



DIA 2022

GLOBAL ANNUAL MEETING

CHICAGO, IL
JUNE 19–23

CALL FOR ABSTRACTS | Submission Deadline: October 11



DIAGlobal.org/DIA2022

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About the DIA 2022 Global Annual Meeting

Learn. Connect. Collaborate.

As the undisputed leader in the life sciences industry, the DIA 2022 Global Annual Meeting is designed to foster the international exchange of actionable insights to improve health globally through the advancement of lifesaving medicines and technologies. **DIA 2022 is the essential global gathering of industry, regulatory, academia, and patients in one venue, hosting thousands of professionals in the pharmaceutical, biotechnology, and medical device communities.** It is an unparalleled experience combining education and networking opportunities that will elevate your skills and knowledge.

This year, DIA 2022 returns to in-person programming on top of a virtual experience that will bring enhanced opportunities to learn, connect, and collaborate. Either in-person or virtual, you will find yourself deeply involved with experts, regulators, patients, and industry leaders as you work together through the incredible challenges faced today to advance science and improve global health.

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 2022 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 2022 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 2022 tracks [click here](#).

DIA is committed to including the voice of the patient at DIA 2022. 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 - October 11, 2021

Types of Abstracts

There are four types of abstracts you can submit for the Global Annual Meeting, including a **session, forum, presentation, or workshop**. 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-minute session concept delivered lecture-style from the podium.

**Helpful Hint! Plan your submission separately and in advance by using this [session abstract template](#). Read a [sample session abstract](#).*



FORUM

A 60-minute concept designed for panel interaction and attendee engagement.

**Helpful hint! Plan your submission separately and in advance by using this [forum abstract template](#). Read a [sample forum abstract](#).*



PRESENTATION

A 20-minute presentation abstract addressing a specific topic. If selected, this abstract will be combined with other abstracts to create a session. Please note: co-presenters are not allowed.

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



WORKSHOP

A 60-minute workshop delivered in an interactive/simulation or role-playing format.

**Helpful hint! Plan your submission separately and in advance by using this [workshop abstract template](#). Read a [sample workshop abstract](#).*

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

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

Introducing DIA 2022

Submitting your abstract for DIA 2022 adds your voice to the collaboration truths that DIA has long stood for—trusted, neutral, knowledge-exchange that results in better regulation and innovation for patients and the global community at large. The selections that are chosen and those that will await another turn push science forward. More than ever, in this new era of challenge and uncertainty, DIA remains committed to our key tenets:

- That patients are our story
- That we seek to understand
- That collaboration is the skill we hone
- That this collaboration must cross organizations, decades, languages, and boundaries to have true global impact

See you in Chicago!

This year, DIA 2022 returns to in-person programming in Chicago, Illinois! We are focused on ensuring a safe and healthy experience for all of our attendees and will send updates on our protocols as we move through the planning of the event. We prefer our speakers and presenters be with us in Chicago, however we realize travel restrictions may deem your in-person participation to be limited. You will be asked to indicate your preferred delivery method during the abstract submission process.

Insider Knowledge.... from an Insider that has Knowledge on Designing Impactful Sessions

Dear Abstract Submitters (or should I say, Knowledge-Sharers),

Thank you for your interest in being a thought leader at DIA 2022. As you prepare to share your work and motivation for bringing your peers together, I want to impart to you our philosophy on how we educate, share knowledge, and inspire attendees at the DIA Global Annual Meeting.

Today's sessions need to be creative, interactive, unique, and of course, informative—and that means continuing to experiment with new styles of content delivery that gets the audience involved. Meetings, whether in-person or virtual, are now placing the same amount of importance on engagement as they are on content.

The key is in balancing both elements, content and engagement, and selecting delivery methods that honors the content while supporting audience interactivity.

Consider these interactive session and presentation ideas as you prepare to submit your presentation, session/forum, or workshop for DIA 2022:

1. Hold an “Ask Us Anything” session
2. Host a “Talk Show”
3. Facilitate a Debate
4. Audience-Infused Panel Discussions with Polling Tools
5. Gamify Presentations with Polling Tools

If you like these ideas and/or have other interactive ideas for your proposed session(s) or presentation(s), we want to hear them! Within your abstract submission, in the Abstract Details section, include a note. We understand that your note will be very high-level and don't expect a full game plan.

We appreciate your consideration in the educational experience you wish to create for our audience. Our Program Development Team is here to help Session Chairs and Speakers with the planning of their sessions. Throughout the process, we will be providing resources to aid in designing session(s) and tools to consider for audience engagement. Not all interactivity ideas will work for all types of sessions, which is perfect—because providing a variety of ways in which to educate our audience is something we take great pride in for the DIA Global Annual Meeting.

Sincerely,

Heather



Heather Seasholtz, CMP, DES
Director, Americas Operations
DIA

DIA 2022 Tracks



Clinical Safety and Pharmacovigilance



Clinical Trials and Clinical Operations



Data and Technology in Clinical Trials



Medical Affairs and Scientific Communication



Patient Engagement



Preclinical Development and Early-Phase Clinical Research



Project Management and Strategic Planning



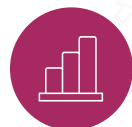
R&D Quality and Compliance



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, advanced therapies, 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. **Update on Regulations and Cross-Industry PV Initiatives:**
 - a. FDA Guidances (especially, Benefit-Risk Guidance to be released in Q4 2021)
 - b. Updates from CIOMS Working Groups
 - c. Updates from ICH- new and ongoing
 - d. Updates from other cross-industry working groups (e.g., TransCelerate, IMI, etc)
 - e. Impact of COVID-19 regulatory and industry collaborations/initiatives/strategies
2. **Special PV Considerations:**
 - a. Immuno-oncology
 - b. Gene therapy
 - c. Pediatrics
 - d. Rare diseases
 - e. Pregnancy
 - f. Biosimilars
 - g. Use of Real-World Evidence (RWE) (e.g., for safety assessments, including for COVID-19 safety assessments)
 - h. Personalized treatments
 - i. Diversity and inclusion in drug-related research and/or safety assessments
3. **Transforming the Drug Safety Organization:**
 - a. From cost center to strategic value provider
 - b. Hot trends and topics in PV audits and inspections
 - c. Diversity and Inclusion in drug safety organizations
 - d. Building a patient-centered drug safety organization
 - e. Qualifications for the new drug safety professional
4. **Benefit-Risk Assessment and Risk Management:**
 - a. COVID-19 pandemic and opioid analgesic abuse
 - b. Sharing learnings externally: publishing results of risk minimization studies
 - c. Impact of COVID-19 on design, implementation, and evaluation of risk minimization strategies
 - d. Integrating risk minimization measures into the healthcare delivery system
5. **Artificial Intelligence in Pharmacovigilance**
 - a. Use in PV: Practical learnings, opportunities, and limitations
 - b. Regulatory challenges and approaches
 - c. Recent advances around the world
 - d. Interpretations by regulators and inspectors
 - e. Wishlist for the future of AI use in PV
6. **Future Directions in Patient Safety**
 - a. Dealing with increasing local safety reporting requirements worldwide
 - b. Challenges in the implementation of local and global risk minimization commitments
 - c. Safety surveillance: methods, data sources, etc.
 - d. Quantitative systems pharmacology for predicting, modeling, and assessing drug safety
 - e. COVID-19 and preparing for future pandemics
 - f. Accumulus and PV
 - g. Drug safety analysis and visualizations
 - h. Experience with implementation of a learning healthcare system for PV and safety
- j. Vaccine safety (e.g., implications of COVID-19 for safety strategies, etc.)
- k. Safety and PV aspects of software as a medical device/combination products
- e. Patient voice in benefit-risk assessment and risk management
- f. Diversity and inclusion in benefit-risk assessment and/or risk management (e.g., supporting countries with fewer resources to help them in designing and implementing patient-centered PV and RM)
- g. Risk communication in the era of COVID-19: What can we learn and apply for PV risk management? How do we handle misinformation? What is the role of patient engagement? How can it affect vaccine hesitancy?
- h. Use of mixed methods and other novel research designs for risk minimization program evaluation
- i. Digital approaches to risk minimization
- j. Ongoing challenge of more useful and meaningful risk minimization effectiveness measurement generally
- k. Treatment decision support for individual patients using shared decision-making tools that reflect patient preferences regarding risks and benefits: What's new in the research? How can we improve shared decision-making tools?

Track 2 | Clinical Trials and Clinical Operations



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

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

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

Included Topic Areas

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

Priority Topics

1. Monitoring: Quality and Compliance in Clinical Operations

- Monitoring plan and risk assessments
- Risk-based monitoring and quality by design
- Quality Tolerance Limits (QTLs): Critical data, parameters, limits—How to define these upfront with limited existing product data
- Proactive monitoring; systems and tools
- Remote processes (remote auditing)

2. Clinical Study/Research Management: The Nuts and Bolts

- Managing research in emerging regions
- Supply chain management (IMP)
- Feasibility and site selection
- Making accurate assessments of protocol complexity
- Building operational flexibility into clinical protocols to be prepared for crisis management
- Risk-based quality management and quality control

3. Innovation in Clinical Trial Design: Pragmatic Trials, Master Protocols, Synthetic Control Arm Trials, Hybrid Trials, Decentralized Trials

- Integration of eSource and electronic health records with EDC
- Electronic clinical outcome assessments (eCOA)
- Incorporating voice of patient in protocol design
- Multimodal data in evolving clinical research
- Modeling outcomes to support clinical development programs

4. Innovation in Partnerships and Collaboration

- Data sharing across pharmaceutical sponsors, regulators, CROs, and academia
- Integrating collaborators from those traditionally outside healthcare/research
- Multi-sponsor trials
- Patient-advocacy-driven approaches

Track 3 | Data and Technology in Clinical Trials



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

- Structured and unstructured data sources
- Data Quality
- Blockchain technology and cloud computing
- Data Standards
- Real-World Data / Evidence
- Mobile / wearable technologies
- Informatic solutions and machine learning
- Endpoints: evolving data requirements to support new endpoints

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

The broad range of data that is generated during biopharmaceutical development, approval, and post-market will be covered in this track including: clinical (including data from electronic health records, wearables, and other mobile apps), and real-world data from large data sets (including registries and national datasets, claims data, and prescription fulfillment).

Priority Topics

1. Harnessing Real-World Data / Evidence

- Data standards
- Data quality/fitness for use
- Study designs
- Regulatory guidance considerations
- Data exchange using common data standards
- Case studies and examples of employing real-world evidence relative to data standards

2. Transformation of the Data Manager to the Data Scientist

- Evolution of clinical data management: merging or separating roles of data manager and data scientist
- Workforce readiness: processes, skills, and experience
- Knowledge to amplify your career

3. Technology and Emerging Data Sources in Clinical Trials

- Effective integration in clinical study process
- Artificial intelligence/machine learning/automation
- Blockchain technology
- Deriving endpoints from wearables, sensors, and novel technology
- Managing and ensuring data validation, quality, and integrity
- eSource opportunities and challenges integrating with clinical trials
- Impact on standard processes

4. Data Source Agility and Risk-Based Approaches

- Case studies demonstrating novel techniques and strategies

- Analytical tools and technologies to support and enable new study models; how to apply risk-based monitoring (RBM) techniques
- How do virtual trials change data management standards and processes?

5. Clinical Trial Research and Data: New and Emerging Standards, Guidance, and Regulations

- ICH M11: Data standards related to standardized protocol template
- GDPR impact on data management practices and processes
- HL7 FHIR Vulcan: Bridging the gaps between clinical care and clinical research data standards
- Modernizing FDA Data Strategy/ EMA Data Guidance
- Cloud-based regulatory submissions and collaboration
- EMA Guideline on computerized systems and electronic data in clinical trials: EMA/226170/2021

Track 4 | Medical Affairs and Scientific Communication



This track will share global insights from medical affairs professionals and medical writers. Sessions will address necessary skills and best practices for compliance in an increasingly cross-functional work environment for the medical affairs, medical information, and scientific communication professional.

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. Health Authority Guidance, Regulations, and Globalization

- EU CTR regulations, ICH, Clinical Transparency, GDPR, etc.
- Identifying impact of COVID-19 in clinical trial documentation and in medical affairs
- Writing for decentralized trials
- Content development, field medical exchange resources, organizational structure, communications, contact center utilization, translation, compliance
- Virtual and hybrid congress management to maximize medical affairs congress presence and deliverables
- Creating submissions that fit multiple regulatory agencies (e.g., US, EU, Japan, China)

2. Creating Strategy and Consistent Scientific Messaging from Clinical Development to Medical Affairs with an Awareness for Diversity, Equity, Inclusion and Health Literacy

- Access to high-quality information
- Education and training for external stakeholders
- Scientific platforms/lexicon
- Cross-functional collaboration
- Protocol and study design development

3. Improving Customer Interactions (Patients, HCPs, Field Medical)

- Omni-channel strategy: Chatbot, websites, interactive content, podcast, social media, etc.
- Innovative patient communications and engagement
- Improving health literacy, increasing palatability of content, and dispelling misinformation
- 360-degree view of the customer: end-to-end navigation and the customer journey

4. Payer Interactions

- HEOR, real-world evidence, dossiers, formulary discussions

- Tailored content needs for key decision makers (e.g., COVID-19)

5. Technology: Systems, Utilization, and Impact of AI, Machine Learning, NLP, etc.

- Implementation of innovative technology globally
- Change management
- Technology innovation/virtual workspace
- Business continuity plan/crisis management
- AI document authoring for clinical study reports

6. Demonstrating Value and Insight Collection

- Collaborating with key stakeholders (e.g., publications, training, medical, early clinical development groups, contact centers, legal, etc.)
- Data mining, insights platforms, data analytics, application of dashboards, and other tools
- Scientific response documents for priority needs (e.g., COVID-19)

- Ensuring Regulatory Compliance and Improving Efficiency and Quality in Regulatory Documents

- Building a quality-minded organization
- New regulations and guidance
- Audit and inspection readiness
- Collaborative authoring, structured content, automated content management, and lean authoring
- Medical, legal, and regulatory (MLR) reviews

7. Leading Teams in Today's Environment

- Diversity, Equity, Inclusion
- Mental Health and Wellbeing
- Flexible working environments and building future organizations
- Developing new talent for regulatory medical writing

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. Getting Strategic: Purposeful Patient Engagement Begins with the End in Mind

- Beyond box-checking:** Whether it's an externally led Patient Focused Drug Development (PFDD) meeting or a Patient Advisory Board, how is your best-practice patient engagement positioned as one element of a bigger strategy to elicit and integrate patient perspectives in small and large trials to improve patient outcomes?
- Fit for purpose:** Designing and scaling a patient engagement activity based on the desired goals. What considerations have been most impactful to build initiative with the end in mind? For example: type of format (e.g., advisory board/focus group, standing council, survey, etc.); duration of engagement; number of patients/perspectives; involvement of advocacy groups in design, implementation, and recruitment.
- Making the whole more than the sum of its parts:** What learnings can you share from starting patient engagement early as a cross-functional initiative, so it informs activities spanning from pre-clinical research to market access (and/or the many steps in between)? Whose partnership did you seek and secure along the way? What challenges and successes have you experienced?
- Defining meaningful endpoints:** How and when is patient input collected to define meaningful endpoints? Which metrics are important to patients vs. industry vs. researchers vs. other stakeholders? Are patient-defined endpoints in line with priorities of other stakeholders? What endpoints are mutually beneficial to measure?

- Diving into data:** Patient Experience Data can be collected in many ways, and FDA is beginning to share its approach to review of these data. Has this impacted the ability to include patients more systematically in design and development? Does early alignment on domains of interest, data standards, and data sharing/contribution agreements help to decrease participant burden and increase the utility and flow of data for various purposes? What other lessons have you learned?

2. Context and Contours: Illuminating Patient Engagement in Different Settings and Disease Areas

- Prevalence:** How does the fact that a condition is rare or prevalent in the population affect patient engagement? Which factors drive patient engagement in rare diseases despite smaller numbers, and how can these be leveraged for other indications?
- Special populations:** How can feedback from children and adolescents be gathered? How have YPAGs, parents, and educational establishments been utilized?
- Patient carer engagement:** Collaborating from the early stages of medicine development
- Geography:** What are some of the practical, pragmatic, and ethical considerations of limiting or expanding patient engagement beyond borders, from gaining a site-specific focus to getting a global set of viewpoints?
- Data and digitalization:** How are decentralized trials [?] patient engagement and vice versa? What is patient acceptance of DCTs?
- Timing:** Whether a condition is chronic or acute may affect the available or optimal

"window" for engaging patients. The question driving patient engagement may also be specific to a point in time, such as developing PROs for early-stage disease vs. end-stage disease. Share examples and perspectives on how to assess timing as a consideration for patient engagement.

- Diversity:** How do patient engagement activities support clinical trial diversity goals? What insights are gained from engaging patients from underrepresented groups on clinical trial design, development of study communications, site-selection strategies, etc., and how do these activities impact enrolling a diverse cohort? What are best practices for reaching and engaging more inclusively, especially for engagement activities that seek to understand disparities in practice, outcomes, or access that may occur by gender identity, race, ethnicity, socioeconomic status, health literacy level, etc.?

3. Scaling Patient Engagement: Moving Across Therapeutic Areas, and More!

- Structure and staffing:** What are your lessons learned about where in the company responsibility for patient engagement is centered and how that function is staffed? Is it centralized or diffused throughout the company? Is it shepherded by one individual per therapeutic area or at a particular stage of development? What type of professional experience best positions someone for success in these roles? How are you building capacity in your organization for more and more meaningful patient engagement? How do you transition crucial relationships and learnings when necessary?

- Training:** How has your enterprise educated staff about this growing expectation for patient perspectives to inform medical product development? How can program and support staff, especially legal and compliance functions, better understand and foster optimal patient engagement activities? Do you have written standards to guide new initiatives? For patient advocacy patients and advocates to prepare them for these new opportunities to share their perspectives?
- Demonstrating return on engagement:** How are you and your collaborators tracking and measuring the outputs and outcomes of patient engagement to demonstrate its impact and value? Can benefits of engagement practices at different stages of the lifecycle be assessed? Ideas for assessing immediate and long-term benefits to the community, the program, and the sponsor are welcome.
- Continuous feedback:** What approaches are most effective to share results with patients who participated in trial design and development or in work at other stages of the lifecycle?

4. "Yes, We Can!" Busting Misconceptions About Patient Engagement and Patient-Focused Medical Product Development

- Policy, regulations, and guidance:** Have you participated in activities to expand knowledge about regulators' expectations for patient engagement practices, or apply existing laws that encourage patient-centered practices (i.e., 21st Century Cures Act) to aid in changing culture or practice at your institution or another? What ideas do you have for

building on existing guidelines to help foster adoption and overcome resistance?

- Precompetitive multistakeholder resources:** Have you developed as part of a regional or global initiative to help de-risk patient engagement? How have these resources been used and what impact did their use have? Publications and case studies involving multiple partners are welcomed.
- Patient organizations:** How have you been able to initiate or lead collaborations with other stakeholders? What tips and lessons learned are broadly applicable to other organizations? Where is the best place to start?
- Managing conflicts of interest:** More and deeper engagement between sponsors and patient organizations can (and has) raised concerns about influence and independence. How is your organization helping define appropriate boundaries and put this conversation in the new context of patient-focused medical product development? What are ways to ensure that collaboration doesn't have unintended consequences for either party?
- De-risking R&D:** How has patient engagement been used as a strategic and systematic tool to de-risk research and development? How have partnerships with the patient community enabled improved research and development outcomes that ultimately benefit both patients and the industry? How are regulators part of this picture? What initiatives have been used to clarify that a product in development serves an unmet need?

Track 6 | Preclinical Development and Early-Phase Clinical Research



Preclinical and early-phase clinical research provides initial dosing and safety data for new drugs. This track focuses on the latest strategies used in early-stage compound selection, updates on safety considerations for both drugs and biologics, how PK/PD affects dosing strategies, and methods to improve data quality and integrity for proper downstream decision-making.

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

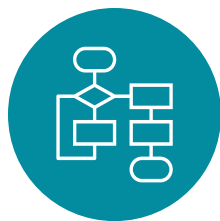
Included Topic Areas

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

Priority Topics

1. **Innovations in Early Development of Vaccines: Translation from Pre-Clinical to Clinical**
 - a. Pre-clinical and early clinical program of vaccine products—differences for cancer vaccines versus infectious disease vaccines
 - b. Translatability of animal data to human data
 - I. Meaningfulness and predictivity of the selected pre-clinical animal model for the human in vivo system
 - II. Optimizing pre-clinical approaches to ensure data quality and informativeness
 - c. Leveraging pre-clinical data (in vitro, in vivo) to predict dose in human
 - d. Quantitative relationship between dose/dosing schedule and immune response
 - e. Pathogen resistance to vaccines and treatment and emergence of new strains (AI opportunities to evaluate and assess impact, strategies for overcoming pathogen resistance); regulatory landscape and considerations for vaccines development around the world—have we lowered the bar for approval?
 - f. Leveraging lessons learned during COVID-19 vaccine development to inform pre-clinical decisions that lead to efficiency in clinical conduct
 - g. Lymphadenopathy (LAP) in vaccine development—development challenges and safety considerations
2. **Diversity, Equity, and Inclusion in Early Drug Development**
 - a. Clinical and scientific importance of diversity in omic studies for discovery science and early clinical development
 - b. Strategies, best practices, and case examples to include more diversity in early drug development to advance discovery and pre-clinical work
 - c. Engaging institutional review boards (IRBs) and independent ethics committees (IECs) on diversity, equity, and inclusion efforts following the pre-clinical phase of the drug development lifecycle
3. **What's New in Gene Therapy**
 - a. Leveraging AI to predict complications in vector integration
 - b. Understanding durability of effect in gene therapy
 - c. Considering the patient journey
 - d. Pre-clinical models for reliable prediction of efficacy and toxicity
 - e. Existing regulatory frameworks and challenges for pre-clinical development and early phase clinical trials
4. **What's New in Gene Editing**
 - a. Recent advances in the field
 - b. Off-target editing: estimating, predicting, and interpreting impact on treatment
 - c. Existing regulatory frameworks and challenges for pre-clinical development and early-phase clinical trials
 - d. Pre-clinical models for reliable prediction of efficacy and toxicity
5. **Innovative New Models and Methods for Medical Product Development**
 - a. Accelerating pediatric therapeutic development
 - b. Model informed drug development
 - I. Leveraging in silico technology to predict toxicity and safety risks
 - II. Value of QSP models to facilitate key decisions in drug development
 - c. 3D organ models for novel pre-clinical testing
6. **Early Development Decisions and Mitigating Challenges in Rare Disease Drug Development**
 - a. Regulatory considerations and decision-making when mechanism of action is not understood
 - b. Prolong new drug life cycle with 505(b)(2) path—optimizing early decision-making to avoid product development failures
7. **Precision Medicines in Early-Phase Clinical Development**
 - a. Strategies for precision dosing
 - b. The use of novel technologies and overcoming scientific and regulatory challenges
 - c. The development and use of biomarkers and companion diagnostics

Track 7 | Project Management and Strategic Planning



This track will illustrate best practices to improve project and program execution, strategic planning, and portfolio management. Sessions will highlight how project managers can be strategic leaders, think creatively and evolve to help teams deliver desired outcomes.

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

Included Topic Areas

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

Priority Topics

1. **Project Management's Role in Influencing Diversity and Inclusion in Building Teams – Engagement, Mentoring, and Equality**
2. **Leveraging Data and Analytics for Strategic Planning and Portfolio Management**
3. **Doing More with Less**
 - a. Perspectives on how to think creatively/ outside the box to achieve business objectives with limited resources
 - b. Perspectives from different organizational types and sizes (e.g., big pharma, biotech, mid-size pharma)
4. **Project Management as a Career**
 - a. How to grow and develop in your current role
 - b. What does Project Management look like across the healthcare continuum (examples of how Project Management principles are applied in different organizations or functions)
 - c. How to grow your PM role strategically
 - d. Being successful working remotely or in a hybrid team model
5. **Project Management Fundamentals (processes, tools, methodologies, skills, emotional intelligence, leadership, managing uncertainty, etc.)**

Track 8 | R&D Quality and Compliance



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

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

Included Topic Areas

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

Priority Topics

- 1. Quality Risk Management: How to Balance Risk and Resources**
 - a. The role of good data governance in promoting clinical trial quality
 - b. Quality Analytics: Strategies for using advanced analytics for quality assurance to improve efficiency, effectiveness, and continuous improvement including use of novel approaches (e.g., machine learning, artificial intelligence, real-world evidence [RWE])
- 2. Ensuring Data Quality and Data Integrity**
 - a. Anomalous data identified: how to further evaluate, understand potential impact, and determine when and what further actions are needed
 - b. Role of electronic systems audit trail data and control of system access in monitoring for GCP compliance
 - c. Understanding investigations, root cause, and implementing an effective CAPA system
 - d. Assessing the reliability of real-world data (RWD)/RWE in the absence of access to source data
- 3. Pharmacovigilance Quality: Optimizing Data Collection to Optimize the Benefit-Risk Profile**
 - a. Assuring effective implementation of risk minimization and control of post-authorization safety studies
- 4. Effective Oversight Strategies: Importance in Clinical Development**
 - a. CRO and vendor oversight
 - b. Risk-based monitoring and its impact on improving clinical trial execution, data quality, and safety of trial participants
 - c. Role of centralized monitoring and centralized quality-assurance activities such as analytics to improve quality and compliance
- 5. Quality Innovation: What Does Clinical Quality Look Like in the Development of Innovative Products?**
 - a. Cell therapies or other nontraditional biopharmaceutical products
 - b. Innovative trial design (e.g., decentralized trials)
- 6. Maintaining GCP During Pandemic Circumstances and Using Lessons Learned to Improve Clinical Trial Conduct Moving Forward**
 - a. Remote and off-site quality control and quality assurance: strategies for monitoring and auditing when travel and on-site review is restricted
 - b. Using good risk assessment/management practices to guide decisions on clinical trial conduct
 - c. Challenges and solutions in obtaining consent during pandemic conditions
 - d. Expanding risk-based monitoring methods (e.g., right fit SDV/SDR, remote monitoring, centralized monitoring)
- 7. Quality Culture:**
 - a. Driving quality and compliance through strategic approaches and critical thinking across the organization to meet the changing landscape
 - b. Competencies needed by quality professionals of the future
- 8. New Approaches to Inspections:**
 - a. Collaboration and cooperation across stakeholders to verify quality and compliance through remote, off-site, and record-sharing approaches
 - b. Other novel approaches including quality analytics

Track 9 | Regulatory



This track is composed of sessions addressing global laws, regulations, guidelines, and guidances that govern prescription biopharmaceutical and device product development, approval, and maintenance. Representatives from FDA, Health Canada, NMPA, PMDA, EMA, MHRA, European Health Authorities and ICMRA authorities, and other regulatory experts will provide global updates, insights, and discussion on current issues through interactive forums. Themes commonly revolve around Global Regulatory Changes and Impact on Global Development Strategies, Global Harmonization/Convergence and Impact on Drug Development and Advances and Innovations to Improve the Practice of Regulatory Affairs, and Regulatory Hot Topics are always prominently featured.

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. Experience with and Regulation of Innovative Approaches to Clinical Trial Design**
 - a. Complex Innovative Designs, including Master Protocols
 - b. Model-Informed Drug Development
 - c. Patient-focused medical product development and patient experience data collection
 - d. Real-World Evidence/Data for use in regulatory decision-making
 - e. Regulators' acceptance of new trial design and conduct, as a result of COVID-19
- 2. Global Development and International Harmonization, Convergence, Reliance, and Cooperation**
 - a. Impact of multiregional clinical trials on global development strategies
 - b. Updates on ICH, IMDRF, ICMRA, WHO, and other harmonization, convergence, and reliance efforts
 - c. Intersection of harmonization, convergence, and reliance efforts
 - d. Effect of emerging regulations on global registration strategies
 - e. Health authority cooperation initiatives, i.e., Project ORBIS, ACCESS Consortium
- 3. Regulatory Topics of Public Health Importance**
 - a. COVID-19 vaccines, therapeutics, and diagnostics development lessons learned and future strategies
 - b. Antimicrobial resistance
 - c. Diversity and inclusion in clinical trials
- 4. Labeling**
 - a. Enhancing information for patients and healthcare providers
 - b. Labeling modernization efforts, including electronic
 - c. REMS and innovative approaches to ensuring patient safety
- 5. Review Modernization**
 - a. US FDA User Fee reauthorization updates
 - b. Electronic submissions, i.e., CTD updates, cloud-based submissions
 - c. Review efficiency initiatives, i.e., RTOR
 - d. Health Authority and sponsor drug development interactions
 - e. New tools health authorities are using to review big data
 - f. Clinical trial transparency initiatives
 - g. Uses of Expedited Programs
- 6. Regulatory Initiatives to Increase Competition**
 - a. Generic drug and biosimilar updates, i.e., GDUFA, BsUFA, emerging policies
 - b. Global generic drug and biosimilar drug development
- 7. Latest Regulatory Developments in Cutting-edge Science**
 - a. Global regulatory considerations for special populations or situations (e.g., rare/orphan, pediatrics, women, etc.)
 - b. Cell and Gene Therapy and Regenerative Medicine Advanced Therapies
 - c. Rare disease endpoint development
 - d. Precision and individualized medicine
 - e. Innovative approaches to drug delivery and drug-device combination products
- 8. Regulatory Considerations for Digital Health in R&D**
 - a. Decentralized clinical trials
 - b. Digital endpoints
 - c. Strategic and technical considerations (i.e., data privacy, IT security, data management, V3, qualification) in the use of digital health technology tools in drug development
 - d. Use of Artificial Intelligence and Machine Learning

Track 10 | Regulatory CMC and Product Quality



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

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

Included Topic Areas

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

Priority Topics

1. Cooperation and Alignment Among Health Authorities to Facilitate Efficient Post-Approval Manufacturing Changes
2. Planning for the Worst: Capacity Planning and Manufacturing Execution to Avoid Drug Shortages
3. New Global Approaches for CMC Dossier Consistency, Efficiency, and Communication
4. Rethinking Fundamental ICH CMC Guidelines: Analytical Procedures, Stability, Specifications, and Risk Assessment
5. Science and Manufacture of New Modalities: How Are They Different From Traditional Biologics and Small Molecules?
6. Efforts Toward Global Convergence of CMC and GMP Expectations
7. Key Regulatory Learnings on Manufacturing Quality and Product Supply During the COVID Pandemic
8. Remote GMP Assessments, Inspections, and Audits: Here to Stay?

Track 11 | Statistics



This track will focus on topics of practical and theoretical statistical interest for professionals who work with medical products, including pharmaceuticals, biologics and biosimilars, combination products and devices, and generics throughout their lifecycle. Sessions will explore topics related to current statistical thinking which inform policy, regulation, development, review, and lifecycle management of medical products in the context of the current scientific and regulatory environments. A new aspect of the track is data science, a multidimensional area with the two major dimensions of curation and analysis. This track is focused on the **analysis dimension**, including analytics and predictive analytics.

DIA recommends this track for: biostatisticians, data scientists (analytics), 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. Using Real-World Evidence for Regulatory Decision-Making

- a. Pragmatic trials
- b. Machine/Targeted learning
- c. Role and application in rare disease and less common disease areas

2. Application and Experience with Novel Clinical Trial Designs

- a. Master protocols and platform trials
- b. Seamless/enrichment designs
- c. Bayesian design
- d. Leveraging external information
- e. Regulatory experience
- f. Simulation best practices

3. Safety and Benefit-Risk

- a. Safety and benefit-risk planning (e.g., program-wide evaluation)

- b. Quantitative benefit-risk approaches
- c. How statistics can inform risk-mitigation strategies

4. Communication and Collaboration

- a. Discussion of regulatory agency guidances and recommendations
- b. Challenges and opportunities in global harmonization
- c. Between analytic data scientists and biostatisticians

5. Estimands and Sensitivity Analyses

- a. Communicating the concept of estimands to clinical colleagues and other disciplines
- b. Case examples and shared experience in implementation
- c. Estimands for safety

6. Data Visualization

- a. Application and role of graphics in late-phase clinical trials
- b. Application to safety assessment
- c. Application in real-world data

7. Precision Medicine

- a. Subgroup identification
- b. Role of biomarkers in precision medicine

8. Dose-finding

- a. Dosing in non-oncology drugs
- b. Trial design and exposure-response analysis for dosing recommendations
- c. Case examples and shared experience in application of MCPMOD

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. Value and access to medicines are complex issues that require analysis from health economic and philosophical perspectives. The Value and Access track will bring together global regulators, industry leaders, academics, patients, and payers who will facilitate discussions and address questions such as:

- What information and evidence are being used to define value?
- What are the ethical considerations when determining access to medical products?
- Do strategies that increase diversity and inclusion in clinical trial research improve access to medicines? 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, bioethicists, health economics outcomes researchers, health economists, statisticians, data modelers, clinical researchers, post-marketing professionals, and regulatory affairs professionals.

Included Topic Areas

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

Priority Topics

- 1. Paying for What Works: Value-Based Contracting Between Payers, Manufacturers, and Providers—Where Do We Go from Here?**
 - a. Value-based contracts and subscription models within state
 - b. Paying for outcomes within Medicare and Medicaid
 - c. How VBCs have panned out for pharma and commercial plans
- 2. Planning Studies to Meet Both Regulator and Payer Needs**
 - a. Choosing endpoints that matter for coverage decisions and ensuring access
 - b. Balancing the needs of clinical trial participants versus commercial outcomes
 - c. Payer/regulator engagement within studies
 - d. FDA and CMS: Parallel Review
- 3. Pricing and Access Determinations: When and How to Engage Stakeholders (patients, payers, HCPs, etc.) During Drug Development Process and During Formulary Decisions?**
 - a. Potential options to engage and solicit input during drug development
 - b. Engaging stakeholders during development of pricing
 - c. Engaging stakeholders during development to ensure equitable access to products
- 4. Impact of Value Frameworks and Evidence-Based Pricing (with ICER, NICE)**
 - a. Potential impact on overall pricing decisions
 - b. Promising strategies and considerations
- 5. Helping Support Access to Treatments for Rare Diseases in Developing Countries**
 - a. Policy update on drug pricing: regulations and legislation
- 6. Using Real-World Evidence for Real-World Payment**
 - a. How can real-world data drive reimbursement and/or increase market access?
 - b. What real-world data demonstrates “value” to both the patient and sponsor?
 - c. Who “owns” data when the patient changes plans, stops treatment, or is “cured”?
 - d. Strategies for data sharing, database linking (e.g., EMR-claims), and maximizing EMR data
 - e. Strategies for the ethical collection, curation, and analysis of data
- Strategies to enhance clinical research in developing countries**
- Key barriers to address with healthcare disparities**
- Promising pricing and access strategies (e.g., COVID-19, gene therapy, rare diseases)**

Track 13 | Professional Development



The Professional 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. Fostering Innovation

- a. Creating psychological safety in teams: trust, continuous learning mindset, fail fast
- b. Rank and file quantifying risk and benefit
- c. Lean start-up methodology
- d. Design thinking: solving the right problems; user-centric solutions; includes tools such as empathy mapping, user personas
- e. Patient engagement: inclusion of patients in design of meaningful solutions/outcomes, not just protocol design (what's the next wave of innovation here?)
- f. Project post-mortem methodology
- g. Growth mindset versus fixed mindset

2. Successfully Managing Your Professional Development

- a. 70/20/10 model
- b. Pinpointing your passion
- c. Making lateral moves: – Career Lattice versus Career Ladder!
- d. Upskilling in the era of constant change and the 4th digital revolution
- e. Identifying skills of the future in life sciences (RWE, decentralized trials, serialization, digital savvy/literacy, “Lightning round”?)

- f. Personal accountability
- g. Gaining mentorship and sponsorship
- h. New ways to learn e.g., microlearning

3. Leading Change: What It Takes to Successfully Transform

- a. Methodology: change management and leadership (2 related and distinct levers)
- b. Key skills/behaviors: adaptability, empathy, vulnerability, inspiring and motivating, strategic communications and storytelling

4. Wellbeing/Mindfulness

- a. Managing pressures of remote work/hybrid working
- b. Practicing mindfulness
- c. Powerful and strategic prioritization

5. Optimizing Hybrid Working Through Exploration of New Engagement Platforms and Tools (beyond MS Teams, Zoom, Webex); e.g., Mural, etc.

6. Decision Making/Data-Driven

- a. Various decision-making models for different decision-making needs

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 DIAglobal.org/Abstract. The deadline for abstract submissions is **October 11, 11:59PM ET**. This deadline will not be extended. Please note: once on the DIA abstract submission homepage, you must select the general session link.
2. Submitted abstracts must not overtly endorse or recommend a specific product or service. To review DIA's Policy Concerning Promotion of Products and Services from the Podium at DIA-sponsored Programs, [click here](#).
3. Proposed abstract title must reflect the abstract content accurately and concisely.
4. Co-presenters, including Co-chairs, will not be allowed.

Notification Date

Submitters will be notified of the status of each abstract by the end of January.

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

Abstract Submission Tips and Tricks

- Do not wait until the last day to submit an abstract. There is usually very high traffic on the website and you want to avoid the risk of any technical difficulties.
- Do not use the “back” button during the submission process.
- Be certain to click “Submit” at the end of the process for a confirmation of receipt. If you do not get confirmation of receipt, DIA did not receive your abstract.
- Review our [submission site process document](#) before logging in.

Questions? Contact DIA at AnnualMeetingProgram@DIAglobal.org

Frequently Asked Questions

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

Q: I submitted a topic during the Call for Topics, and it appears under the suggested topics for the Global Annual Meeting. Do I still have to submit a session or speaker abstract?

A: Yes, you must submit an abstract to be considered as a chair or speaker for DIA 2022.

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
- Plans for interactivity between the speakers and audience

Q: May an author submit more than one abstract?

A: Authors may submit multiple abstracts. *Do not submit the same exact abstract more than once.*

Q: What information is required from the author?

- A:**
- Full contact information
 - Participant disclosure information and speaker authorization for use of presentation materials, which allows DIA to distribute your presentation to registrants of the Global Annual Meeting

Q: Can there be more than one author name?

A: Only one author name may be submitted.

Q: May I include or recommend an additional speaker name for the topic in which I am interested?

A: You may recommend an additional speaker(s) for a session, forum, or workshop only.

Q: Do I have to use the [DIA website](#) to submit the abstract?

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

Q: Are there abstract templates or samples available?

A: Yes, there is a sample abstract as well as a form that you may use to prepare your abstract in advance.

[Session abstract template](#)

[Session abstract sample](#)

[Forum abstract template](#)

[Forum abstract sample](#)

[Workshop abstract template](#)

[Workshop abstract sample](#)

[Presentation abstract template](#)

[Presentation abstract sample](#)

Q: May someone submit the abstract on my behalf?

A: 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 Chicago, IL or virtually present.

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

A: Authors will be notified by the end of January. 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 January 24.