURSE
A Short Course is a “hands-on”, interactive learning experience for a group of 25-50.
• A half-day short course consists of three hours and 15 minutes of instruction, and will have a lead instructor and no more than one co-instructor
• A full-day short course consists of six hours and 30 minutes of instruction, and the short course will have a lead instructor and no more than two co-instructors
*Helpful hint! Plan your submission separately and in advance by using this short course abstract template.

The abstract author is considered the session chair, speaker, or instructor (depending on which type of abstract is submitted) and will be responsible for the following:

• Adhering to the program development policies and guidelines
• Meeting program development timelines
• If chairing a program offering:
  • Recruiting speakers and ensuring good representation/diversity in the selection of speakers
  • Please note: No more than one participant from the same company is permitted to speak within the same program offering; the Annual Meeting has a global focus, and therefore we encourage global perspectives
  • Communicating with speakers regarding their role and reviewing presentation materials
  • Managing the program offering, including the facilitation of audience questions and answers
  • At the time of submitting a session abstract, please indicate at least one individual who will be invited to participate in the offering. Please do not extend an invitation until a formal response from DIA has been received.
• If leading a workshop or short course:
  • Ensuring the workshop provides onsite learning in the form of activities or demonstrations
  • Ability to facilitate 75-100 attendees for a workshop and 25-50 for a short course
• If presenting a presentation:
  • Working with Chair and other presenters in creating a balanced session
  • Preparing and delivering a PowerPoint presentation
2020 Track Offerings

DIA 2020 Tracks

- Clinical Safety and Pharmacovigilance
- Clinical Trials and Clinical Operations
- Data and Data Standards
- Medical Affairs and Scientific Communication
- Patient Engagement
- Preclinical Development and Early-Phase Clinical Research
- Project Management and Strategic Planning
- R&D Quality and Compliance
- Regulatory
- Regulatory CMC and Product Quality
- Statistics
- Value and Access
- Professional Development
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 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 “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.

Priority Topics

1. **Update on Regulations and Cross-Industry PV Initiatives**
   a. Updates from CIOMS (e.g. DILI Report)
   b. Updates from ICH (e.g. E19 and E2D (R1))
   c. Combination products (e.g. EU MDR)
   d. Practical approaches to General Data Protection Regulation and PV
   e. Updates from other organizations/cross-industry initiatives

2. **Special PV Considerations**
   a. Immuno-oncology
   b. Gene therapy
   c. Artificial Intelligence
   d. Pediatrics
   e. Rare diseases
   f. Pregnancy
   g. Biosimilars

3. **Transforming the Drug Safety Organization**
   a. From a cost center to a value provider: strategies to demonstrate value internally
   b. Global QPPV role- how has it been operationalized?
   c. Hot trends and topics in PV audits and inspections
   d. Safety management planning: pre- to post-market continuity
   e. Transforming the role of the Local Safety Officer – from tactical to strategic?
   f. Budgeting in the Drug Safety Department to support risk minimization development and evaluation, and patient preference studies
   g. Sharing learnings externally; publishing results of risk minimization studies and the impact of

4. **Benefit Risk Assessment and Risk Management**
   a. Patient voice in benefit-risk assessment
   b. Benefit-risk communication to patients
   c. Post-market risk communications
   d. Informed consent- patient friendly language
   e. Patient voice in Safety: What has been tried? What has worked?
     • Patient labeling
     • Risk minimization, REMS
     • PASS
   f. Organizational structures for engaging and co-creating with patients: what models have been tried? What has been learned?
   g. Globalization of risk management (e.g. LATAM, MENA and Asia Pacific countries)
   h. Individual versus population

5. **Brave New World: Cutting Edge Issues for the Future of PV**
   a. Pragmatic uses of artificial intelligence in PV
   b. Novel approaches to evidence planning, production and evaluation in safety science, including synthesis of data and analytics from varied data sources (e.g. real world evidence, social media sources)
   c. Digital health technologies, including wearables
   d. Bioethical considerations in PV
   e. Learning Health System- update from EMA/PRAC/FDA/IOM

i. Minimizing the burden or risk management on healthcare system: examples from US and EU
   • Opioids and safe use
Track 2 | Clinical Trials and Clinical Operations

This track covers clinical research development and operations. Sessions explore current and innovative methods to: evaluate technology advances/systems to support clinical research programs and integrate cross-functional management, 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/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 Compendium]; specific therapeutic areas; telemedicine, eHealth, mobile health, wearables, EHR, clinical trial diversity, collaborations; ICH(E); GCP, audit/inspection, global study execution, and management.

Priority Topics

1. Evolving Technology in Clinical Research
2. Patient-Centered Endpoints – wearables and endpoints, continuous monitoring, validation, data integrity, therapeutic/diagnostic applications, regulatory considerations
3. Monitoring – Quality and Compliance in Clinical Operations
   a. Monitoring plan and risk assessments
   b. Critical data – tolerance limits
   c. Analytics and data integrity-proactive monitoring; systems and tools
   d. Remote processes, eSource, electronic health records
4. Clinical Study Management – The Nuts and Bolts
   a. eTMF/document management, impact of GDPR,
   eConsent, technology and collaboration, protocol development, supply chain management (IMP), patient recruitment/retention, social media and patient centricity, feasibility and site selection, training, managing data monitoring committees/adjudication committees
5. Managing Global Trials - Focus on Global Coordination and Emerging Regions
   a. Out-source models, CRO vendor oversight, protocol planning, country selection, regional team coordination; emerging/developing research regions (Africa, India, China, Japan, ASEAN, Middle East, Latin America)
6. The Future is Here
   a. Virtual trials-models, design, operations, challenges
   b. “Site-less” trials/decentralized trials - case studies
   c. Precision medicine/innovations in study design
   d. Biomarkers, genomics and diagnostics
   e. Trial simulation
   f. Real world data and analytics
7. Clinical Operations – Are You Ready for Inspection?
   a. Inspection readiness, TMF, computer systems, SOPs, organization, training, document management, CAPA process, risk management, site compliance, regulatory expectations (FDA, EMA, MHRA), “mock” inspections simulations
8. Device, Diagnostic, Combination Products Trials
   a. Trial design, conduct and operations (compared to drug studies); study populations, safety reporting, US and EU compared
Track 3 | Data and Data Standards

This track will specifically focus on:

- Data sources, standards, quality, handling, and regulatory requirements
- Current and emerging applications of data
- Technologies for capturing data direct from patients

The broad range of data that is generated and analyzed during biopharmaceutical development, approval, and post-market will be covered in this track including: clinical (including eClinical 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).

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, eClinical (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

Informatics, bioinformatics, data standards and standardization, data management, data quality, data systems, data integration, compliance, bioethics, data security, data privacy, transparency, big data, data sources, real-world data/real world evidence (RWD/RWE), eClinical, mobile data, EHRs, information technology, information systems, operational best practices, exploratory data techniques, data integration from multiple disparate data sources, technology to support patient reported data and outcomes.

Priority Topics

1. Real World Evidence:
   a. Data harmonization, standardization, quality, and regulatory considerations
   b. Case studies and examples of employing real world evidence relative to data standards

2. Career Progression in Data Management:
   a. Merging roles of data management and clinical operations
   b. Novel opportunities in a connected world
   c. Knowledge to amplify your career

3. Wearable Technology and Internet of Things (IoT):
   a. Case studies demonstrating use of wearable technology in clinical research
   b. EHR data/eSource opportunities and challenges integrating with clinical trials
   c. Data validation challenges and opportunities

4. Virtual Trials:
   a. Case studies demonstrating novel techniques and strategies
   b. Analytical tools and technologies to support and enable virtual trials – how to apply RSM techniques
   c. How do virtual trials change data management standards and processes?

5. Impact of Updated Standards, Guidance, and Regulations on the Data Professional:
   a. ICH E6 R2, ICH E9 R1, PDUFA VI, new Part 11
   b. GDPR impact on data management practices and processes
   c. Impact of Brexit on data management processes, standards, and data storage

6. Data Integrity:
   a. Measuring and monitoring best practices
   b. Data integration: pros, cons – best practices for sharing clinical trial data
   c. Impact of risk-based monitoring on data management processes and standards
Track 4 | Medical Affairs and Scientific Communication

This track will share insights from medical affairs professionals and medical writers across the globe. Sessions within the track will address necessary skills and best practices for working cross-functionally and compliantly within medical affairs, medical information, and scientific communication.

DIA recommends this track and associated sessions to professionals involved in medical or regulatory scientific writing, medical communications, and medical information. Medical science liaisons are also a key audience.

Included Topic Areas

Medical information; medical science liaison; medical writing; medical affairs roles throughout product lifecycle, stakeholder management, advisory boards, compliance.

Priority Topics

1. **Technology-Systems: Utilization and Impact of AI, Machine Learning, and NLP**
2. **Demonstrating Value-Collaborations: Insights, Data Analytics, Dashboards**
3. **Globalization: Content Development, Field Medical Exchange Resources, Organizational Structure, Communications, Contact Center, Translation, Compliance, Maximizing Medical Affairs Congress Presence and Deliverables**
4. **Payor Interactions: HEOR, RWE, Dossiers, Formulary Discussions**
5. **Channels for Customer Interactions (HCPs, Patients, Field Medical): Chatbot, Websites, Interactive Content, Podcast, Social Media, etc.**
6. **Consistent Messaging Across Clinical Development through Medical Affairs**
   - Education and training
   - Scientific platform
7. **Balancing Clinical Transparency with Data Protection Regulations**
8. **Efficiencies in Documentation-Structured Content, Lean Authoring, etc.**
Track 5 | Patient Engagement

This track addresses meaningful patient engagement in medical product development, from early product development, and approval, through maintenance phases. It focuses on important questions for all stakeholders, including:

- How do we meaningfully engage patients and incorporate their voices into decision-making throughout the medical product lifecycle?
- How do we become truly patient- (and people-) centric in our approach?
- How do we operationalize patient-centric approaches in our day-to-day work?
- How can we measure the effectiveness of our efforts, both for patient outcomes and to meet the needs of other stakeholders such as industry and regulatory decision-makers?
- What have we learned that can be used to drive more meaningful patient engagement?
- How do stakeholders best work together to leverage their collective power and expertise to promote meaningful involvement of patients?

DIA recommends this track and associated sessions to professionals involved in: patient affairs, patient advocacy, patient groups, patient support services, medical affairs (including CMOs and MSLs), clinical trial design and optimization, clinical research and operations, regulatory affairs, regulatory agency, corporate and government affairs, safety and pharmacovigilance, outcomes research, epidemiology, and Health Technology Assessment.

Included Topic Areas

Meaningful patient engagement (PE), patient-centered drug development, patient centricity, fostering patient-centric culture, PE approaches, best practices for PE, building collaborative relationships with patients and patient groups, engaging with diverse patient populations, partnering with patients, science of PE, operationalizing PE, PE metrics, PE tools and resources, patient advocacy, lessons learned in PE, PE outcomes.

Priority Topics

1. Development, Collection, Utility, and Impact of Patient Experience Data (Case Studies—What Has Worked and What Did Not Work)
   a. Determining meaningful data points to collect
   b. Novel partnerships to generate long-term real-world evidence
   c. Measuring and communicating benefit-risk
   d. Role of caregivers
   e. Regulatory implications and experiences
   f. Implications for rare disease

2. Developing, Executing, and Evaluating Meaningful Collaborations Between Patients and Industry Across the Entire Therapeutic Lifecycle (Pre-Clinical Through Commercialization)
   a. Examples of various levels of collaborations throughout research, development, and commercial
   b. Results and outcomes for patient communities
   c. Evaluation (company and patient community perspectives)
   d. Where do we go next?
   e. Beyond label inclusion
   f. Regulatory filings (e.g. informed decision making)

   a. Regional similarities and differences (including more than North America and Europe)
   b. How to measure global impact
   c. Multi-stakeholder collaborations
   d. Regulatory considerations

   a. Plain language summaries: determining what endpoints to include, disseminating to patients, understanding use in real world
   b. Communication during a clinical trial and impact of GDPR
   c. Opportunities and challenges in clinical trial advertising and promotion
   d. Announcements and disclosure of company and program information to patient communities (i.e. study failure, program closures, mergers, acquisitions, new program announcements)
   e. Publication planning: how to incorporate patient advocacy opportunities and needs into program strategy

5. Understanding Landscapes of Patient Advocacy Organizations and Communities and Implications for Drug Development
   a. Different models of patient organizations (i.e. support group, awareness, education, research, policy, etc.)
   b. Evolution of how patient communities (i.e. multi-stakeholder, mergers, acquisitions) and their impact on research and therapeutic advances
   c. Opportunities and challenges in therapeutic areas and patient communities that have multiple patient stakeholder organizations

6. Patient Engagement and Involvement in Clinical Trial Development, Execution, Recruitment, Enrollment, and Retention
   a. Incorporating patient input into study design
   b. Overcoming internal barriers to patient engagement
   c. Understanding who can and cannot engage with patients
   d. Role of CROs and vendors
   e. Determination of endpoint selection
   f. Implications for the breadth/spectrum of disease populations (i.e. rare disease, cancer), including fit for purpose endpoints

7. Patient Engagement Opportunities, Challenges, and Experiences in Preparing for Launch and Post-Launch
   a. Health Technology Assessment: ICER, NICE, HAS, etc.
   b. Market access, pricing, reimbursement
   c. Marketplace impact on study and clinical trial design
   d. Regulatory and compliance considerations for regional launches
   e. Specific examples of sponsor-patient group collaborations during pre- and peri-launch

8. Challenges and Opportunities with Sustaining Patient Engagement Within Companies
   a. Developing and implementing organizational structures
   b. Determining operational and resource needs required for consistency and success
   c. Overcoming internal barriers to patient engagement
   d. Identifying and partnering with key internal stakeholders
   e. Impact of patient engagement on the biopharmaceutical industry’s business and organization
   f. Differences between patient engagement, patient advocacy, patient support services
Track 6 | Preclinical Development and Early-Phase Clinical Research

Preclinical and early-phase clinical research provide initial safety, tolerability, and efficacy data for new drugs. This track focuses on topics ranging from early-stage compound selection, PK/PD, and safety considerations for both drugs and biologics, dosing strategies, novel preclinical models, and data integrity for proper downstream decision-making.

DIA recommends this track and associated sessions to professionals involved in: pharmacology and toxicology, nonclinical safety testing, clinical research, clinical operations, safety and pharmacovigilance, project management, patient centricity, and statistics; formulation science, pharmacokinetics/pharmacodynamics, epidemiology, toxicology, and regulatory affairs.

Included Topic Areas
Personalized medicine, clinical trial data disclosure, collaborations, bioethics, compliance, stem cells, regenerative therapies, cell and gene therapies, gene editing, organoids/microphysiological systems, ICH (S), study endpoints, integration of the ‘patient’s voice’ early in preclinical development to define/refine the patient population and clinical endpoints, and challenges in rare and common diseases.

Priority Topics

1. Innovative Approaches for Improving Success in Early Clinical Development
   a. The role of AI in reducing early phase attrition
   b. The role of real world data in driving efficient early clinical development decisions
   c. Use of sensors and wearables in early clinical development
   d. Virtual trial models in early clinical development

2. Leveraging Patient Advocacy Groups to Accelerate the Drug Development Journey from Preclinical to Proof of Concept

3. Learning from Oncology: Basket Trials in Rare Diseases Based on Shared Molecular Targets
   a. Beyond dose escalation: approaches for establishing starting dose in gene therapy
   b. Adaptive trial designs for rare diseases

4. The Ultimate Personalized Medicine: Therapies for Single Rare Disease Patients

5. Microbiome-Derived Therapeutics: Targets Outside the GI Tract
   a. Biomarkers for Microbiome safety and efficacy
   b. Mechanism of Action
   c. Manufacturing and other challenges

6. Developing Medical Countermeasures-Animal Rule and Other Hurdles

7. Inflammatory Disease Product Development-Animal Models and Clinical Challenges

8. Current Considerations with Gene Therapy and Gene Editing Approaches
   a. Newborn screening for pediatric trials
   b. Long-term patient monitoring
   c. Nonclinical models and safety challenges
**Track 7 | Project Management and Strategic Planning**

This track will illustrate best practices to improve project and program execution, strategic planning, and portfolio management, as well as how to collaborate more effectively with internal and external stakeholders to achieve project and program objectives. Attendees will hear recommendations from industry leaders on how to lead and manage projects and initiatives successfully across the entire medical product spectrum.

DIA recommends this track and associated sessions to professionals involved in or interested in making a career move into: project management, portfolio management, and decision-making, alliance management, clinical development, clinical operations, marketing/commercialization, and CROs/Vendors.

**Included Topic Areas**

Topics include product development, launch preparation, effective lifecycle management, and critical leadership topics such as leading in the midst of ambiguity. Other topics include project management, program management, portfolio management, alliance management, decision sciences, strategic planning, risk planning, and mitigation transformative partnerships, funding, product lifecycle planning, and data transparency.

**Priority Topics**

1. Collaborative PM Approaches to Patient Focused Drug Development
2. Leveraging a Strategic PMO (Building Resiliency, Delivering Value, Establishing Core Capabilities, Business Continuity Planning and Project Resourcing)
3. Strategic Integration of Acquired Assets or Companies
4. Project Management Fundamentals (Processes, Tools, Reporting, Scheduling, Resourcing, Methodologies)
5. Applying Decision Science to Enhance Effective Leadership of Teams and Portfolio Prioritization
6. Leadership Skills for Effective Project Management (Conflict Management, Issue Resolution, Emotional Intelligence, Transparency)
7. Considerations for Initiating, Managing and Expanding on Lifecycle Management
8. Innovative Approaches to Identifying and Managing Risk
Track 8 | R&D Quality and Compliance

This track provides a comprehensive view of the quality landscape across the preclinical, clinical, and pharmacovigilance domains. The track focuses on innovative and risk-proportionate approaches to managing quality that are appropriate to an evolving development paradigm and in a global context. Sessions will address key topics in GLP, GCP, and PV quality, providing knowledge and resources needed to implement pragmatic, proactive, and effective quality management.

DIA recommends this track and associated sessions to professionals within biopharma, CROs, and regulatory agencies interested or working in: research and development, clinical research, clinical, preclinical, or PV quality, clinical monitoring, regulatory affairs, regulatory operations, compliance, pharmacovigilance, quality control/quality assurance, and clinical quality management systems.

Included Topic Areas

ICH E series guidelines, clinical quality management systems, quality risk management, quality culture, clinical quality-by-design, proactive quality, quality indicators, risk indicators, clinical quality metrics, data quality, data integrity governance/frameworks, GCP, GLP, audits, risk-based auditing, inspection management, CAPAs, compliance, compliance oversight, global oversight.

Priority Topics

1. Quality Risk Management: How to Balance Risk and Resources
   a. Importance of developing and maintaining a culture of quality
   b. How good data governance promotes clinical trial quality
   c. Quality Analytics: Effective strategies for using quality system data to drive continuous improvement

2. Ensuring Data Quality and Data Integrity
   a. Anomalous Data Identified – how to further evaluate, understanding potential impact, and determine when and what further actions are needed
   b. Role of electronic systems audit trail data and control of system access in monitoring for GCP compliance
   c. Best practices for design, operation, and maintenance of electronic clinical outcome assessment (eCOA) tools and devices

3. Pharmacovigilance: Optimizing Data Collection and Quality to Support Bringing Safer and More Effective Products to Patients in the Setting of Divergent Global Regulatory Requirements

4. Effective Oversight Strategies: Importance in Clinical Development
   a. CRO and vendor oversight
   b. Has Risk-Based Monitoring improved clinical trial execution, data quality, and safety of trial participants?
   c. Role of centralized monitoring (and centralized quality assurance activities such as analytics) to improve quality and compliance

5. What Does Quality Look like for Innovative Trial Designs?

6. What Does Clinical Quality Look like in the Development of Innovative Products (e.g. Cell Therapies or Other Non-Traditional Biopharma Products)?

7. Perspectives on ICH Renovations and the Changing Global Clinical Quality Landscape

8. Informed Consent and the Emergence of Econsent: Global Perspectives and Challenges
Track 9 | Regulatory

This track addresses global laws, regulations, guidelines, and guidances that govern prescription biopharmaceutical and device product development, approval, and maintenance. Representatives from FDA, EMA, PMDA, MHRA, BfArM, and ICMRA authorities, and other regulatory experts will provide global updates, insights, and discussion on current issues, opportunities, and challenges through interactive forums. DIA recommends this track and associated sessions to professionals involved in: regulatory affairs and strategy, regulatory operations, regulatory information management, regulatory agencies, government affairs, legal affairs and compliance, policy and intelligence, clinical research and operations, PV, HTA, project management, and service providers developing tools and resources for use by sponsors and CROs.

Included Topic Areas
Regulatory affairs, regulatory policy, regulatory intelligence, regulatory strategy, global and US advertising and promotional regulations and laws; regulatory operation best practices, regulatory science, eSubmissions, regulatory document management; regulation pertaining to study endpoints, product labeling, biosimilars, combination products, advanced therapies (e.g. regenerative medicine, tissue products, gene therapy), companion diagnostics, devices.

Priority Topics

1. PDUFA VI & 21st Century Cures
   a. Pilot projects: Complex Innovative Designs (CID) and Model-Informed Drug Development (MIDD)
   b. Patient-focused medical product development
   c. Real World Evidence (RWE)
2. Global Development and International Harmonization/Convergence
   a. Global development strategies and impact on clinical trial design and implementation (e.g. multi-regional clinical trial)
   b. Updates on ICH, IMDRF, and other harmonization/convergence initiatives
   c. Effect of emerging regulations on global registration strategies
   d. Compare/contrast health authority approaches to regulatory interactions with industry
3. Regulatory Topics of Public Health Importance
   a. Global regulatory considerations for special populations or situations (e.g. rare/orphan, pediatrics, women, etc.)
   b. Opioids
   c. Antimicrobial Resistance
   d. Cell/Gene Therapy
   e. Regenerative Medicine Advanced Therapies
4. Regulatory Communications
   a. Communications during drug shortages, cyber-security challenges, and emergencies,
   b. Communications with patients and healthcare providers
   c. Global labeling modernization efforts
5. Review Modernization
   a. Integrated Reviews
   b. Cloud based submissions
   c. Regulatory Operations: pre- and post-marketing
   d. Meeting Management
6. Regulatory Initiatives to Increase Competition
   a. GDUFA and BsUFA Updates
   b. Global generic drug and biosimilar policies
   c. Regulator – HTA interactions
7. Combination Products/Devices
   a. Software as a Medical Device
   b. Human Factors
   c. Bridging Studies
   d. MDUFA Updates
8. Digital Health for Regulatory Decision Making
   a. Data privacy, cybersecurity, qualification, validation
   b. Use of digital tools pre- and post-marketing
   c. Prescription Drug Use Related Software
   d. Use of Artificial Intelligence / Machine Learning
Track 10 | Regulatory CMC and Product Quality

The Regulatory CMC and Product Quality Track provides a comprehensive view of risk-based approaches across the product lifecycle. The track scope spans from the scientific understanding gained through product and process development to lifecycle expectations for Global Regulatory CMC submissions, CGMP, and Quality Systems. Sessions will address the increasing regulatory complexity of development and manufacturing for worldwide markets, accelerated development timelines, new technologies, emerging regulations, and increased scrutiny of manufacturing operations and data.

This track is recommended for regulatory affairs, manufacturing, quality assurance, and quality control professionals involved in: drug development and/or manufacturing for small molecule drugs, biologics, and vaccines.

Included Topic Areas

CMC expectations for dossiers, quality management system expectations, new technologies, patient-centered quality risk management of products, and ICH quality related guidelines (Q & M topics).

Priority Topics

1. Progress on and Implementation of New ICH Quality Guidelines
2. Accelerated Development – CMC Case Studies
3. FDA Quality Initiatives for Modernizing Review and Inspection
4. New Digital Technologies for Pharmaceutical Manufacturing
5. Quality Considerations for Drug-Device Combination Products
6. Quality Considerations for Biosimilars
7. Patient Centric Quality Standards or Biologics
8. Manufacturing and Quality Considerations for Cell & Gene Therapies
Track 11 | Statistics

This track will focus on topics of theoretical and practical interest to statisticians and clinical trialists who work with medical products, including pharmaceuticals, biologics and biosimilars, combination products and devices, and generics throughout their lifecycle. Sessions will explore current statistical thinking which informs policy, regulation, development, review, and lifecycle management of medical products in the context of the current scientific and regulatory environments.

DIA recommends this track to professionals involved in or seeking to advance their skills in biostatistics, including: biostatisticians, 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.

Priority Topics

2. Surrogate Endpoints and Biomarkers
3. How Statistics Contribute Meaningfully to GCP (ICH E6 R2)
   a. Centralized / risk-based monitoring
   b. Quality tolerance limits
   c. Key performance indicators
   d. Detection of data anomalies
4. Statisticians Collaboration Among Different Disciplines
   a. Artificial intelligence and machine learning
   b. Data scientists
   c. Epidemiologists / Clinicians
   d. Pharmacologists
5. Global Harmonization of Complex and Innovative Trial Designs
   a. Platform trials
   b. Seamless / enrichment
   c. Bayesian applications
   d. Leveraging external information
6. Using and Interpreting P-Values: Understanding Clinical Meaningfulness and Statistically Significant
7. Safety and Benefit-Risk
   a. Program-wide benefit-risk evaluation
   b. Utility of Data Monitoring Committees
8. Communications
   a. FDA Draft Guidances (e.g. Adjusting for Covariates, Multiple Endpoints)
   b. Statistical concepts for non-statisticians
Track 12 | Value and Access

The healthcare landscape is evolving into one assessed on value, and there is a need to understand the impact of this movement on all stakeholders: providers, payers, biopharma, and ultimately patients. The Value and Access track will bring together global regulators, industry leaders, patients, and payers who will facilitate discussions and address questions such as:

- What information and evidence is being used to define value?
- Who is making or influencing access decisions?
- How can real-world data be leveraged to drive access to medicines?
- What are the regulatory and legal considerations surrounding value-based contracting conversations with payers?

DIA recommends this track and associated sessions to: payers, health economics outcomes researchers, health economists, statisticians, data modelers, clinical researchers, post-marketing professionals, and regulatory affairs professionals.

Included Topic Areas

Comparative effectiveness research, health technology assessment, real-world outcomes, value-based healthcare; drug pricing, reimbursement and access, commercialization, product lifecycle considerations.

Priority Topics

1. Paying for What Works: Value-Based Contracting Between Payers, Manufacturers, and Providers – Where Do We Go from Here?
   a. Outcome-based contracts and subscription models within states
   b. Paying for outcomes within Medicare and Medicaid
   c. How has VBCs panned out for pharma and commercial plans

2. Planning Studies to Meet Both Payer and Regulator Needs
   a. Choosing endpoints that matter for coverage decisions
   b. Payer/regulator engagement within studies
   c. FDA and CMS – Parallel Review

   a. Potential options to engage and solicit patient input into pricing access strategies during drug development
   b. What does it mean to be patient focused when developing pricing and access strategies

4. Impact of Value Frameworks and Evidence-Based Pricing (with ICER, NICE)
   a. Potential impact on overall pricing decisions
   b. Promising strategies and considerations

5. Ensuring Access to Treatments for Rare Diseases in Developing Countries
   a. Key barriers
   b. Promising strategies

6. Using Real World Evidence for Real World Payment
   a. How can real world data drive reimbursement and/or increase market access?
   b. What real world data demonstrates “value”?
   c. Who “owns” data when the patient changes plans, stops treatment, or is “cured”?
   d. The ethics, interoperability, and challenge of real world data sharing

7. Policy Update on Drug Pricing-Regulations and Legislation

8. Pricing and Access Strategies for High-Priced Therapies (e.g. Gene Therapy)
Track 13 | Professional Development

The Professional Education and Development track focuses its content on topics that improve and support ongoing personal growth for career and team success. This broad category includes: interpersonal skills, soft skills, leadership, goal-setting, life-long learning, career transitions (career growth, lateral career transitions, and entrepreneurship), social media/new media, and self-awareness to assess strengths and gaps.

Included Topic Areas

Networking, improving productivity and self-productivity, interpersonal relationships, diversity, hiring, leadership, technology, making a lasting impression, running remote meetings and workplace dynamics.

Priority Topics

1. Best Practices for Business Communications
5. Mindfulness in the Workplace
6. How Written Communication Impacts Professional Development Relationships (Could Also Tie in with #1)
7. Self-Awareness and Career Growth
8. Diversity: Improved Project Performance with More Voices, Unique Problem-Solving, How Diversity Amplifies a Workplace
Abstract Submission Requirements

Please read the following instructions carefully; incorrect or incomplete abstracts will not be considered.

1. All abstracts must be submitted online to DIAhome.org/Abstract. The deadline for abstract submissions is Thursday, September 12, 11:59PM ET. This deadline will not be extended. Please note: once on the DIA abstract submission homepage, you must select either the general session or short course link.

2. Submitted abstracts must not overtly endorse or recommend a specific product or service. To review DIA’s Policy Concerning Promotion of Products and Services from the Podium at DIA-sponsored Programs, click here.

3. Proposed abstract title must reflect the abstract content accurately and concisely.

4. Co-presenters, including Co-chairs, will not be allowed.

Notification Date

Submitters will be notified of the status of each abstract no later than the week of November 4.

Please note that DIA and the DIA AMPC have the right to request authors to revise abstracts. Potential revisions include direction of topic, blending with another submission, or revising the proposed level of difficulty.

Abstract Submission Tips and Tricks

• Do not wait until the last day to submit an abstract. There is usually very high traffic on the website and you want to avoid the risk of any technical difficulties.

• Do not use the “back” button during the submission process.

• Be certain to click “Submit” at the end of the process for a confirmation of receipt. If you do not get confirmation of receipt, DIA did not receive your abstract.

• Review our submission site process document before logging in.

Questions? Contact DIA at AnnualMeetingProgram@DIAglobal.org
Frequently Asked Questions

The following are helpful hints and frequently asked questions regarding abstract submissions for the DIA Global Annual Meeting.

Q: I submitted a topic during the Call for Topics, and it appears under the suggested topics for the Global Annual Meeting. Do I still have to submit a session or speaker abstract?
A: Yes, you must submit an abstract to be considered as a chair or speaker for DIA 2020.

Q: What constitutes a quality abstract?
A: Information provided in the “Abstract Details” section should include specific details or data to support your abstract submission:

- Unbiased content that does not promote a product, service, or organization; abstracts deemed to be promotional will be excluded from consideration
- Innovative and cutting edge information, or new developments related to the topic
- Real world applications, such as case studies or demonstrations
- A global perspective
- A session or presentation title that is compelling and attractive to potential attendees
- Content that is cross-functional and interdisciplinary, if possible/appropriate
- A clear target audience with clear learning objectives

Q: May an author submit more than one abstract?
A: Authors may submit multiple abstracts. Do not submit the same exact abstract more than once.

Q: What information is required from the author?
A: Full contact information
- Participant disclosure information and speaker authorization for use of presentation materials, which allows DIA to distribute your presentation to registrants of the Global Annual Meeting

Q: Can there be more than one author name?
A: Only one author name may be submitted.

Q: May I include or recommend an additional speaker name for the topic in which I am interested?
A: You may recommend an additional speaker(s) for a session, forum, or workshop only.

Q: Do I have to use the DIA website to submit the abstract?
A: Yes. Only abstracts submitted via the DIA website will be considered for inclusion in the program. You are encouraged to prepare your abstract in a separate document prior to submitting on our website. Abstract information should then be copied and pasted from the prepared document as plain text.

Q: Are there abstract templates or samples available?
A: Yes, there is a sample abstract as well as a form that you may use to prepare your abstract in advance.

- Session abstract template
- Forum abstract template
- Workshop abstract template
- Presentation abstract template
- Short Course abstract template

Q: May someone submit the abstract on my behalf?
A1: Yes, for sessions, forums, and workshops, a submitter will have the option to complete author information even if they will not be the designee onsite in Washington, DC.
A2: Not for Short Courses. For the Short Courses the Instructor must complete the submission form.

Q: When will I be notified if my abstract has been accepted?
A: Authors will be notified by November 8. Accepted abstract authors are requested to confirm their participation as a chair or speaker with DIA by logging into Speakers Corner and confirming and updating information by December 2.