



CHARTING NEW HORIZ®NS





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ABOUT THE DIA 2024 GLOBAL ANNUAL MEETING

DIA 2024 commemorates our 60th anniversary as a neutral and transparent global forum, fostering the exchange of ideas to propel scientific and medical innovation forward. Anchored in the theme "Charting New Horizons," *DIA 2024* will unite industry leaders, regulators, academics, and patients to navigate the future of healthcare development.

At its core, *DIA 2024* aims to amplify diverse voices and showcase global expertise through integrated education and networking opportunities. This unparalleled event serves as a cornerstone platform where thousands of brilliant minds converge to innovate solutions and catalyze knowledge creation.

With over 180 on-site sessions spanning 13 educational tracks, attendees will have the chance to deepen their understanding within their field and explore enriching new horizons.



GLOBAL HEAD OF BUSINESS OPERATIONS

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- Jack Foster, MBA Chief Financial Officer
- Maria Vassileva, PhD Global Head of Science & Scientific Strategy
- Timothy Hess Vice President of IT
- Katie Hill, MAT Senior Vice President & Managing Director, Global Products and Professional Education
- Ania Mitan, MBA, MPharma Senior Vice President & Managing Director, DIA EMEA, India and Singapore

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- · Jens Grueger DIA Director
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- · Jörg Schläpfer, PhD Council of Regulators
- Younjoo Park Council of Regulators
- Sabine Haubenreisser Council of Regulators
- Alison Cave Council of Regulators
- Samvel Azatyan, PhD Council of Regulators



KEYNOTE SPEAKERS AND PLENARY

We are thrilled to unveil the esteemed keynote speakers for DIA 2024, who will ignite conversations and lead us into the future of life sciences innovation! Without further ado, join us in our excitement to welcome:



Tom and Emily Whitehead

Patient Experience with CAR T-Cell Therapy

Hear firsthand the incredible journey of Emily Whitehead, the pioneering pediatric patient who defied the odds and became the first in the world to undergo CAR T-cell therapy. Tom and Emily will share their invaluable insights into the transformative power of CAR T-cell therapy, offering a unique perspective that promises to captivate and inspire.



Dean Kamen, DEKA Research & Development Corp.

Future of Regenerative Therapies, How Public-Private Partnerships Can Impact Advancement

Join visionary inventor Dean Kamen as he delves into the future of regenerative therapies and the pivotal role of public-private partnerships in driving innovation forward. With a track record of groundbreaking technologies, Dean will illuminate the path toward revolutionary advancements in life sciences.

ESTEEMED PANELISTS WITH GLOBAL PERSPECTIVES

Possibilities and Boundaries in Charting New Horizons



EMA Perspective
Emer Cooke, Executive Director of the European Medicines Agency



FDA Perspective Peter Marks, Director of the Center for Biologics Evaluation and Research



Patient Perspective
Stacy Hurt, Chief Patient Officer, Parexel



Innovation Perspective Dean Kamen, DEKA Research & Development Corp.



Industry Perspective Carsten Linnemann, PhD, Co-founder and CEO of Neogene Therapeutics, AstraZeneca Group



Moderator David Mukanga, Deputy Director of Africa Regulatory Systems, Bill and Melinda Gates Foundation



KEY TRACKS



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.



Clinical Trials and Clinical Operations 🗹

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



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:

- · Current and innovative methods to evaluate technology
- Structured and unstructured data sources
- Data quality
- Blockchain technology and cloud computing
- Data standards
- Real-world data/evidence

- Mobile/wearable technologies
- Informatic solutions and machine learning
- Evolving data requirements to support new endpoints
- Data visualization
- DEI strategies to ensure representative and unbiased data



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.



Patient-Focused Drug Development 🗷

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?



Translational Delivery Technologies and Precision Medicine 🗹

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





TRACK

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TRACK

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Project Management and Strategic Planning 📿

This track will illustrate best practices to improve project and program execution, strategic planning, and portfolio management. Sessions will highlight how to collaborate more effectively with internal and external stakeholders to achieve optimal efficiencies in project and program development. DIA recommends this track and associated sessions to professionals involved in or interested in making a career move into project management, portfolio management, and decision-making, alliance management, clinical development, clinical operations, marketing/commercialization, and CROs/Vendors. Topics related to bioethical issues are also welcome and may be considered for a special track in the meeting.

R&D Quality and Compliance 🗹

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

Regulatory 🖸

This track is composed of sessions addressing global laws, regulations, guidelines, and guidance's that govern prescription biopharmaceutical and device product development, approval, and maintenance. Representatives from FDA, Health Canada, NMPA (National Medical Products Administration), PMDA (Pharmaceuticals and Medical Devices Agency), EMA, MHRA (Medicines and Healthcare products Regulatory Agency) (Medicines and Healthcare products Regulatory Agency), European Health Authorities and ICMRA authorities, and other regulatory experts will provide global updates, insights, and discussion on current issues through interactive forums. Themes commonly revolve around global regulatory changes and impact on global development strategies, global harmonization/convergence and impact on drug development and advances and innovations to improve the practice of regulatory affairs, and regulatory hot topics.



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.

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.



Value and Access 🗹

The healthcare landscape is evolving into one assessed on value, and there is a need to understand the impact of this movement on all stakeholders: providers, payers, biopharma, and patients. Value and access to medicines are complex issues that require analysis from health, economic, and philosophical perspectives. The Value and Access track will bring together global regulators, industry leaders, academics, patients, and payers who will facilitate discussions and address questions such as:

- What information and evidence are being used to define value?
- What are the ethical considerations when determining access to medical products?
- Do strategies that increase diversity and inclusion in clinical trial research improve access to medicines? Who is making or influencing access decisions?
- How can real-world data be leveraged to drive access to medicines?
- What are the regulatory and legal considerations?



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.





DIAMOND SESSIONS

DIAmond Sessions represent rare opportunities for deeper connection with leaders in life sciences through insightful dialogue. Join us in charting new horizons toward the future of transformative global healthcare.

DIA 2024 DIAmond Sessions will allow for deeper discussions into critical themes from the keynote plenary session. Expect thoughtprovoking conversations around some of the major themes of DIA 2024, including AI innovation, Regulatory Convergence, and Combination Products – from cutting-edge technologies to novel approaches to research and development.



Navigating the Trusted, Responsible, and Ethical Horizon of Artificial Intelligence: Uniting **Healthcare Perspectives**

11:00AM-12:00PM PT

Artificial Intelligence (AI) is making its presence known in healthcare, presenting unprecedented opportunities and challenges. It is crucial to devise strategies that ensure its ethical and responsible utilization for the betterment of healthcare and society. This imperative can only be met by harnessing the collective power of the broad healthcare ecosystem. Join us for an engaging DIAmond session featuring esteemed panelists from technology companies, pharmaceuticals, patient advocacy groups, and academia/ research to delve into how we can leverage the momentum of AI while establishing a foundation of trust.



International Regulatory Convergence: Regulatory Science to Address Challenges Brought by Pharmaceutical Innovation

10:00-11:00AM PT

Innovative approaches have the potential to create new opportunities for patients, but they also bring challenges to regulators, called to evaluate and supervise products for which traditional regulatory approaches might not be appropriate. Global regulators will discuss how regulatory science is key to develop solutions and how regulators worldwide need to work together to overcome such challenges.

WEDNESDAY JUNE 19

Pioneering New Frontiers: Advanced Drug Delivery Technologies and Cell/Gene Therapies in **Combination Products**

10:00-11:00AM PT

Advanced therapies and combined advanced therapies are emerging as innovative medical products due to their contribution to advancing medical care and are thus expected to have major impact in the coming years. The successful development of combination products will require great collaboration within the industry to overcome regulatory, clinical, and technical challenges. When developing an advanced therapy product, there are many things to be considered - relationships between tissue, biologic, and device development as well as early establishment of regulatory and clinical strategies, understanding user needs, determining product requirements, as well as device manufacturing variation.



EMA-FDA Question Time

9:15-10:15AM PT

In this interactive forum experts from EMA and FDA will address guestions from the audience and share their experiences of collaboration in specific areas as well as on how both Agencies collaborate in addressing current regulatory, scientific, and communication challenges. Attendees will gain an overall understanding of the regulatory and scientific collaboration between EMA and FDA; be able to describe experience and explore specific areas of collaboration between the two agencies; and examine how EMA and FDA are addressing regulatory and scientific challenges in new areas.

FDA Town Hall

10:45AM-12:00PM PT

The FDA Town Hall is the forum to hear from FDA leadership about Center priorities. The audience will be invited to submit guestions of general interest. This interactive session features collaborative discussion around FDA Center strategies and priorities.



SCHEDULE AT-A-GLANCE

MONDAY, JUNE 3 - TUESDAY, JUNE 11

Pre-Conference Short Courses (Virtual) Schedule

9:30AM-12:30PM	Half-Day Morning Pre-Conference Short Courses
1:00-4:00PM	Half-Day Afternoon Pre-Conference Short Courses

SATURDAY, JUNE 15

Registration Hours 8:00AM-5:00PM **Exhibitor Registration**

SUNDAY, JUNE 16

Registration Hours

8:00-9:00AM Registration for Full Day Pre-Conference Short Courses* 8:00AM-6:00PM Attendee, Speaker, and Exhibitor Registration

Schedule

9:00AM-5:00PM Full Day Pre-Conference Short Courses* *Space is limited for Pre-Conference Short Courses. Onsite Registration is available, but not guaranteed. 7:00-9:00PM **DIA Annual Meeting Networking Reception,* USS Midway** *Space is limited. Pre-registration is required.

MONDAY, JUNE 17

Registration Hours

7:00AM-5:30PM Attendee, Speaker, and Exhibitor Registration

Schedule

7:00-8:00AM	Coffee and Light Refreshments	
7:00-7:45AM	Annual Meeting Orientation	
8:00-10:00AM	Opening Plenary and Keynote Address	
10:00AM-5:30PM	Exhibit Hall Open	
10:00-11:00AM	Coffee Break (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall) Student and Professional Posters (Exhibit Hall) Student Case Competition (Content Hub)	
11:00AM-12:00PM	DIAmond and Educational Tracks	
12:00-2:00PM	Luncheon Service	
12:15-2:15PM	Student and Professional Posters (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall) Content Hubs and Community Rounds	
2:15-3:15PM	Educational Tracks	
3:30-4:30PM	Educational Tracks	
4:30-5:30PM	Opening Reception (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall)	

TUESDAY, JUNE 18

Event

6:00-7:45AM

CISCRP's Medical Heroes Appreciation 5k Walk & Run Event

Registration Hours

7:00AM-5:15PM Attendee, Speaker, and Exhibitor Registration

Schedule	
7:00-8:00AM	Coffee and Light Refreshments
8:00-9:00AM	Educational Tracks
9:00AM-5:00PM	Exhibit Hall Open
9:00AM-4:30PM	Professional Posters Open (Exhibit Hall)
9:00-10:00AM	Coffee Break (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall)
10:00-11:00AM	DIAmond and Educational Tracks
11:00-1:00PM	Community Networking Lunch/Luncheon Service
11:15AM-1:15PM	Innovation Theater Presentations (Exhibit Hall) Content Hubs and Community Rounds Professional Posters (Exhibit Hall)
1:15-2:15PM	Educational Tracks
2:15-3:15PM	Refreshment Break (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall) Content Hubs and Community Rounds Professional Posters (Exhibit Hall)
3:15-4:15PM	Educational Tracks
4:30-5:30PM	Educational Tracks

WEDNESDAY, JUNE 19

Registration Hours

7:00AM-5:15PM	Attendee, Speaker, and Exhibitor Registration	
Schedule		
7:00-8:00AM	Coffee and Light Refreshments	
8:00-9:00AM	Educational Tracks	
9:00AM-3:30PM	Exhibit Hall Open	
9:00-10:00AM	Coffee Break (Exhibit Hall) Innovation Theater Presentations (Exhibit Hall)	
10:00-11:00AM	DIAmond and Educational Tracks	
11:00AM-1:00PM	Luncheon Service	
11:15AM-1:15PM	Content Hubs and Community Rounds Innovation Theater Presentations (Exhibit Hall)	
1:15-2:15PM	Educational Tracks	
2:15-3:15PM	Refreshment Break (Exhibit Hall) Content Hubs and Community Rounds Innovation Theater Presentations (Exhibit Hall)	
3:15-4:15PM	Educational Tracks	
4:30-5:30PM	Educational Tracks	

THURSDAY, JUNE 20

Registration Hours

7:00-11:00AM Attendee and Speaker Registration Schedule 7:00-8:00AM Coffee and Light Refreshments 8:00-9:00AM **Educational Tracks** 9:15-10:15AM **Educational Tracks** 10:15-10:45AM Coffee Break 10:45AM-12:00PM FDA Town Hall



Don't miss live updates to the schedule. Follow us on LinkedIn.



DIA 2024 IS DESIGNATED AS A "PATIENTS INCLUDED" EVENT

We're proud to announce that the DIA 2024 Global Annual Meeting is designated as a "Patients Included" meeting!

This means that we are committed to incorporating the experience of patients as experts in living with their condition while ensuring they are neither excluded nor exploited.

For more information, visit the Patients Included website.

DIA and the Global Annual Meeting Program Committee have assessed that the program successfully meets all five of the Patients Included charter clauses:

Patients or caregivers with experience relevant to the meeting's central theme actively participate in the design and planning of the event, including the selection of themes, topics, and speakers.

- The DIA 2024 program agenda has been structured to incorporate the patient perspective within a dedicated Patient Engagement Track. The Program Committee includes patient representatives, who have responsibility for building the Patient Engagement track, advising on appropriate inclusion of patient perspectives in sessions throughout all 13 educational tracks, and serving as resources to identify gualified patient speakers.
- Patients invited to speak in sessions receive complimentary registration.
- DIA facilitates the attendance of patients or patient partners at the DIA 2024 Global Annual Meeting through the Patient Partners Program.
- In addition, DIA 2024 offers a special registration fee for patients and patient organization representatives of \$250 if registered by May 15. After May 15, the standard patient registration rate of \$265 will apply. Access the Patient Registration Form.

Patients or caregivers who have firsthand experience with the issues being addressed will actively take part as members of the physical audience.

- Patients and Patient Partners with experience or interest in furthering the impact of their involvement in medical product development are featured as speakers, panelists, and discussants throughout the program.
- The Patient Partners speaker initiative assists the Program Committee and session developers with finding the right patient and/or patient partner to speak in the program.

The disability requirements of participants are accommodated. All applicable sessions, breakouts, ancillary meetings, and other program elements are open to patient delegates.

 DIA 2024 will be held at the San Diego Convention Center. The facility features accessible entrances, registration and open areas, meeting rooms, parking, and provides assistive devices. DIA has also reserved sleeping room blocks at special conference rates in hotels near the convention center. A complete list of hotels can be viewed here. For specific questions, please contact the hotel directly.

Virtual access is guaranteed before and after the meeting.

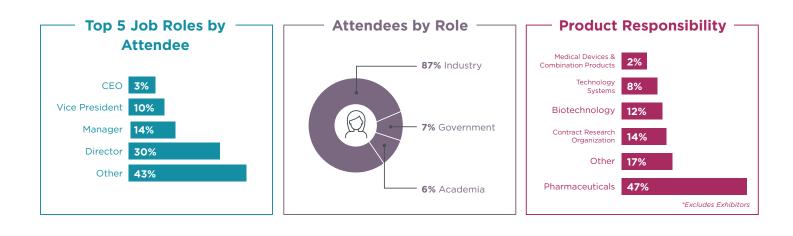
- The hashtag #DIA2024 will be actively promoted prior to and during the event across social media platforms so participants, as well as those unable to attend the event, can join the conversation and discuss presentations and key takeaways.
- DIA will post speaker presentation slides to the DIA website prior to the meeting and for six months after the meeting for viewing and downloading by attendees.

If you have any questions, please contact us at CustomerService@DIAglobal.org or 1.888.257.6457.





DIA 2023 GLOBAL ANNUAL MEETING ATTENDANCE STATS



Why Should You Attend in 2024?

Global Attendees



250+

Exhibitors

Top 30

Biopharmaceutical Companies Participate

2024 Features	13 Tracks in 2024
DIAmond Sessions	Clinical Safety and Pharmacovigilance Project Management and Strategic Planning
Community Roundtables	Clinical Trials and Clinical Operations R&D Quality and Compliance
Innovation Theaters	Data and Technology • Regulatory
Pre-Conference Short Courses	Medical Affairs and Scientific Regulatory CMC and Product Quality
Content Hubs	 Communication Patient-Focused Drug Development Statistics and Data Science Value and Access
Executive Networking	Value and Access Translational Dolivory
Student and Professional Posters	Technologies and Precision Medicine • Professional Development