60TH ANNIVERSARY

DIA 2024

GLOBAL ANNUAL MEETING

SAN DIEGO, CA | JUNE 16-20

CHARTING NEW HORIZONS

CALL FOR ABSTRACTS

Submission Deadline:

Extended to

September 21

DIAglobal.org/DIA2024

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About the DIA 2024 Global Annual Meeting

Charting New Horizons: DIA 2024 | 60th Anniversary:

As the undisputed leader in the life sciences industry, the DIA 2024 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 2024 is the essential global gathering of industry, regulators, academia, and patients in one venue, hosting thousands of professionals in the pharmaceutical, biotechnology, diagnostics, and medical device communities. It is an unparalleled experience combining education and networking opportunities that will elevate your skills and knowledge.

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 2024 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 worldwide. 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 2024 programming 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 2024 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 2024 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 2024 tracks click here.

DIA is committed to including the voice of the patient at DIA 2024. 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 September 21, 2023 11:59PM ET

Types of Abstracts

There are four types of abstracts you can submit for DIA 2024, 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-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 attendees.

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

Introducing DIA 2024

By submitting your abstract for DIA 2024, you become an integral part of the collaborative principles DIA has upheld for years - a platform of trust, neutrality, and knowledge exchange that leads to enhanced regulation and innovation, benefiting patients and the global community at large. The abstracts 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:

- Patients are our story that we seek to understand
- Collaboration is the skill we hone that crosses various organizations, languages, and boundaries to have true global impact.

See you in San Diego!

With the theme of ***Charting New Horizons*** DIA's global network transforms professional expertise into actionable progress for all. The goal of the DIA 2024 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.

Insider Knowledge....

Thank you for your interest in being a thought leader at DIA 2024. 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 or challenge.

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 2024:

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.

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 **September 21, 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. Only full session, forum, workshop and short course abstracts will be accepted; presentation abstracts will NOT be accepted.
4. Abstract submissions must include 1-2 speakers. The author of the abstract, upon acceptance, will be responsible for recruiting speakers, per the listed guidelines in Speakers Corner.
   - DIA does not allow more than one participant from the same company to present within the same program offering (this includes Session Chairs and speakers).
5. Proposed abstract title must reflect the abstract content accurately and concisely.
6. 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 abstact.
- 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 2024.

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
- The name, and contact information of at least two speaker recommendations (do not list yourself) that you would like to include. (Do not confirm their participation until the abstract is accepted.)

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 San Diego, CA.

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.

DIA 2024 Tracks

- Clinical Safety and Pharmacovigilance
- Clinical Trials and Clinical Operations
- Data and Technology
- Medical Affairs and Scientific Communication
- Patient Engagement
- Translational Delivery Technologies and Precision Medicine
- Project Management and Strategic Planning
- R&D Quality and Compliance
- Regulatory
- Regulatory CMC and Product Quality
- Statistics and Data Science
- 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 Pharmacovigilance Regulations, Cross-Industry Initiatives, and International Collaborations**
2. **Special Pharmacovigilance Considerations**
   - Special populations (e.g., pediatrics, pregnancy)
   - Rare diseases
   - Underrepresented groups
   - Novel treatments (e.g., immuno-oncology)
3. **Transforming the Drug Safety Organization**
   - Inspections
4. **Benefit-Risk Assessment and Risk Management**
5. **Artificial Intelligence and Technology in Pharmacovigilance**
6. **Novel Approaches and Future Directions in Patient Safety**
7. **Pharmacogenomics**
8. **Patient Engagement and Patient Safety in Pharmacovigilance**
9. **Device and Combination Product Pharmacovigilance**

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.

Priority Topics

1. **Design and Operational Considerations for Research Involving "Schedule 1" Substances - Psychedelics, Cannabis, etc.**
2. **Topics Related to Clinical Trials with Modern Study Designs Including Adaptive Studies, Platform Studies, Master Protocols, Pragmatic Studies, Use of External Controls, and Use of RWE/RWD to Inform Study Design and Drug Development Programs**
3. **The Clinical Site of 2024 and Beyond- What is the Present and Future State of Clinical Research Sites in Workforce and Training, Contracting and Budget Considerations, Infrastructure, Organization, and Oversight**
4. **Best Practices for Forward-Thinking Clinical Project Management - the Management of International Research Studies, Incorporation of Diversity Considerations, Making Data-Driven Decisions on Site Selection, and Participant Recruitment Planning**
5. **Endpoint Sciences- PRO/ePRO, Surrogate Endpoints and Validation, the Appropriate Use of Digital Biomarkers**
6. **Informed Consent and Communicating with Study Participants- How do we Communicate Increasingly Complex Study Information in a Respectful, Informative, and Innovative Way?**
7. **Artificial Intelligence (Generative AI) and its Role and Future Uses in Clinical Trial Operations**

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 data sources
- Data quality
- Blockchain technology
- Cloud computing
- Data standards
- Real-world data (RWD) and real-world evidence (RWE)
- Mobile and wearable technologies
- Informatic solutions and machine learning
- Endpoints: Evolving data requirements to support new endpoints
- Data linkage

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.

Priority Topics

1. **Harnessing Real-World Data and Real-World Evidence**
   - Data exchange using common data sources
   - Data quality and fitness for use
   - Evaluating the accuracy of real-world data linkage in the US
   - Payor expectations for real-world data
   - Regulatory guidance considerations
2. **Emerging Technologies and Data Sources**
   - Artificial Intelligence (AI), Automation, Machine Learning (ML), Natural Language Generation (NLG), and Natural Language Processing (NLP)
     - Blockchain technology and Web3
     - Deriving endpoints from wearables, sensors, and novel technology
     - Effective integration in the clinical study process
     - Managing and ensuring data validation, quality and integrity
     - eSource opportunities and challenges integrating with clinical trials
   - Computer software assurance versus computer system validation: How do you transition?
   - Decentralized clinical trials: Collection sharing and standardization of data
   - Digital solution for remote monitoring including SaMD
   - Emerging uses of synthetic data
   - Technology security requirements
3. **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
   - Application of risk-based monitoring (RBM) techniques
   - Impact of virtual trials changing data management standards and processes
4. **Data Sharing and Exchange**
   - FDA Technology and Data Modernization Action Plans
   - Cloud-based regulatory submissions and collaboration
   - Structured data submissions
   - EMA Guideline on computerized systems and electronic data in clinical trials: EMA/226170/2021
5. **New and Emerging Standards, Guidance, and Regulations**
   - Health authority regulations and guidances around the use of generative AI (e.g, explainability, referencability, and ethics)
   - ICH M11: Data standards related to standardized protocol template
   - GDPR impact on data management practices and processes
   - cHL7 FHIR (Fast Healthcare Interoperability Resources) Vulcan Accelerator Program: Bridging the gaps between clinical care and clinical research data standards

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.

Priority Topics

1. **Health Authority Guidance, Regulations, and Globalization**
   - New discussions on the EU (European Union) CTR (Clinical Trial Regulation) regulations, ICH, Clinical Transparency, GDPR, CTIS (Clinical Trials Information System) compliance, and other related topics
   - Development and use of the FDA Assessment Aid, best practices in Real-Time Oncology Review (RTOR) procedures, and Project Optimus
   - Success stories and lessons learned in regulatory medical writing and medical affairs from accelerated submissions to global regulatory agencies
   - Discussions and regulations surrounding the use of technology in regulatory submissions, medical writing, publications, and medical affairs, including artificial intelligence (AI), large language learning models (LLM), machine learning, and generative AI, automation, authoring platforms, etc.
2. **Strategy, Scientific and Regulatory Messaging, during Clinical Development and Medical Affairs Including Awareness of Diversity, Equity, and Inclusion**
   - Access to high-quality information for the general public from clinical development
   - Use of new scientific platforms, lexicons, and patient-focused organizations for the dissemination of information to external stakeholders
   - Use of data and analytics to gain insights and inform strategy in Medical Affairs
   - Leveraging cross-functional and cross-domain insights to Inform on strategy in Medical affairs
3. **Technology: Systems, Utilization, and Impact of AI in Medical Writing**
   - Implementation of innovative solutions using technology (e.g., content reuse, automation, etc.) with medical writing and medical publications
   - Change and process management, caution/considerations, and impact for the implementation of technology solutions with medical writing
   - Customization and personalization of data for real-time presentation/data visualization and uses of graphical data
   - Leveraging technology tools and systems for clinical regulatory reviewers/teams/sponsors
4. **Improving Customer (Patients, HCPs, Field Medical) and Payer Interactions**
   - Improving health literacy, increasing content palatability, and dispelling medical/scientific misinformation using innovative patient communication and engagement types
   - Implementation and strategies for returning clinical trial results to participants
   - Implementation and strategies for virtual key opinion leader engagement and augmented reality medical science liaison (MSL) data, content, and structure.
   - Success stories in omni-channel communications such as websites, interactive content, podcasts, social media, and other types of communication
5. **Ensuring Regulatory Compliance and Improving Efficiency and Quality in Regulatory Documents and Submissions**
   - Utilization of AI, LLM, NLP, generative AI, and structured content authoring tools in the development of clinical and nonclinical regulatory documents
   - Discussions on new regulations and guidance in clinical and nonclinical regulatory medical writing
   - Discussions on the required change management at the individual, reviewer, CRO, and sponsor level to support structured content authoring, automation, and the use of AI-related tools
   - New tactics for the acceleration of submissions from the clinical study report (CSR) to regulatory filing on an individual agency or global perspective
   - Ensuring adequate key messaging techniques throughout the clinical development process from early development through clinical regulatory filing
6. **Management of Teams, CROs, and Sponsors in an Increasing Decentralized Network**
   - Regulatory document development in an increasing decentralized working environment
   - Managing CROs, sponsors, and other outsourced vendors in the medical writing and medical affairs space
   - Practices in effective communication, coaching, and managing with distributed teams
   - Diversity, equity, and inclusion
   - Flexible working environments and building successful working networks, globally

Track 5
Patient Engagement

This track addresses meaningful patient engagement (PE) 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 contract manufacturing organizations [CMOs] and medical science liaisons [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 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: Serving Patient and Industry Goals**
   - How have successful patient-focused strategies been developed and implemented as part of your medical product development strategy? What key learnings, challenges and best practices can be shared to develop strategies to engage patients early (e.g., development or preclinical) and continuously keep the end in mind?
   - How are different types of patient experience data (PED) being collected and appropriately ensuring early alignment on key considerations (e.g., domains of interest, data standards) to inform development programs? How and when is PED collected to define meaningful endpoints? How have recent regulatory guidances changed the thinking around endpoint selection?
   - How does early regulatory engagement enhance the incorporation of PED in development programs and regulatory decision-making? How are regulators considering the collected PED?
   - What are we learning about the burden of trial participation and how to support better coordination, alleviate burden, or support participants?
2. **Context and Contours: Illuminating Patient Engagement in Different Settings and Disease Areas**
   - What are key considerations, challenges, learnings and best practices for developing/implementing patient-focused strategies and appropriately engaging patients (including children, adolescents, patient carers) in rare disease medical product development?
   - How have patient and carer insights from underrepresented groups on clinical trial design, study communications, site-selection strategies, etc., impacted the enrollment of a diverse cohort?
   - How have decentralized clinical trials made clinical trials more patient centric?
3. **Scaling Patient Engagement Across the Development Cycle**
   - What are lessons learned in how a company identified and centered responsibility for PE,how was that function staffed, how was capacity built to increase meaningful PE, and what strategies were used to educate the overall organization on the importance of PE? How are you measuring success in your structure?
   - How are you and your collaborators tracking and measuring the outputs and outcomes of PE to demonstrate its impact and value? What metrics are being developed and used?
   - How are you making participant data return feasible and actionable for participants to support their decision-making? How are lay summaries, synopses, and publications with patient authors supporting this feedback loop and how is the feedback benefiting participants and development?
   - How could digital engagements or simulations provide greater insights into some conditions?
4. **"Yes, We Can!" Sharing Best Implementation Practices About Patient Engagement and Patient-Focused Medical Product Development**
   - How have you contributed to expanding knowledge about regulators' expectations for PE practices, or applying existing laws that encourage patient-centered practices to aid in changing culture or practice at your institution or another?
   - Describe key activities, resources, and initiatives that have been developed regionally or globally to de-risk PE and how to best raise awareness of these resources. What are existing gaps in current practice and regulatory guidance that need to be addressed?
   - What are best practices and lessons learned that patient organizations could share regarding collaborations with other stakeholders?
5. **De-risking Research and Development:**
   - How has PE been used as a strategic and systematic tool to de-risk research and development and enable improved research and development outcomes that benefit both patients and the industry?

Track 6
Translational Delivery Technologies and Precision Medicine

Preclinical and early-phase clinical research provides initial dosing and safety data for the next generation of products. This track focuses on the latest precision medicine strategies used in compound selection from libraries, utilizing biomarkers, updates on risk management safety considerations, impact to dosing strategies, next generation drug delivery, companion diagnostics and methods to improve data quality and integrity for proper downstream decision-making. Precision medicine is an innovative approach that considers individual differences in patients' genes, environments, and lifestyles. Millions of people have already been touched by the area of precision medicine that has grown directly from biomedical research.

DIA recommends this track and associated sessions to professionals involved in pharmacology and toxicology, nonclinical safety testing, clinical research, clinical operations, medical devices/combination products, biomarkers and companion diagnostics, 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, devices and diagnostics, integration of the 'patient's voice' user needs early in preclinical development to define/refine the patient population and clinical endpoints, and challenges in rare and common diseases.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. **What's New in the Evolving Space of EU In Vitro Diagnostic Regulation (IVDR)**
   - IVDR content for clinical trial application (CTA) submissions
   - IVDR - notified body review challenges and opportunities of companion diagnostics (CDx)
   - Quality management system optimization to meet IVDR requirements
   - Clinical Trials - IVDR impact and strategies for success
2. **Innovative Opportunities in Dose Optimization**
   - Dose optimization in practice - lessons learned
   - Current challenges in dose optimization design
3. **Application of Artificial Intelligence (AI) and Machine Learning (ML) in Precision Medicine**
   - Developing AI/ML models for predictive diagnosis
   - Target selection - successes and current practices
   - Molecule design
   - Patient selection for clinical trials
4. **Disruptive Technologies in the Next Generation of Drug Delivery**
   - Nanomedicine, nanotech particles, nanodiamonds
   - Patient centric technologies
5. **New Concepts and Applications in Gene Editing**
   - Gene editing in practice - current research and lessons learned
   - Patient perspectives on gene editing technology
6. **Regulatory Precision Medicine Initiatives**
   - FDA - IVD/CDx pilot for oncology
   - FDA - proposed rule to regulate laboratory developed tests (LDTs)
   - EU partnership on personalized medicine
   - NMPA personalized medicine developments
7. **Clinical Development and Adaptive Translational Strategies**
   - Adaptive design for biomarker-driven trials
   - Designs using drug delivery platform for curative therapies and cell-gene therapy
   - Drug delivery and companion diagnostics for cell and gene therapy and gene editing
8. **Digital Biomarkers utilization in Clinical Trials**
   - Digital health technologies (DHTs) for prognostic and predictive biomarkers
   - Virtual/augmented reality, next generation
   - Biomarker-driven digital therapeutics
9. **Bioethics Landscape within Precision Medicine**
   - Informed consent for next generation therapies (e.g., cell-gene therapy, gene editing)
   - Disparities and equity in access to biomarker testing and targeted therapies

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 (PM), 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 PM, 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. **Strategic Planning, Portfolio Management and Governance Decisions across all stages of Drug Development**
   - How/when to use artificial intelligence (AI), real-world evidence (RWE) and real-world data (RWD) and analytics to optimize programs, research or trials
   - Incorporating patient perspective and patient centric integrated evidence plans into development plans, trial designs and decision making
   - Best practices for effective feasibility assessments that provide valuable insights for program development
   - Project management office (PMO) best practices for optimizing development
   - Software technology, systems, and applications to maximize efficiency
2. **Project Management Fundamentals for Drug Development**
   - Leadership, planning, managing ambiguity, agile, methodologies, tools, and processes
   - Leveraging PM skills for change management enterprise initiatives, and R&D deliverables
   - PMO and portfolio oversight fundamentals
   - PM skills and knowledge for program complexities including companion diagnostics, wearables, AI, RWD and RWE
   - Core competencies and superpowers needed for a successful career as a Program Leader or Program Manager
   - Adapting your planning, ways of working, and mindset to thrive in emerging regulatory and external changes (e.g., EU CTA directive, FDA's Project Optimus, post-COVID ways of working)
3. **Business of Project Management in Drug Development**
   - Governance management, including internal and partnership/collaboration governance models
   - Alliance management
   - Project managing in a collaboration
   - Business development and licensing
   - Evolution of the role of Program Leader and Program Manager
   - Finance
   - Legal

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 good laboratory practice (GLP), good clinical practices (GCP), and pharmacovigilance (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.

Priority Topics

1. **Quality by Design (QbD) and Quality Risk Management (QRM)**
   - Updates to ICH E6R3, Annex 1
   - Strategies for incorporating QbD principles, including focusing resources on the critical to quality factors
   - Strategies for incorporating stakeholders' involvement in identifying a study's critical to quality factors, including identifying risks to the critical to quality factors and implementing risk mitigation/management strategies
   - Sponsor, CRO and service provider oversight measures that are fit for purpose and tailored to the complexity of and risks associated with the trial
   - Quality tolerance limits/how to further evaluate, understand potential impact, and determine when and what further actions are needed
   - Use of good risk assessment/management practices to guide decisions on clinical trial conduct
   - Risk management and collaborative transparency between regulators and sponsors
2. **Maintaining GCP Compliance and Data Quality when Using Modern Trial Designs and Operational Approaches, Such as Decentralized Trials, Pragmatic Trials, Master Protocol Designs, and Studies Using Real-World Data (RWD).**
   - Updates to ICHE6R3 Annex 2
   - Risk-based approaches and issue management to support modern trial designs
   - Strategies for using advanced analytics for compliance and quality assurance for efficiency, effectiveness, and continuous improvement including use of novel approaches (e.g., machine learning, artificial intelligence, real-world evidence [RWE])
   - Strategies for assessing the reliability of RWD and RWD sources
   - Challenges and solutions in obtaining consent in remote, electronic and/or decentralized ways
   - Strategies for ensuring data reliability of digital health technology-derived data
3. **Pharmacovigilance Quality: Optimizing Data Quality to Achieve PV Compliance Targets and Accurately Assess Benefit Risk Profiles- Using Advanced Analytics for Good Pharmacovigilance Practices Quality**
4. **The Role of Good Data Governance in Promoting Clinical Trial Quality**
   - Update on new data governance section in ICHE6R3
   - Audit trail review to ensure data integrity
5. **Risk-Based Quality Monitoring (RBQM)**
   - Use of on-site, remote, and off-site quality control and quality assurance strategies for monitoring and auditing
   - Expanding risk-based monitoring methods (e.g., right fit SDV/SDR, remote monitoring, centralized monitoring)
6. **Evolving Approaches to GCP/PV Quality, and to Inspections and Associated Inspection Outcomes**
   - Collaboration and cooperation across stakeholders to verify quality and compliance through innovative approaches whether remote, on-site or hybrid
   - Collaboration between regulators and/or sponsors on innovative approaches to GCP/PV quality (e.g., use of advanced analytics, new methodologies, etc.)
   - Evolving approaches to computer system validation (e.g., machine learning and artificial intelligence)

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 various regulatory health authorities and agencies, 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, 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, pharmacovigilance, 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.

Priority Topics

1. **New Regulatory Programs and Recent Legislative Initiatives**
   - PDUFA VII/FDORA implementation
   - EU Legislation
   - Policy opportunities and threats to biomedical innovation (IRA, ODA, misinformation, etc.)
2. **Clinical Trial Innovation and Modernization**
   - Digital health technologies (DHTs) and decentralized trials
   - Innovative designs for late-stage development or pivotal studies
   - Novel surrogate endpoints
   - Strategies for rare diseases
3. **Artificial Intelligence**
   - Drug development
   - Data review and assessment
   - Regulatory intelligence
   - Streamlined generation of regulatory submissions
   - Emerging policies in AI
4. **Diversity and Equity in Health Research**
5. **Real-World Data (RWD) and Real-World Evidence (RWE)**
   - RWE for regulatory decision-making with a focus on efficacy/effectiveness
   - Learnings from FDA PDUFA VII “Advancing RWE Program”
6. **Cell and Gene Therapy, Vaccines, and Advanced New Modalities**
   - Cell and gene therapy regulatory landscape and case studies
   - Innovation in vaccine development
   - Platform technologies
   - Sponsor-health authority engagement
7. **Global Regulatory Collaboration and Harmonization**
   - ICH updates and new initiatives
   - Reliance pathways and work sharing
   - Regional initiatives e.g., African Medicines Agency, LATAM, Project ORBIS)
   - Multi-jurisdictional regulations and cross-agency coordination (privacy, scheduling, diagnostics, reimbursement/HTA, etc.)
8. **Combination Products**
   - Fixed-dose combinations
   - Drug-device combinations
9. **Benefit/Risk and Patient Focused Drug Development**
   - Structured approaches for benefit/risk assessment
   - Patient preference data and patient reported outcomes (PRO)
   - Labeling and benefit/risk communication to patients and healthcare providers
10. **Innovation in Inspections and Compliance**
11. **Expedited Programs**
    - Accelerated submission delivery
12. **Diagnostics and Digital Therapeutics**

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 those in 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. **International Convergence and Harmonization for Product Quality – ICH, ICMRA, PIC/S, and IPRP**
2. **Trends in Product Quality: Substances of Concern (Excipients, PFAS, DEG/EG, Dioxide, Environmental Risk Assessment)**
3. **One Global Dossier for Regulatory CMC**
4. **Drug Shortage Avoidance Strategies: Innovation, Incentives and New Requirements**
5. **Building Trust Between Regulators: Reliance and Recognition for Product Quality**
6. **Regulatory CMC and Quality Challenges with Cell and Gene Therapy Products**
7. **Innovative Technologies - Artificial Intelligence in Regulatory CMC, Advanced Manufacturing, Next Sequencing Generation (NGS)**
8. **Inspections in the Post-COVID World**
9. **Patient-Centric Quality Standards: Specification Setting Based on Patient Needs**

Track 11
Statistics and Data Science

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.

Priority Topics

1. **Innovative Clinical Trials and Statistical Methods**
   - Practical experiences and lessons learned from the FDA's CID and EMA's CCT programs
   - Applications and experiences with master protocols
   - Rare diseases and gene therapy studies
   - Single arm studies with or without external controls
   - Use of real-world data and real-world evidence in clinical development
2. **Estimands**
   - Experience implementing estimands from industry and regulatory perspective
   - Practical applications and lessons learned working with non-statisticians
   - Applications of estimands beyond randomized controlled trials (RCT)
   - Estimands for safety and benefit-risk
3. **Safety and Benefit-Risk**
   - Update on FDA Standard Safety Displays and FDA Medical Queries (FMQs)
   - Applications of appropriate statistical methodologies to properly interpret safety data
   - 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
   - Integrated safety analysis
4. **Statistical Methods Underlying AI/ML**
   - Explainability of AI/ML models
   - Statistical methods for Open AI generative models such as ChatGPT, Bard, etc.
   - Statistical aspects of practical application of large language models in drug development
   - The hope versus hype of AI/ML tools used in drug development
5. **Communication and Collaboration**
   - Introduction to statistical concepts for clinical trials (from randomization, blinding, t-test, ANCOVA and Chi-square tests to MMRM, Estimands, logistic regression and beyond)
   - Understanding meaningful changes – beyond just the p-values
   - Data Sciences training and use of existing libraries
   - Implementation of use of open-source tools for interactive data analyses or visualization for registration studies
6. **Non-Traditional Regulatory Submissions**
   - Submissions in R
   - Interactive docker submissions
7. **Therapeutic Area/Indication Specific Challenges Requiring Different Statistical Approaches**
   - Oncology studies
   - Neurology studies
   - Other therapeutic areas/indications
8. **Current Challenges and Opportunities in Data Sciences**
   - Handling data use/privacy
   - Data curation

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.

Priority Topics

1. **Inflation Reduction Act (IRA) 9 Months After the First Round of Implementation**
   - What is the impact of pending lawsuits?
   - Do the changes to Medicare Part D affect patient behavior with respect to the value of prescription drugs?
2. **What is the Value/Role of ICER in the US and Today and in the Future?**
   - How does the evolution of science toward bespoke, expensive therapies (e.g., cell and gene therapies) elevate the need for an HTA or pricing body?
3. **Let's Talk about the Evolution of Health Care Toward Value-Based Care**
4. **How do Drug Shortages Affect Patients' Access to Medicines?**
5. **The Centers for Medicare and Medicaid Services (CMS) Payment for Alzheimer's Drugs and the Registry Requirements That tie into Coverage**
   - Are we seeing a change in the evidentiary requirements that CMS is putting forth for coverage decisions? Is this the future?
6. **Prescription to Over-the-Counter (OTC) Switches with the Potential for Huge Impact**
   - Opill - does OTC birth control change access to contraceptive care?
   - Narcan - patient trends and utilization of Narcan after the switch

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. **Attracting, Developing, and Retaining Talent**
   - Developing talent in a resource constrained environment
   - Diversity in recruitment
   - Leveraging diverse talent
   - Talent recruitment and retention strategies in the new world of work
   - Where do I find the job market?
   - Transferable skills across sectors and functional domains
   - Early talent – building bench strength
   - If promotion is not a retention strategy, what is?
   - Situational leadership
2. **Professional and Personal Growth**
   - Personal branding
   - Talent acquisition
   - Navigating corporate culture – map to the mine field
   - Importance of style flexing
3. **Impact of Culture within Clinical Research**
   - Importance of diverse staffing
   - Building and leading high performing teams
4. **Leadership Skills**
   - Critical thinking
   - Black box versus public information
   - Agility – leading people through change (collaboration with the project management group)
   - Lead from the middle (leadership without authority and matrix leadership)
   - Leading and managing a multi-generational/highly technical team
   - Business acumen – must have tool in the toolbox
   - Strategic versus tactics (activity versus impact)
5. **Changing Technology**
   - Artificial intelligence (AI) 101 (What to ask, how to apply, ethics/ decision making, critical thinking)
6. **Strategic Partnerships / Vendor Management**
   - Decoding the vendor management alphabet soup (NDA, IND, SOW, MSA and more)
   - Negotiating and incentivizing vendors to build win-win partnerships