2022 Annual Report

Collaborate to Innovate

DIA

INCLUSIVE ▶ GLOBAL ▶ INDIVIDUAL ▶ DIGITAL

LEADERSHIP MESSAGE

The urgency of DIA's core mission was never as evident as when the outbreak of war in Ukraine threatened the care and safety of patients and forced clinical trials to be canceled or put on hold, eliminating some patients' only hope for survival. In cooperation with the Ukraine Clinical Research Support Initiative, we shared with our community the experiences and challenges faced by investigators, sponsors, ethics committees, regulatory authorities, and clinical trial participants in Ukraine and the region. We also collaborated with global organizations to put the safety of research participants and professionals first, relocating people and families and providing continuity in any way possible.

The conflict in Ukraine once again spotlighted the powerful ability of our healthcare community to advance our mission, and impacted DIA's core area of focus in 2022: innovative clinical research that is safe, ethical, inclusive, and patient-centric. With our neutral DIA platform, we were able to collaborate and educate in these key areas and emphasize the achievements of our community. We focused our efforts on creating efficient regulatory frameworks that support safe life cycle research innovation and provide faster access to medicines. We also helped advance patients' involvement and voice in medical product development, accelerate health innovation initiatives within their roles, and design a tool that benchmarks organizational best practices in patient engagement.

The success of these efforts is evident in our journals, in the outputs of our DIA Communities, and in the active participation of thousands of people around the globe: Compared with just two years ago, 40% more conference attendees convened in person; and we attracted 30% more social media followers, 25% more learners, and 70% more professionals reading our publications. Our DIA Communities and Working Groups also continue to grow and expand internationally, as does our research and resource portfolio.

We have repeatedly shown that to achieve ambitious goals we need a neutral yet bold convener that brings everyone to the table to work together and remain at the forefront of critical issues and emerging healthcare trends. That is DIA. It's a great time to be associated with what we do, so join us in working toward transformative success in a volatile world. Together we can be fiercely ambitious and drive bold, innovative problem solving to enhance health, lengthen life, and reduce illness and disability for everyone worldwide.

We look forward to working with you to make DIA even more impactful. Let us learn, collaborate, and innovate together in the years ahead.

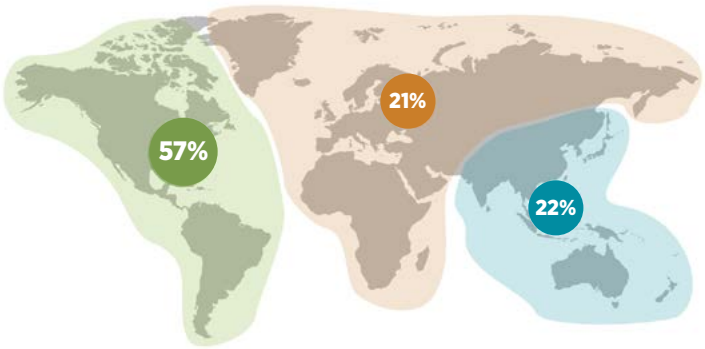
Sincerely,

Cynthia L. Verst
Chair of DIA Board and Executive Committee

Marwan Fathallah
President and Global Chief Executive

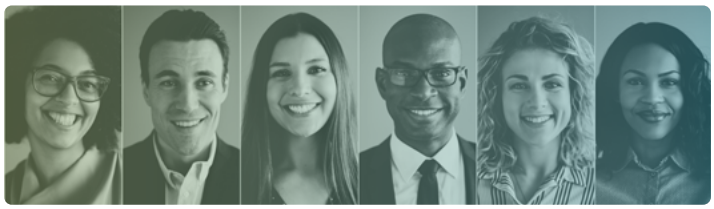
GLOBAL IMPACT IN NUMBERS

Networks and Connections



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

16,900+ professionals from across the healthcare sector came together in **54 meetings** and **900+ sessions** to **EXCHANGE** knowledge and **ADVANCE** strategies for better healthcare for all



We've **TRAINED 5,100+ learners** in **142+** courses and **REACHED 60,300+ followers** across the globe via our social media channels

5,000+ GLOBAL COLLABORATORS in **35** global **DIA Communities** and **Working Groups**

TOP 5 GLOBAL DIA COMMUNITIES
with the most member enrollments

1. Regulatory Affairs Community
2. Clinical Research Community
3. Clinical Safety and Pharmacovigilance Community
4. Good Clinical Practices and Quality Assurance Community
5. Statistics & Data Science Community

NEW DIA COMMUNITIES
launched in Japan

Open Innovation Community
Clinical Pharmacology Community
Bioethics Community

GLOBAL IMPACT IN NUMBERS

Knowledge Access

We **SHARED** insights in **250+ articles & podcasts** garnering **467,700+ views and listens**

15 podcasts
6,600+ downloads

112 *Global Forum* articles
130,500+ views

126 *TIRS* articles
330,400+ downloads

Global Financials

US$ Millions	2022*	2021	2020	2019
Revenue	22.4	25.32	23.58	28.52
Program service expense	20.69	19.24	18.77	23.85
General and administrative expense	5.27	4.35	4.87	4.97
Operating results	(3.53)	1.74	(0.05)	(0.31)
Non-operating items	(2.25)	1.15	1.29	1.60
Change in net assets	(5.78)	2.89	1.24	1.29

*preliminary unaudited results

By capitalizing on our global reach and thought leadership, we continued to drive progress in areas that bring safe and innovative therapies to patients who need them. 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.

A World in Crisis: Global Impacts of the Conflict in Ukraine

The war in Ukraine has brought with it an unprecedented crisis in clinical trials, challenging our established regulatory, ethics, and Good Clinical Practice standards. It has raised new questions about the protection of the vulnerable, the right to inclusion in clinical trials, access to medicines, adaptive trial designs, and the collection and processing of clinical trial data in a changing environment.

Together with the Ukraine Clinical Research Support Initiative (UCRSI), DIA created an international collaborative webinar series to share with our community the experiences and challenges faced by investigators, sponsors, ethics committees/IRBs, regulatory authorities, and—above all—clinical trial participants in Ukraine and the region.

- Ethical Considerations in Supporting Research Participants in Ukraine
- Impact of Ukraine Crisis on Patients and Clinical Development
- Regulatory Considerations for Clinical Trials Responding to the War in Ukraine
- The War in Ukraine and Good Clinical Practice
- Questions of Ethics in Clinical Trials & The War in Ukraine – Part 1 & Part 2
- Cancer Clinical Trials in Ukraine: The Impact of the War on the Patients, the National Clinical Research Framework, and the Region
- Protocols, Research Participants, and Safety in the Context of War

Publication Highlights

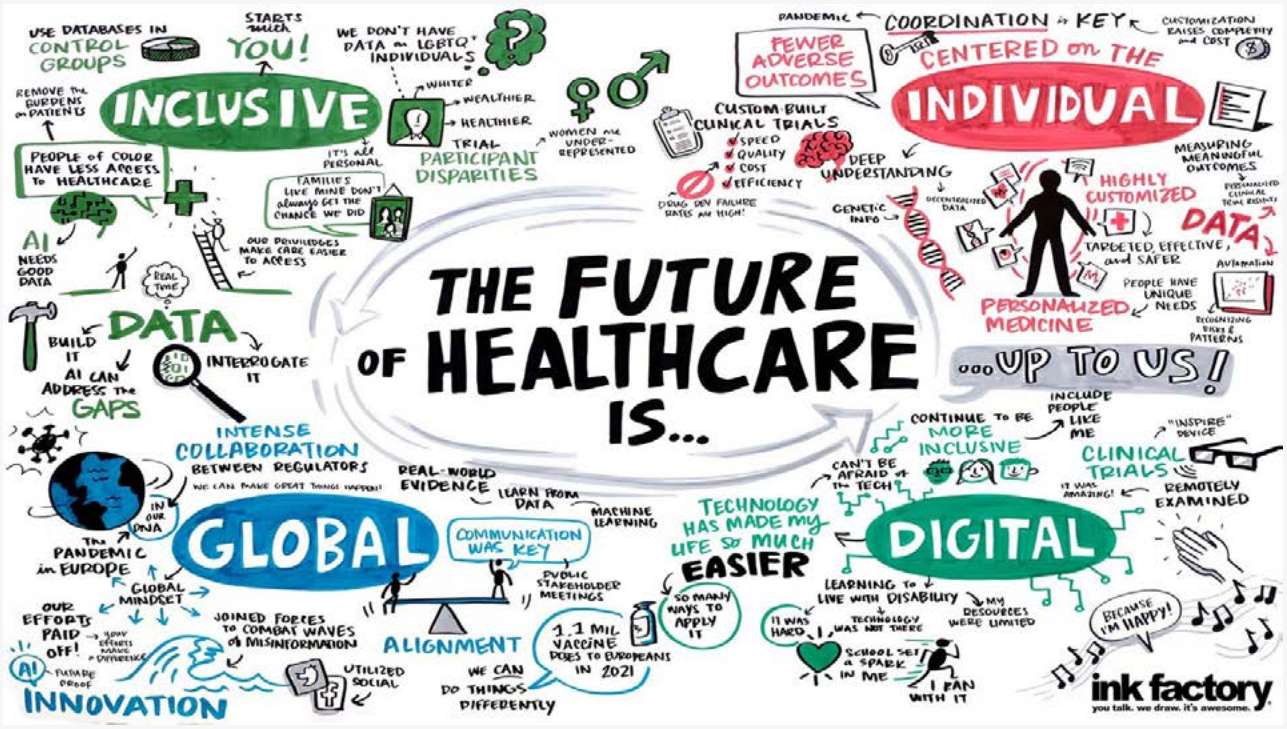
Special Issues and Collections on emerging issues published in our peer-reviewed journal *Therapeutic Innovation & Regulatory Science* (*TIRS*) and online magazine *Global Forum* (*GF*) highlighted important advances across the medical product development landscape.

- Accelerating Pediatric Drug Development (Special Issue, *TIRS*)
- The Digital Virtuous Loop (Special Issue, *GF*)
- Bayesian Clinical Trials (Special Section, *TIRS*)
- Clinical Research in Ukraine – Part 1 & Part 2 (Special Section, *GF*)
- Patient Preferences to Inform Decision Making in Medical Product Development (Special Collection, *TIRS*)
- Pharmacovigilance (Special Section, *GF*)

The Future of Healthcare

Recognizing and adapting to a new era of global change and uncertainty, DIA's key tenets of bringing truly global perspectives to the product development process remained unchanged.

The *DIA 2022 Global Annual Meeting*, convened in Chicago (IL) under the theme "Collaborate to Innovate," celebrated one of DIA's first post-pandemic global in-person meetings to bring industry, regulators, academics, and patients together to co-create, problem-solve, and discuss global and local challenges facing professionals in the life sciences community. The opening plenary set the tone for the entire meeting and explored the question "What is the Future of Healthcare?" Answers from four connected perspectives—Inclusive, Global, Individual, Digital—were documented in real time by graphic artist Alison Vellas (Ink Factory).



4,000+
PARTICIPANTS

580+
SPEAKERS

230+
SESSIONS

500+
EXHIBITORS

Quicker Access to Innovative Technologies for Patients

DIA's thought catalyst efforts within Regulatory Science focused on creating efficient regulatory frameworks that support innovation and provide faster access to medicines.

- DIA held its first *Health Technology Assessment (HTA) Forum* in response to the EU Regulation on Health Technology Assessment (EU HTA) that entered into force in January 2022. The regulation ensures an efficient use of resources and strengthens the quality of HTA across the union to bring innovative healthcare technologies to patients faster. The DIA HTA Forum provided a neutral platform for various stakeholders to discuss steps toward creating a successful European system that transcends current national practices and accomplishes the primary goal of faster patient access.
- Collaborative Think Tank exercises in six regulatory specialty meetings took place in the EMEA region, inspiring discussions among global regulatory authorities and industry that continued throughout the remainder of the year. For example, outcomes of collaborative exercises on the use of reliance pathways for post-approval changes at the *DIA Accelerating CMC Workshop* went far beyond the duration of the workshop. Discussions continued throughout the rest of the year and led to the conception of a new pre-conference workshop on reliance, to take place before *DIA Europe 2023*.
- DIA has formally established a multistakeholder Think Tank Consortium to develop an approach toward better access to care and more efficient healthcare delivery in low- and middle-income countries. The consortium will work together to create a "playbook" for tailoring strategies and tactics according to market and disease state. A pilot program will demonstrate a mechanism for creating tailored, affordable solutions, while an open application process will solicit ongoing challenges for this mechanism to address. This open process will create awareness of the problems faced by those working on the frontlines of bringing therapies to patients. It will also create a process for identifying challenges that local partnerships and regional customization can solve.

To learn more about the DIA Think Tank Consortium, or to learn how to contribute and help, please contact science@DIAglobal.org.

Patients as Partners

DIA has long recognized that patients are a significant driver in the discovery and development of safe, transformative treatments. For more than two decades, we have worked with industry to shape the culture of patient involvement in medical product development as well as the tools to reliably quantify it. Our Patient Scholars Program, for example, facilitates conversations with diverse patient advocates and representatives from across the globe that help advance patients' understanding of and involvement in medical product development and positively impact healthcare innovation initiatives within their roles.

- In 2022, as part of DIA's commitment to supporting educational opportunities for patient advocates, we awarded more than 20 patients across the globe in-person or virtual 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.
- We completed phase 3 of the DIA/Tufts Patient Engagement Preparedness, Capabilities, Experience, and Impact study that culminated in the creation of a tool that measures and benchmarks organizational best practices in patient engagement (PE). Additionally, the tool helps track how organizations and industry are mobilizing to engage patients. Throughout phase 3, we involved participants in our Patient Scholars Program, and both working group and patient steering group members provided input as the research progressed.

"Working with DIA throughout the PE research made me feel validated as a patient—meaning the patient's voice, questions, concerns, and recommendations were highly regarded and taken into consideration. This experience allowed me to work alongside a supportive group of researchers who also had the patient's best interest at heart to accelerate healthcare initiatives."

– Wenora Johnson, Research/ Patient Advocate, Colorectal, Endometrial & Basal Cell Carcinoma Cancer Survivor, Lynch Syndrome

Supporting Equitable Breakthroughs in the Life Sciences

As a global, people-centered organization, we are committed to fostering, cultivating, and preserving a culture of diversity, equity, and inclusion (DEI) across all our activities where diverse talent is leveraged to achieve better health for all. Since 2020, we have worked tirelessly to dismantle barriers and move beyond describing the problems that exist in this space, emphasizing instead the approaches and solutions our field has invested in.

To put the patient at the center of any healthcare business, we focused our community engagements, meetings, and scientific publications on topics such as:

- how to engage and fund Community-Based Organizations (CBOs) to build trust within all patient populations;
- how changes in protocol design and development affect DEI in clinical trials and beyond;
- how to appropriately define data and population parameters from a race and ethnicity perspective;
- strategies and best practices for actively involving under-represented communities in pediatric drug development programs;
- inclusive professional recruitment and training strategies that increase diversity in the healthcare talent pool and reflect the patient communities they serve;
- why trans/nonbinary research benefits all communities;
- how to address vaccine hesitancy in different ethnic communities; and
- how representation bias in genomic research data affects effective cancer care.

Reflections from DIA's Departing Global Chief Executive

At the end of 2022, after a decade at the helm, DIA Global Chief Executive Barbara Lopez Kunz stepped into the next chapter of her career. She shared reflections on her DIA tenure with *Global Forum* Editor-in-Chief Alberto Grignolo.

A Bigger "Why": Highlights from Our Conversation with Departing DIA Global Chief Executive

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