



DIA 2023
GLOBAL ANNUAL MEETING
BOSTON, MA | JUNE 25-29

ILLUMINATE

CALL FOR ABSTRACTS

EXTENDING THE CALL FOR ABSTRACTS TO **TUESDAY OCTOBER 11**
so you have an opportunity to submit all your great ideas to ILLUMINATE
the stage at DIA Global Annual Meeting 2023



DIAGlobal.org/DIA2023

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About the DIA 2023 Global Annual Meeting

Illuminate:

As the undisputed leader in the life sciences industry, the DIA 2023 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 2023 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. The meeting will empower expertise by bringing forward expert knowledge and empower collaboration by creating opportunities to work collaboratively toward solutions.

DIA encourages abstracts that highlight future trends; offer unique ideas; share interesting case studies; foster diversity, equity, and inclusion; and accelerate innovation. The goal of the DIA 2023 Global Annual Meeting is to amplify different voices, recognizing expertise across the globe, bring together experts to solve problems, and reimagine current processes to enhance health and well-being. We welcome abstracts that think broadly and boldly about the future of healthcare, as well as those that shine a light on the tactical and practical skills necessary for effective healthcare product development.

DIA 2023 will offer in-person programming that will bring enhanced opportunities to learn, connect, and collaborate. 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 2023 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 2023 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 2023 tracks [click here](#).

DIA is committed to including the voice of the patient at DIA 2023. 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.

Deadline is October 11, 2022 11:59PM ET

Types of Abstracts

There are four types of abstracts you can submit for DIA 2023, including a session, forum, 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-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](#).*



WORKSHOP

A 60- or 90-minute workshop delivered in an interactive/simulation or roleplaying format. A limited number of workshops will be selected as “solution rooms,” providing a neutral forum for open discussion, focusing on specific topics relevant to the DIA community to explore. Solution rooms encourage debate, sharing of diverse viewpoints, and delving into new ideas and solutions, with the goal of a summary document, publication, framework, or other tool that is published by DIA and shared with meeting attendees and DIA membership.*

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



SHORT COURSE

A Short Course is a “hands-on”, interactive learning experience for a group of 25-50.

- A half-day short course consists of three hours and 15 minutes of instruction, and will have a lead instructor and no more than one co-instructor
- A full-day short course consists of six hours and 30 minutes of instruction and the short course will have a lead instructor and no more than two co-instructors

**Helpful hint! Plan your submission separately and in advance by using this [short course abstract template](#).*

The abstract author is considered the session chair and will be responsible for the following:

- Adhering to the program development policies and guidelines
- Meeting program development timelines
- If chairing a program offering:
 - o 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)
 - o Communicating with speakers regarding their role in the session and reviewing presentation materials; PowerPoint presentations are required from each speaker
 - o Managing the session, including the facilitation of audience questions and answers from the podium
- If leading a workshop:
 - o Ensuring the workshop provides onsite learning in the form of activities or demonstrations
 - o Ability to facilitate 75-100 attendees for a workshop

Introducing DIA 2023

Submitting your abstract for DIA 2023 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 Boston!

With the theme of *Illuminate* DIA's global network transforms professional expertise into actionable progress for all. The goal of the DIA 2023 Global Annual Meeting is to amplify different voices, recognize expertise from across the globe, bring together experts to solve problems and reimagine current processes to enhance health and well-being.

We are focused on ensuring a safe and healthy in-person meeting experience for all of our attendees in Boston.

Insider Knowledge...

Thank you for your interest in being a thought leader at DIA 2023. As you prepare to share your work and motivation for bringing your peers together, please note DIA's 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, are now placing the same amount of importance on engagement as they are on content. We are looking for solution-focused content that encourages participants to problem-solve and find practical applications to an issue.

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 ideas as you prepare to submit your presentation, session/forum, or workshop for DIA 2023:

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 Sessions with Polling Tools

If you like these ideas and/or have other interactive ideas for your proposed session(s), forum(s), and workshop(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.

DIA 2023 Tracks



Clinical Safety and Pharmacovigilance



Clinical Trials and Clinical Operations



Data and Technology



Medical Affairs and Scientific Communication



Patient Engagement



Translational Sciences and Precision Medicine



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 (International Council for Harmonisation) "E2" guidelines to developing markets; benefit-risk assessment and management; epidemiologic studies and impact on labeling; safety considerations for combination products, medical devices, generic products (including biosimilars), and advanced therapies; companion diagnostics; pharmacovigilance audits/inspections; use of digital technology for risk identification, minimization, and communication; patient-centric labeling and risk minimization methods; application of artificial intelligence to pharmacovigilance; generating meaningful insights on medical product safety from social media and other new data sources; optimizing the global pharmacovigilance footprint (including local safety offices and partners); and considerations for signal detection and management across the product lifecycle. Topics related to bioethical issues in clinical safety and pharmacovigilance.

Priority Topics

1. **Update on Regulations and Cross-Industry PV Initiatives**
 - a. FDA Guidances
 - 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, ICMRA (International Coalition of Medicines Regulatory Authorities), etc.), including PHUSE and other initiatives regarding grouping of adverse event terms
 - e. Recent impact of COVID-19 of regulatory and industry collaborations/initiatives/strategies
 - f. Cross-industry and regulatory: AE (Adverse Events) groupings in safety
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) for safety assessments, including for COVID-19 and monkeypox
 - h. Personalized treatments
 - i. Diversity and inclusion in drug-related research and/or safety assessments: How representative is our safety data?
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. Increasing representation of safety voices beyond the US and Europe
 - e. Building a patient-centered drug safety organization
 - f. Qualifications for the new drug safety professional
 - g. Maintaining safety and compliance in self-managed organizations
 - h. TransCelerate PVA (Personal Values Assessment) agreements survey
 - i. Organizational "merger" of drug safety and device safety
4. **Benefit-Risk Assessment and Risk Management**
 - a. COVID-19 pandemic
 - b. Opioid analgesic abuse
 - c. Sharing learnings externally: publishing results of risk minimization studies
 - d. Impact of COVID-19 on design, implementation, and evaluation of risk minimization strategies
 - e. Integrating risk minimization measures into the healthcare delivery system
 - f. Patient voice in benefit-risk assessment and risk management within industry and regulatory agencies
 - g. 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)
 - h. Safety and risk management in rural and underserved areas, for patients in clinical studies and routine medical practice [Note: This topic was submitted by Track 2, not safety specific.]
 - i. Risk communication and future pandemics (industry and regulator view): 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?
 - j. Use of mixed methods and other novel research designs for risk minimization program evaluation
 - k. Digital approaches to risk minimization
 - l. Ongoing challenge of more useful and meaningful risk minimization effectiveness measurement generally
 - m. Treatment decision support for individual patients using shared decision-making tools that reflect patient preferences regarding risks and benefits: What is new in the research? How can we improve shared decision-making tools?
5. **Artificial Intelligence in Pharmacovigilance**
 - a. Practical examples: opportunities, benefits, and limitations
 - b. Regulatory challenges and approaches
 - c. AI in Software as a Medical Device
 - d. Interpretations by regulators and inspectors
6. **Future Directions in Patient Safety**
 - a. Dealing with increasing local safety reporting requirements (e.g., SUSAR submission) worldwide including low- and middle-income countries
 - 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 visualization serving the needs of industry and regulators
 - h. Experience with implementation of a learning healthcare system for PV and safety
 - i. Reimagining a safety submission: Rolling integrated safety summary, interactive safety
 - j. Wish list for the future of AI use in PV

Track 2 | Clinical Trials and Clinical Operations



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

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

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

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

Included Topic Areas

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

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

Priority Topics

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

1. The Evolution of Study Endpoints

- a. Endpoint science (how to select, validate, and measure endpoints)
- b. Deriving endpoints from wearables, sensors, and novel technology
- c. eCOA/ PRO

2. Clinical Study/Research Management

- a. Managing research in emerging global regions
- b. Making accurate assessments of protocol complexity and participant burden
- c. Planning for and managing mid-study disruption (natural, political, etc.)
- d. Incorporating change management strategy into clinical trial planning (DCT (Decentralized Clinical Trials) adoption, etc.)
- e. Making clinical trials more accessible to more participants
- f. Data-driven feasibility assessment and modeling for trial planning, optimization, and execution
- g. Applications of artificial intelligence, natural language processing, and machine learning in clinical trial conduct: beyond theory and into practice
- h. Considerations for supply chain integrity for decentralized trials and in times of disruption

3. Innovation in Clinical Trial Designs

- a. Pragmatic Trials
- b. Decentralized Trials
- c. Master Protocols
 - i. Umbrella Trials
 - ii. Basket Trials
 - iii. Platform Trials
- d. Applications of real-world data in clinical trial design (including synthetic control arms)
- e. Lessons learned as "novel" designs become more common

4. Innovation in Partnerships and Collaboration

- a. Data sharing across pharmaceutical sponsors, regulators, CROs, and academia
- b. Integrating collaborators from those traditionally outside healthcare/ research
- c. Designing and managing multi-sponsor trials (e.g., platform studies)
- d. Real world data collaborations in external control arms, market access studies, and pragmatic trial designs
- e. Using real-world data to enhance understanding of the patient's journey
- f. Leveraging industry consortia

5. Clinical Development Program Planning

- a. Planning for clinical development programs rather than individual studies
- b. Strategies to save time and reduce costs in end-to-end clinical development
- c. Best practices for working with patients and patient advocates on drug development programs
- d. Biomarker selection, development, and implementation strategies
- e. Begin with the end in mind: Obtaining and considering stakeholder needs throughout Evidence Generation Planning

6. Next Generation Site/Investigator Collaboration

- a. Implementation of decentralized trials at the ground level
- b. System integration best practices
- c. Strategies to influence diversity, equity and inclusion in trial enrollment and patient engagement
- d. Managing modern site delivery needs (resourcing, compensation, system overload)
- e. Site network/consortia engagement strategies
- f. Identifying, training, and initiating sites in underserved regions

Track 3 | Data and Technology



Innovative technologies are improving efficiency in the collection of data from clinical trials through the product development lifecycle to patients. This track focuses on recent developments in clinical data curation, data development, and harnessing data across the product lifecycle 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 / Real-World Evidence
- Mobile / wearable technologies
- Informatic solutions and machine learning
- Data visualization
- Endpoints: evolving data requirements to support new endpoints
- Diversity, Equity, and Inclusion – strategies to ensure representative and unbiased data?

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, 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. Topics related to bioethical issues in data and technology are also welcome and may be considered for a special track in the meeting.

Priority Topics

- 1. Harnessing Real-World Data and Real-World Evidence**
 - a. Data standards
 - b. Data quality/fitness for use
 - c. Study designs
 - d. Regulatory guidance considerations
 - e. Data exchange using common data standards
 - f. Case studies and examples of employing real-world evidence relative to data standards
- 2. Transformation of the Data Manager to the Data Scientist and Steward**
 - a. Evolution of clinical data management: merging or separating roles of data manager and data scientist
 - b. Enhanced collaboration of data sharing across partner organizations and health authorities
 - c. Workforce readiness: processes, skills, and experience
 - d. Knowledge to amplify your career
- 3. Technology and Emerging Data Sources**
 - a. Effective integration in clinical study process
 - i. Artificial intelligence, machine learning, automation
- 4. Data Source Agility and Risk-Based Approaches**
 - a. Case studies demonstrating novel techniques and strategies
 - b. Analytical tools and technologies to support and enable new study models; how to apply risk-based monitoring (RBM) techniques
 - c. Applications of Natural Language Generation/Processing Techniques/Tools
 - i. Blockchain technology
 - ii. Deriving endpoints from wearables, sensors, and novel technology
 - iii. Managing and ensuring data validation, quality, and integrity
 - iv. eSource opportunities and challenges integrating with clinical trials
 - c. Digital solutions for remote monitoring including SaMD
 - i. Impact on standard processes
 - d. Decentralized trials: collection sharing and standardization of data
- 5. New and Emerging Standards, Guidance, and Regulations Impacting Data, Data Standards, and Technology**
 - a. ICH M11: Data standards related to standardized protocol template
 - b. GDPR impact on data management practices and processes
 - c. cHL7 FHIR (Fast Healthcare Interoperability Resources) Vulcan: Bridging the gaps between clinical care and clinical research data standards
 - d. Modernizing FDA Data Strategy/ EMA (European Medicines Agency) Data Guidance
 - e. Cloud-based regulatory submissions and collaboration
 - f. Structured Data Submissions
 - g. EMA Guideline on computerized systems and electronic data in clinical trials: EMA/226170/2021
 - c. How do virtual trials change data management standards and processes?

Track 4 | Medical Affairs and Scientific Communication



This track will share global insights from medical communication professionals, across the industry. Sessions will address best practices and emerging trends for delivering value across internal and external customers and collaborators. The aim of this track is enhancing cross-functional professional skillsets, including project management and leading effective teams.

DIA recommends this track and associated sessions to professionals involved in regulatory, scientific, and publication writing as well as medical communications and medical information professionals.

Included Topic Areas

Medical information; medical/omnichannel engagement; medical communication; regulatory writing; medical affairs roles throughout product lifecycle, internal and external customer management. Topics related to bioethical issues in medical affairs and scientific communication are also welcome and may be considered for a special track in the meeting.

Priority Topics

- 1. Health Authority Guidance, Regulations, and Globalization**
 - a. Response to EU (European Union) CTR (Clinical Trial Regulation) regulations, ICH, Clinical Transparency, GDPR, CTIS (Clinical Trials Information System) compliance, etc.
 - b. Best Practices for Protocol Writing to Accommodate Estimands
 - c. Stand-alone submissions for ex-US health authorities
 - d. Success stories/lessons learned from accelerated submissions with lean writing
 - e. Development of the FDA assessment aid
- 2. Creating Strategy and Consistent Scientific Messaging from Clinical Development to Medical Affairs with an Awareness for Diversity, Equity, Inclusion and Health Literacy**
 - a. Access to high-quality information
 - b. Education and training for external stakeholders
 - c. Scientific platforms/lexicon
 - d. Cross-functional collaboration
 - e. Protocol and study design development using real-world evidence (RWE)
- 3. Improving Customer Interactions (Patients, HCPs, Field Medical), Payer interactions**
 - a. 360-degree view of the customer: end-to-end navigation and the customer journey (NOTE: priority topic)
 - b. Omni-channel implementation success stories: websites, interactive content, podcast, social media, etc.
 - c. Innovative patient communications and engagement
 - d. Improving health literacy, increasing palatability of content, and dispelling misinformation
 - e. Returning individual participant results in clinical trials
- 4. Technology: Systems, Utilization, and Impact of AI, Machine Learning, NLP (Natural Language Processing), etc.**
 - a. Implementation of innovative technology globally
 - b. Change management
 - c. Technology-enabled patient narrative creation
 - d. Technology innovation/virtual workspace
 - e. Business continuity plan/crisis management
- 5. Ensuring Regulatory Compliance and Improving Efficiency and Quality in Regulatory Documents**
 - a. New regulations and guidance
 - b. Collaborative authoring, structured content, automated content management, and lean authoring
 - c. Medical, legal, and regulatory (MLR) reviews
- 6. Leading Teams in Today's Environment**
 - a. Communication, Coaching and Managing distributed teams (in-house, hybrid, distributed)
 - b. Diversity, Equity, Inclusion
 - c. Flexible working environments and building future organizations
 - d. Managing 3rd party medical writing support
- f. AI-enabled key message generation in efficacy**

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 (Medical Science Liaison)), 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. Topics related to bioethical issues are also welcome and may be considered for a special track in the meeting.

Priority Topics

- Getting Strategic: Purposeful Patient Engagement Begins with the End in Mind**
 - Beyond box-checking: Whether it is 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? How does the publication of recent guidances, such as for earlier regulatory interactions and COA development, change the thinking behind patient research and endpoint selection?
- 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 Young Person Advisory Groups, parents, and educational establishments been utilized?
 - Patient career 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 (Decentralized Clinical Trials)?
- 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 increasingly meaningful patient engagement? How do you transition crucial relationships and learnings when necessary? How are you measuring success in your structure?
 - 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 various 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?
- “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 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 does not 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 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 | Translational Sciences and Precision Medicine



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, preclinical studies, and challenges in rare and common diseases. Topics related to bioethical issues are also welcome and may be considered for a special track in the meeting.

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 omics 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

3. What's New in Gene Therapy

- a. Leveraging AI to predict complications in vector integration
- b. Understanding durability of effect 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
- d. Artificial intelligence and digital technologies in support of preclinical or early clinical development

6. Early Development Decisions and Mitigating Challenges in Rare Disease Drug Development

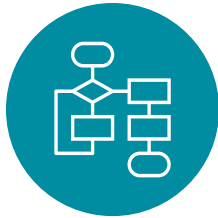
- a. Regulatory considerations and decision-making when the mechanism of action is not understood
- b. Prolong new drug life cycle with 505(b)(2) path—optimizing early decision-making to avoid product development failures
- c. Challenges on translational aspects of pre-clinical findings and how to expedite these.

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

8. The Microbiome Factor in Drug Discovery and Development

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 to collaborate more effectively with internal and external stakeholders to achieve optimal efficiencies in project and program development.

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

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 across the Healthcare Continuum – Engagement, Mentoring, and Equality**
2. **Leveraging Data and Analytics for Strategic Planning, Portfolio Management and Governance Decisions**
3. **Maximizing Efficiency/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, vendors, CROs, academic institutions, etc.)
 - c. Leveraging your PM tools to redefine inflection points and decision-making
4. **Project Management as a Career**
 - a. How to grow and develop in your current role
 - b. Ways to strategically plan for long-term career growth as a PM professional
 - c. Growing your career while working remotely or in a hybrid team model
5. **Project Management Fundamentals (processes, tools, methodologies, skills, emotional intelligence, leadership, managing uncertainty, managing remote/hybrid teams, 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 (Good Laboratory Practice), 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 (Corrective and Preventive Actions), compliance, compliance oversight, global oversight. Topics related to bioethical issues are also welcome and may be considered for a special track in the meeting.

Priority Topics

- 1. Quality by Design and Quality Risk Management: How to Balance Risk and Resources**
 - a. Updates to ICH E8(R1)
 - b. The role of good data governance in promoting clinical trial quality
 - c. 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])
 - d. The role of quality by design (QbD) and the use of risk-based approaches in quality risk management: Strategies for incorporating QbD principles (e.g., plan, do, check, act workflow)
 - e. Approaches for focusing resources on the critical to quality factors (as described in ICH E8 R1) to ensure the safety of trial participants and that trial data produced is of sufficient quality to give reliable results
- 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 design, audit trails, system access, user management, and IT (Information Technology) security in data quality and monitoring for GCP compliance
 - c. Understanding investigations, root cause, and implementing an effective CAPA (Corrective and Preventive Actions) system
 - d. Assessing the reliability of real-world data and real-world data sources (RWD)/RWE
 - e. Application of data science
- 3. Pharmacovigilance Quality: Optimizing data quality to achieve PV compliance targets and accurately assess benefit risk profiles**
- 4. Risk-Based Approach to Clinical Trial Oversight: Risk management and collaborative transparency between regulators and sponsors**
 - a. Updates to ICH E6(R3)
 - b. CRO and service provider oversight measures that are fit for purpose and tailored to the complexity of and risks associated with the trial
 - c. Risk-based approaches and issue management to support innovation: impact on improving clinical trial execution, data quality, and safety of trial participants
 - d. Role of centralized monitoring and centralized quality-assurance activities such as analytics to improve quality and compliance
- 5. Quality Innovation: Considerations for ensuring clinical trial quality when using innovative trial designs (e.g., decentralized trials, adaptive designs, pragmatic trials)**
- 6. Maintaining GCP and data quality in a changing clinical trial landscape that is implementing more pragmatic and proportionate approaches for clinical trials.**
 - a. Use of on-site, remote, and off-site quality control and quality assurance strategies for monitoring and auditing
 - b. Using good risk assessment/management practices to guide decisions on clinical trial conduct
 - c. Challenges and solutions in obtaining consent in remote, electronic +/- decentralized ways
 - d. Expanding risk-based monitoring methods (e.g., right fit SDV/SDR, remote monitoring, centralized monitoring)
 - e. Regulatory challenges: Innovating to meet GCP compliance requirements versus need for regulatory flexibility
- 7. Quality Culture: Empowering Quality professionals in enabling innovation**
 - 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. Evolving approaches to inspections and associated inspection outcomes**
 - a. Collaboration and cooperation across stakeholders to verify quality and compliance through innovative approaches whether remote, on-site or hybrid
 - b. Collaboration between regulators

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 (National Medical Products Administration), PMDA (Pharmaceuticals and Medical Devices Agency), EMA, MHRA (Medicines and Healthcare products Regulatory Agency) (Medicines and Healthcare products Regulatory Agency), 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 (Health Technology Assessment), 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. Topics related to bioethical issues are also welcome and may be considered for a special track in the meeting.

Priority Topics

- 1. Innovative Approaches to Clinical Development Programs and Trial Design, including experience with acceptance for regulatory decision making and case studies (e.g., complex innovative designs, use of digital health technologies in a clinical development program, model informed drug development, decentralized clinical trials, novel biomarkers and endpoints, patient centric approaches, real-world evidence)**
- 2. Global Development and International Harmonization, Convergence, Reliance, and Cooperation**
 - a. Updates on ICMRA, ICH, IMDRF, WHO, and other harmonization, convergence, and reliance efforts
 - b. Intersection of harmonization, convergence, and reliance efforts
 - c. Effect of emerging regulations on global registration strategies
 - d. Health authority cooperation initiatives, i.e., Project ORBIS, ACCESS Consortium
 - e. Impact of multiregional clinical trials on global development strategies
- 3. Regulatory Topics of Public Health Importance**
 - a. Pandemic preparedness, including vaccines, therapeutics, and diagnostics development lessons learned and future strategies, i.e., COVID-19, monkeypox, the next global health threat
 - b. Regulatory continuity planning in the event of disaster, i.e., future proofing against a cyberattack, clinical site disruption due to catastrophic events
- 4. What's New in Labeling**
 - a. Enhancing information for patients and healthcare providers
 - b. Labeling modernization efforts, including electronic
 - c. REMS (Risk Evaluation and Mitigation Strategy) and innovative approaches to ensuring patient safety
 - d. Labeling for artificial-intelligence driven software and medical devices
 - e. Experience with adding patient experience data
- 5. Regulatory Initiatives to Increase Competition**
 - a. Generic drug and biosimilar updates, e.g., GDUFA, BsUFA, emerging policies
 - b. What is new in global generic drug and biosimilar drug development
- 6. Latest Regulatory Developments in Cutting-Edge Science and Review**
 - a. Global regulatory considerations for special populations or situations (e.g., rare/orphan, pediatrics, maternal health, etc.)
 - b. Cell and gene therapy and regenerative medicine; advanced therapies
 - c. Antimicrobial resistance
 - d. Diversity and inclusion in clinical trials
 - e. Health literacy
 - f. Implications of new legislation
- 7. Harnessing Big Data/Bioinformatics to Answer Regulatory Questions**
 - a. The use of Big Data/bioinformatics for drug development and regulatory decision making (e.g., real-world data, artificial intelligence, and machine learning)
 - b. Issues at the intersection of drug information interoperability and cybersecurity
 - c. Cybersecurity, data privacy, IP considerations
 - d. Enhancing regulators and other stakeholders' capacity to access and utilize big data/bioinformatics
 - e. Cloud-based submissions
- 8. Rare Disease and Precision Medicine**
 - a. Rare disease endpoint development
 - b. Precision and individualized medicine
 - c. Innovative approaches to drug delivery, combination products, and companion diagnostics
 - d. Connected health (e.g., digital wraparound of a pill)
 - e. Digital therapeutics
 - f. Enhancements to review program efficiency, e.g., STAR (Split Real Time Application Review), RTOR (Real Time Oncology Review)

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 (Current Good Manufacturing Practice), 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). Topics related to bioethical issues are also welcome and may be considered for a special track in the meeting.

Priority Topics

1. International Convergence for Product Quality: ICMRA, PIC/S and IPRP
2. Trends in Product Quality: Nitrosamines and Titanium Dioxide
3. Patient-Centric Quality Standards: Specification Setting Based on Patient Needs
4. One Global Dossier for Regulatory CMC
5. Drug Shortage Avoidance Strategies: Innovation, Incentives and New Requirements
6. Building Trust Between Regulators: Reliance and Recognition for Product Quality
7. Regulatory CMC Challenges with Cell and Gene Therapy Products

Track 11 | Statistics



This track will focus on topics related to the practice and application of statistical methods in medical product development 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. Topics related to bioethical issues are also welcome and may be considered for a special track in the meeting.

Priority Topics

1. Complex Innovative Designs

- Practical experiences and lessons learned from the CID Pilot Program
- Applications and experiences with master protocols and platform trials
- Leveraging external information

2. Safety and Benefit-Risk

- Applications of appropriate statistical methodologies to properly interpret safety data
- Towards improved planning in the design of clinical development programs to evaluate risks and benefit-risk assessment
- Applications of quantitative benefit-risk methods
- Statistical methodologies for signal detection in randomized clinical trials

3. Application of Bayesian Methods in Drug Development

- Bayesian design and analysis of randomized clinical trials
- Rare diseases

- Pediatric trials
- Synthetic controls

4. Estimands

- Practical applications and lessons learned working with non-statisticians
- Applications of estimands beyond the RCT (Randomized Clinical Trials)
- Estimands for safety and benefit-risk

5. Machine Learning and Use of Artificial Intelligence in Drug Development

- Opportunities for applications in early clinical development to post-market applications
- Application in signal detection (safety, non-compliance)
- Machine / Targeted learning
- Natural language processing

6. Patient-Focused Drug Development

- PRO validation
- Digital endpoints

- Pragmatic trials
- Real-world evidence
- Decentralized Trials

7. Causal Inference in Medical Product Development

- Applications to establish clinical evidence in real-world evidence and clinical trials
- Applications in rare disease settings
- Bridging causal inference and clinical trials
- Leveraging external control data in randomized clinical trials

8. Communication and Collaboration

- Explain commonly used complex statistical methods (e.g., MMRM, estimands, logistic regression, Bayesian Statistics) to non-statisticians
- Use of data visualization to augment/enhance data presentation
- Use of dynamic data analysis and visualization and experiences with submissions to regulatory agencies

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 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

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

Priority Topics

- 1. Paying for What Works: Value-Based Contracting (VBC) Between Payers, Manufacturers, and Providers—Where Do We Go from Here?**
 - a. VBCs (Value Based Contracting) 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 Centers for Medicare and Medicaid Services (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
 - d. How patient groups, community leaders, academia, investors, and industry are adjusting to challenging market conditions to continue to drive therapeutic innovation
 - e. What are the factors that most influence patient access (i.e., regulatory bodies – FDA, NCCN, cost/payers alone, physician preference, clinical evidence, etc.)
- 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. Supporting Access to Treatments in Developing Countries**
 - a. Policy updates on drug pricing: regulations and legislation
 - b. Strategies to enhance clinical research in developing countries
 - c. Key and structural barriers to address with healthcare disparities
 - d. Promising pricing and access strategies (e.g., COVID-19, gene therapy, rare diseases)
- 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

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, managing your career development, diversity, hiring, leadership, technology, making a lasting impression, running remote meetings and workplace dynamics.

Specific domain expertise examples are welcome, however please embed those in the context of cross-functional professional development needs.

Priority Topics

1. Successfully Managing Your Professional Development

- a. Developing your 30 second elevator speech
- b. Finding a mentor
- c. Developing a career plan
- d. Imposter Syndrome
- e. Personal brand
- f. Negotiating your next offer
- g. Networking in a virtual environment

2. Leadership Skills

- a. Retaining talent
- b. Hybrid teams
- c. Developing the next generation
- d. Developing experienced talent
- e. Developing skills of the future, today!
- f. Leading diverse talent
- g. Fostering psychological safety
- h. Leadership

3. Mindfulness and Well-Being

- a. Moral and sexual harassment in HCP environment
- b. De-stressing techniques

4. The Business of Life Sciences R&D

- a. Preparing to manage a departmental budget
- b. Master Services Agreements, and other business legal documents we all need to understand
- c. Revenue stream, and why it matters to everyone, even scientists
- d. Calculating “risk” in terms of the bottom line
- e. Beyond Promotions: How to be on a Board of Directors
- f. Entrepreneurship - within the organization
- g. Managing the financial profit-loss

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 for DIA 2023.

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](#)

[Short course abstract template](#)

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 Boston, MA.

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.