2020 Annual Report

Reuniting Communities Globally

DIA

Leadership Message

Emanating from one of the biggest healthcare crises in modern history, we are experiencing the most substantial disruption in healthcare innovation to date. Pandemic adaptations have changed the status quo in more ways than one, fundamentally impacting not only our day-to-day lives but also how medicines are developed and healthcare is delivered to patients worldwide.

The pandemic has also made us acutely aware of the life sciences community's extraordinary resilience, forcing us to draw on abilities we did not know we had. The challenges of 2020 have tested, yet reconfirmed, the strengths of our community: The uniquely global and collaborative mindset of DIA members, including regulatory authorities, patients and volunteers, and industry, was crucial in mobilizing and uniting the globe in pursuit of better health outcomes for all. Virtual platforms, digital tools, and technologies helped us move forward with our mission of bringing healthcare professionals together to network, share experiences, and advance their fields of expertise together, resulting in the remarkable advances we have seen over the past years.

The pandemic also brought into stark relief systemic healthcare inequities and the lack of diversity in the drug development lifecycle, the healthcare profession, and society as a whole. Although diversity, equity, and inclusion have always been hallmarks of how DIA operates, the events of 2020 have invigorated the discussion and our fierce commitment to addressing these issues. We recognize that we all must learn how to do better and be actively inclusive, to identify and nurture the rich diversity present in our society. Only then will healthcare truly advance.

As we have adjusted to shifts in "business as usual" and continue to learn, exchange opinions, and work towards advancing lifesaving medicines, we must use this moment to prioritize and accelerate our efforts to make a difference in 2021 and beyond.

Sincerely,

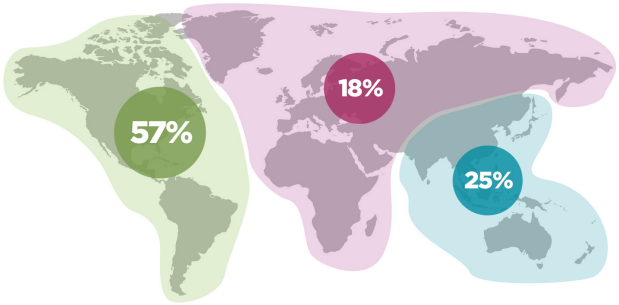
Lingshi Tan
Chair, DIA Board of Directors

Barbara Lopez Kunz
Global Chief Executive, DIA

Global Impact in Numbers

Networks and Connections

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



16,000+ experts came together in **54** meetings and **700+** sessions to **EXCHANGE** knowledge and **ADVANCE** strategies for better healthcare for all

We've **TRAINED 4,000+ learners** in **114+** on-demand courses and **REACHED 45,000+ followers** via our Social Media channels

Thousands of **GLOBAL COLLABORATORS** came together in **50+ DIA Communities** and **Working Groups**.

Global Impact in Numbers

Knowledge Access

We **SHARED** insights in **291** articles and podcasts, gathering **279,000+ views and listens**

24 podcasts
11,000+ downloads

100 *Global Forum* articles
101,000+ views

167 *TIRS* articles
165,000+ views

SHARING INSIGHTS and **ENGAGING REMOTELY** in a Global Pandemic

DIA DIRECT Webinar Series ▶ **17** webinars

COVID-19 Resource Center ▶ **156** curated resources

Remote Engagement ▶ **44** virtual meetings

TWO NEW MEETINGS launched

Master Protocols
9 sessions

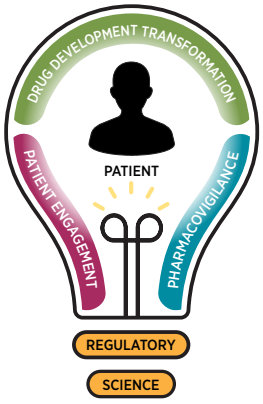
Digital Technology in Clinical Trials
9 sessions

Financials

(Dollars in Millions)	2020	2019	2018
Revenue	23.6	28.5	28.5
Program service expense	18.6	23.9	24.2
General and administrative expense	4.5	5.0	4.2
Operating results	0.5	-0.3	0.1
Non-operating items	1.3	1.2	-0.8
Change in net assets	1.8	1.4	-0.7

Contributions to Science

Safe, Transformative Drugs with Patients in Mind



In 2020, we redefined our thought leadership focus to areas that drive innovative, transformative drug development with safety and patients front and center. 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.

DIA has a long history of working with industry to build a culture of patient involvement in drug development as well as the tools to reliably quantify it. In the context of our unwavering commitment to patients, we launched our first Patient Engagement (PE) Certificate Program, created two new online courses, and released an aggregate report of our multi-phase PE study conducted in partnership with Tufts University:

- The ***Patient Engagement Certificate Program*** follows a competency-based training curriculum that is based on the DIA Patient Engagement Competency Framework developed with experts working in the field. It provides the functional knowledge and skills needed to incorporate meaningful PE throughout the product lifecycle and embed patient focus into the culture of an organization.
- The two new eLearning Modules incorporate important PE concepts for industry into the DIA Learning portfolio: The first module, ***Legal and Compliance Considerations for Engaging Patients as Partners***, reviews ethical, legal, and regulatory requirements for patient contact and engagement, as well as emerging points of consensus about fair practices for engaging patients, care partners, and patient advocates. The second module, ***Creating a Patient-Focused Culture***, provides an overview, strategy, and resources to help shift culture to enable necessary change and subsequent action for organizations to be more patient-centered.
- The aggregate report compiles results from our DIA/Tufts *Patient Engagement Preparedness, Capabilities, Experience and Impact* study. Currently under review in DIA's peer-reviewed journal *Therapeutic Innovation & Regulatory Science* (TIRS), the article *"Evaluating the Feasibility and Validity of a New Tool to Assess Organizational Preparedness and Capabilities to Support Patient Engagement in Drug Development"* describes how to assess the adoption and integration of patient-centric initiatives and the validation of the tools used.

Top of mind in 2020 was also Pharmacovigilance and Drug Safety: In our *Pharmacovigilance and Risk Management Strategies Conference*, participants addressed tangled pharmacovigilance topics that were at the tip of the iceberg in 2020, as industry and regulatory authorities across the globe quickly pivoted from theory to action in response to COVID-19. A digital **Real-World Evidence Resource Kit** and more than ten articles and podcasts supplemented the discussion around regional and global regulatory developments, primary sources of risk, and risk management tools.

Similarly, two meetings on ***Master Protocols*** and ***Advancing Complex Innovative Clinical Trail Designs*** brought together multidisciplinary working groups from across the healthcare sector to address crucial innovations in clinical trials, the development of new tools and approaches to support the innovation, and the positive impacts these innovations have on patients. In collaboration with PhRMA, BIO, and FDA, the *Advancing Complex Innovative Clinical Trail Designs* meeting resulted in a digital Complex Innovative Designs Resource Kit with access to articles, podcasts, session recordings from DIA events, and other topic-specific content. In fact, in 2020 alone, our publications and podcasts on drug development transformation-related topics such as real-world evidence, master protocols, and innovative trial designs gained more than 47,000 reads and listens.

Catalyzing Global Conversations in the Fight Against COVID-19

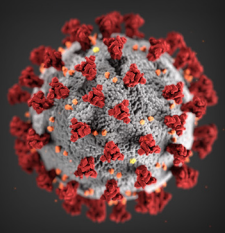
With support from the **DIA Knowledge Brigade**, our new series of live, virtual panel discussions, brought together numerous experts from across the healthcare product development continuum, and across the globe, to discuss lasting impacts of the coronavirus crisis and how to accelerate therapies to patients during the pandemic. Thousands of attendees from around the world engaged in the conversation about how to battle this pandemic. Articles, podcasts, and curated content available in our **COVID-19 Resource Center** further explored important insights and advances in the fight against COVID-19.

Webinars, podcasts, and articles on topics such as:

- Clinical trials during the pandemic
- Diversity, equity, and inclusion
- Estimands and analysis considerations
- Remote monitoring
- Patient-focused medicines development
- Study and data integrity
- Pandemic preparedness and use of RWE
- Diagnostic testing now and in the future
- Vaccines and other therapies
- Drug shortages and supply chain management
- Post-pandemic paradigm shifts, new dimensions of value

DIA In Focus

COVID-19 Resource Center



150+ Curated Resources

50K+ Total Viewers

Updated weekly to include resources that explore all facets of the pandemic.

- **17** webinars
- **50+** articles
- **8** podcasts
- **45** videos
- **35** other resources

The safety of our DIA community remains our priority as we monitor the COVID-19 outbreak and follow updates from the WHO and others.

Commitment to Diversity and Inclusion

As a neutral, global organization, we are dedicated to dismantling barriers by fostering, cultivating, and preserving a culture of diversity, equity, and inclusion. This commitment applies to the health priorities we address as we carry out our mission as well as to the opportunities and environment we provide for our staff, volunteers, members, and other stakeholders to work together.

Because the conversation around diversity in early drug development is crucially important, we have worked tirelessly in 2020 to bring to our members DIA's first ***Diversity, Equity, and Inclusion in the Drug Development Lifecycle Meeting***, to be held in 2021. We also launched the **Diversity & Inclusion in Life Sciences Community** to discuss and develop inclusive practices across drug development and the pharmaceutical industry. A **podcast**, **webinar**, and several articles on this topic have further supported our effort to keep the conversation going and bring 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 are particularly focused on addressing topics such as:

- how to engage institutional review boards (IRBs) and independent ethics committees (IECs) on these efforts,
- change management best practices, successful strategies for awareness, recruitment, and participant retention in clinical trials, and
- post-marketing equity for traditionally underrepresented populations.