DIA

2025 DIA Annual Report

Building Partnerships. Shaping Solutions.

GLOBAL PERSPECTIVES • SHARED EXPERTISE • COLLECTIVE IMPACT

Leadership Message

Dear Friends, Colleagues, and Partners,

The past year reminded us that progress in healthcare is rarely achieved in isolation. Across the life sciences ecosystem, 2025 was marked by significant change and uncertainty. Regulatory agencies, industry, academia, healthcare providers, and patient organizations faced evolving policy environments, resource constraints, rapid technological disruption, and growing pressure to accelerate innovation while ensuring quality, affordability, and access. At the same time, advances in areas such as artificial intelligence, precision medicine, genomics, and novel therapeutics continued to reshape what is possible for patients around the world.

In times of complexity and change, collaboration becomes more important than ever. As a trusted neutral convener, DIA continued to bring together diverse stakeholders from across the healthcare ecosystem to exchange knowledge, share perspectives, and work toward solutions to some of the most pressing scientific and regulatory challenges facing our industry. By fostering open dialogue and evidence-based collaboration, we help create the conditions for innovation to thrive.

This year also marked an important evolution in DIA's scientific strategy. Building on our longstanding role as a global forum for discussion and learning, we expanded our focus on translating dialogue into action. Through new research partnerships, global consortia, executive roundtables, and other collaborative initiatives, DIA is helping to advance practical frameworks, generate trusted evidence, and support meaningful progress in areas ranging from artificial intelligence and obesity drug development to patient-centered research and regulatory convergence.

As we look ahead, we remain optimistic about the future. Scientific innovation continues to move at an extraordinary pace, creating new opportunities to improve health outcomes and address unmet patient needs. DIA's role is to ensure that these advances are supported by collaboration, shared learning, and multidisciplinary engagement, bringing together the expertise needed to turn scientific promise into real-world benefit.

We are grateful to our members, volunteers, partners, and staff whose dedication and commitment make this work possible. Together, we are strengthening the connections, partnerships, and exchange of knowledge that advance science, healthcare, and ultimately, the lives of patients worldwide.

With appreciation and hope,

Junaid Bajwa
Chair, Board of Directors
Senior Partner
Flagship Pioneering

Marwan Fathallah
President and Global
Chief Executive

CONNECTING EXPERTISE ACROSS BORDERS

Healthcare innovation depends on collaboration. Across regions, disciplines, and sectors, DIA serves as a trusted convening force that brings together the people shaping the future of healthcare.

Our global network spans more than **75 countries**, creating opportunities for professionals to exchange perspectives, align on emerging challenges, and accelerate progress toward better health outcomes worldwide.

DIA COMMUNITIES: WHERE COLLABORATION BECOMES ACTION

The most meaningful advances in healthcare happen when expertise is shared.

Through DIA Communities and Working Groups, professionals from around the world collaborate year-round to exchange knowledge, address emerging issues, and develop practical approaches to complex challenges facing the healthcare ecosystem.

These communities create lasting connections among experts while fostering professional dialogue, collective learning, and cross-functional collaboration that drive innovation forward.

The continued engagement of DIA Communities demonstrates the value of bringing diverse voices together around a common purpose: advancing healthcare for patients worldwide.

Regulatory Affairs, Clinical Research, Clinical Safety and Pharmacovigilance, Medical Writing, and Professional Development remain among DIA's largest global communities, reflecting the breadth of expertise and collaboration across the healthcare product lifecycle.

These communities help shape conversations, share emerging best practices, and cultivate expertise across disciplines and regions.

EXPANDING ACCESS TO KNOWLEDGE

Access to timely, trusted information remains essential in a rapidly evolving healthcare environment.

Through educational programs, professional development opportunities, publications, and thought leadership, DIA continues to support lifelong learning and informed decision-making across the global healthcare community.

Whether through training, expert insights, or practical resources, DIA equips professionals with the knowledge needed to navigate complexity, adapt to change, and contribute to better outcomes for patients and society.

The impact of these efforts extends far beyond individual programs, strengthening capabilities, fostering innovation, and supporting a more connected global healthcare ecosystem.

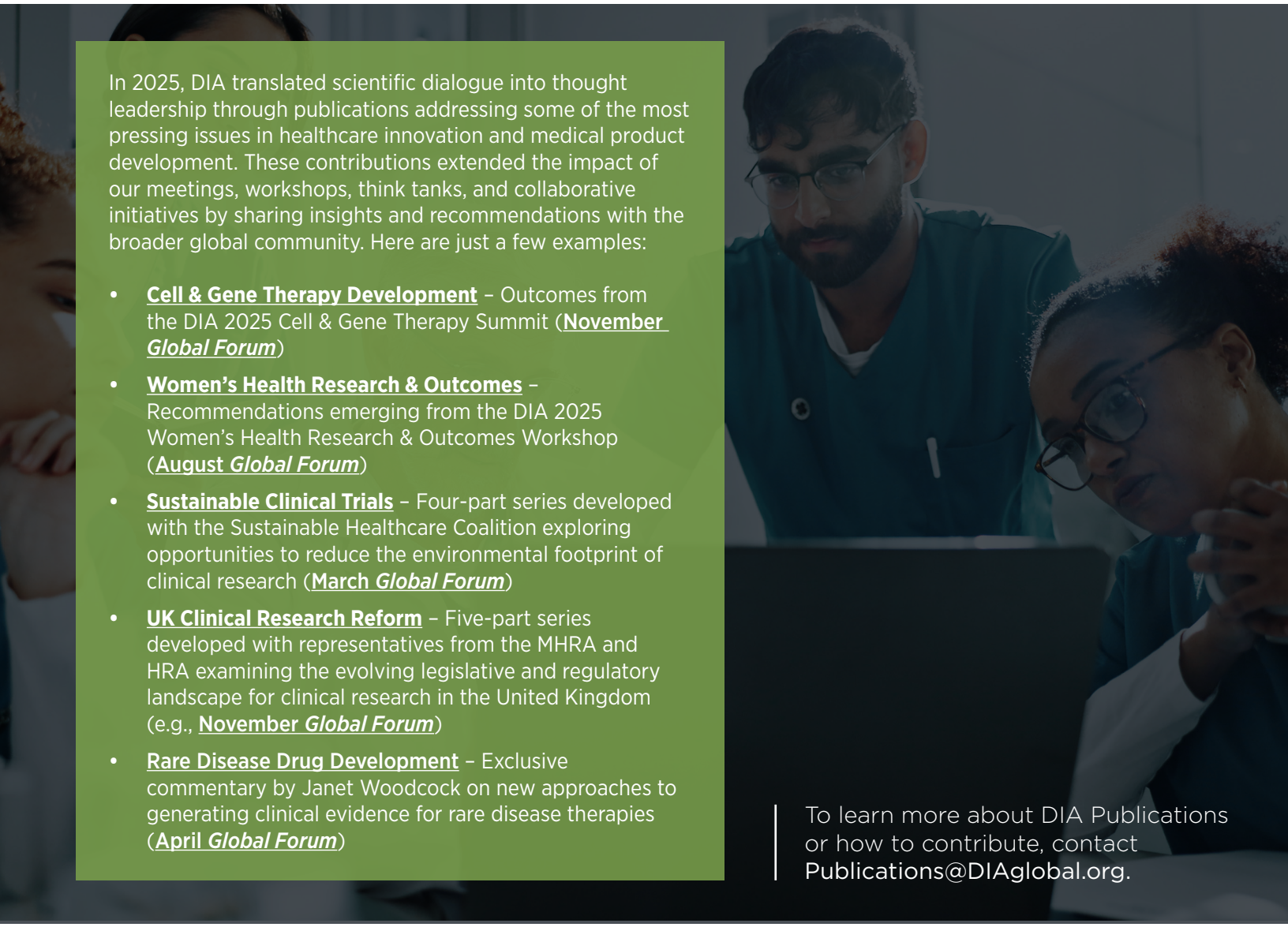
NEW COURSES IN 2025

- Generative AI for Regulatory Affairs (Americas)
- ICH GCP Guideline Rewrite: The Future is Now (Europe)
- Navigating Future Parallel HTA and EMA Processes in the EU (Europe)
- Automation and AI in Signal Management - Workshop (Europe)

Global Forum

Therapeutic Innovation & Regulatory Science

Scientific Publication Spotlight



In 2025, DIA translated scientific dialogue into thought leadership through publications addressing some of the most pressing issues in healthcare innovation and medical product development. These contributions extended the impact of our meetings, workshops, think tanks, and collaborative initiatives by sharing insights and recommendations with the broader global community. Here are just a few examples:

- **Cell & Gene Therapy Development** – Outcomes from the DIA 2025 Cell & Gene Therapy Summit (**November *Global Forum***)
- **Women's Health Research & Outcomes** – Recommendations emerging from the DIA 2025 Women's Health Research & Outcomes Workshop (**August *Global Forum***)
- **Sustainable Clinical Trials** – Four-part series developed with the Sustainable Healthcare Coalition exploring opportunities to reduce the environmental footprint of clinical research (**March *Global Forum***)
- **UK Clinical Research Reform** – Five-part series developed with representatives from the MHRA and HRA examining the evolving legislative and regulatory landscape for clinical research in the United Kingdom (e.g., **November *Global Forum***)
- **Rare Disease Drug Development** – Exclusive commentary by Janet Woodcock on new approaches to generating clinical evidence for rare disease therapies (**April *Global Forum***)

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

Special Collections published in DIA's peer-reviewed scientific journal, ***Therapeutic Innovation & Regulatory Science (TIRS)***, are among the journal's most successful initiatives, extending scientific dialogue beyond our global events, workshops, research initiatives, and communities. They capture post-meeting insights and ongoing multi-stakeholder discussions on topics shaping the future of healthcare and medical product development.

The following Collections remain open for contributions, providing an ongoing forum for sharing research, perspectives, and practical experience across the life sciences ecosystem.

Current Special Collections

- Recent Advances in Oncology Clinical Trials
- The Inflation Reduction Act and Its Impact on Innovation, Access, and Affordability
- AI in Drug Development
- Bayesian Clinical Trials
- Decentralized Clinical Trials (DCTs): Adoption, Experience, and Future Considerations
- Data Monitoring Committees: Issues and Myths All Trial Sponsors and Vendors Should Know

Scientific Collaboration for Real-World Impact

From Convening Conversations to Collaborative Science

2025 marked a transformative year for DIA's global scientific strategy. Building on its longstanding role as a trusted neutral convener, DIA expanded its impact through structured research partnerships, global consortia, executive roundtables, and **collaborative scientific initiatives** designed to generate actionable outcomes for the life sciences community.

Key milestones included the establishment of the new **Division of Research Partnerships**, creating a formal pathway from dialogue to measurable results, and the launch of the **Global Science Content Center of Excellence**, strengthening alignment and scientific programming across regions worldwide.

A New Model for Scientific Collaboration

The transition from one-time convenings to sustained, outcome-driven scientific collaboration reflects DIA's unique role as a neutral convener and our mission to harness knowledge exchange to solve global problems. By bringing together diverse stakeholders around shared challenges, we are creating collaborative research partnerships that generate trusted evidence and advance healthcare innovation for the benefit of patients worldwide.

Executive Roundtables

Catalysts for Strategic Action

Through executive roundtables, we created neutral forums where regulators, industry leaders, healthcare professionals, researchers, patient representatives, and other key stakeholders could collaboratively address evolving scientific, regulatory, and operational challenges.

These discussions enabled participants to align on emerging priorities, identify practical solutions, and help shape future frameworks for healthcare innovation and medical product development. The resulting insights informed strategic recommendations, highlighted barriers to progress, and catalyzed future scientific and policy initiatives.

2025 Roundtables

1. **Shaping the Future of Obesity Drug Development**
   Convened cross-sector experts to address barriers, clinical trial innovation, and future frameworks for obesity drug development and associated comorbidities. Summarized insights from this roundtable are currently under review and will be published in ***Global Forum***.

2. **Cell and Gene Therapy Summit**
   Brought together global stakeholders to identify actionable strategies for advancing cell and gene therapy development, regulatory science, and patient access. Summary findings were published in the **November 2025 issue of *Global Forum***.

3. **Shaping the Future Regulatory Framework for Pharmacy Compounding**
   Facilitated dialogue on evolving regulatory frameworks, patient safety, quality standards, and the future of pharmacy compounding practices. Key insights from the workshop will be summarized in a Global Forum article and captured in a comprehensive outcomes report highlighting the discussions, key findings, and recommendations.

These discussions directly informed new collaborative initiatives and laid the foundation for future consortia and research programs.

Global Consortia

From Dialogue to Collective Action

Building on momentum generated through executive roundtables and scientific exchange, we launched two major global consortia that unite regulators, industry, academia, and other stakeholders in long-term collaboration focused on developing actionable frameworks, shared standards, and meaningful scientific outcomes.

Obesity Consortium

40 experts across 10 organizations

Established from Executive Roundtable outcomes and launched in 2025, the **Obesity Consortium** engages regulators, including FDA and EMA, to advance biomarker validation, clinical endpoints, and innovative multi-indication trial design approaches for obesity research. By building consensus around standardized, fit-for-purpose clinical measures and endpoints the outputs of this work are expected to reduce development inefficiencies, strengthen regulatory review, and accelerate patient access to safe, effective obesity therapies worldwide.

Working Groups

- Standardizing label-enabling efficacy endpoints
- Designing clinical trials for multiple indications

Planned Outputs

- Core clinical endpoint set proposal
- Multi-indication trial design frameworks
- Body composition & physical function standards
- White papers and peer-reviewed publications
- Global scientific presentations

Artificial Intelligence Consortium

44 members across 22 organizations

Launched at the DIA Global Annual Meeting in 2025, the **AI Consortium** brings together pharmaceutical companies, regulators, academia, and technology organizations to advance practical and responsible implementation of AI across the drug development lifecycle. Outputs are coordinated across three working groups and will serve as foundational resources for organizations implementing AI in clinical, regulatory, and operational contexts.

Focus Areas

- Compensation design and derivation
- Benchmarking and variability analysis
- Clinical trial performance outcomes

Planned Outputs

- AI terminology and governance frameworks
- Validation guidance concepts
- Consensus-driven white papers and publications

Research Partnerships

Collaborative Research Driving Healthcare Innovation

In 2025, we significantly expanded our role in collaborative scientific research through multi-stakeholder initiatives designed to address critical challenges in medical product development, clinical research, patient engagement, and global regulatory alignment. These projects bring together regulators, industry, academia, patient communities, and technology partners to generate practical frameworks, evidence, tools, and scientific insights that advance innovation across the healthcare ecosystem.

Tolerability Study (Oncology)

This **patient-centered research initiative** focuses on redefining treatment tolerability in immuno-oncology by integrating patient experience into clinical trial design and regulatory decision-making. It addresses the need for more holistic approaches to evaluating treatment burden by incorporating patient-reported outcomes, symptom experience, daily functioning, and quality-of-life considerations alongside traditional safety measures. Through collaboration with regulators, academia, patient organizations, and industry partners, the study aims to advance more meaningful and standardized approaches to tolerability assessment across cancer treatments.

Key Activities

- Conceptual model development
- Patient and healthcare provider interviews
- Development of practical tools and guidance for clinical trials and PROs
- Presentation of findings at global scientific meetings and dissemination through publications

Planned Outputs

- Recommendations for tolerability assessment frameworks and trial design
- Comprehensive guide defining core tolerability concepts
- Recommendations for clinical trial design, analytical methods, and PRO tool implementation
- Evidence to support more informed patient–clinician conversations and regulatory evaluation of cancer therapies

Research Partnerships

Participant Compensation Project

39 members across 14 organizations

Conducted in partnership with the **Tufts Center for the Study of Drug Development** (Tufts CSDD), this **multi-stakeholder research study** brings together patient advocates, clinical researchers, sponsors, and other clinical trial stakeholders and examines how participant compensation practices influence clinical trial performance and participant engagement.

By analyzing compensation approaches across trial phases, therapeutic areas, and levels of protocol complexity, the study seeks to better understand their impact on recruitment, retention, enrollment diversity, and overall trial execution. The project addresses a critical knowledge gap in clinical research by generating benchmarking data and practical recommendations to support more patient-centered, equitable, and operationally effective clinical trial design.

Focus Areas

- Compensation design and derivation
- Benchmarking and variability analysis
- Clinical trial performance outcomes

Planned Outputs

- Sponsor benchmark reports
- Aggregate analyses
- Publications and presentations

DIA/Horizon NextGen Project (Europe)

21 organizations across Europe, the US, and Switzerland

As a partner in the Horizon Europe-funded **NextGen initiative**, DIA is helping advance the secure integration of multimodal genomic and health data to support personalized cardiovascular medicine. The project brings together stakeholders from research, industry, and regulatory communities to address scientific, governance, and implementation challenges associated with large-scale health data infrastructures.

Our contributions focus on stakeholder engagement, regulatory alignment with key European initiatives such as the European Health Data Space (EHDS) and 1+ Million Genomes, and dissemination of project outcomes to the broader regulatory science community. Through workshops, publications, and collaborative dialogue, the initiative aims to accelerate the adoption of best practices for the responsible use of genomic data in healthcare and research.

Key Activities

- Regulatory alignment with key European initiatives
- Stakeholder engagement
- Dissemination and adoption of best practices

Planned Outputs

- Stakeholder engagement framework
- Best practice guidance for genomic data infrastructures
- Publications, presentations, and workshops
- Dissemination materials supporting regulatory alignment and adoption of personalized cardiovascular medicine

Global Alignment & Regional Impact

DIA strengthened global scientific alignment through regional engagement models that foster collaboration across regulatory systems and healthcare ecosystems. Highlights included the inaugural **Latin America Reliance Pre-Conference Workshop**, which convened regulators, industry, and regional stakeholders to advance reliance and regulatory convergence across the region. The launch of the **Global Science Content Center of Excellence** further enhanced cross-regional coordination and consistency in scientific programming worldwide.

Advancing Reliance in Latin America

The inaugural **DIA Latin America Reliance Pre-Conference Workshop** marked an important milestone in advancing regional regulatory collaboration. Held as a closed-door session ahead of the DIA Latin America Annual Meeting, the workshop convened representatives from 12 regulatory authorities as well as key industry and regional partners to explore how reliance principles are being translated into practice across Latin America.

The strong engagement and subsequent publication of a bilingual **summary report** reinforced DIA's role as a trusted neutral convener supporting regulatory convergence, collaboration, and innovation throughout the region.

Building on this success, DIA will host the Reliance Pre-Conference Workshop once again in 2026 as a closed-door session ahead of the **Latin America Annual Meeting**.

In 2025, DIA was proud to partner with the following organizations through the Global Supporter Program:

Thank You to Our Global Supporters!

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