



DIA 2021
GLOBAL ANNUAL MEETING

PHILADELPHIA, PA
JUNE 27-JULY 1

CALL FOR ABSTRACTS | Submission Deadline: September 15



DIAGlobal.org/DIA2021

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About the DIA 2021 Global Annual Meeting

DIA's Global Annual Meeting is the largest, longest-running event in the life sciences industry designed to foster the international exchange of actionable insights to improve health globally through the advancement of lifesaving medicines and technologies. **The DIA 2021 Global Annual Meeting (DIA 2021) will bring together industry, regulatory, academia, and patients in one venue, hosting thousands of professionals in the pharmaceutical, biotechnology, and medical device communities from more than 50 countries around the globe.** The DIA Global Annual Meeting boasts more than 450 exhibiting companies, over 13+ tracks, and more than 250 sessions.

DIA 2021 provides you with a rare opportunity to build on what you already know in the development of new therapies and accelerate efforts to enhance health and well-being. Where else can you meet with people from around the world, share knowledge, experience cross-functional content with real-world application from top speakers in the industry, and network with peers to build new relationships across multiple disciplines?

Abstract Tip!

Our **Track Chairs have highlighted priority topics** within their educational tracks to provide direction on content they would like to receive via the Call for Abstracts. **You may submit abstracts addressing priority topics and/or topics relevant to the DIA 2021 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 2021 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 2021 tracks [click here](#).

DIA is committed to including the voice of the patient at DIA 2021. DIA's Patient Partner initiative continues to ensure that the perspectives of patient communities are part of the discourse in all of our content formats. **We encourage patients and patient representatives to submit abstract proposals, not only into the Patient Engagement track, but to all relevant tracks.** The AMPC will be looking for these during the abstract selection process.

Submission Deadline - September 15, 2020

Types of Abstracts

There are five types of abstracts you can submit for the Global Annual Meeting, including a **session, forum, presentation, workshop, or half- and full-day short courses**. Each abstract type is defined herein and has its own format and structure and cannot be altered. You may submit more than one abstract.



SESSION

A 60- or 75-minute session concept delivered lecture-style from the podium.

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



FORUM

A 60- or 75-minute concept designed for panel interaction and attendee engagement.

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



PRESENTATION

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

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



WORKSHOP

A 60- or 75-minute workshop delivered in an interactive/simulation or role-playing format.

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



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 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, speaker, or instructor (depending on which type of abstract is submitted) and will be responsible for the following:

- Adhering to the program development policies and guidelines
- Meeting program development timelines
- If chairing a program offering:
 - Recruiting speakers and ensuring good representation/diversity in the selection of speakers
 - Please note: No more than one participant from the same company is permitted to speak within the same program offering; the Annual Meeting has a global focus, and therefore we encourage global perspectives
- Communicating with speakers regarding their role and reviewing presentation materials
- Managing the program offering, including the facilitation of audience questions and answers
- At the time of submitting a session abstract, please indicate at least one individual who will be invited to participate in the offering. Please do not extend an invitation until a formal response from DIA has been received.
- If leading a workshop or short course:
 - Ensuring the workshop provides onsite learning in the form of activities or demonstrations
 - Ability to facilitate 75-100 attendees for a workshop and 25-50 for a short course
- If presenting a presentation:
 - Working with Chair and other presenters in creating a balanced session
 - Preparing and delivering a PowerPoint presentation

Introducing DIA 2021 *Collaboration Without Boundaries*

In a world where challenges know no boundaries, DIA 2021 is the connection. The DIA 2021 Global Annual Meeting pushes beyond walls, beyond borders. It's *Collaboration Without Boundaries* and we're fiercely proud of it.

Submitting your abstract for DIA 2021 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

Will DIA 2021 be In-Person, Virtual, or Both?

DIA is closely monitoring COVID-19 and guidances issued by the CDC and WHO. In the midst of continued uncertainty and calling upon the successes from our first virtual Global Annual Meeting, we are presently planning for a hybrid approach for DIA 2021 that would combine both in person and virtual learning opportunities for Session Chairs, speakers, and attendees. Details for our proposed hybrid meeting model will be shared by end of February 2021.

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

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

Thank you for your interest in being a thought leader at DIA 2021. As you prepare to share your work and motivation for bringing your peers together, I want to impart to you our philosophy on how we educate, share knowledge, and inspire attendees at the DIA Global Annual Meeting.

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

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

Consider these interactive session and presentation ideas as you prepare to submit your presentation, session/forum, workshop, and/ or short course ideas for DIA 2021:

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

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

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

Sincerely,

Meredith



Meredith O. Kaganovskiy, CMP
Senior Project Manager, Global Annual Meeting
DIA

DIA 2021 Tracks



Clinical Safety and Pharmacovigilance



Clinical Trials and Clinical Operations



Data and Data Standards



Medical Affairs and Scientific Communication



Patient Engagement



Preclinical Development and Early-Phase Clinical Research



Project Management and Strategic Planning



R&D Quality and Compliance



Regulatory



Regulatory CMC and Product Quality



Statistics



Value and Access



Professional Development

Track 1 | Clinical Safety and Pharmacovigilance



This track provides an overview of the global regulatory environment in the field of clinical safety and pharmacovigilance for medical products (biopharmaceutical products and medical devices), with a focus on pragmatic approaches to protecting patient safety and incorporating the patient voice into the complex and evolving pharmacovigilance ecosystem. Forward-thinking sessions address the application of new technologies and methods to streamline pharmacovigilance systems and processes to enhance protection of patient safety as products become more complex, new data sources drive new analytical techniques, regulatory requirements become more detailed, and medical product development becomes more global.

DIA recommends this track and associated sessions to professionals involved in: drug safety/pharmacovigilance, medical product safety risk assessment, pharmacoepidemiology (including real world evidence generation), post-market studies (including Large Simple Safety Studies and pragmatic safety studies), statistics, benefit-risk assessment and management, benefit-risk communication (including professional and consumer medical product safety labeling), regulatory affairs, clinical research (including clinical trial design), medical affairs, and health outcomes.

Included Topic Areas

New initiatives, and emerging regulatory requirements and expectations regarding drug safety-related policies, processes and best practices, and quality metrics, especially those relating to patient engagement; data privacy; Good Pharmacovigilance Practices (GVPs), including insights into revised modules; pre- and post-market safety; expansion of ICH “E2” guidelines to developing markets; benefit-risk assessment and management; epidemiologic studies and impact on labeling; safety considerations for combination products, medical devices, generic products (including biosimilars), and advanced therapies; companion diagnostics; pharmacovigilance audits/inspections; use of digital technology for risk identification, minimization, and communication; patient-centric labeling and risk minimization methods; application of artificial intelligence to pharmacovigilance; generating meaningful insights on medical product safety from social media and other new data sources; optimizing the global pharmacovigilance foot print (including local safety offices and partners); and considerations for signal detection and management across the product lifecycle.

Priority Topics

- 1. Update on Regulations and Cross-Industry PV Initiatives:**
 - a. When harmonization isn't working: what's the fix?
 - b. FDA Guidances (e.g. benefit-risk—released Q4)
 - c. Updates from CIOMS Working Groups
 - d. Updates from ICH
 - e. Updates from other cross-industry working groups (e.g., TRANSCCELERATE, IMI, etc.)
 - f. Impact of COVID-19 regulatory and industry collaborations/initiatives/strategies
- 2. Special PV Considerations:**
 - a. Immuno-oncology
 - b. Gene therapy
 - c. Pediatrics
 - d. Rare diseases
 - e. Pregnancy
 - f. Biosimilars
 - g. COVID-19 (e.g., Use of real world evidence for safety assessments; COVID-19 in the Oncology population)
 - h. Personalized treatments
- 3. Transforming the Drug Safety Organization:**
 - a. From a cost center to a strategic value provider
 - b. Global QPPV role: how has it been operationalized?
 - c. Hot trends and topics in PV audits and inspections
 - d. Safety management planning: pre- to post-market continuity
 - e. Budgeting for Safety's expanded role (e.g., pharmacoepidemiologic analyses; risk minimization development and evaluation, and patient preference studies)
 - f. Diversity and inclusion
- 4. Benefit-Risk Assessment and Risk Management:**
 - a. COVID-19 pandemic and opioid analgesic abuse
 - b. Sharing learnings externally: publishing results of risk minimization studies
 - c. Impact of COVID-19 on design, implementation, and evaluation of risk minimization strategies
- 5. Future Directions in Patient Safety**
 - a. Integrating risk minimization measures into the healthcare delivery system
 - b. Patient voice in benefit-risk assessment and risk management
 - c. 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)
 - d. Risk communication in the era of COVID-19: What we can learn and apply for PV risk management?
 - e. Use of mixed methods and other novel research designs for risk minimization program evaluation
- 6. Diversity and inclusion in drug-related research and/or safety assessments**
 - a. Diversity and inclusion in drug-related research and/or safety assessments
 - b. Vaccine safety (e.g., Implications of COVID-19 for safety strategies, etc.)

Track 2 | Clinical Trials and Clinical Operations



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

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

Included Topic Areas

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

Priority Topics

1. Patient-Centered Endpoints

- Deriving endpoints from wearables, sensors, and novel technology
- eCOA
- Continuous Monitoring
- Data Validation, Data Integrity
- Therapeutic / Diagnostic applications
- Regulatory considerations – application of guidance

2. Monitoring – Quality and Compliance in Clinical Operations

- Monitoring plan and risk assessments
- Quality Tolerance Limits (QTLs) - Critical data – parameters - limits - How to define these upfront with limited existing product data?
- Latest Approaches to Monitoring
- Proactive monitoring; systems and tools
- Remote processes (remote auditing)
- Monitoring case studies during COVID-19

3. Clinical Study/Research Management – The Nuts and Bolts

- Managing Research in Emerging Regions
- eTMF / Document Management
- Impact of GDPR
- eConsent
- Protocol Design and Development
- Supply Chain Management (IMP)
- Patient Recruitment and Retention
- Social Media and Patient Centricity in Recruitment
- Feasibility and Site Selection
- GCP Training
- Managing Data Monitoring Committees

4. How do Crises Impact Drug Development?

- The impact of COVID-19 pandemic on trial design and conduct
- Requiring major industry advancement

- Preparing for crisis situations (future pandemics, natural disasters, etc.); Building operational flexibility into clinical protocols?

5. The Future of Clinical Research is Here

- Complete Innovative Trial Design: Pragmatic Trials, Master Protocols, Synthetic Control Arm Trials, Hybrid Trials
- Decentralized / Siteless Trials - models, design, operations, challenges, case studies
- Mobile Technology, Precision Medicine, Biomarkers, Genomics, and Diagnostics
- Use of Real World Data / Real World Evidence
- Integration of eSource and Electronic Health Records with EDC
- Artificial Intelligence / Machine Learning
- Automation

6. Diversity in Clinical Research

- Representation in Clinical Research

- Barriers to participation of racially and ethnically diverse patients
- Practical solutions to improve inclusion in Clinical Trials
- The role of community engagement in recruiting minority populations

7. Innovation in Partnerships and Collaboration

- Data sharing across pharmaceutical sponsors, regulators, CROs, and academia
- New and enhanced strategies that encourage information and idea exchange across stakeholders
- The next generation of open innovation: expanding collaborations with new partners (e.g. health foundations, patient organizations, and regulatory scientists)
- Common approaches to addressing and collaborating with new entrants (e.g. Google, Uber, Amazon)

Track 3 | Data and Data Standards



Data science is a multidimensional area that includes two major dimensions: Curation and Analysis. This track focuses on the curation dimension, 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
- Data Standards
- Real World Data / Evidence
- Mobile / wearable technologies
- Informatic solutions and machine learning
- Endpoints: evolving data requirements to support new endpoints

DIA recommends this track and associated sessions to professionals involved in: informatics (bio and medical), data standards and quality control (and regulatory standards implementation specialists), data quality, clinical data management, clinical trial design, clinical operations, eClinical (electronic health records), submissions and global submissions, health economics outcomes research, biostatistics, medical writing, real world evidence roles, epidemiology, post-market studies, regulatory affairs and operations, and statistics.

Included Topic Areas

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

Priority Topics

1. Real World Data / Evidence

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

2. Transformation of the Data Manager to the Data Scientist

- Merging or separate roles of data management and clinical data scientist
- Novel opportunities in a connected world
- Knowledge to amplify your career

3. Emerging Data Sources in Clinical Trials

- Effective integration in clinical study process
- Managing and ensuring data validation, quality, and integrity
- eSource opportunities and challenges integrating with clinical trials
- Impact on standard processes

4. Data Source Agility

- Case studies demonstrating novel techniques and strategies
- Analytical tools and technologies to support and enable virtual trials – how to apply RBM techniques
- How do virtual trials change data management standards and processes?

5. New and Emerging Standards, Guidance, and Regulations

- ICH relevant guidelines
- GDPR impact on data management practices and processes
- HL7 FHIR Vulcan: Bridging the gaps between clinical care and clinical research data standards
- Modernizing FDA Data Strategy/ EMA Data Guidance
- Cloud-based regulatory submissions and collaboration

Track 4 | Medical Affairs and Scientific Communication



This track will share insights from medical affairs professionals and medical writers across the globe. Sessions within the track will address necessary skills and best practices for working cross-functionally and compliantly within medical affairs, medical information, and scientific communication.

DIA recommends this track and associated sessions to professionals involved in medical or regulatory scientific writing, medical communications, and medical information. Medical science liaisons are also a key audience.

Included Topic Areas

Medical information; medical science liaison; medical writing; medical affairs roles throughout product lifecycle, stakeholder management, advisory boards, compliance.

Priority Topics

- 1. Technology: Systems, Utilization, and Impact of AI, Machine Learning, NLP, etc.**
 - Implementation of new system configurations globally
 - Change management
 - Technology innovation/virtual workspace
 - Business Continuity Plan/Crisis Management
- 2. Demonstrating Value and Insight Collection**
 - Collaborating with key stakeholders (eg., Publications, Training, Medical, Early Clinical Development groups, Contact Centers, Legal, etc.)
- 3. Globalization**
 - Content development, field medical exchange resources, organizational structure, communications, contact center, translation, compliance
 - Virtual congress management to maximize medical affairs congress presence and deliverables
- 4. Payor Interactions**
 - HEOR, RWE, dossiers, formulary discussions
 - Data mining, insights platforms, data analytics, application of dashboards, and other tools
 - Scientific response documents for priority needs (eg. COVID-19)
- 5. Improving Customer Interactions (HCPs, Patients, Field Medical)**
 - Channels-Chatbot, websites, interactive content, podcast, social media, etc.
 - Content Communication to ensure awareness
- 6. Creating Strategy and Consistent Scientific Messaging From Clinical Development to Medical Affairs with an Awareness for Diversity, Disparity, and Inclusion**
 - Education and training
 - Scientific platforms/Lexicon
- 7. Following Health Authority Guidance and Regulations**
 - EU CTR regulations, ICH, clinical transparency, GDPR, etc
 - Identifying impact of COVID-19 in clinical trial documentation and in Medical Affairs
- 8. Improving Efficiency and Quality in Regulatory Documents**
 - Collaborative authoring, structured content, automated content management, lean authoring, MLR reviews, other improvements

Track 5 | Patient Engagement



This track addresses meaningful patient engagement in medical product development, from early product development, and approval, through maintenance phases. It focuses on important questions for all stakeholders, including:

- How do we meaningfully engage patients and incorporate their voices into decision-making throughout the medical product lifecycle?
- How do we become truly patient- (and people-) centric in our approach?
- How do we operationalize patient-centric approaches in our day-to-day work?
- How can we measure the effectiveness of our efforts, both for patient outcomes and to meet the needs of other stakeholders such as industry and regulatory decision-makers?
- What have we learned that can be used to drive more meaningful patient engagement?
- How do stakeholders best work together to leverage their collective power and expertise to promote meaningful involvement of patients?

DIA recommends this track and associated sessions to professionals involved in: patient affairs, patient advocacy, patient groups, patient support services, medical affairs (including CMOs and MSLs), clinical trial design and optimization, clinical research and operations, regulatory affairs, regulatory agency, corporate and government affairs, safety and pharmacovigilance, outcomes research, epidemiology, and Health Technology Assessment.

Included Topic Areas

Meaningful patient engagement (PE), patient-centered drug development, patient centricity, fostering patient-centric culture, PE approaches, best practices for PE, building collaborative relationships with patients and patient groups, engaging with diverse patient populations, partnering with patients, science of PE, operationalizing PE, PE metrics, PE tools and resources, patient advocacy, lessons learned in PE, PE outcomes.

Priority Topics

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

- Beyond box-checking:** Whether it's an externally-led Patient Focused Drug Development (PFDD) meeting or a Patient Advisory Board, how is your best-practice patient engagement positioned as one element of a bigger strategy to elicit and integrate patient perspectives in small and large decisions that advance innovation and improve patient outcomes?
- 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 success have you experienced?
- Diving into data:** Patient Experience Data can be collected in many different ways, as FDA's guidances describe. How has early alignment on domains of interest, data standards, and data sharing/contribution agreements helped to decrease participant burden and

increase the utility and flow of data for various purposes? What other lessons have you learned?

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

- Prevalence:** How does the fact that a condition is rare or prevalent in the population affect patient engagement strategy? What are the advantages to driving patient engagement in rare diseases in spite of smaller numbers?
- 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.
- Timing:** Whether a condition is chronic or acute may affect the available or optimal "window" for engaging patients. The question driving patient engagement may also be specific to a point in time, such as developing PROs for early-stage disease vs. end-stage disease. Share examples and perspectives on how to assess timing as a consideration for patient engagement.

d. **Diversity:** Draw on your experiences to point toward better practices for reaching and engaging more inclusively, especially for engagement activities that seek to understand disparities in practice, outcomes, or access that may occur by gender identity, race, ethnicity, socio-economic status, health literacy level, etc.

3. **Scaling Patient Engagement: Moving Beyond Early Adopters, Expanding Across Therapeutic Areas, and More!**

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

b. **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 organizations, how do you inform patients and advocates to prepare them for these new opportunities to share their perspectives?

c. **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? Ideas for assessing immediate and long-term benefits to the community, the program, and the sponsor are welcome.

4. **"Yes We Can!" Busting Myths 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?

b. **Precompetitive multi-stakeholder initiatives:** What frameworks or resources have you developed as part of a regional or global initiative to help de-risk patient engagement? Publications and case studies involving multiple partners are welcomed.

c. **Managing conflicts of interest:** More and deeper engagement between sponsors and patient organizations can (and has) raised concerns about influence and independence. How is your organization helping define appropriate boundaries and put this conversation in the new context of patient-focused medical product development? What are ways to ensure that collaboration doesn't have unintended consequences for either party?

Track 6 | Preclinical Development and Early-Phase Clinical Research



Preclinical and early-phase clinical research provide initial safety, tolerability, and efficacy data for new drugs. This track focuses on topics ranging from early-stage compound selection, PK/PD, and safety considerations for both drugs and biologics, dosing strategies, novel preclinical models, and data integrity for proper downstream decision-making.

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

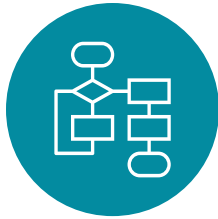
Included Topic Areas

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

Priority Topics

1. **Innovations in Early Development of Vaccines: Tackling COVID-19 and Beyond**
 - a. Clinical program of Vaccine products—differences for cancer vaccines vs infectious disease vaccines
 - b. Translatability of animal data to human data
 - c. Quantitative relationship between dose/dosing schedule and immune response
 - d. Regulatory landscape and considerations for vaccines development around the world
 - e. COVID-19 impacts—what changed, and lessons learned of developing vaccines in the COVID-19 era
2. **Diversity and Inclusion in Early Drug Development**
 - a. Leveraging patient advocacy groups to accelerate the drug development journey from preclinical to proof of concept
 - b. Implications for dose selection, modeling and simulation of drug response in diverse clinical trial populations in early development
 - c. Overcoming distrust to ensure diversity and inclusion in trials of genetically driven drug targets
3. **Continuing the Conversation: What’s New in Gene Therapy and Gene Editing**
 - a. Leveraging AI to predict complications in vector integration
 - b. Understanding durability of effect in cell and gene therapy
 - c. Considering the patient journey—cancer vs rare disease patients
 - d. Managing pandemic related challenges (supply chain, patient access, etc.)
 - e. Off-target editing—how do you estimate, predict, and interpret impact in treatment?
4. **Translation from Preclinical to Clinical in Anti-Infectives (e.g. Malaria, TB, COVID-19)**
 - a. Meaningfulness and predictivity of the selected preclinical animal model for the human in vivo system
 - b. Optimizing preclinical approaches to ensure data quality and informativeness (e.g. acute vs chronic animal models, short-term vs long-term treatment, in vitro parameters relevant for (or that can be reflected into in vivo systems etc.)
 - c. Leveraging preclinical data (in vitro, in vivo) to predict dose in human
5. **Challenges and Opportunities in Early Development of RNA Therapeutics**
 - a. Challenges in translation from pre-clinical to clinical
 - b. Strategies for drug metabolism, pharmacokinetics, and translating animal to human
 - c. Challenges with scale-up and delivery
 - d. Considerations for mRNA as vaccines vs rare disease therapeutics
 - e. Opening Pandora’s box—opportunities and challenges of self-replicating RNA as a therapeutic
6. **Epigenetic Drugs: Taking it to the Clinic—An Up and Coming Mode of Targeting Disease**
 - a. Using modified genome editors to regulate the epigenome
 - b. Challenges with delivery and stability
 - c. Risk mitigation for off-target effects
7. **Antibody-Drug Conjugate Drug Development: From Patient to Treatment Selection**
 - a. Manufacturing challenges
 - b. PK Considerations
 - c. Patient selection strategies in early trial design
 - d. Translational needs to optimize target antigen expression to clinical therapeutic benefit
 - e. New strategies to design next-generation ADCs
 - f. Strategies in pre-clinical and early development to reduce risk of failure
8. **Antibody Enhanced Disease**
 - a. Relevance and implications in drug development
 - b. Availability and translatability of animal models
 - c. Overcoming safety challenges for clinical development
- d. Mutagenic nucleoside analogs as anti-viral drugs - opportunities, risks, and challenges
- e. Pathogen resistance - (AI opportunities to evaluate and assess impact, strategies for overcoming pathogen resistance)
- d. Biomarkers for drug response
- e. Combo treatments with other drugs. e.g. with immunotherapy in cancer

Track 7 | Project Management and Strategic Planning



This track will illustrate best practices to improve project and program execution, strategic planning, and portfolio management, as well as how to collaborate more effectively with internal and external stakeholders to achieve project and program objectives. Attendees will hear recommendations from industry leaders on how to lead and manage projects and initiatives successfully across the entire medical product spectrum.

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

Included Topic Areas

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

Priority Topics

1. Project Management's Role in Influencing Diversity and Inclusion in Building Teams – engagement, mentoring and equality
2. Adaptability and Business Continuity Learnings from a Global Pandemic or Other Disruptive Events and Integrating into Future Planning
3. Leveraging Artificial Intelligence and Predictive Analysis for Project and Portfolio Management Decision-Making
4. Leading in the Midst of Ambiguity (conflict management, issue resolution, emotional intelligence, transparency)
5. Strategic Integration of Acquired Assets or Companies and Management of Alliances and Partnered Programs
6. Project Management Fundamentals (processes, tools, reporting, scheduling, resourcing, methodologies)

Track 8 | R&D Quality and Compliance



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

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

Included Topic Areas

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

Priority Topics

1. **Quality Risk Management: How to Balance Risk and Resources**
 - a. How good data governance promotes clinical trial quality
 - b. Quality Analytics: Effective strategies for using quality system data to drive continuous improvement including use of novel approaches (e.g. machine learning, artificial intelligence, real world evidence)
2. **Ensuring Data Quality and Data Integrity**
 - a. Anomalous data identified – how to further evaluate, understand potential impact, and determine when and what further actions are needed
 - b. Role of electronic systems audit trail data and control of system access in monitoring for GCP compliance
3. **Pharmacovigilance Quality: Optimizing Data Collection to Optimize the Benefit-Risk Profile - assuring effective implementation of risk minimization, and control of post authorization safety studies**
4. **Effective Oversight Strategies: Importance in Clinical Development**
 - a. CRO and vendor oversight
 - b. Has risk-based monitoring improved clinical trial execution, data quality, and safety of trial participants?
 - c. Role of centralized monitoring (and centralized quality assurance activities such as analytics) to improve quality and compliance
5. **Quality Innovation: What Does Clinical Quality Look Like in the Development of Innovative Products (e.g. cell therapies or other non-traditional biopharma products) and Innovative Trial Design (e.g. decentralized trials)**
6. **Maintaining GCP During Pandemic Circumstances and Using Lessons Learned to Improve Clinical Trial Conduct Moving Forward**
 - a. Remote and off-site quality control and quality assurance: strategies for monitoring and auditing when travel and on-site review is restricted
 - b. Using good risk assessment/management practices to guide decisions on clinical trial conduct
 - c. Challenges and solutions in obtaining consent during pandemic conditions
7. **Quality Culture: Driving Quality and Compliance Through Strategic Approaches and Critical Thinking Across the Organization to Meet the Changing Landscape**
8. **New Approaches to Inspections: Collaboration and Cooperation Across Stakeholders to Verify Quality and Compliance Through Remote, Off-Site, and Record Sharing Approaches**
 - 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

Track 9 | Regulatory



This track addresses global laws, regulations, guidelines, and guidances that govern prescription biopharmaceutical and device product development, approval, and maintenance. Representatives from FDA, EMA, PMDA, MHRA, BfArM, and ICMRA authorities, and other regulatory experts will provide global updates, insights, and discussion on current issues, opportunities, and challenges through interactive forums.

DIA recommends this track and associated sessions to professionals involved in: regulatory affairs and strategy, regulatory operations, regulatory information management, regulatory agencies, government affairs, legal affairs and compliance, policy and intelligence, clinical research and operations, PV, HTA, project management, and service providers developing tools and resources for use by sponsors and CROs.

Included Topic Areas

Regulatory affairs, regulatory policy, regulatory intelligence, regulatory strategy, global and US advertising and promotional regulations and laws; regulatory operation best practices, regulatory science, eSubmissions, regulatory document management; regulation pertaining to study endpoints, product labeling, biosimilars, combination products, advanced therapies (e.g. regenerative medicine, tissue products, gene therapy), companion diagnostics, devices.

Priority Topics

- 1. Experience with and Regulation of Innovative Approaches to Clinical Trial Design**
 - a. Complex Innovative Designs (CID) and Model-Informed Drug Development (MIDD)
 - b. Patient-focused medical product development
 - c. Real World Evidence (RWE)/Data (RWD) for use in regulatory decision-making
 - d. Decentralized clinical trials (DCT) and Platform Trials
 - e. Digital endpoints
 - f. Impact of COVID-19 and regulators' openness to new trial designs
- 2. Global Development and International Harmonization/Convergence**
 - a. Global development strategies and impact on clinical trial design and implementation (e.g., multi-regional clinical trial)
 - b. Updates on ICH, IMDRF, and other harmonization/convergence initiatives
 - c. Effect of emerging regulations on global registration strategies
 - d. Compare/contrast health authority approaches to regulatory interactions with industry
 - e. Global collaboration on COVID-19 therapeutics and vaccines: lessons learned
- 3. Regulatory Topics of Public Health Importance**
 - a. COVID-19 vaccines and therapeutics
 - b. Diversity in clinical trials
 - c. Global regulatory considerations for special populations or situations (e.g., rare/orphan, pediatrics, women, etc.)
 - d. Antimicrobial Resistance
 - e. Cell/Gene Therapy, and Regenerative Medicine Advanced Therapies
 - f. Rare disease endpoint development
- 4. Labeling Communications**
 - a. Communications with patients and healthcare providers
 - b. Global labeling modernization efforts
 - c. REMS and innovative approaches to ensuring patient safety
- 5. Review Modernization**
 - a. Aspects of FDA/CDER/OND modernization, i.e., Integrated Reviews
 - b. Electronic submissions, i.e., Cloud-based submissions
 - c. Review efficiency initiatives, i.e., ORBIS, RTOR
 - d. Health Authority/sponsor drug development interactions
 - e. Impact of COVID-19 and lessons learned
- 6. Regulatory Initiatives to Increase Competition**
 - a. Generic drug and biosimilar updates, i.e., GDUFA, BsUFA, emerging policies
 - b. Global generic drug and biosimilar drug development
- 7. Regulatory considerations for interactions with HTA/payor**
 - a. Regulatory-HTA/payor interactions
 - b. Integration of value parameters in drug development
- 8. Regulatory Considerations for Digital Health in R&D**
 - a. Data privacy, cybersecurity, qualification, validation
 - b. Use of digital tools pre- and post-marketing
 - c. Use of Artificial Intelligence / Machine Learning
 - d. The future of regulatory information and FDA submission processes
 - e. Digital health applications and combination products

Track 10 | Regulatory CMC and Product Quality



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

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

Included Topic Areas

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

Priority Topics

1. Learnings from Remote GMP Assessments and Inspections
2. Opportunities and Examples for Mutual Reliance and Recognition of CMC Assessment Across Multiple Regulatory Agencies
3. Building Manufacturing and Regulatory Capabilities for Rapid Response to Public Health Emergencies
4. Balancing Local Versus Global Supply Chains for Manufacturing Robustness and Agility
5. Advances in Patient-Centric Quality Standards for Specification Setting
6. Defining Quality for Cell and Gene Therapy Products
7. Current and Future Opportunities for Modernizing Pharmaceutical Manufacturing
8. ICH Quality – Advancing New Topics and Refreshing Foundational Guidelines

Track 11 | Statistics



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

DIA recommends this track for: biostatisticians, data scientists (analytics), statistical programmers, clinical pharmacologists, health economists, epidemiologists, regulatory scientists, physicians, project leaders, and other clinical development practitioners.

Included Topic Areas

Statistics, biostatistics, Bayesian statistics, novel statistical tools, data standards, analysis and analysis sets, data interpretation, data visualization, trial planning and design, adaptive designs, innovative designs, model-informed drug development, data monitoring committees, precision medicine and subpopulation analysis, biomarkers, multi-regional clinical trials, endpoint assessment, real world evidence, pragmatic trials, use of historical control, pediatric/rare disease drug development.

Priority Topics

- 1. Using Real World Evidence for Regulatory Decision-Making**
 - a. Pragmatic trials
 - b. Machine / Targeted learning
 - c. Natural language processing
- 2. Impact of COVID-19 on Clinical Development: COVID and Non-COVID Treatments**
 - a. Decentralized trials
 - b. Missing data (i.e. estimands)
 - c. Platform trials
- 3. Global Harmonization of Complex and Innovative Trial Designs**
 - a. Master protocols
 - b. Seamless / enrichment designs
 - c. Bayesian applications
 - d. Leveraging external information
- 4. Diverse Patient Population Representation in Trials and Applicability of Results: The Role of Statistics**
- 5. Ensuring Appropriate Statistical Inference**
 - a. Use and practice of reporting p-values
 - b. Approaches to ensure proper interpretation
- 6. Safety and Benefit-Risk**
 - a. Planning (e.g. program-wide evaluation)
 - b. Quantitative approaches
- 7. Communication and Collaboration**
 - a. Discussion of regulatory agency guidances and recommendations
 - b. Between analytic data scientists and biostatisticians

Track 12 | Value and Access



The healthcare landscape is evolving into one assessed on value, and there is a need to understand the impact of this movement on all stakeholders: providers, payers, biopharma, and ultimately patients. The Value and Access track will bring together global regulators, industry leaders, patients, and payers who will facilitate discussions and address questions such as:

- What information and evidence is being used to define value?
- Who is making or influencing access decisions?
- How can real-world data be leveraged to drive access to medicines?
- What are the regulatory and legal considerations surrounding value-based contracting conversations with payers?

DIA recommends this track and associated sessions to: payers, health economics outcomes researchers, health economists, statisticians, data modelers, clinical researchers, post-marketing professionals, and regulatory affairs professionals.

Included Topic Areas

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

Priority Topics

- 1. Paying for What Works: Value-Based Contracting Between Payers, Manufacturers, and Providers – Where Do We Go from Here?**
 - a. Value-based contracts and subscription models within states
 - b. Paying for outcomes within Medicare and Medicaid
 - c. How has VBCs panned out for pharma and commercial plans
- 2. Planning Studies to Meet Both Payer and Regulator Needs**
 - a. Choosing endpoints that matter for coverage decisions
 - b. Payer/regulator engagement within studies
 - c. FDA and CMS – Parallel Review
- 3. Pricing and Access Determinations: When and How to Engage Stakeholders (patients, payers, HCPs, etc.) During Drug Development Process and During Formulary Decisions?**
 - a. Potential options to engage and solicit input during drug development
 - b. Engaging stakeholders during development of pricing and access strategies
- 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. Ensuring Access to Treatments for Rare Diseases in Developing Countries**
 - a. Policy update on drug pricing-regulations and legislation
 - b. Key barriers to address with healthcare disparities
 - c. 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”?
 - c. Who “owns” data when the patient changes plans, stops treatment, or is “cured”?
 - d. Strategies for data sharing, data-base linking (e.g. EMR-claims), and maximizing EMR data

Track 13 | Professional Development



The Professional Education and Development track focuses its content on topics that improve and support ongoing personal growth for career and team success. This broad category includes: interpersonal skills, soft skills, leadership, goal-setting, life-long learning, career transitions (career growth, lateral career transitions, and entrepreneurship), social media/new media, and self-awareness to assess strengths and gaps.

Included Topic Areas

Networking, improving productivity and self-productivity, interpersonal relationships, diversity, hiring, leadership, technology, making a lasting impression, running remote meetings and workplace dynamics.

Priority Topics

1. **Barriers to Collaboration**
2. **Mindfulness**
3. **Technology: How to Use or Reviews of Collaboration Tools**
4. **Diversity, Disparity, and Inclusion**
 - a. How to have these difficult conversations, how to listen and learn
 - b. Be vulnerable – this is critical to having meaningful discussions and pushing teams forward through challenging discussions and times to create connection.
5. **Education on the Industry's Business**
 - a. Understanding Budgets
 - b. Understanding Master Service Agreements and Contracts
 - c. R&D understanding, Commercial, and vice versa
6. **Being a Consultant**
 - a. How to start
 - b. How to maintain
7. **Workforce Transformation**
 - a. How do sponsors engage with independent workforce/contractors; how have other industries done this
 - b. Remote Teams – Creating team cohesion from afar
8. **Get Comfortable Being Uncomfortable:**
 - a. Working Remotely as the New Norm: Juggling kids, elders, pets, spouses, and other distractions without losing your mind or burning out and or/your train of thought in the workday
 - b. Transparent conversations – articulate your needs to your boss and your family
 - c. Struggling in silence - people are going through a hard time and don't feel comfortable speaking up. Provide actionable advice around how to identify that struggle (especially virtually—and it is “in silence”) and then actionable ways for managers to address it

Abstract Submission Requirements

Please read the following instructions carefully; incorrect or incomplete abstracts will not be considered.

1. All abstracts must be submitted online to DIAhome.org/Abstract. The deadline for abstract submissions is **September 15, 11:59PM ET**. This deadline will not be extended. Please note: once on the DIA abstract submission homepage, you must select either the general session or short course 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 no later than the week of December 14.

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

Abstract Submission Tips and Tricks

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

Questions? Contact DIA at AnnualMeetingProgram@DIAglobal.org

Frequently Asked Questions

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

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

A: Yes, you must submit an abstract to be considered as a chair or speaker for DIA 2021.

Q: What constitutes a quality abstract?

A: Information provided in the “Abstract Details” section should include specific details or data to support your abstract submission:

- Unbiased content that does not promote a product, service, or organization; abstracts deemed to be promotional will be excluded from consideration
- Innovative and cutting edge information, or new developments related to the topic
- Real world applications, such as case studies or demonstrations
- A global perspective
- A session or presentation title that is compelling and attractive to potential attendees
- Content that is cross-functional and interdisciplinary, if possible/appropriate
- A clear target audience with clear learning objectives
- Plans for interactivity between the speakers and audience

Q: May an author submit more than one abstract?

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

Q: What information is required from the author?

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

Q: Can there be more than one author name?

A: Only one author name may be submitted.

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

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

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

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

Q: Are there abstract templates or samples available?

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

[Session abstract template](#)

[Session abstract sample](#)

[Forum abstract template](#)

[Forum abstract sample](#)

[Workshop abstract template](#)

[Workshop abstract sample](#)

[Presentation abstract template](#)

[Presentation abstract sample](#)

[Short Course abstract template](#)

Q: May someone submit the abstract on my behalf?

A1: Yes, for sessions, forums, and workshops, a submitter will have the option to complete author information even if they will not be the designee onsite in Philadelphia, PA or virtually present.

A2: Not for Short Courses. For the Short Courses the Instructor must complete the submission form.

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

A: Authors will be notified by December 18. 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 14.