DIA 2018

Boston, MA | June 24-28

CALL FOR ABSTRACTS

Submission Deadline:
September 23, 2017

DIAglobal.org/DIA2018

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About the DIA 2018 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 2018 Global Annual Meeting (DIA 2018) 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 2018 boasts more than 450 exhibiting companies, over ten tracks, and more than 160 sessions.

DIA 2018 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?

Types of Submissions

New this year, you may submit abstracts addressing priority topics and/or topics relevant to the DIA 2018 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 2018 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 2018 tracks click here.

DIA is committed to including the voice of the patient at DIA 2018. 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 23, 2017

Types of Abstracts

There are five types of abstracts you can submit for DIA 2018, 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 3 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 6 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.*

DIA 2018 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

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), postmarket 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

Good Pharmacovigilance Practices (GVP) – including insights into the revised Modules V and VI, the new Pediatric pharmacovigilance (PV) guidance, other PV regulations and guidances, pre and postmarket safety and PV requirements, ICH(E) guidelines related to safety, benefit-risk assessment and management, epidemiologic studies, safety considerations for combination products, medical devices, generic products (including biosimilars), advanced therapies, companion diagnostics; Pharmacovigilance System Master File (PSMF), PV audits/inspections; use of digital technology for risk minimization and risk communication purposes; patient-centric labeling and processes for developing such labeling; patient-centric risk minimization methods, application of artificial intelligence in PV, generating meaningful insights on medical product safety from social media and other new data sources (e.g., “big data”); optimizing the global PV footprint (including Local Safety Offices and Partners); considerations for signal detection in the pre and postmarket.

Priority Topics

1. Practical applications of real world evidence
   a. Hands on applications and practical messages
2. Use of pharmacoepidemiology in assessment of safety issues
   a. Use of data and assessment in product issues
   b. How can databases be used? Use of external databases
   c. Effectiveness of risk minimization efforts
3. Globalization of pharmacovigilance
   a. How are people doing this?
   b. Risk management plans
   c. Role of the qualified person
4. New and evolving PV requirements
   a. Module 6 changes
   b. Combination products rule
   c. Medical device regulation in the EU
5. Patient support programs
   a. Push for data and how best to use outputs
6. Signal detection and management
   a. How does it differ pre-marketing and postmarketing?
   b. Social media
7. Implications of automation
   a. Data visualization and dashboards from multiple data streams

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
- Optimize clinical trial enrollment and novel techniques for subject retention
- Evaluate the clinical utility and endpoint development with the use of mobile/digital technology
- Identify clinical questions and gaps resulting in barriers to efficient clinical research development/management
- Review optimal Clinical Operations management structures in small, medium, and large companies
- Apply innovative protocol techniques, designs, and technology to accelerate decision-making/development
- Assess the impact of ICH E6 (R2) on clinical study management and monitoring including risk review of assessment and root cause analysis tools
- Review technological advances in clinical research operations including site management, patient enrollment, and project management tools
- Review advances in patient centricity in relation to protocol optimization (quality-by-design), the use of technology and PRO
- Review currently accepted endpoints in selected therapeutic areas and validation considerations for potential future endpoints
- Determine competencies and training for Clinical Research Associates and other research staff
- Discuss advances in logistics for managing and distributing investigational products
- Program challenges and solutions in global clinical and multi-regional clinical trials
- Program management advances in Sponsor/CRO collaborations and vendor oversight
- Discuss the evolving value of real-world data including study designs, operational considerations
- Operational procedures and advances in studies with gene and cell therapies

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. Utilization of mobile/digital technology in clinical trials
   a. potential endpoint acceptability
   b. capturing patient input
2. Patient centricity in study design, particularly with rare disease considerations and best practices for obtaining and incorporating subject and advocacy group input in protocol design
3. Application of patient input and advocacy groups in enrollment and retention
4. Best practices for balancing patient input with sponsor decision-making (i.e., Protocol feasibility issues)
5. Technological methods and approaches to increase clinical trial management and operational efficiencies
6. New collaborations tools for sponsors and CROs to improve clinical trial operational efficiency
7. Latest innovation for managing investigational product and global clinical supply
   a. Data integrity for electronic records in clinical trials, best practices for:
      I. Managing electronic record interoperability/integration
      II. Monitoring the audit trail and compliance with Part 11
8. Clinical operation considerations in trials with adaptive designs
9. Optimal management and staff organization and resource deployment for clinical operations departments in biopharmaceutical companies of various sizes
10. Considerations and latest developments for common protocol templates
11. Clinical trial regulatory and operational considerations for new treatments: gene and cell therapy, biomarkers
12. Clinical research staff competency requirements and training solutions
    a. Clinical research associates, data managers, medical monitors
    b. Academic research centers
13. Revised ICH E6 R2 requirements: best practices for clinical operations in risk identification, management, and root cause analysis
14. Real World Evidence (RWE) – program designs
    a. Value of RWE in clinical trial decision-making
    b. Variety of trial designs for collection of RWE – operational and regulatory considerations
15. Innovations in enrollment, recruitment, and retention
16. Innovations in central/remote monitoring and site management
17. Global clinical trials and multi-regional clinical trials
    a. Operational challenges and opportunities
    b. Effective execution of global clinical trials
    c. Case studies for large global clinical trials
    d. Technological advances for tracking and managing global clinical trials
18. New approaches and innovations in effectively collaborating with CROs and Sponsors
19. Site level operational challenges in implementation of clinical trial designs
20. Current endpoints and the future of endpoints in selected therapeutic areas
    a. Validation of patient reported outcomes
    b. Clinical outcome measures (FDA); regulatory considerations and patient reported outcomes

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 postmarketing 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, postmarket 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. Data privacy and data protections – how to collect needed data without violating country-specific requirements
2. Integrating data – pros, cons – best practices for sharing clinical trial data
3. The data needs of purchasers and payers in the clinical research enterprise
4. Challenges of real-world data in regulatory submission
   a. Sources
   b. Standards
   c. Uses
   d. Quality
5. FDA's updates on regulations, standards strategy, and initiatives (PDUFA VI, CDMs, new Part 11)
6. Big data - current and emerging technologies, management, and analytics; standard data structures
7. Evolving data standards
8. Artificial intelligence and machine learning and their application in clinical trials
9. Risk-based monitoring – best practices for central monitoring and lessons learned from implementation
10. The evolution of CDM in the light of digital data gathering – changing roles and responsibilities
11. EHR data/eSource, wearable health – opportunities and challenges in integration with clinical trials
12. Role of Real World Evidence – data harmonization and standardization, regulatory and registration considerations, and data quality
13. Risk-based monitoring and the roles and responsibilities of various stakeholders

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 life cycle, stakeholder management, advisory boards, compliance.

Priority Topics

1. Medical affairs role in patient centricity: innovations to impact (e.g., engaging patients' social networks to determine priority patient outcomes to drive medical strategy)
2. Collaboration across the medical affairs ecosystem to advance patient care, including case studies of industry and advocacy groups collaborations; or at the US medical affairs and global affairs/affiliate-level
3. Achieving true customer centricity: roles and innovative ways medical affairs are developing and improving customer experience
4. Utilizing big data (i.e., text analytics, digital listening) into actionable insights that create value for medical teams and informs medical strategy
5. Analyzing and incorporating the medical education grants team and education outcomes data into the medical strategy development process; methods for transferring value from these symposia
6. Applying health economics, real world evidence and outcomes partnerships across medical affairs (e.g., use of RWE in medical information deliverables; MSL communication of RWE; training of managed care liaisons)
7. Biosimilar considerations for medical affairs professionals, including medical information support of biosimilars and future outlook for communicating about biosimilars
8. Defining meaningful metrics to highlight medical affairs value (e.g., medical information, publications, CME, investigator-sponsored research, MSL touch points, KOL activities) and how to ensure they resonate with key internal stakeholders
9. Digital, data, and new technologies in medical affairs for driving customer impact and value
10. Globalizing and regionalizing medical information contact centers
11. Evolution of medical information response delivery channels
12. Clinical trial results disclosure: what have we learned from EMA Policy 0070 implementation and ClinicalTrial.gov postings?
13. CTD regulatory defense strategies: how best to prepare your response to Health Authority queries'
14. Innovative and effective authoring strategies to facilitate accelerated regulatory submissions
15. Best practices for implementing lay summaries and communicating results to patients
16. The role of scientific communications in medical key message development, knowledge

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 life cycle?
- 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. Outcomes of collaboration between industry, patient advocacy groups, and regulators during research and development phases of product development
   a. Operationalizing the outcomes of patient-focused drug development meetings
   b. Workshop proposals encouraged
2. Patient initiatives at FDA
   a. Lessons learned from existing interactions
   b. FDA Patient Representative Program
   c. FDA plans for new initiatives
3. How patient engagement is changing the biopharmaceutical industry's organizational culture: success stories and lessons learned from experience with rare and common diseases
   a. Overcoming internal barriers
   b. Implementation process
   c. Outcomes and results
4. Measuring the impact of PE: the return on engagement (ROE)
   a. Benefits and importance of measuring ROE
   b. Effective tools for measuring impact
   c. Approaches for assessing return for stakeholders, including sponsor/researcher, patient, regulator, and payer
   d. Case studies of measuring ROE in rare and common disease programs
   e. Remaining needs to advance the PE metrics field
5. Beyond the need for multi-stakeholder engagement: so what does it look like?
   a. Precompetitive collaborations, among both patient advocacy groups and industry entities, to advance the field of PE
   b. Effective use of stakeholder mapping techniques to identify partners
   c. Specific examples of executed partnerships
6. Success stories and lessons learned in implementing partnerships to advance awareness and education about and participation in research among communities that are disproportionately impacted, under-represented, and under-served
7. Examples of value-based collaborations implemented after product launch
   a. Partnerships with patients, clinicians, industry, and payers
   b. Product education and medicine adherence
   c. Populations with their first approved therapy
8. Understanding the patient experience using web-based registries and platforms
   a. Different roles of patient advocacy groups in collecting patient-reported data
   b. Utility of data, including impact on development of endpoints and measurement of symptoms
   c. Unique challenges faced by rare diseases
9. Opportunities and challenges in the new era of diagnostics
   a. Companion diagnostics
   b. Next-generation sequencing
   c. Impact on patient outcomes
10. Evolution of patient advocacy groups: a new type of peer and partner
    a. Importance of neutrality and independence
    b. Understanding and addressing potential conflicts of interest
    c. Role of clinicians in this new era of health care
    d. Opportunities and challenges
11. Best practices and lessons learned in patient-focused (patient-centered) medicines development

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.

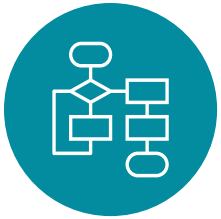
Included Topic Areas

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. Program design considerations in pediatric oncology - the importance of the clinical indication
2. Best practices in early-stage product development decision-making: data sharing and expanded communication of potential toxicity
3. The future of drug development: leveraging artificial intelligence in compound screening, genomics, and evaluating toxicity in the 21st Century
4. Stem cells in tissue engineered products: current challenges and prospects in regenerative medicine
5. Novel paradigms in drug delivery: implications for improved efficacy, patient compliance, and cost savings
6. Can drug development be accelerated? New tools and technologies confront stark realities and necessary regulatory oversight
7. Critical challenges in Phase 1 and early PK studies in rare disease indications and special populations; balancing drug interactions, concurrent illnesses, and background disease in optimizing protocol design
8. Preclinical and early-stage challenges for sponsors, CROs, academics, and regulators in development of personalized medicine products
9. How can the microbiome inform and impact drug development and what challenges does it present to sponsors, testing labs, and regulators?
10. Reconciling FDA and EMEA guidelines for first-in-human (FIH) studies: how to get the most bang for your buck in Phase 1
11. Leveraging novel preclinical animal models for diabetes and other metabolic diseases: informing Phase 1 and ensuring patient safety
12. Integrating postmarket data into current clinical development: lessons learned from real-world patient data
13. The double-edged sword of CAR-T immunotherapy development: patient specificity meets preclinical challenges
14. Goodbye large CRO...hello Niche providers: the growing need and use of small, specialty CROs for complex products
15. When to pull the plug: how to know if your program is in trouble and when to cut your losses
16. Biosimilars: why is the EU so far ahead of the US? What are the key differences in expectations on either side of the Atlantic?
17. Understanding and leveraging the animal rule for development of therapies for serious infectious diseases
18. Drug-device and biologic-device combination products: working with multiple FDA centers and how much is enough?
19. Transitioning a product from academia to the fast-paced world of a biotech: from publications to IND and into the clinic
20. Cellular immunotherapies in oncology: are there really any good animal models and how to get into Phase 1

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 life cycle 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 life cycle planning, and global commercialization considerations.

Priority Topics

1. Leadership capabilities that enable effective project and portfolio management
2. Stakeholder management, including considerations for effective management of strategic partnerships
3. Drug development topics that incorporate project planning elements and considerations
4. Regulatory landscape and evolving requirements that affect project execution
5. Mapping the patient journey through clinical trial participation and impacts on planning
6. Decision-making tools, processes, and approaches
7. Project management skills and capabilities
8. Evaluating asset profiles and strategies for managing portfolio decisions
9. Managing project level risk
10. Portfolio/strategic management

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. How do the changing approaches to clinical research [risk-based monitoring (RBM), quality by design (QbD), technology/cloud, ePRO, eConsent, virtual trials, real world evidence, etc.] affect your QMS/ Quality Management practices
2. ICH E6/E8 renovation: an update on transformation of expectations
3. Vendor qualification and oversight — are current practices working to ensure quality performance?
4. Impact of data governance practices and data standards on data quality: using predictive analytics
5. Impact of quality-by-design approach on clinical trial planning, conduct, and outcomes
6. Risk-based quality management in pharmacovigilance: improving data quality and patient safety, while reducing effort expended on low value activities
7. Best practices for quality risk management in clinical trials

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. Implications for global development strategy
   a. Expedited registration pathways, novel development strategies and novel approvals
      I. Biomarkers/CDx
      II. Real-world data/real world evidence, biomarkers, clinical outcome assessments, including PROs
      III. Novel products, e.g., gene therapy/gene editing, combination products, tissue agnostic products
      IV. Case studies in rare and common diseases
2. Common Protocol Template: content and automation
3. Global harmonization/convergence impact to drug development
   a. Expansion of ICH membership as well as other global harmonization activities (e.g., APEC-RHSC, IMDRF)
   b. Effect of emerging regulations on global development (e.g., IDMP, import/export, CMC)
   c. Effect of emerging regulations on global registration strategies
4. Life Cycle Management
   a. Managing PMR/PMCs in a global environment: best practices on increasing communication, transparency and criteria to manage PMRs/PMCs from different regulators
5. Regulatory considerations for special populations or situations
   a. Pediatrics, orphan drugs, ultra-rare diseases, etc.
   b. Recent legislation to understand impact on global development plans with regard to differences in EU/US approach
6. Innovation and technologic advancements to improve the practice of regulatory affairs
   a. For example, enhancing regulatory intelligence (AI), improving decision-making in regulatory science, the role of policy in affecting change, etc.
   b. Case studies using the multi-stakeholder approach; integrating the patient, advocacy groups, clinicians, KOLs, regulators, and payers in developing regulatory strategy for rare and common diseases
7. Hot topics
   a. Biosimilars – a global update and reducing time to market
   b. Combination products
   c. Complex drug development
   d. FDARA/"UFA"
   e. Expanded access
   f. Ad/Promo
   g. Generics drug review process/priorities
8. Communications about products
   a. Patient-focused drug development versus Health Care Provider drug development: who knows what is really best for patient care?
   b. Global perspective: what is happening in other regions?
9. Labeling: is it time to modernize labeling? – given RWE, PFDD, Pediatrics, and the need for additional information by stakeholders, is it time to rethink the content/format of prescriber and patient labeling and make it more accessible and timely for HCPs and patients [CBE labeling, Patient Medication Information (PMI), e-labeling]?

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 life cycle. The track scope spans from the scientific understanding gained through product and process development to life cycle 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. Opportunities for streamlining post approval life cycle management under ICH Q12
2. CMC challenges for breakthrough therapies and other worldwide accelerated approval programs
3. Expectations for ICH M9 “Biopharmaceutics Classification System Based Biowaivers”
4. Global implementation of new technologies
5. Modernizing and harmonizing inspectional approaches
6. Case studies in drug shortage prevention
7. Understanding and adapting to new regulations for drug-device combination products

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 life cycle. Sessions will explore current statistical thinking which informs policy, regulation, development, review, and life cycle 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. Benefit-risk at the subgroup and patient level
2. Novel data visualization applications
3. Using real world evidence for regulatory decision-making
4. Use of historical controls in clinical trials
5. Drug development informed by the “Patient Voice”
6. Orphan drugs/rare diseases/pediatric drug development

Track 12 | Value and Access

The health care 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, postmarketing professionals, and regulatory affairs professionals.

Included Topic Areas

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

Priority Topics

1. Biosimilars, interchangeables, and non-interchangeable: what are the evidence needs? How will reimbursement impact access?
2. Technology and data solutions to assess value and drive reimbursement (e.g., mHealth topics, and others)
3. Developing and partnering on evidence needs for value assessment, including methods focusing on patient-centered care
4. Evolving payment systems and payers needs for radical personalized medicines with focus on rare diseases, genetic approaches (e.g., CRISPR, gene editing) and impact on reimbursement
5. Value-based contracting: lessons from the field of value-based contracts, indication-based pricing, and bundled payments
6. Comparative effectiveness research and current application in decision-making
7. Innovative models and approaches describing the future of value-based care
8. Early HTA scientific advice: optimizing your clinical development program to support reimbursement and patient access
9. Approaches and methods for using Real World Evidence to increase market access
10. Best practices and approaches for medical monitoring in non-interventional studies (NIS) to ensure health care value

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 **Saturday, September 23, 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 1, 2017.

Please note that DIA and the DIA 2018 Annual Meeting Program Committee 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 2018.

Q: I submitted a topic during the Call for Topics, and it appears under the suggested topics for the DIA 2018 tracks. 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 2018.

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?

A: Yes, a submitter will have the option to complete author information even if they will not be the designee onsite in Boston, MA.

Q: When will I be notified if my abstract has been accepted?

A: Authors will be notified the week of November 1, 2017. 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 1, 2017.