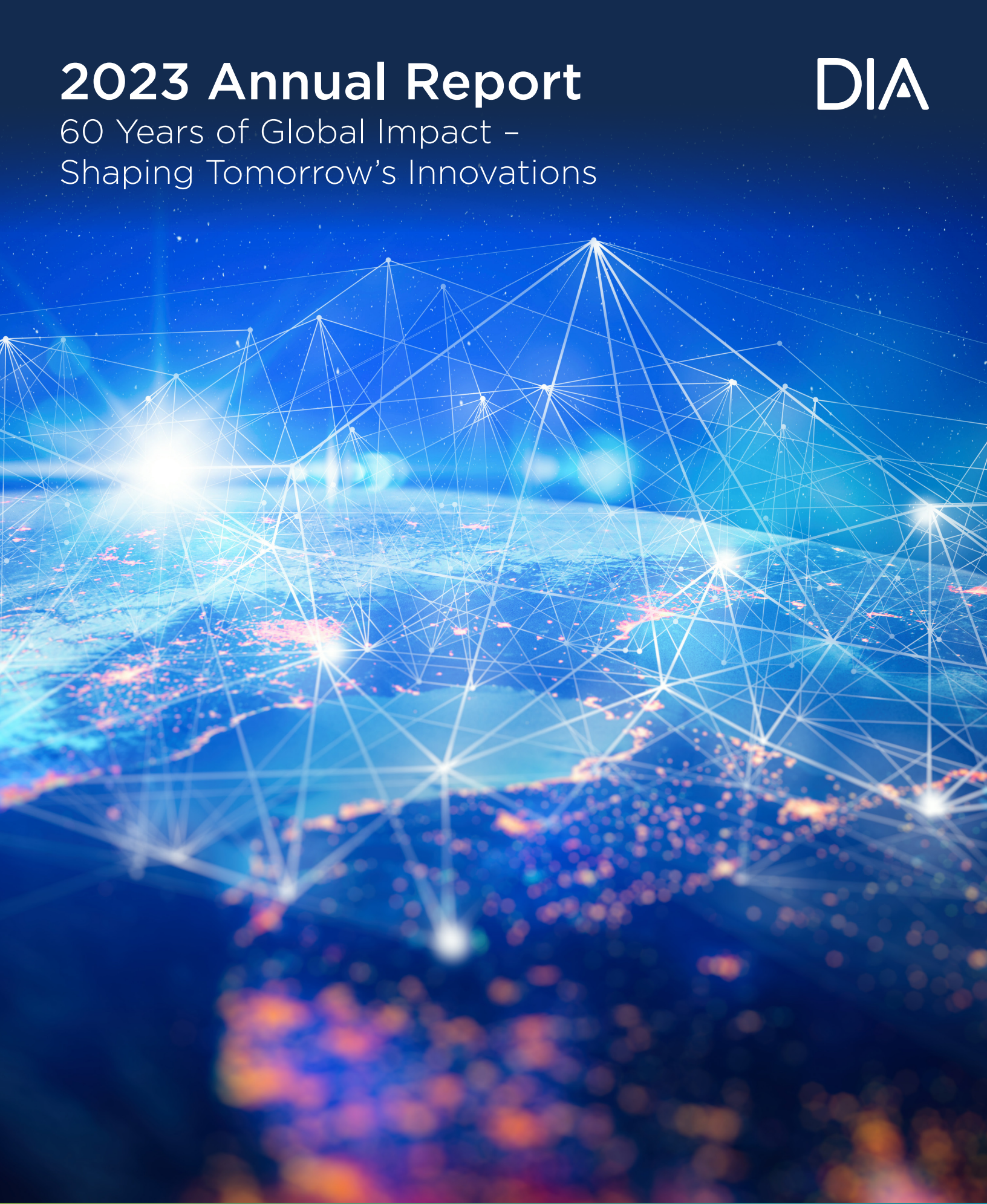
2023 Annual Report

60 Years of Global Impact – Shaping Tomorrow's Innovations

DIA



INFORMED ▸ INCLUSIVE ▸ INNOVATIVE

Leadership Message

Imagine a world where patients have access to quality, compassionate care no matter who they are or where they live. In this world, scientific breakthroughs extend lifespan—and health span—for us all. Of course, this dream is not new.

Sixty years ago, a group of pharmaceutical and medical professionals gathered in Philadelphia to address challenges in sharing drug information to improve patient care. This was the inaugural meeting of the Drug Information Association (DIA) and the birth of our organization.

While DIA was formed to help manage the incredible quantity of new information about drugs generated constantly across the globe, our focus has expanded over the years. We now cover the entire continuum of medical product development, including drugs, devices, diagnostics, and digital health technologies. We also work on product registration and patient access issues. And as our focus expanded, our global engagement and impact grew as well.

Today, DIA has evolved into a world-class, leading life science organization that facilitates multistakeholder collaborations, prioritizes transformative innovations, and enables breakthroughs that help all patients, irrespective of their background, live better lives.

As we celebrate 60 years of global impact, we find ourselves both reflecting on our achievements and focusing on our path forward. Our gratitude to those who have supported us throughout the years and each member of our tightly knit community is immeasurable. From our humble beginnings, we have grown to become the only global multidisciplinary life science organization with members in more than 80 countries.

2023 was another demonstration of our impact as a major stakeholder in the medical product and biomedical innovation community. We engaged more than 16 million life science professionals through our meetings, educational events, publications, online platforms including social media, and research studies. Our agenda, simple yet profound, still resonates and meets a critical need: we serve as a global catalyst for scientific discovery, multidisciplinary problem-solving, high-quality education, and biomedical collaborations across sectors, while improving best practices with evidence generation, transparent discussion, innovative research, and impactful learning.

Looking to the future—investing in our work as a neutral convener, as a key integrator grounded in sound science and multistakeholder collaborations—we look forward to focusing on the transformative potential of generative AI in medical product development; ushering in the new era of cell, gene, and other advanced therapies; and playing a role as a major stakeholder in the quickly evolving healthcare and biomedical innovation landscape. We will continue to work closely with regulators, the life science industry, educational institutions, and government leaders around the world to foster innovation in pharmaceutical drug development, diagnostics and device development, and clinical trial innovations, while ensuring patient safety. Patients will always be front and center in the work we do, as we are all patients, after all.

Please join our unparalleled community, contribute your best thinking, get inspired, and unite with colleagues to drive the changes needed to deliver affordable, safe, accessible treatment options and healthcare solutions for patients worldwide. We are all in this together.

Sincerely,

Michael Rosenblatt
Chair of DIA Board, Chair of Executive Committee

Marwan Fathallah
President and Global Chief Executive

Global Impact in Numbers

Networks and Connections

As a **GLOBAL** organization, we connect healthcare professionals from **80+ countries**

26K+ professionals from across the healthcare sector came together in **168 meetings and educational events** to **EXCHANGE** knowledge and **ADVANCE** strategies for better healthcare for all.

We **REACHED 66K+ followers** globally via our social media channels and gathered **16M+ online views** across our product portfolio.

3.5K+ GLOBAL COLLABORATORS in **44** global **DIA Communities** and **Working Groups**

LARGEST 5 GLOBAL DIA COMMUNITIES

1. Regulatory Affairs Community
2. Clinical Research Community
3. Clinical Safety and Pharmacovigilance Community
4. Medical Writing Community
5. Professional Development Community

COMMUNITY NEWS

DIA AI in Healthcare Community launched to share industry learnings and create best practices.

RIM framework created by the DIA Regulatory Affairs Community's Regulatory Information Management (RIM) Working Group (to be published as a Kindle digital book in 2024).

Global Impact in Numbers

Knowledge Access

DOWNLOADS/VIEWS/LISTENS

GF Articles & Podcasts

126K views/listens

TIRS Articles

445K downloads

Collaborative Problem-Solving to Advance Better Health for All

In today's dynamic landscape of medical innovation, convening a diverse array of stakeholders is critical. But multistakeholder collaboration isn't just a conversation: It is a crucial step towards illuminating the path forward, where the pursuit of innovation harmonizes with dedication to patient benefit and the betterment of the entire healthcare industry. Across regions, our activities are informed by advancements that shape the use of disruptive technologies, individualized therapies, and real-world evidence (RWE), ensure pre- and post-market safety, and engage diverse patient pools at every step of the way.

Unlocking Global Regulatory Advancements

Open dialogue and the free sharing of knowledge and experience increase mutual understanding across the healthcare sector and help identify actionable steps for all stakeholders to put healthcare innovations and advancements into widespread practice.

In partnership with the Saudi FDA, DIA offered the first *DIA Middle East* Meeting in alignment with Saudi Vision 2030 and its public health policies. Regulatory strategy, reliance and international collaboration, clinical trials, pharmacovigilance, CMC, and innovation were among the topics discussed at the meeting.

In a *DIA Europe 2023*-affiliated reliance workshop, senior regulatory experts representing health authorities from all around the world joined industry representatives to discuss more effective and efficient information sharing to enable risk-based reliance reviews, the interpretation of product sameness, and the impact of diverging country-specific requirements. Reliance can be effectively used to focus resources and speed up submission and registration of medical products, allowing patients to gain earlier access to life-saving medicines in international markets where submission and regulatory approvals lag far behind.

The ultimate vision the industry is working towards is the submission of a single, core dossier for one product to multiple regulatory authorities using a cloud-based system that keeps data safe and secure. The working group identified the convergence and harmonization of Common Technical Document (CTD) Modules 1 and 3 as an area of immediate focus and developed a list of concrete action items for industry and regulators to address jointly. The more detailed outcomes of this workshop are described in this report. This milestone in our journey towards more regulatory collaboration has sparked a continuing dialogue between regulatory authorities and industry to enhance transparency across working practices, share reliance case study experiences, and identify common solutions.

Publication Highlights

Special Issues 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 Clinical Research (Special Section, *GF*)
- Clinical Research in Ukraine – Part 1 & Part 2 (Special Section, *GF*)
- Solving the Rubik's Cube of Competing Forces to Realize the Future of Clinical Research (Special Section, *GF*)
- Bayesian Clinical Trials (Special Collection, *TIRS*)
- Digitization and Digitalization (Special Section, *GF*)
- Research and Regulation in Latin America – Part 1 & Part 2 (Special Section, *GF*)
- Decentralized Clinical Trials (DCTs): Adoption, Experience, and Future Considerations (ongoing Special Collection, *TIRS*)
- Data Monitoring Committees: Issues and Myths all Trial Sponsors and Vendors Should Know (ongoing Special Collection, *TIRS*)
- Patient Preferences to Inform Decision Making in Medical Product Development (ongoing Special Collection, *TIRS*)

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

Partnering with Patients

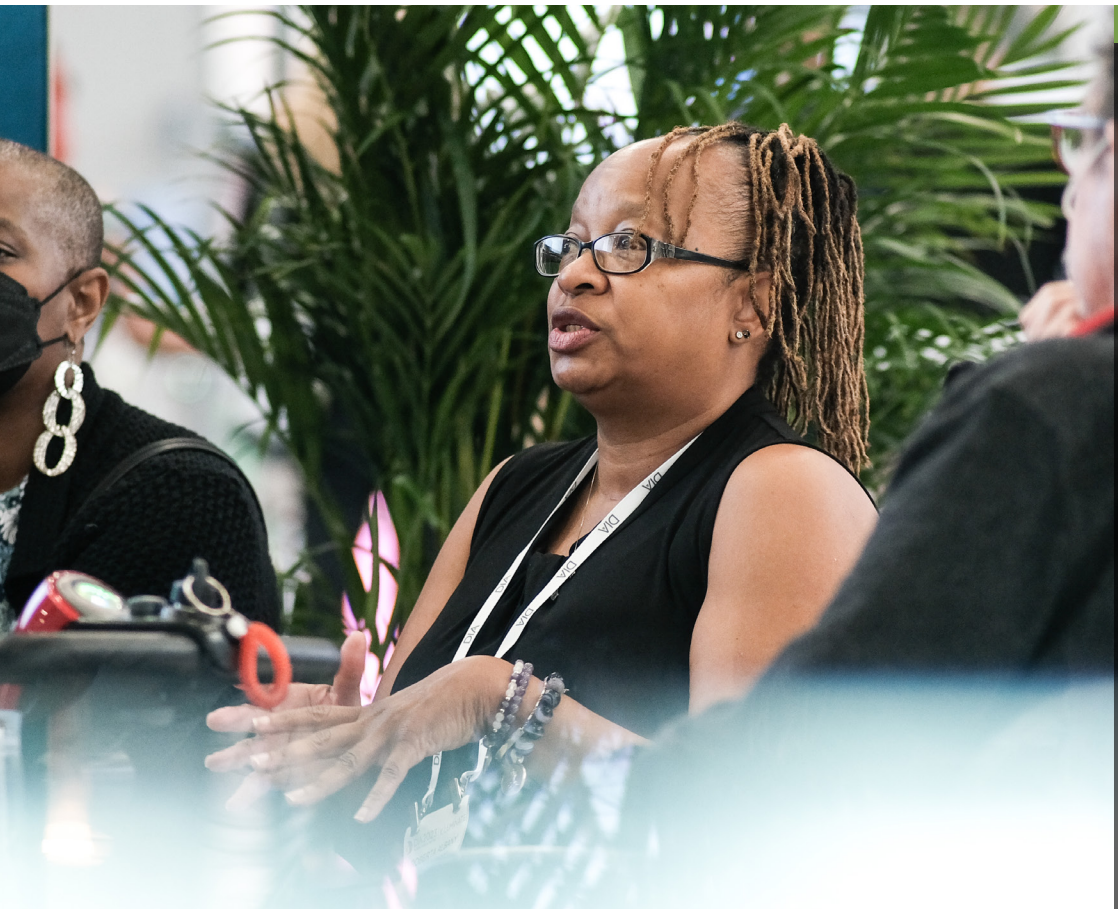
A crucial part of DIA's mission is to be a facilitator of cultural change in the healthcare industry by demonstrating the value of integrating patient perspectives across the product development pipeline. For more than two decades, we have worked with industry, regulators, and patient advocacy groups to shape the culture of patient involvement in medical product development as well as the tools to consistently apply and reliably quantify it. This approach drives efficiency and ensures that new therapies address the real needs of patients.

- In 2022, we began a collaboration with a multistakeholder group that included the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Patients' Forum (EPF) to develop a Patient Engagement Action Plan that describes seven actionable steps to move the needle in patient engagement (PE) and provides multiple examples of PE initiatives by regulators, patient organizations, multistakeholder nonprofits, and the Innovative Medicines Initiative (IMI), among others.

  After this successful initial collaboration, our work with EFPIA and the EPF continued in 2023 and culminated in a virtual co-creative session in which participants developed a roadmap for successfully implementing those seven steps, published in February 2023. To continue shining a light on these topics, we have established an ongoing collaboration with government organizations like EFPIA and the Patient Engagement Open Forum (PEOF) as well as patient organizations, including EPF and the European Patients' Academy on Therapeutic Innovation (EUPATI).

- DIA's Patient Scholars Program facilitates conversations with diverse patient advocates and representatives from across the globe. The program's goal is to advance patients' understanding of and involvement in medical product development and positively impact healthcare innovation initiatives within their roles.

In 2023, as part of DIA's commitment to supporting educational opportunities for patient advocates, we awarded more than 21 patient scholarships to attend the *DIA Global Annual Meeting* or *DIA Europe*. Patients actively engaged in discussions, provided testimonials, and contributed as panelists—a crucial opportunity to amplify patients' voices and encourage knowledge exchange. Patients were also awarded a one-year complimentary membership and meeting registration to gain access to both the networking and the educational opportunities DIA offers.



"Far too often, conferences place discussions about enrolling missing populations at the end of their meeting. By that time, the people who would benefit most from these solutions [...] may have already left the conference altogether. My opportunity to speak [at DIA] was scheduled and presented on the first day of DIA GAM 2023."

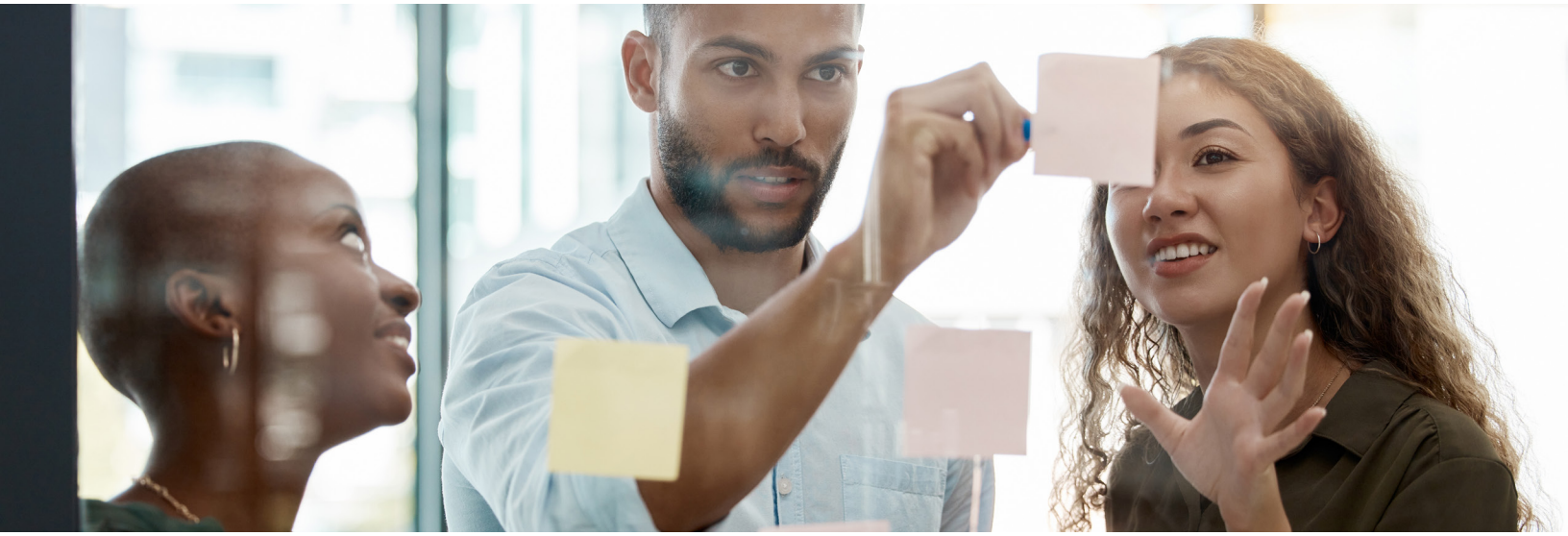
– Roberta Albany, Founder/ CEO of Cancer In The Know and patient advocate for the Southwest Oncology Group (SWOG) Cancer Research Network

Watch our interview with Roberta on health equity.

Framing the Challenge with DIA Research & Think Tanks

Adopting new, transformative solutions for unmet medical needs is complex, time-consuming, and expensive. Hence, DIA has developed Research Programs and Think Tanks to generate evidence that helps integrate innovation in medical product development.

DIA RESEARCH – In 2023, DIA and collaborators initiated three research projects on advancing the use of AI in biopharmaceutical development. With these projects, 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

Examining the Current Use and ROI of Artificial Intelligence Supporting Drug Development: Tufts CSDD, DIA, and a working group comprised of pharmaceutical and biotechnology companies and CROs have embarked on a study to examine and map the current use of and experience with artificial intelligence (AI), including machine learning (ML) and natural language processing (NLP), that support the continuum of drug development.

2

Artificial Intelligence for Adverse Events Reporting and Drug Safety Monitoring: Conceived in 2023, we are currently inviting organizations to participate in this collaborative research study. Study findings will save participating organizations time and money by (a) understanding how a diverse RWD-based algorithm is developed; (b) learning the successes and limitations of the algorithm development process; (c) gaining insight into responsible use of AI; and (d) utilizing aspects of the algorithm to reproduce, standardize, and scale AI and ML in signal detection from myriad data sources (including EHRs, RCTs, social media, and claims data) by processing and retrieving results in real time.

3

Understanding and Measuring Treatment Tolerability of Immune-Oncology (IO) Treatment in Selected Cancers: Understanding tolerability of IO and other therapies is essential in fulfilling the 21st Century Cures Act mandate to incorporate patient preference data into clinical decision-making. For this reason, DIA is establishing a Working Group of industry leaders—including representatives from patient advocacy groups, oncologists, healthcare providers, and researchers—to further the understanding of tolerability of I-O therapies in select cancers and to develop guidance on:

- the design of trials to measure comparative differences in tolerability;
- endpoint definitions related to tolerability;
- analytical methods to quantify tolerability; and
- the use of tolerability data to inform healthcare provider & patient decision-making, benefit-risk appraisal, and product labeling.

DIA THINK TANKS – The *2023 Global Annual Meeting* (*DIA 2023*) introduced a new discussion and workshop format under its Think Tank umbrella aimed at fostering collaborative problem-solving and innovation within our community. A series of DIAmond sessions followed by Solution Rooms tailored to the topic of each session provided a vibrant platform for igniting meaningful, in-depth conversations that created action plans to address critical industry challenges. Each Solution Room was crafted as an all-encompassing forum designed to extend and deepen discussions initiated during the DIAmond sessions.

1

DIAmond Session:
Constellation of Efforts to Increase Representation in Clinical Research

- **Solution Room:** *Shortening the Focal Length to Implementing Diversity, Equity, and Inclusion in Clinical Research & Development*

  The current lack of diversity in clinical trials has far-reaching implications for healthcare and patient outcomes. Medical breakthroughs and groundbreaking treatments that save lives aren't truly transformative if they are only tested on a narrow slice of the population. Progress in healthcare means ensuring that innovations reach every corner of our society.

- **Output:** Participants identified and addressed barriers to implementing diversity, equity, and inclusion initiatives in clinical research. The Solution Room culminated in a comprehensive document and a summary outlining key challenges and proposed strategies to overcome these barriers.

2

DIAmond Session:
Full Exposure: Artificial Intelligence to Advance, Replace, and Add Efficiency for Patient Benefit

- **Solution Room:** *In the Shadow of Uncertainty for the Future of Generative AI in Medicines Development: Collaboration to Illuminate the Way*

  The transformative potential of generative AI in medicine development requires responsible practices in the pursuit of overall patient benefit. By converging the voices of all stakeholders in one collective dialogue, we can revolutionize diagnostics, drug discovery, and patient care.

- **Output:** Attendees prioritized critical challenges posed by generative AI in medicine development and explored potential solutions and best practices. The Solution Room emphasized the importance of multistakeholder collaboration in navigating the evolving landscape of AI technologies. The outcomes of the Solution Room were reported in a comprehensive document and summarized in a *Global Forum* article. The key challenges and strategies identified are forming the basis for a follow-up DIAmond and Solution Room session in 2024. This Solution Room will dive deeper into the ethical and responsible use of AI and serve as a means to further develop an actionable plan that effectively addresses AI use issues and ensures patient benefit.

3

DIAmond Session:
Shining the Light on ALS: A Case Study for Illumined Therapeutic Development

- **Solution Room:** *Coming Out of the Dark—A Wholistic Approach to Therapeutic Development*

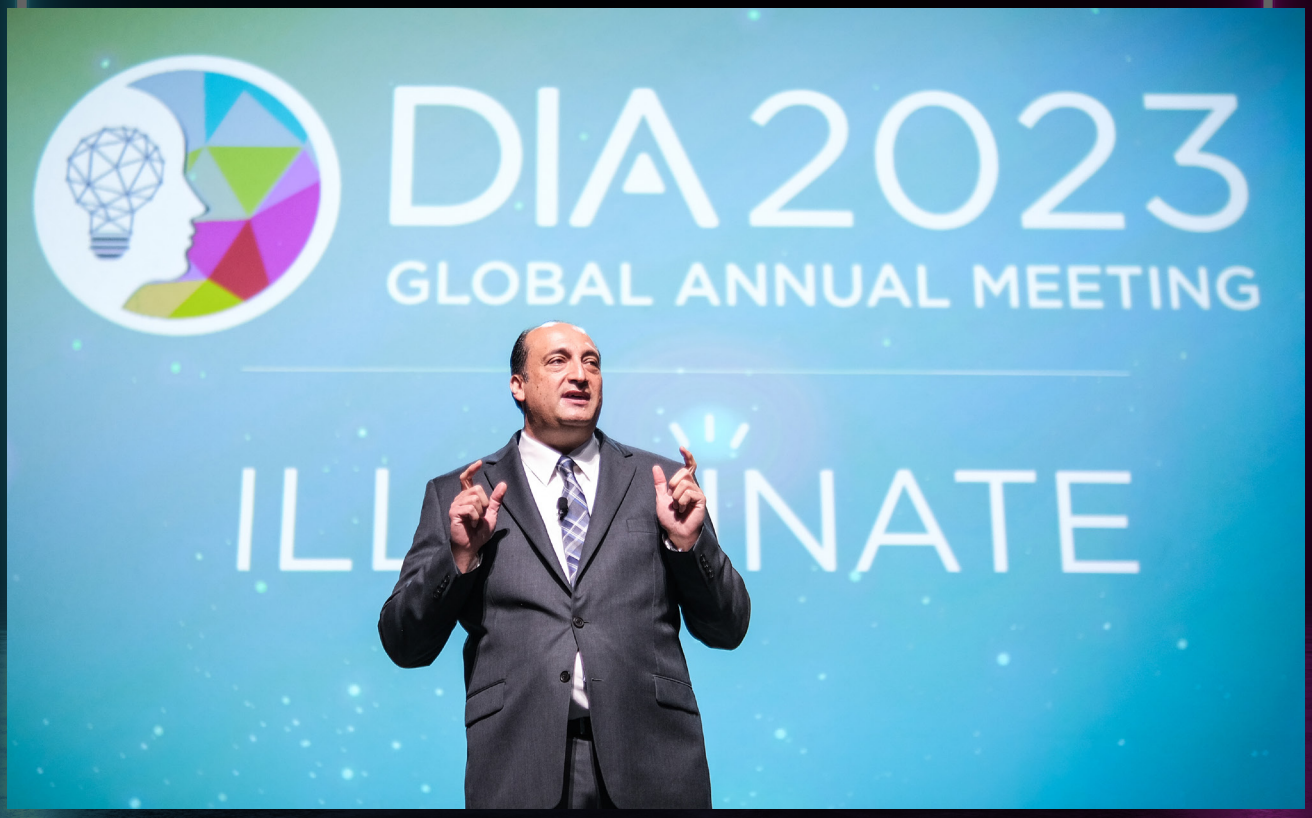
  Advancements in the amyotrophic lateral sclerosis (ALS) development ecosystem have created opportunities to better integrate patient preferences, consider the role of survival versus other endpoints in therapeutic development, and translate lessons to other therapeutic areas. The range of treatment modalities now available is promising for patients, but frameworks to guide prioritization are lacking. The development of efficient solutions for patients is impeded by a multitude of challenges that require collective efforts from researchers, policymakers, and other stakeholders.

- **Output:** Participants collectively developed a problem statement and decision-making framework for advancing therapeutic development in amyotrophic lateral sclerosis (ALS). The Solution Room provided valuable insights into considerations for the use of study endpoints in decision-making processes, highlighting the importance of a holistic approach to therapeutic development.

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

Reflections from DIA's New Global Chief Executive on His First Year at DIA

At the end of 2023, after his first year at the helm, DIA President and Global Chief Executive Marwan Fathallah reflects on DIA's role in the future of healthcare and its commitment to supporting the next generation of healthcare professionals with a call to action.



The Future of Healthcare Hinges on Inspiring Tomorrow's Leaders Today

Marwan Fathallah
Global Chief Executive, DIA