

2021 Annual Report

Building Global Coalitions to Promote Innovation

DIA



SAFE ► INCLUSIVE ► PATIENT-CENTRIC

LEADERSHIP MESSAGE

As the world continued to navigate COVID-19 in 2021, our community worked to respond to the needs of patients. Despite the hurdles, we observed great success with record speed. To date, 37 vaccines have been approved around the world for the prevention of COVID-19, and nearly 100 others remain in development. Similarly, almost 100 therapeutics to treat or prevent the disease are in development.

These achievements were possible because of previously unprecedented international multistakeholder collaborations, with public-private partnerships and global initiatives creating unparalleled efficiencies across the product development pipeline. They also spurred innovation in other areas that led to tremendous successes in cancer interventions, rare diseases, and other conditions. We saw real-world evidence integrated into regulatory decisions, new clinical trial modalities used that were built on digital inputs, and data integration in virtually all aspects of product development and licensure. These transformative advancements directly impacted DIA's core areas of focus in 2021: safety, inclusivity, and patient-centricity. With our neutral DIA platform, we were able to collaborate and educate in these key areas and amplify some of the greatest achievements of our community.

Although COVID-19 has drastically changed our lives and we only now are seeing a return to more normal routines, the pandemic continues to spotlight an ongoing global issue: implicit bias and underrepresented populations in clinical research and healthcare as a whole. The impact these disparities have on minority populations and medical innovations are manifold and have brought a new focus on these topics critical to the future of our community.

To make progress toward greater diversity, equity, and inclusion in the drug development lifecycle, we have led the way in sharing knowledge and fostering coalitions that move beyond simply describing the problems that exist in this space. Instead, we emphasized approaches and solutions and initiated important dialogue about health equity and inclusion of minority populations in clinical trials. The outcomes of our efforts are evident in our journals, our DIA Communities outputs, the active participation of thousands of people around the globe, and our financial outcomes.

Let's be as intentional about diversity in clinical drug development as we are about pre- and post-market safety. With the industry conversation that is being brought to the forefront, what more can be done to improve trust, reduce barriers, and create equitable access to healthcare today? That is our shared mission, and we look forward to working with you to see that become a reality in 2022 and beyond.

Sincerely,



Judith Ng-Cashin

Chair, DIA Board of Directors

A handwritten signature in blue ink that reads "JNgC".



Barbara Lopez Kunz

Global Chief Executive, DIA

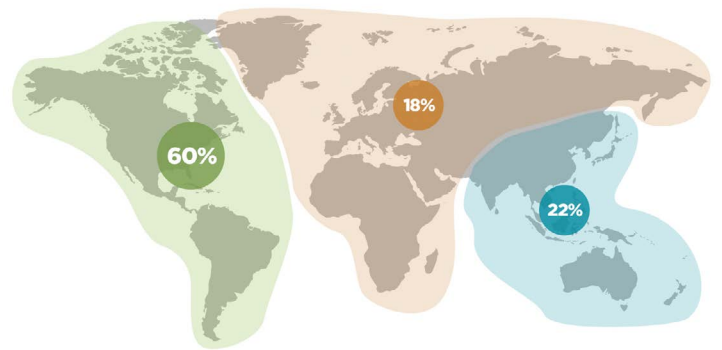
A handwritten signature in blue ink that reads "Barbara L. Kunz".



GLOBAL IMPACT IN NUMBERS

Networks and Connections

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



19,000+ professionals from across the healthcare sector came together in **51 meetings** and **900+ sessions** to **EXCHANGE** knowledge and **ADVANCE** strategies for better healthcare for all



We've **TRAINED 5,400+ learners** in **111+ courses** and **REACHED 47,000+ followers** across the globe via our Social Media channels



Thousands of **GLOBAL COLLABORATORS** in **50+** global **DIA Communities** and **Working Groups**

GLOBAL IMPACT IN NUMBERS

Knowledge Access

We **SHARED** insights in **270+ articles & podcasts** gathering **354,000+ views and listens**



FOUR NEW SPECIALTY MEETINGS launched

Diagnostics and Personalized Medicine

9 sessions
93 attendees

Impact of Project Management in Healthcare Product Development

13 sessions
87 attendees

Advanced Therapies: Innovations in CMC

11 sessions
107 attendees

Diversity, Equity, and Inclusion in the Drug Development Lifecycle

5 sessions
129 attendees



NEW GLOBAL DIA COMMUNITIES introduced

Diversity & Inclusion Community

Bioethics Community

Digital Acceleration Community

Medical Writing Regional Communities (China, India, UK)

Financials

US\$ Millions	2021	2020	2019
Revenue	21.1	18.6	28.5
Program service expense	6.3	6.7	11.0
General and administrative expense	16.0	16.9	17.8
Operating results	(1.2)	(5.1)	(0.3)
Nonoperating items	4.5	6.3	1.4
Change in net assets	3.2	1.2	1.1



CONTRIBUTIONS TO SCIENCE

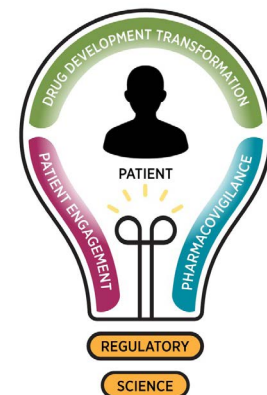
Safe, Transformative Drugs with Patients in Mind

In 2021, we continued to focus our global thought leadership in areas that drive innovative, transformative drug development with safety and patients front and center. Across regions, our activities are informed by advancements in regulatory science that guide the entire drug development lifecycle. These advancements shape how healthcare professionals use disruptive technologies and RWE, ensure pre- and post-market safety, and engage patients in the process from start to finish.

▶ SAFE

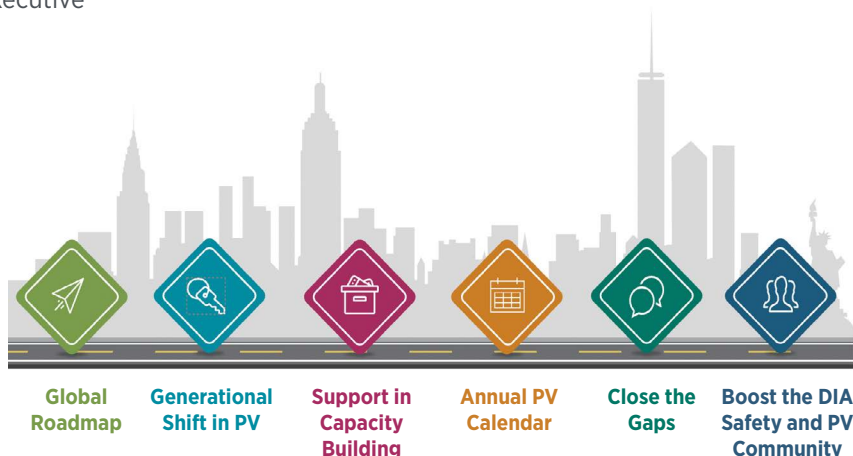
Protecting patient safety worldwide and delivering the right products at the right time, with the right benefits and risks, remained one of our top priorities in 2021:

- Building on the success of the previous year, experts attending our global ***Pharmacovigilance and Risk Management Strategies Conference*** addressed the growing complexity of safety and pharmacovigilance issues heightened by the rapid development of multiple COVID-19 vaccines, the evolving knowledge about the disease, and pervasive misinformation about its prevention and treatment.
- We also finalized a strategic Pharmacovigilance (PV) roadmap that provides structure and consistency to our global annual cadence of PV workshops and meetings. Two ***special sections on PV published in Global Forum*** supplemented this cadence with 12 articles covering the use of artificial intelligence, patient reporting, RWD/RWE, regional regulatory developments, and advanced analytics in PV. An additional nine Global Forum reports were selected for translation and reprint in *Pharmaceutical Industry-Healthcare Executive*



▶ PATIENT-CENTRIC

DIA also has a long history of working with industry to shape the culture of patient involvement in drug 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 the context of our unwavering commitment to patients, we created the two final modules of our comprehensive Patient Engagement eLearning Program and incorporated participants of our Patient Scholars Program into phase 3 of our multiphase patient engagement study conducted in partnership with Tufts University:

- The new ***Patient Engagement Evaluation and Metrics*** and ***Developing a Comprehensive Patient Engagement Program*** eLearning modules are the final two courses that complete the six-module Patient Engagement curriculum, the training component of DIA's ***Patient Engagement Certificate Program***. This program provides the functional knowledge and skills needed to incorporate meaningful patient engagement throughout the product lifecycle and embed patient focus into the culture of an organization.
- Phase 3 of the DIA/Tufts Patient Engagement Preparedness, Capabilities, Experience, and Impact multiphase study integrates patient scholars and their voices to support the development of patient-centric practices within the medical product development lifecycle and ultimately improve the efficiency and quality of clinical studies and their results.

DIA also collaborated with the Innovative Medicines Initiative (IMI) PREFER Project to deliver the DIA/IMI **PREFER** Patient Preferences Workshop. Funded by IMI PREFER and its Partners, the workshop was complimentary for all participants. 490 participants from industry, global regulatory authorities, patient organizations, and academia attended the workshop and navigated through the value of patient preference studies, methods and frameworks, and the use of patient preferences in regulatory decision making.

“I was inspired to join DIA as a patient scholar because I’d spoken at various DIA events before and have always found them incredibly educational and informative. This has helped to further my advocacy journey and has improved the accessibility of such events to advocates like myself.”

“The neutrality of the DIA platform is very important to me as an educated patient because it provides a forum for open and honest discussions that are free from bias. This encourages everyone to critically assess where we are on certain issues and enables us to move forward in true partnership with other stakeholders.”

– Trishna Bharadia, Owner, The Spark Global: “Putting the Patient Voice into the Healthcare Journey”; Ambassador of the MS Society UK, ADD International, & Lyfebulb; Patient Engagement editor, DIA Global Forum

Similarly, two meetings on ***Advanced Therapies: Innovations in CMC*** and ***Diagnostics and Personalized Medicine*** brought together multidisciplinary working groups from across the healthcare sector to explore crucial innovations in advanced therapies, novel technologies and sequencing methods supporting innovative diagnostics, and the regulatory challenges associated with these increasingly complex tools and therapies. To address the unmet need of oncology patients in China, the ***DIA China Oncology Innovation Forum***, held for the first time in 2021, was designed to accelerate China’s innovative cancer drug development safely and successfully.

In response to the continuing COVID-19 crisis, DIA has joined regulatory authorities in their focus on providing support for the rapid development of vaccines and treatments and the expedited approval and implementation of agile regulatory systems. At the ***2021 NIFDS-DIA Workshop*** held in Korea, former and current regulators from the FDA and EMA as well as experts from the pharmaceutical industry explored ways to facilitate the global development and regulation of COVID-19 vaccines and treatments. Participants also addressed the tools and legal strategies used in the development and regulation of new drugs in general.

Several new global DIA Communities have also done their part: Our new ***Digital Acceleration Community*** and ***Bioethics Community*** shared technological solutions and best practices for common problems in medical product development. Three new regional branches of our Medical Writing Community in the UK, India, and China explored critical regional topics, such as region-specific requirements for authoring new drug market applications, advances in scientific writing to improve global communications about healthcare products, intricacies of authoring periodic reports in safety writing, clinical document preparation for NDA/BLA (New Drug Application/Biologics License Application) submissions, and many more. Community members include medical monitors, physicians, and regulatory affairs professionals as well as representatives from global and local pharmaceutical, CRO, and biotech companies.



Catalyzing Global Conversations to Drive Diversity, Equity, and Inclusion

► INCLUSIVE

As a neutral, global organization, we are committed to fostering, cultivating, and preserving a culture of diversity, equity, and inclusion (DEI) across all our regions. This dedication applies to both the health priorities we address and the work environment we provide for our staff, volunteers, members, and other stakeholders.

From discovery to post-marketing, the conversation around DEI is crucially important at all stages of the product development pipeline. Since 2020, we have worked tirelessly to share knowledge and foster coalitions to dismantle barriers. In our meetings, publications, and DIA Community activities, we moved beyond describing the problems that exist in this space, emphasizing instead the approaches and solutions our field has invested in.

In 2021, we launched the **Diversity & Inclusion in Life Sciences Community** to discuss and develop inclusive practices across the industry, spanning the entire product development lifecycle. Community members responded to the Patient-Centered Outcomes Research Institute's (PCORI) 2021 Request for Information (RFI) on the Science of Engagement Funding Initiative to provide honest feedback, comments, and perspectives on the points presented in the request.

We also brought to our members DIA's first **Diversity, Equity, and Inclusion in the Drug Development Life Cycle Meeting**. Thought leaders from industry, clinical research sites, patient engagement, academia, regulatory agencies, and public policy addressed critical questions in various discussions and exercises, including how we can improve as an industry, increase accountability, and ensure sustainable DEI approaches. Several articles on this topic have further supported the conversation and brought different perspectives to the table.



To truly put the patient at the center of clinical trials and at the center of any healthcare business, we particularly focused on topics such as:

- how to engage institutional review boards (IRBs) and independent ethics committees (IECs) to ensure appropriate representation in R&D;
- change management best practices, successful strategies for awareness, recruitment, and participant retention in clinical trials;
- how to **link regulations with DEI in decentralized clinical trials**;
- **regulatory frameworks** for building healthcare equity and inclusion; and
- best practices for **access to clinical trials and post-marketing equity** for traditionally underrepresented populations.

