DIA

2024 DIA Annual Report

Strengthening Connections, Advancing Innovation

COLLABORATIVE • TRANSFORMATIVE • PATIENT-FOCUSED

Leadership Message

Dear Friends, Colleagues, and Partners,

Reflecting on 2024, we are excited to share how DIA continues to evolve to meet the needs of the global health sciences community. In a world defined by complexity and rapid change, we remain focused on what matters most: leading with science, strengthening cross-sector global collaboration, and creating trusted pathways for innovation that serve patients everywhere.

In service of our mission, we partnered to launch some pivotal research studies—including a global analysis of participant compensation in clinical trials, and a patient tolerability reporting initiative in oncology, conducted with AbbVie, Sanofi, and Kyowa Kirin. These efforts are helping to reimagine clinical development from a patient-centered, evidence-based perspective.

We also deepened our commitment to advancing responsible AI across the drug development lifecycle. Our partnership with Tufts University and our exciting DIA AI Consortium brought together regulators, industry, and academia to align on practical applications and shared standards. Similarly, our collaboration with the Harvard-MIT Center for Regulatory Science convened global leaders around the future of cell and gene therapies, helping navigate scientific, regulatory, and access challenges.

To help sustain this critical work, we also launched our Global Supporter Program. This initiative represents a major step toward ensuring that DIA can continue to lead from a place of neutrality and purpose—not only through meetings, but through research, education, and year-round engagement. We're grateful to the organizations who joined us as inaugural partners in this effort.

These milestones reflect DIA's unique, critical role: as a global, neutral convener where stakeholders across industry, regulatory agencies, academia, and patient organizations come together to exchange ideas, collaborate, and accelerate progress toward better health for all. And our role is more critical than ever.

In a time of growing geopolitical uncertainty and rapid technological change, trusted, evidence-based dialogue is essential. Innovation knows no borders—but navigating complexity demands shared understanding, aligned standards, and sustained commitment. As an independent, mission-driven nonprofit, DIA brings together diverse voices to drive unbiased, science-based progress. But we can't do it alone.

To our Global Supporters, Meeting Supporters, members, volunteers, and staff—thank you. Your support makes this work possible.

We invite you to help strengthen this global community. Together, we can keep healthcare innovation collaborative, inclusive, and focused on what matters most: patients.

With appreciation,

Marwan Fathallah
President and Global Chief Executive

Kihito Takahashi
Chair of DIA Board
Chair of Executive Committee

Global Impact in Numbers

Networks & Connections

UNITED, AROUND THE WORLD

As a **global** organization, we connect healthcare professionals from **75+ countries** to advance patient care worldwide.

ACTIVE & ENGAGED

Professionals from across the healthcare continuum came together in more than **135 meetings and educational events** to exchange knowledge and advance strategies for better healthcare for all.

135	26,000+	75+	180+
Meetings	Attendees	Countries	Sessions

MAKING AN IMPACT

We **reached 57K+ followers** globally via our social media channels and gathered **690M+ social views** across our product portfolio.

DIA COMMUNITIES: MEMBERS IN ACTION

Network. Learn. Lead.

DIA Communities are active online forums where members connect and form cross-disciplinary teams to share information, raise concerns, mentor one another, and publish their shared work—accomplishing more as a group than any one person could alone.

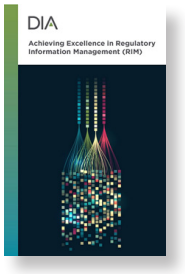
There were nearly 6K+ Global Collaborators in **37** global **DIA Communities** and **Working Groups**

5 LARGEST GLOBAL DIA COMMUNITIES

1. Regulatory Affairs
2. Clinical Research
3. Clinical Safety and Pharmacovigilance
4. Medical Writing
5. Clinical Trial Disclosure

COMMUNITY NEWS

DIA published its first eBook, *Achieving Excellence in Regulatory Information Management (RIM)*—a comprehensive best practices guide developed by the Regulatory Affairs Community. Evolving from a series of collaborative white papers, this milestone publication reflects the collective expertise of RIM professionals and is now available on Kindle.



DIA IN THE NEWS

A respected global thought leader

More than **50+ members of the press** attended our events worldwide, **featuring DIA in 76 media placements**. Represented publications included *STAT, Inside Health Policy, Endpoints,* and ABC10 San Diego, resulting in **174M total impressions**.

Nearly 20 press releases promoted key conferences, study milestones, and organizational updates, and **12 articles and op-eds, bylined by our Global Science Team**, highlighted DIA's leadership in AI, regulatory trends, health equity, clinical trial innovation, and more.

We've **trained 4K+** learners in **205 courses** and **shared** insights in **280 articles** & gathering **570K+** views.

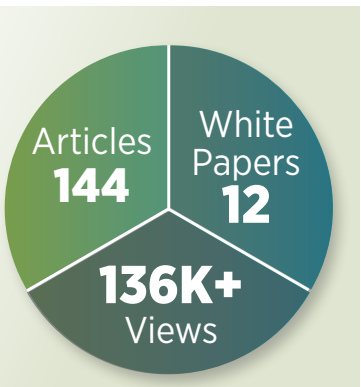
Global Impact in Numbers
Knowledge Access

Publication Highlights

Special Sections and Collections on emerging topics published in our peer-reviewed journal *Therapeutic Innovation & Regulatory Science* (*TIRS*) and online magazine *Global Forum* (*GF*) highlighted important advances across the medical product development landscape.

- AI in Drug Development (Special Collection, *TIRS*)
- Certificate of Pharmaceutical Product (CPP) – Part 1 & Part 2 (Special Section, *GF*)
- Data Monitoring Committees: Issues and Myths all Trial Sponsors and Vendors Should Know (ongoing Special Collection, *TIRS*)
- Decentralized Clinical Trials (DCTs): Adoption, Experience, and Future Considerations (ongoing Special Collection, *TIRS*)
- Identification of Medicinal Products (IDMP) – Part 1 & Part 2, (Special Section, *GF*)
- The Inflation Reduction Act and Its Impact on Innovation, Access, and Affordability (ongoing Special Collection, *TIRS*)
- Life Sciences 2024ward Predictions (Special Section, *GF*)
- Representative Clinical Trials (Special Section, *GF*)

To learn more about DIA Publications or how to contribute, please contact ***Publications@DIAglobal.org***.



Advancing Evidence to Inform Patient-Driven Practices

As part of our commitment to advancing patients' needs in drug development, DIA initiated two pivotal research efforts in 2024: a **landscape analysis on participant compensation in clinical trials** and a **global study on tolerability reporting**. These studies aim to generate evidence that informs policy, supports innovation, and ultimately improves the experience of trial participants worldwide.

Landscape Analysis: Participant Compensation in Clinical Trials

DIA launched a comprehensive, multi-stakeholder landscape analysis to understand how clinical trial participants are compensated across regions, therapeutic areas, and trial phases. This consortium explores key variables such as reimbursement for expenses, compensation for time and burden, and regulatory or ethical guidance influencing compensation practices. By gathering insights from sponsors, sites, patient advocates, and regulators, we aim to identify patterns, gaps, and opportunities for harmonization. Preliminary findings will be shared at the *2025 Global Annual Meeting*, and the full report was published in *Global Forum*, supporting more transparent and equitable frameworks for participant engagement. By leveraging this consortium, DIA and its collaborators have outlined a new study to kick off in 2025 that will assess participant compensation practices and their association with clinical trial performance.

Global Tolerability Reporting Study

Tolerability—how patients experience and manage the side effects of investigational therapies—is an often-overlooked but critical dimension of safety and efficacy. DIA's Tolerability Study explores how patients and healthcare providers understand, collect, and report tolerability data in oncology treatment areas. Conducted in collaboration with AbbVie, Sanofi, and Kyowa Kirin, this study, this survey-based research seeks to elevate the role of patient-reported outcomes and improve standardization of tolerability measures. The findings will provide actionable recommendations for industry and regulatory bodies to ensure tolerability is more consistently captured and meaningfully integrated into trial design and decision-making.

DIA Spotlights the Future of AI in Healthcare in 2024

In 2024, DIA placed a major spotlight on the evolving role of artificial intelligence (AI) in healthcare, offering a range of sessions, discussions, and publications focused on its impact and responsible use.

At the *DIA 2024 Global Annual Meeting*, more than 30 key sessions explored AI's applications across the healthcare ecosystem. Notably, the DIAmond session *Navigating the Trusted, Responsible, and Ethical Horizon of Artificial Intelligence: Uniting Healthcare Perspectives* included a solutions room, "Responsible AI," designed as a multidisciplinary, neutral, collaborative space to spark impactful dialogue focused on cross-sector partnerships for responsible AI use and strategies to mitigate AI risk.

When discussing responsible AI, it's critical that stakeholders have clarity and alignment around terms to reduce miscommunications and enhance collaboration. A structured framework to evaluate responsible AI provides the ability for assessments, consistency, accountability, and confidence in the use of AI in the healthcare spectrum. To accomplish these objectives, solution room members used the OECD AI Principles, which provide a framework for developing AI in a way that respects human rights and aligns with democratic values while fostering innovation. Participants first translated the OECD principles to implementable practices, then discussed potential challenges to and opportunities resulting from such practices.

The output, Responsible Use of AI in Healthcare: Work in Progress, was published in the October 2024 issue of *Global Forum* and outlines the work accomplished at the session and in the solution room.

In addition, "Demystifying AI in Healthcare: Common Challenges AI Can Help Solve" (*Global Forum*, June 2024), authored by the co-chairs of DIA's AI in Healthcare Community, provided expert perspectives on how AI is reshaping clinical research, patient care, and regulatory strategies. DIA-led research projects focused on AI (see below) are generating new insights into the responsible use of AI in medical product development. Through its events, research, and publications, DIA continues to serve as a vital convener for multi-stakeholder dialogue around the responsible integration of AI in life sciences and healthcare worldwide.

Advancing Healthcare Innovation Through AI

Adopting new, transformative solutions for unmet medical needs is complex, time-consuming, and expensive. As a thought leader and collaborative force in the global life sciences community, we've developed Research Programs and Consortia/Think Tanks to generate evidence that helps integrate innovation in medical product development, to benefit patients everywhere.

AI continued to transform healthcare by accelerating drug discovery, personalizing patient treatment, and streamlining clinical operations. Advanced machine learning models are now helping predict disease progression, optimize clinical trial designs, and identify potential therapeutic targets faster than ever before. AI-driven diagnostic tools, particularly in imaging and pathology, have improved accuracy and efficiency, allowing healthcare providers to detect conditions earlier and intervene more effectively. At the same time, ethical considerations around data privacy, bias, and regulatory oversight have become more prominent, prompting a stronger emphasis on responsible AI development and deployment across the industry.

DIA and collaborators initiated a research project and cross-sector consortium focused on advancing the use of AI in biopharmaceutical development. With these initiatives, we aim to generate new knowledge in the areas of AI and regulatory science to support more efficient and modernized approaches to developing innovative medical treatments for patients.

1. **AI Adoption in Clinical Development:** DIA and the Tufts University Center for the Study of Drug Development are investigating the key applications, challenges, and ROI of utilizing AI in clinical development activities.

2. **Cross-Sector Partnerships:** DIA's AI Consortium brings together pharmaceutical and biotech companies, global regulators, and academic institutions to foster cross-sector collaboration. The Consortium advances shared goals, promotes ethical frameworks and technical standards, and accelerates the responsible adoption of AI in drug development. Through this partnership, members gain a clearer understanding of AI's value, enabling more informed decision-making and greater regulatory alignment worldwide.

Looking ahead, DIA-developed training and courses in AI will equip life science professionals with the knowledge and skills needed to navigate emerging technologies, align with evolving regulations, and stay ahead in this rapidly advancing field.

To learn more about DIA Research and Think Tanks or how to contribute and help, please contact ***Science@DIAglobal.org***.

Driving Progress in Cell and Gene Therapy

To advance the future of cell and gene therapies (CGT), an area at the forefront of transformative healthcare innovation, DIA partnered with the Harvard-MIT Center for Regulatory Science to host a landmark Executive Roundtable. Bringing together leaders from the FDA, industry, and academia, this forum tackled critical issues including regulatory uncertainty, manufacturing hurdles, and the urgent need for harmonized frameworks. Then-acting FDA CBER Director Peter Marks emphasized the importance of 2024 as a defining year for advancing solutions in CGT development, particularly for therapies targeting rare diseases. Leaders from this roundtable contributed to an outcomes article, published in our May *Global Forum*.

This critical session set the stage for various sessions at the *DIA 2024 Global Annual Meeting* that addressed key scientific and regulatory challenges facing the CGT field. "Pioneering New Frontiers: Advanced Drug Delivery Technologies and Cell/Gene Therapies in Combination Products" explored the convergence of novel therapies with complex delivery technologies, underscoring the need for multidisciplinary collaboration. Other sessions, such as "Regulatory Considerations in Trial Design for Cell and Gene Therapies," highlighted trial design complexities—especially for pediatric populations—and the role of biomarkers and data modeling in navigating regulatory pathways. In addition, "Bringing Transformational Treatments to Patients: Regulatory Convergence and Reliance on Cell and Gene Therapy Products" focused on strategies for global regulatory harmonization to accelerate patient access, particularly in underserved regions.

Similarly, in Japan, DIA held two major Cell and Gene Therapy Products Symposia: The 8th Symposium, held in January, marked a shift from the "introductory stage" to a "growth phase" for regenerative medicine in Japan. Discussions emphasized post-marketing evaluation strategies, the application of Japan's Post-Approval Change Management Protocol (J-PACMP) system, and the critical role of real-world data in assessing long-term efficacy and safety. Later in December, the 9th Symposium addressed the development of next-generation CGT products, including economic considerations, manufacturing challenges for extracellular vesicle therapies, and advancements in adeno-associated viral vector technologies. Participants also explored evolving regulatory expectations and the need for strategic Chemistry, Manufacturing, and Controls (CMC) planning to accelerate innovation.

Through these global initiatives, DIA reaffirmed its commitment to fostering collaboration, advancing scientific and regulatory innovation, and improving patient access to life-changing cell and gene therapies around the world.

Patient Voice at the Center

The *2024 DIA Global Annual Meeting* in San Diego opened with a powerful keynote from Emily and Tom Whitehead, sharing their personal journey with CAR T-cell therapy. Emily, the first pediatric patient to receive this groundbreaking treatment for acute lymphoblastic leukemia, spoke alongside her father about the life-changing impact of medical innovation and the critical role of patients in shaping the future of research.

Joining the plenary was renowned inventor Dean Kamen, who highlighted how public-private partnerships are accelerating regenerative medicine. A follow-up panel featuring leaders from the FDA, EMA, and Gates Foundation underscored the importance of regulatory innovation and patient-centric approaches in advancing global healthcare.

This inspiring session set the tone for the meeting, reminding attendees that behind every breakthrough are the lives it transforms.

The more
we work together,
the better
work we'll do.

Global Supporter Program Launch
DIA launched its inaugural Global Supporter Program—a transformative step toward building long-term, mission-aligned partnerships with leading organizations across the healthcare and life sciences ecosystem. This new model provides year-round engagement opportunities and amplifies the voices of our supporters while enabling DIA to advance its mission, expand its global impact, and maintain its commitment to neutrality and scientific decision making. It marks a pivotal shift focusing on strategic collaboration, ensuring a sustainable business model for the future.

Launching our Donation Platform
As a not-for-profit organization, DIA's donation platform invites individuals and organizations to directly support our mission of advancing health innovation for patients worldwide. These contributions help us grow our reach, invest in new initiatives, and provide greater access to educational and collaborative opportunities for professionals around the globe. Every gift strengthens our ability to serve as a trusted, neutral convener—and to drive meaningful progress in medical product and therapeutic development.

Thank You to Our Global Supporters!