DIA 2019

GLOBAL ANNUAL MEETING
SAN DIEGO | JUNE 23-27

CALL FOR ABSTRACTS

Submission Deadline:
September 12

DIAglobal.org/DIA2019

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About the DIA 2019 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 2019 Global Annual Meeting (DIA 2019) 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 2019 boasts more than 450 exhibiting companies, over 13+ tracks, and more than 250 sessions.

DIA 2019 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 2019 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 2019 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 2019 tracks click here.

DIA is committed to including the voice of the patient at DIA 2019. 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 - Saturday, September 12

Types of Abstracts

There are five types of abstracts you can submit for DIA 2019, 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. The abstract author is considered the session chair and will be responsible for the following:

- Adhering to the program development policies and guidelines
- Meeting program development timelines
- Recruiting no more than three speakers and ensuring good representation/diversity in the selection of speakers (no more than one participant from the same company is permitted)
- Communicating with speakers regarding their role in the session and reviewing presentation materials; PowerPoint presentations are required from each speaker
- Managing the session, including the facilitation of audience questions and answers from the podium

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.

**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. The abstract author is considered the chair and will be responsible for:

- Adhering to the program development policies and guidelines
- Recruiting panel participants and ensuring good representation/diversity in their selection
  - Please note that the Annual Meeting has a global focus, and therefore the session should be globally oriented
- Communicating with panel members regarding their role in the forum and reviewing any presentation materials, although PowerPoint presentations are not required
- Managing the forum, including the facilitation of audience questions and answers from the podium

**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 within a session. The abstract author is considered the presenter (co-presenters are not allowed) and will be responsible for the following:

- Adhering to the program development policies and guidelines
- Meeting program development timelines
- Working with Chair and other presenters in creating a balanced session
- Preparing and delivering a PowerPoint presentation

**Helpful hint! Plan your submission separately and in advance by using this presentation abstract template. Read a sample presentation abstract.*

WORKSHOP

A 75-minute workshop delivered in an interactive/simulation or role-playing format. The abstract author is considered the facilitator of the workshop and will be responsible for the following:

- Adhering to the program development policies and guidelines
- Meeting program development timelines
- Ensuring the workshop provides onsite learning in the form of activities or demonstrations
- Managing the workshop which will include 75-100 attendees, including the facilitation of audience questions and answers from the podium

**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.*

DIA 2019 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 foot print (including local safety offices and partners); and considerations for signal detection and management across the product lifecycle.

Priority Topics

1. **What's new in PV regulation and guidance?**
   a. Incorporating the patient voice in the benefit-risk management process
   b. General data protection regulation and PV
   c. Combination products
   d. GVP V and globalization of RMPs
   e. Safety signals, GVP IX, EVDAS, and beyond disproportionality
   f. ICH E-19: Optimizing safety data collection
2. **PV audits/inspections**
   a. New hot spots
3. **The science of safety analytics**
   a. Practical application of AI
4. **The evolving world of PV data**
   a. Real World Evidence and labeling
   b. Impact of digital/wearable technology
5. **Safety management planning**
   a. Pre- and post-market continuity
6. **Application of "Routine" PV**
   a. Rare diseases
   b. Orphan drugs
   c. Immuno-oncology
   d. Gene therapy, including new guidance
7. **Pragmatic approaches to globalization of PV**
   a. Adoption of tier 2 ICH E2 guidelines in new regions
   b. The "responsible" person

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; endpoints; 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. **Developing technology in clinical research**
   a. Applications of blockchain, artificial intelligence, automation
   b. Internet of things
   c. Cognitive technology, voice recognition
2. **Mobile technology in clinical trials, M-Health, ePRO/eCOA, endpoints**
   a. Technology, sensors, Smartphone, actigraphy, wearables
   b. Patient-centered endpoints/outcomes, validation, data integrity, and regulatory considerations
3. **Evolving best practices in risk management and compliance with ICH E6 R2**
   a. Risk analysis, threshold determinations, processes, systems, documentation
   b. Root cause analysis and CAPA
   c. Compliance in small to mid-sized companies: Quality Systems, SOPs, vendor oversight, and risk management
4. **Advances in monitoring and managing clinical trials**
   a. Monitoring plan: risk, KPIs, collaboration with data management, and QA
   b. Monitoring modalities (remote, centralized, onsite)
   c. Data quality: eSource, electronic health records (Part 11)
   d. eTMF and document management
   e. e-Consent process: documentation, impact of GDPR
5. **Protocol development**
   a. Technology: digital solutions, common protocol template
   b. Collaborations and information sharing: patient engagement, investigators, advocacy
   c. Effective feasibility assessment processes: study design and enrollment
6. **Global Trials, partnerships, and cross-functional collaborations**
   a. CRO partnerships – collaborations, management, oversight, KPIs
   b. Managing complex vendor landscapes/ logistics: labs, samples, IMP, enrollment
   c. Optimizing country selection
   d. Real time Quality Assessments
   e. Clinical operations: collaboration with PV, QA, data management, and regulatory
7. **Managing investigational medicinal products and the supply chain**
   a. Managing investigational product: forecasting, distribution, account
   b. Technology: electronic labeling, smart packaging, scanners/tracking
   c. Monitoring patient adherence, technology
8. **Clinical trials in the next decade**
   a. Cross industry collaboration: data sharing, Master Protocols, capacity/capability
   b. Personalized healthcare, rare diseases, genomic medicine, real-world data
   c. Virtual trials/decentralized trials: role of the sponsor, investigator/coordinator, IRB/EC, regulators throughout the study lifecycle
9. **Operational challenges: companion diagnostics, biomarkers, endpoints**
   a. Gene/Oligonucleotide Therapy
   b. Cell Therapy
   c. Alzheimer Disease
10. **Innovation in enrollment, recruitment, and retention**
11. **Best practices in clinical operations inspection management and readiness: preparation, execution, response, collaboration with quality assurance**

Track 3 | Data and Data Standards

This track will address data from the perspectives of:

- Sources, standards, quality, handling, and regulatory requirements
- Current and emerging applications of data and technologies for capturing data direct from patients

The full spectrum of data and its uses to support biopharmaceutical development, approval, and post-marketing applications will be covered in this track including: clinical (including eClinical 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. **GDPR: impact on data management practices and processes**
2. **Updated standards, guidance, and regulations: impact on the data professional**
   a. ICH E6 R2, ICH E9 R1, PDUFA VI, new Part 11, etc.
3. **Data integrity: measuring and monitoring best practices**
4. **Data integration: pros, cons – best practices for sharing clinical trial data**
5. **The evolution of CDM in the digital world: changing roles and responsibilities**
6. **EHR data/eSource, wearable health: opportunities and challenges in integration with clinical trials**
7. **Real World Evidence: data harmonization, standardization, quality, and regulatory considerations**
8. **Virtual trials: what are they, how do you deliver and what does it mean to the CDM**

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. **Utilization and impact of AI, machine learning, and NLP in medical affairs**
2. **The value of medical affairs across the lifecycle of the product**
3. **Global medical information perspectives from outside the United States**
4. **Topic-based authoring to support accelerated CTD submissions**
5. **Applying HEOR, real world evidence, and outcomes partnerships across medical affairs to meet HCP needs**
6. **Evolution of medical information response delivery channels**
7. **FDA regulated promotion and free speech: communication with payers and formularies, and HCPs**
8. **Maximizing medical affairs congress presence**
9. **Statistics for nonstatisticians**
10. **GDPR impact in clinical development, medical affairs, and medical information**
11. **Structured authoring in clinical development**
12. **Identifying key messages: protocol to publication**
13. **Clinical transparency and disclosure**
14. **Collaborating with patient advocacy groups in the orphan product space**
15. **Communicating study results to patients and patient advocacy groups**
16. **Medical Affairs roles for the future**
17. **Where do medical affairs' professionals gather and gain their role expertise?**

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. **Patient engagement opportunities, challenges, and experiences in preparing for launch and post-launch**
   a. Health Technology Assessment: ICER, NICE, HAS, etc.
   b. How and when to partner with Commercial and Market Access
   c. Patient programs, product-agnostic, and product-specific education
   d. Regulatory and compliance considerations for regional launches
2. **Impact of patient engagement on the biopharmaceutical industry's business and organization**
   a. Developing and implementing organizational structures
   b. Identifying and partnering with key internal stakeholders
   c. Understanding and measuring impact of engagement on both the business and patients
3. **Development, collection, utility, and impact of patient experience data**
   a. Novel partnerships to generate long-term real world evidence
   b. Measuring and communicating benefit-risk
   c. Role of caregivers
   d. Regulatory implications and experiences
4. **Developing, executing, and evaluating meaningful collaborations between patients and industry across the entire therapeutic lifecycle**
   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?
5. **Beyond the United States: global implications, challenges, and ideas for patient advocacy and patient engagement**
   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
6. **Patient engagement and involvement in clinical trial development, execution, recruitment, enrollment, and retention**
   a. Who can and can't engage with patients?
   b. Remote sites and home healthcare
   c. Role of CROs in patient engagement
   d. Implications for the breadth/spectrum of disease populations
7. **Opportunities and challenges in the digital age of patient engagement**
   a. Handheld devices
   b. Automation
   c. Artificial intelligence
   d. Implications for organization of patient communities

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, and safety considerations for both drugs and biologics, as well as dosing strategies to 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.

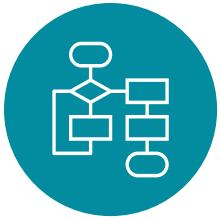
Included Topic Areas

Personalized medicine; gene editing; clinical trial data disclosure; collaborations; bioethics; compliance; stem cells, regenerative therapies, gene therapies, etc.; ICH (S), study endpoints; integration of the 'patient's voice' early in preclinical development to define/refine the patient population and clinical endpoints: challenges in rare and common diseases.

Priority Topics

1. **Cellular immunotherapies for oncology: preclinical challenges and monitoring clinical toxicity**
2. **Novel CNS therapies and challenges in developing products for cognitive disorders**
3. **Accelerating rare disease product development: partnering with rare disease consortia during early development**
4. **Botanical products – Navigating the regulatory jungle**
5. **The virtual drug development model: minimizing overhead and maximizing chances for Phase 1 success**
6. **Tissue engineered and regenerative medicine products: preclinical and early clinical considerations**
   a. 3-D Printing of tissues and organs
   b. Use and safety considerations for human stem cells
7. **RNA-based therapies: CMC, nonclinical, and clinical challenges with a novel product class**
8. **Leveraging artificial intelligence in early stage development**
9. **Vaccine development for emerging viral diseases**
10. **Challenges in vaccine development for serious epidemic diseases in remote locations**
11. **The growing use of nucleic acid-based vaccines**
12. **Emerging genome editing technologies**
13. **Impact of New FDA guidance for gene therapies**
14. **Drug development for ocular diseases: new therapies, regulations and patient perspectives**

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.

Topics include product development, launch preparation, effective lifecycle management, and critical leadership topics such as leading in the midst of ambiguity. 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

Project management, program management, portfolio management, alliance management, vendor management, decision sciences, strategic planning, risk planning, and mitigation transformative partnerships, funding; product lifecycle planning, and global commercialization considerations.

Priority Topics

1. **Integration and validation of new drug digital tools and methods into clinical development (e.g. machine learning, artificial intelligence, mobile health platforms)**
2. **Project management structure in different healthcare organizations (e.g. health authority, hospitals, research centers, NGOs)**
3. **Effective incorporation of patient perspective into clinical development (e.g., cultural considerations, return of information about the clinical trial – "lay summaries", individual participant results)**
4. **Strategic integration of acquired assets or companies**
5. **Business continuity and organization resiliency (e.g. succession planning, project resourcing: capabilities and bandwidth)**

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 sponsor, CRO, and regulatory agency organizations 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. **Enhancing quality and efficient compliance: how to balance between risk and resources?**
   a. Impact of data governance practices on data quality
   b. Defining critical data and key risk indicators
   c. Impact of quality-by-design approach on clinical trial planning, conduct, and outcomes
   d. Optimizing CI and site staff training to ensure quality conduct of clinical trials
   e. Using predictive analytics to enhance quality and compliance
   f. Risk-based monitoring world: auditing and impact of remote monitoring on quality oversight
   g. Role of centralized monitoring to improve quality and compliance
2. **CRO and vendor identification, qualification, audit management, and oversight**
   a. Are current practices working to ensure quality performance?
   b. Case studies and lessons learned
3. **Regulator's and industry's perspectives on:**
   a. Best practices in hosting regulatory inspections and sponsor audits
   b. Inspectional trends and findings
   c. Regulatory focus and oversight: Is it changing?
   d. How do regulatory inspectional findings impact inspected entities' quality and risk management planning activities?
   e. EU CTR implementation
   f. Case studies on falsification and misconduct in clinical trials and regulatory reporting requirements
4. **IRBs' role in improving risk management and quality management systems in the clinical trial enterprise**
5. **Novel trial designs: maintaining quality**
   a. Real World Evidence: How does its use challenge quality and compliance programs?
   b. Decentralized trials: How do they challenge quality and compliance programs?
6. **ICH renovation**
   a. ICH E6(R2): How have you addressed changes designed to promote quality management?
   b. Best practices for quality risk management in clinical trials
   c. E8 renovation: an update on transformation of expectations

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. **Novel global development strategies and approvals, including industry and regulator pilot projects and newly emerging precedence**
   a. New technologies, e.g., gene therapy/gene editing/cellular therapies
   b. Tissue agnostic/molecularly targeted products
   c. Complex Innovative Designs (CID) and Model-Informed Drug Development (MIDD)
   d. Real-world data/real world evidence
   e. Patient-focused medical product development
   f. Use of digital technologies in product development
   g. Human factors studies and challenges in advancing drug delivery technologies
2. **Innovation and technologic advancements to enhance regulatory decision-making**
   a. Artificial intelligence, blockchain, genomic data, machine learning
3. **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
4. **Global regulatory considerations for special populations or situations**
   a. Pediatrics (including neonates), orphan drugs, rare diseases, geriatrics
5. **Hot topics**
   a. Biosimilars
   b. Global expanded access/Right-to-Try updates
   c. Generics drug review process/priorities
      I. Development of complex generics, implications for lifecycle management of innovator products
6. **Regulatory Communications**
   a. Opportunities for early engagement with regulators during medical product development
   b. Communications during drug shortages, cyber-security challenges, and emergencies,
   c. Communications with patients and healthcare providers
   d. Global labeling modernization efforts

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.

The 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. **New technologies**
2. **Update on ICH quality topics**
3. **Recent CMC changes in China**
4. **Interface between CMC assessment and inspection**
5. **Comparability for complex generic and biotech products**
6. **Challenges and opportunities in product quality: lifecycle management**
7. **cGMPs for combination products**
8. **Development and manufacturing challenges for advanced therapies medicinal products**
9. **Efficient preparation of global CMC dossiers**
10. **Paradigm shift: patient-focused quality standards (i.e. clinically relevant specifications)**

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

1. **Raise your clinical research game with basic statistical knowledge**
   a. Randomization, blinding, analysis populations
   b. T-test, ANOVA, ANCOVA, Chi-square, Fishers, time-to-event/ Kaplan-Meier
2. **Data visualizations are coming: Are you ready?**
   a. Static and dynamic
   b. Safety and benefit-risk applications
3. **Rare diseases**
4. **Pediatric drug development**
5. **Complex Innovative Designs/Model-Informed Drug Development**
6. **Using real world evidence for regulatory decision-making**
7. **Surrogate endpoints and biomarkers**
8. **How statistics contribute meaningfully to GCP (ICH E6 R2)**
   a. Centralized / risk-based monitoring
   b. Quality tolerance limits
   c. Key Performance Indicators
   d. Risk perception and communication
9. **Innovative advances with a statistical twist**
   a. Bayesian applications, ie. informative priors
   b. Historical information
   c. Artificial intelligence
   d. Machine learning
   e. Clinical analysis standards
10. **Important considerations in clinical trials**
    a. Multi-regional clinical trials (ICH E17)
    b. Multiplicity
    c. Missing data
    d. Preparing for regulatory meetings, including creating questions/ briefing documents
    e. Use of statistics to inform decision-making
11. **Getting the questions right (ICH E9 R1)**
    a. Estimands
12. **Patient-focused drug development**
13. **How to collaborate effectively as a statistician**

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. **Biosimilars, interchangeables, and non-interchangeable: What are the evidence needs? How will reimbursement impact access? Are there any data on differences in outcomes?**
2. **Progress reports on value-based contracting between payers, manufacturers, and providers – What's working and what's not?**
   a. Case examples
   b. Role of benefit versus risk
3. **Meeting unmet medical need for patients, regulators, and payers**
4. **Evolving payment systems and payer needs for radical personalized medicines with focus on rare diseases, genetic approaches (e.g., CRISPR, gene editing), and impact on reimbursement**
5. **Planning studies to meet payer and regulator needs**
6. **Breakthrough designations and accelerated access programs**
7. **Approaches and methods for using Real World Evidence to assess value, drive reimbursement, and increase market access**
   a. Roles of:
      I. Patient registries
      II. EHRs
      III. Claims data
   b. Quality of Real World Evidence
   c. Methods of Real World Evidence
   d. Visualizing and modeling Real World Evidence
8. **Assessing value: approaches from patients, payers, manufacturers, regulators, and clinicians**
   a. Tools and examples for value and outcomes assessment
   b. Considerations with rare diseases

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. **Networking: hands-on networking, networking for people who hate networking, networking by personality profile, networking at conferences**
2. **Workplace dynamics: broadcasting happiness, creating a more positive workplace, strategies for more productive workspaces**
3. **Interpersonal relationships: co-worker interactions, feedback/review and critique, generational interaction and synergizing, communication styles, Myers Briggs/DISC/DOPE**
4. **Benefits of diversity: improved project performance with more voices, unique problem-solving, how diversity (age/gender/career background/LGBTQ/race/ethnicity) amplifies a workplace**
5. **Diversity leadership in healthcare: What does leadership look like for diverse groups (new-to-career, millennials, women in healthcare, people of color, etc.)?, challenges of leadership for diverse groups, workplace perceptions for diverse groups**
6. **Hiring based on skillsets, creative hiring strategies, cross-career/cross-functional strengths, asking good questions to hire talent, maximizing resume keywords and buzz words**
7. **Leadership: courageous leadership, service leadership, team dynamics, workplace culture**
8. **Career transitions: career growth/lateral career transitions/entrepreneurship, building a consulting practice (legal, financial, business development, marketing), work-life balance**
9. **Best practices in new technology: LinkedIn, apps for productivity, social media, remote meetings**

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 **Wednesday, September 12, 11:59PM ET**. This deadline will not be extended.

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 will not be allowed.

Notification Date

Submitters will be notified of the status of each abstract no later than the week of November 5.

Please note that DIA and the DIA 2019 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 DIA 2019.

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 2019.

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 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 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	Session abstract sample
Forum abstract template	Forum abstract sample
Workshop abstract template	Workshop abstract sample
Presentation abstract template	Presentation abstract sample
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 San Diego, CA.

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 the week of November 5. 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 3.