DIA 2025

GLOBAL ANNUAL MEETING

WASHINGTON, DC | JUNE 15-19

CALL FOR ABSTRACTS

Submission Deadline:
September 12

DIAglobal.org/DIA2025

Table of Contents

About DIA 2025 ____ 3

Introduction ____ 5

General Submission Requirements ____ 6

Frequently Asked Questions ____ 7

2025 Track Offerings ____ 8

Track 1 | Clinical Safety and Pharmacovigilance ____ 9

Track 2 | Clinical Trials and Operations ____ 10

Track 3 | Data and Technology ____ 11

Track 4 | Medical Affairs and Scientific Communication ____ 12

Track 5 | Patient Impact on Product Development ____ 13

Track 6 | Personalized Medicine, Combination Products, and Diagnostics ____ 14

Track 7 | Project Management and Strategic Planning ____ 15

Track 8 | R&D Quality and Compliance ____ 16

Track 9 | Regulatory ____ 17

Track 10 | Regulatory CMC and Product Quality ____ 18

Track 11 | Statistics and Data Science ____ 19

Track 12 | Professional Development ____ 20

Track 13 | Executive: Key Challenges and Decisions in Life Sciences Innovation ____ 21

About the DIA 2025 Global Annual Meeting

DIA 2025

As the undisputed leader in the life sciences industry, the DIA 2025 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 2025 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 2025 Global Annual Meeting is to amplify different voices, recognize 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 2025 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 2025 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 2025 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 2025 tracks click here.

DIA is committed to including the voice of the patient at DIA 2025. 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 Impact on Product Development track, but to all relevant tracks. The AMPC will be looking for these during the abstract selection process.

Deadline is September 12, 2024 11:59PM ET

Types of Abstracts

There are four types of abstracts you can submit for DIA 2025, 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.

**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.*

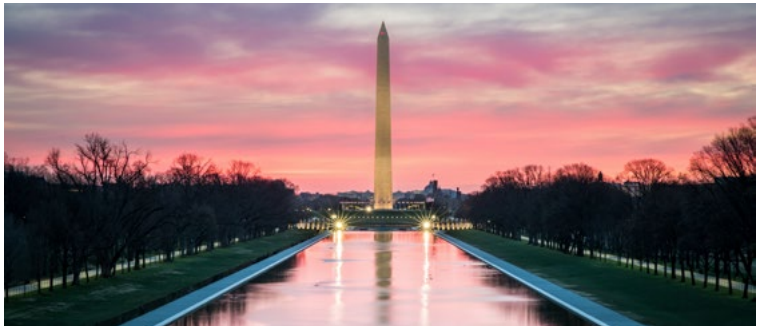
The abstract author is considered the session chair and will be responsible for the following:

- 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 2025

By submitting your abstract for DIA 2025, 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 Washington, DC!

DIA's global network transforms professional expertise into actionable progress for all. The goal of the DIA 2025 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 2025. 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 2025:

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 12, 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 2025.

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
Poster 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 Washington, DC.

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. Instructions for accessing Speakers will be provided via the acceptance email.

DIA 2025 Tracks

- Clinical Safety and Pharmacovigilance
- Clinical Trials and Operations
- Data and Technology
- Medical Affairs and Scientific Communication
- Patient Impact on Product Development
- Personalized Medicine, Combination Products, and Diagnostics
- Project Management and Strategic Planning
- R&D Quality and Compliance
- Regulatory
- Regulatory CMC and Product Quality
- Statistics and Data Science
- Professional Development
- Executive: Key Challenges and Decisions in Life Sciences Innovation

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., immune oncology)
3. **Benefit-Risk Assessment and Risk Management**
   - Structured benefit-risk assessment
   - Evaluation of risk minimization strategies
4. **Artificial Intelligence and Technology in Pharmacovigilance**
5. **Novel Approaches and Future Directions in Patient Safety**
6. **Pharmacogenomics**
7. **Patient Engagement and Safety in Pharmacovigilance**
8. **Pharmacovigilance for Devices and Combination**

Track 2
Clinical Trials and Operations

This comprehensive track covers the latest advances in clinical research development and operations. Sessions cover innovative design strategies, establishing efficiencies in operations, and effective integration of patient outcomes in clinical trial design. 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); 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. **Operationalization of Study Design**
   - Planning, design, and conduct from start up to close out – Use of innovative study designs and Real-world Data/Real-world Evidence
   - Lessons Learned from implementation decentralized clinical trials (DCT)
   - Operationalizing patient input/engagement
3. **The Future of Clinical Research Sites**
   - Workforce Training, Infrastructure, and Technological Integration for 2025 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**
   - Leveraging AI in project management - Early on and during the study
   - The management of international research studies
   - Incorporation of diversity considerations, making data-driven decisions on site selection and participant recruitment planning
   - Prescriptive vs predictive analytics for clinical trial planning
5. **Vendor Implementation and Management**
   - Challenges and opportunities for vendor selection and qualification
   - Integration of timelines and contracts
6. **AI and Generative AI as Your Co-Pilot**
   - From protocol optimization to realistic patient data synthesis – Doing more with less
   - AI protocol optimization considerations for protecting human participants
   - Best Practices for AI-Driven Clinical Project Management
7. **Considerations Before Start-Up: Challenges and successes**
8. **Diversity and Inclusivity in Clinical Trials**
   - Achieving diversity through broadening eligibility criteria to implementing diversity action plans (DAPs)
   - Insights on how to remove barriers to participation for research naïve sites
9. **Innovative Study Designs for Modern Clinical Trials**
   - Use of real-world data/real-world evidence (RWD/RWE)
   - Digital health technology (DHT) and DHT as part of the patient journey
   - Adaptive trial designs
10. **Effective Use Cases of Site Burden Reduction**
    - Staff retention
    - Risk-based quality management adoption levels, components and tools
    - RWD/RWE data quality, use, and regulatory guidelines
    - Sustainability of project delivery
    - Tools to increase site monitoring effectiveness

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
- Digital health outcomes
- Cloud-based regulatory submissions
- Data standards
- Real-world data (RWD) and real-world evidence (RWE)
- Data integration, sharing, and protection
- Global health authority collaboration
- AI and emerging technologies
- Emerging policies and regulations

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, structured data submissions, and global submissions, health economics outcomes research, biostatistics, medical writing, real-world evidence, pharmacoepidemiology, post-market studies, and regulatory affairs and operations.

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), real-world data from large data sets, including registries and national datasets, claims data, and payor/HTA expectations for real world data, and new technologies to support HTA and regulatory submissions.

Priority Topics

1. **Pharmacoepidemiology and Real-world Evidence (RWE)**
   - Evaluating fit for purpose/relevance and reliability
   - Digital health outcomes
   - Data integration reliability and accuracy
   - Payor/Health Technology Assessment (HTA) expectations for real-world data (RWD)
2. **Access and Equity**
   - Digital health literacy
   - Understanding diversity of treatment effects
   - Patient identification and recruitment
   - Data privacy and security (data protection in the digital age)
   - Data sharing with patients (lessons learned/case studies)
3. **AI and Emerging Technologies**
   - Case studies of AI applications in drug development lifecycle (Phase I through Phase IV)
   - New technologies to support regulatory and HTA submissions
   - Use of AI and emerging technologies to support expedited pathways
   - Validation of outcomes for regulatory use
   - Leveraging emerging technologies to optimize trial experiences for patients
4. **Data Access, Standards, Sharing and Exchange**
   - Health Authority technology and data modernization strategies
   - Cloud-based regulatory submissions and collaboration
   - Regulatory collaboration framework leveraging technologies
   - Structured data submissions
5. **Driving Adoption through Policies and Regulations**
   - Industry and Health Authority perspectives on emerging technology policies (e.g., AI/GenAI)
   - Regional regulatory reforms and global health authority collaboration
   - Evolving regulatory pathways, data standards (e.g., M11, M4Q), and intersection with security and privacy regulations

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) ICH updates, clinical transparency, GDPR, CTIS compliance, and other related topics
   - Development and use of the FDA Assessment Aid, metrics based on RTOR, START pilot, NDRP, IND modernization, and updates on regulatory workstreams
   - Success stories and lessons learned from experiences of accelerated submissions to global regulatory agencies with practical and tactical advice for in regulatory medical writing managers and/or and medical affairs managers
   - Submissions to global regulatory agencies
2. **Building Strategy, Scientific and Regulatory Messaging, Medical Affairs and Medical Writing to Foster Awareness of Diversity, Equity, and Inclusion**
   - Insights on how to ensure the general public has access to high-quality information derived 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
   - Writing strategies associated with alignment/implementation of the guidance Patient-Focused Drug Development: collecting comprehensive and representative input
3. **Technology in Medical Writing and Medical Affairs: Case Studies, Metrics, Implementation, and Change Management**
   - Case studies on innovative solutions utilizing technology (e.g., structured content authoring, content reuse, automation, AI, combination solutions, etc.) within Medical Writing in the development of clinical and nonclinical regulatory document and publications
   - Change and process management, caution/considerations for technology implementation, and impact of implementation of technology solutions on the process of medical writing
   - Customization and personalization of data for real-time presentation/data visualization and uses of graphical data
   - Discussion and regulations surrounding the use of technology in regulatory submissions, medical writing, publications, and medical affairs, including AI, LLMs, machine learning, generative AI, and authoring platforms
4. **Improving Customer (Patients, HCPs, Field Medical) and Payer Interactions**
   - Improving health literacy, increasing content palatability, using innovative patient communication and engagement tactics
   - Implementation and strategies for returning clinical trial results to participants
   - As it pertains to Medical Writing and Medical Affairs, the demonstration of HEOR, real-world evidence, and real-world data via case studies and/or benefits to payers
5. **Ensuring Regulatory Compliance and Improving Efficiency and Quality in Regulatory Documents and Submissions**
   - Discussions on new regulations and guidance in clinical and nonclinical regulatory medical writing
   - Medical Writing and leveraging disease, region and country-specific guidances in trials and submissions
   - 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. **Medical Writing and Medical Affairs Career Journey, Skill Development, and Reskilling in a Changing Environment**
   - Strategies, success stories, and metrics to inform and enlighten medical writing management (advanced)
   - Cautionary advice and metrics: what can go wrong and what is the impact
   - Advice on defining new skills, curriculum development, and creating key performance indicators
7. **The Role of Medical Affairs in Bridging Clinical Development and Market Access**
   - Trends in reassignment of HEOR teams to centers of excellence in RWE or under Medical Affairs.

Track 5
Patient Impact on Product Development

This track represents the fusion of the patient-focused drug development and value and access tracks, emphasizing the critical intersection of patient-centric approaches and value-driven healthcare. It focuses on the integration of patient-centric methods in medical product development and the evolving landscape of value-based care and healthcare access. The track aims to address meaningful patient engagement (PE) throughout the product lifecycle and tackle the complex issues surrounding value assessment and market access. Attendees will explore how patient outcomes and value-driven healthcare can guide R&D strategies. This track brings together global regulators, industry leaders, academics, patients, and payers to discuss and address critical questions for all stakeholders.

Patient-Guided Medical Product Development:

- How do we meaningfully engage patients and incorporate their voices into decision-making throughout the medical product lifecycle?
- How do we operationalize patient-centric approaches in our day-to-day work?
- How do we measure the value of efforts
- 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?

Value and Access in Healthcare:

- 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 improve access to medicines?
- What are the regulatory and legal considerations?

DIA recommends this track and associated sessions to professionals involved in patient affairs, advocacy, or support services; clinical trial design and optimization; regulatory affairs/agencies; corporate and government affairs; health economists; outcomes researchers; epidemiologists, Health Technology Assessment (HTA) staff; payers; bioethicists, and data scientists.

Included Topic Areas

Patient engagement (PE): Meaningful collaboration, best practices, and tools; Patient-centric development: Patient-guided drug creation and fostering a patient-first culture; Diverse patient partnerships: Engaging diverse populations and building collaborative relationships; Operationalizing PE: Implementing strategies, metrics, and resources; Patient advocacy: Insights and outcomes from effective advocacy; Comparative effectiveness: Research and real-world outcomes; Inclusion and Ethics: Diversity, equity, inclusion, and ethical clinical research; Healthcare evaluation: Health Technology Assessment (HTA) and value-based care; Economic considerations: Drug pricing, reimbursement, access, commercialization, and lifecycle management.

Priority Topics

1. **Sustainable and Quantifiable Clinical Trial Diversity and Inclusion Approaches**
   - Case studies and lessons learned from clinical trial diversity action plans (e.g., community collaborations, impact of decentralized clinical trials [DCTs])
   - Expanding the definition of diversity beyond race and ethnicity (e.g., pregnant, lactating individuals)
   - Methods to address bias in clinical decision-making to increase diversity
   - Information/communication equity in clinical trials
2. **Value Impact of Patient Engagement in Drug Development**
   - Utilizing patient engagement as a strategic and systematic tool to de-risk research ahead of development
   - Integration of patient engagement into benefit-risk assessment in drug development
   - Generating patient-relevant outcomes and evidence for improved access
   - Insights on utilizing and communicating patient preferences in clinical research and regulatory evaluations of medicinal products
3. **Effective Collaboration from the Patient Advocate's Perspective**
   - Understanding the benefits for patients and advocates
   - Evidence-based advocacy for health equity and access
   - Case studies of impactful drug development collaborations that increased product value for patient communities
   - Methods to improve the pace of medicines development
   - Integrating clinical research as a care option
4. **Democratizing Patient Experience Data (PED) through AI and Digital Innovations**
   - The role of AI in enhancing patient experience data
   - AI's contribution to shared healthcare decision-making
   - Ethical and data privacy considerations in patient engagement and AI
   - Case studies of AI improving the use of PED in R&D
   - Managing the evolving complexity of risk in highly digitized clinical trials
   - Frameworks for systematic patient engagement (PE) across pipeline indications, lifecycle management, and post-market access
5. **Overcoming Barriers to Patient Engagement Across Organizations**
   - Real-world evidence (RWE) and its impact on value and access
   - Examples of RWD and RWE informing access and value assessment
   - Combining formulary data with claims to examine access barriers and clinical outcomes
6. **Drug Shortages**
   - Understanding the causes and effects on patient care and outcomes
   - Developing patient-centered remediation strategies
   - Long-term implications for patient health and access to essential medications
   - Case studies on the impact of shortages on patient outcomes and how they were addressed
   - Collaborative approaches with patients and healthcare providers to prevent and mitigate shortages
7. **CMS' National Coverage Determination for Alzheimer's Disease**
   - One year in, what is its impact on patients and access?
8. **The EU's General Pharmaceutical Legislation/GPL and Joint EMA HTA Assessment**
   - What is the status of negotiations of the two regulatory proposals?
   - How will the EU Council manage the discrepancy with the Commission and Parliamentary versions of the GPL?
   - What are the benefits and risks of a centralized HTA?

Track 6
Personalized Medicine, Combination Products, and Diagnostics

Precision medicine will combine medicine, diagnostics, and medical device technologies in unique ways to maximize healthcare services and outcomes. This track focuses on the latest precision medicine strategies used in compound selection from libraries, innovative combination products, 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. 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, 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 product development, preclinical and clinical studies, and challenges in rare and common diseases.

Priority Topics

1. **What's New in the Evolving Space of Global Diagnostic Regulation**
   - Implications and current climate of the EU AIA at the intersection of EU Clinical Trial Regulation (CTR), EU Medical Device Regulation (MDR)/In Vitro Device Regulation (IVDR) and the EU Medicines Regulatory Framework for combination product development
   - Companion diagnostics (CDx) global updates
   - Quality management system optimization to meet diagnostic requirements
   - Clinical Trials: IVDR impact and strategies for success
2. **Medical Devices and Next Generation of Drug Delivery**
   - Nanomedicine, nanotech particles, nanodiamonds
   - Patient centric technologies
   - EU MDR
   - FDA Device Initiative (Updates on the DRAFT Guidance on EDDOs, platform technologies, use-related risk analysis application, and combination product user fees)
   - International Medical Device Regulators Forum (IMDRF) AI/ML medical device development guidance
   - Combination products
3. **New Concepts and Applications in Gene Editing Delivery**
   - Gene editing in practice: current research and lessons learned
   - Patient perspectives on gene editing technology
4. **Regulatory Precision Medicine and Advanced Therapy Initiatives**
   - FDA: Final rule feedback and updates to regulate laboratory developed tests (LDTs)
   - EU partnership on personalized medicine
   - Personalized medicine developments: global regulatory updates
   - cATMP products and regulatory pathways for unmet medical needs
   - Development, clinical, manufacturing, safety (pre/post market) and integrated regulatory strategies
5. **Clinical Development and Adaptive Translational Strategies**
   - Adaptive design for biomarker-driven trials
   - Designs using device platform for curative therapies and cell gene therapy
   - Combination products and companion diagnostics for cell and gene therapy and gene editing
6. **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
7. **Pre-Clinical Modeling Development for Emerging Technologies**
   - Selection of an appropriate model for advanced therapies
   - AI modeling to drive tailored personalized treatments
   - Tissue models and liquid biospecimens
   - Pre-market safety and risk management review and application
   - Supplier and/or laboratory selection of pre-clinical data
8. **Digital Pathology and Precision Diagnostics within Precision Medicine**
   - Application of AI and machine learning technology in medical product development
   - Digital pathology in good laboratory practices (GLP) and good manufacturing practices (GMP) and CDx
   - Liquid biopsy as a novel diagnostic tool
   - Patient selection for clinical trials
   - Molecule design

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. **Drug Development Decision Making**
   - Use of artificial intelligence (AI), real-world evidence (RWE) or real-world data (RWD), analytics, or patient perspectives to optimize drug development and launch readiness
2. **Patient Centric Drug Development**
   - Incorporating patient perspectives and patient centric integrated evidence plans into development plans and launch strategies
3. **Inclusion of Low and Middle-income Countries (LMIC) in Development Planning**
   - Best practices for inclusion of LMICs into development plans and what PMs need to know to develop realistic plans, timelines, budget, and resources
4. **Program Management/Leadership Capabilities**
   - Insights on effective leadership capabilities, planning, managing ambiguity, agile or hybrid approaches, KPI development, and communication. Topics should be rooted to drug or device development
5. **Program Management, Program Leadership, and/or Portfolio Oversight in The Asset Value Chain**
   - Insights on best practices, effective risk management, optimization, etc. across the pharmaceutical development value chain (from discovery to launch excellence). Abstracts may include presentations on stages of development or dive into project management of functional areas, e.g., CMC, Medical Affairs, Regulatory, Clinical Operations
   - Leveraging shared knowledge or challenges in exciting frontiers which may have additional complexity, risk, and opportunities in application of end-to-end program management. Abstracts may include presentations from subject matter experts on focused areas such as (CMC, Regulatory Affairs, Clinical Pharmacology, Safety, etc.)
     - e.g., cell and gene therapy, RNA and DNA based therapeutics, gene editing, digital therapeutics, micro biome-based therapeutics, nanomedicine, radionuclides, Bispecifics, etc.
6. **Collaboration Excellence**
   - How to bring value to the pharmaceutical value chain through strategic alliances, consortiums, and academic, vendor, and sponsor partnerships.
     - Best practices, capabilities, lessons learned
7. **Transformation Management**
   - Unique considerations, best practices, real-world experiences in leading organizational and digital transformations

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), Risk-based Quality Management (RBQM), and Risk-Based Monitoring (RBM)**
   - Updates on ICH E6R3 Annex 1 and strategies for implementation
   - Strategies for teams to work cross-functionally to successfully integrate quality into the design of the trials from the beginning, during the design and planning phases. Considering the trial's scientific merits, clinician and patient perspectives, lessons learned from past trials, and operational feasibility
   - Strategies for incorporating stakeholders' involvement (e.g., patient groups, clinical investigators, statisticians, data scientists and other key stakeholders) in QbD including their input when identifying a study's critical to quality factors, identifying risks to the critical to quality factors, and implementing risk mitigation/management strategies
   - Strategies for implementing clinical trial quality management that is fit-for-purpose and tailored to the complexity of and risks associated with the trial
   - Use of risk assessments and data analytics to guide decisions on clinical trial conduct (e.g., QTL development and monitoring, evaluation of QTL deviations and their potential impact, and implementation of preventative and/or corrective actions)
   - Strategies for using advanced analytics for quality control and assurance to improve efficiency, effectiveness, and continuous improvement including use of novel approaches (e.g., artificial intelligence and machine learning)
   - Innovative quality control and quality assurance strategies for monitoring and auditing, including expanding risk-based monitoring methods (e.g., right fit SDV/SDR, onsite, remote monitoring, centralized monitoring)
   - Innovative ways to improve risk management and collaborative transparency between regulators and sponsors
   - Considerations and applications of QbD for non-interventional post authorization safety studies to promote compliance with GPvP requirements.
2. **Maintaining good clinical practice (GCP) compliance and data quality in trials that use (1) RWD to support regulatory decision-making and (2) agile and flexible operational approaches, such as trials that incorporate decentralized and pragmatic elements and adaptive clinical trial designs (e.g., master protocols)**
   - Updates to ICHE6R3 Annex 2
   - Risk-based approaches and issue management to support agile and flexible operational approaches
   - Innovative strategies for assessing the quality and reliability of real-world data (RWD) and its sources
   - Strategies for ensuring data quality in trials that use digital health technology-derived data
   - Challenges and solutions in obtaining informed consent remotely or using electronic technology
3. **The role of good data governance in promoting clinical trial quality**
   - ICHE6R3 data governance updates
   - Audit trail review to ensure data integrity, potentially including team roles and responsibilities
   - Approaches to robust data mapping as a method for identifying and mitigating risks to data quality , potentially including services provided by CROs and other service providers
   - Data governance case examples
   - Evolving approaches to data governance using artificial intelligence and machine learning (e.g., protocol deviation trending, query resolution)
4. **Regulatory Convergence**
   - Collaboration and cooperation across regulators and other stakeholders to verify quality and compliance through innovative approaches (remote, on-site, and hybrid)
   - Collaboration between regulators and/or sponsors on innovative approaches to GCP/PV quality
   - Collaboration and approaches to regulatory inspections
5. **Pharmacovigilance Quality:**
   - Optimizing data quality to achieve PV compliance targets and accurately assess benefit-risk profiles.
   - Future advancements in PV and how to maintain compliance when using novel approaches (e.g. AI, non-interventional post authorization safety studies advancements, additional risk minimization measures, and digitalization of the product information)

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
   - New legislation in key markets
   - 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. **Special Population in Health Research and Product Development**
5. **Utilization of Real-world Data (RWD) and Real-world Evidence (RWE)**
   - RWE for regulatory decision-making with a focus on efficacy/effectiveness
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 (quality and management 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. **Enablers for One Global Dossier for Regulatory CMC**
    - ICH M40(RS), IDMP, Structured Data
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 - AI in Regulatory CMC, Manufacturing, Next Sequencing Generation (NGS) and Platform Technologies**
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/real-world evidence in clinical development
   - Bayesian Approaches
2. **Current Challenges and Opportunities in Data Science and AI**
   - Handling data use and privacy
   - AI Ethics
   - GxP validation (computer system validation) for AI-based systems
3. **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 (RCTs)
   - Estimands for safety and benefit-risk
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. **Quantitative Methods for Benefit-Risk**
   - Application of appropriate statistical methodologies to properly interpret safety data
   - Improved planning in the design of clinical development programs to evaluate risks and benefit-risk methods
   - AI and statistical methodologies for signal detection in RCTs
   - Integrated safety analysis
6. **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)
   - Data Science training and use of existing libraries
   - Leveraging open-source tools for data science, including application in analysis to support regulatory decisions
7. **Therapeutic Area/Indication Specific Challenges**
   - Oncology studies
   - Neurology studies
   - Other therapeutic areas/indications
8. **Study Design and Analysis for Post-Marketing Studies**

Track 12
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
   - Navigating corporate culture – map to the mine field
   - Importance of style flexing
   - Define and enable Feedback Cycle
   - Timing of career transition – (when is it time)
3. **Impact of Culture within an Organization**
   - Importance of diverse staffing
   - Building and leading high performing teams
4. **Leadership Skills**
   - Critical thinking
   - Situational Leadership
   - 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)

Track 13

Executive: Key Challenges and Decisions in Life Sciences Innovation

The Executive Track is tailored for senior leaders and decision-makers in the life sciences industry. This track focuses on emerging innovation and challenges that decision-makers face as they navigate the complex ecosystem of moving from research and development to approval and market access. It will focus on strategic insights and explore the intersections of industry, regulators, payers, and the entire ecosystem in shaping the future of healthcare.

Priority Topics

1. **Generative Artificial Intelligence (GenAI) and Digital Transformation: Leveraging AI and technology for business and product transformation to improve overall outcomes and accelerate personalization and delivery**
2. **Advanced Therapies and Innovation: Accelerating the pipeline from discovery to delivery of advanced therapies. Understanding the possibilities and finding solutions to barriers**
3. **Regulatory Strategy: Collaborating and guiding an evolving regulatory landscape to provide therapies quickly and safely to patients.**
4. **Collaborating Across the Ecosystem: Navigating complexity and working with key stakeholders for integrated effective solutions.**