Barbara Lopez Kunz – President & Global Chief Executive, Drug Information Association (DIA)

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Reflecting on a transformational decade at the helm of the Drug Information Association (DIA), Barbara Lopez Kunz highlights some of the key achievements and most significant trends that have emerged during her tenure. Lopez Kunz points to the DIA's evolution into a truly global knowledge-sharing platform, the COVID-19 pandemic's impact on digitalisation across the healthcare arena, the potential of big data and AI in accelerating decision-making, regulatory alignment and learnings, clinical trial diversity, and much more.

The COVID-19 pandemic caused massive shifts in the healthcare landscape, impacting stakeholders at every level. As an organization whose mission is to connect its network of members from across healthcare and life sciences, what have been the biggest changes that the Drug Information Association (DIA) has faced during this time?

From the perspective of DIA and the role we play in the healthcare arena, the pandemic created a huge innovation ecosystem like nothing we have seen before. In the traditional sense of drug and diagnostic development, COVID-19 affected everything we do, and this experience has created an opportunity for new knowledge to be created and shared and inspired people to work more collaboratively to have better health system outcomes for patients.

We have been busy responding to the pressure of the pandemic on the regulatory review process, integration of data, clinical trials, post-licensure data surveillance, HTA decisions, across all segments of healthcare. We saw a huge push for diagnostic testing and significant efforts to gain an understanding of the COVID-19 disease epidemiology and transmission. We also saw pharmaceutical companies begin to look at cures, prevention measures, and repurposing of drugs. For their part, regulators utilized real-world data to inform regulatory approval of repurposed therapies and new vaccines in record time.

Today, we aim to help our community continue to solve problems in this same, accelerated way for other disease areas. Pandemic lessons guided refinement of our DIA *Thought Catalyst* strategy, which guides us to ask the right questions and isolate existing problems we can help solve using our collaborative platform. Going forward, how do we ensure that learning and successes from the pandemic are part of how we do drug development in the future?

The pandemic served as a catalyst for rapid digitization across many fronts. As DIA, we had established platforms to convene digitally to ensure that people could access the knowledge they need in a curated way and share their insights across the global health and life sciences ecosystem This part of our strategy is called *Knowledge Concierge* and aims to deliver precisely what life science professionals are seeking through digital tools that deliver tailored, relevant content that is easy to assimilate.

Despite the challenges it created, the pandemic forced changes which today allow the DIA platform to work more efficiently. Although the past years were incredibly difficult on many levels, they catapulted DIA to a new level of effectiveness in delivering our mission.

You mentioned the use of data during the pandemic for the purpose of making regulatory decisions. As we have exited this state of emergency, there seems to be a disconnect between the regulators and industry about what is appropriate data and how it can be used. What is your take on the potential of big data and AI to be used in the acceleration of decision making going forward?

As we near the end of 2022, we see artificial intelligence and automation deployed effectively across the whole ecosystem. Health authorities are using AI to augment safety signal detection and to automate case adjudication and other tasks. Technology is even being used to identify false claims and illegal drug marketing. Multi-stakeholder groups are putting initiatives in place to explore the application of AI in other areas. These are all promising signs that regulators, industry,

and other stakeholders, are working together to build bridges to take advantage of the opportunities that AI presents.

Even so, there is a need for evidence to support the integration of data and the application of machine learning approaches. In fact, a current DIA-led research study is exploring the application of AI and ML for adverse event reporting, which we expect to be extremely useful. Still, there is a strong need to continue to educate and build trust and support for AI-based approaches. We need more discussion around a common language for data and for consistency around how data is collected. Furthermore, social, ethnic, and geographic bias in data is a challenge that needs to be recognized. As it stands, data is sometimes not generalizable and cannot always be utilized to draw accurate conclusions.

We also need to get more comfortable with data sharing. The more data we have, the higher the probability that we are going to establish better analytics to minimize some of the impacts of missing or inaccurate data. Still, as somebody who came up through research, I understand that you cannot fully remove humans from data. There is a biological, medical, and clinical understanding that must be associated with the use of data; otherwise, we risk being led to wrong conclusions. It is important to recognize that the pace of change is rapid, creating a challenge to remain current and to build the guidance and frameworks that will allow us to use data effectively.

While everyone may be excited about the prospect of using data, if we look at the disparities between established regulatory bodies like the FDA and those from emerging countries, they are much younger and less prepared to collect and utilize their own data.

This is where global organizations like DIA, the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), and others play a role in helping to share knowledge and establish expert dialogue to advance the entire system. DIA has focused efforts in many countries where regulatory policies are being established, and we have served as a convener and educator to accelerate the uptake of established policies. We continue to do this form of outreach, working side by side to play a role in bringing best practices and latest approaches, including data-intensive tools and processes, to the forefront. Digital tools have enabled our reach.

We have also worked in tandem with the ICH over many years. ICH has focused on bringing developed and emerging regulatory authorities together and encouraging participation in expert working groups to create and share best practices and guidelines. Still, issues take time to resolve,

and frequently new challenges evolve that are unanticipated.

This is why DIA has long held such a crucial role in driving the sharing and exchange continuously, identifying new opportunities and unifying around common goals. We have repeatedly demonstrated that working together and sharing openly accelerates the rate of learning and problem solving. We have also long held a philosophy that we will collaborate always with a singular goal – our mission to enable the advancement of therapies to patients.

You also mentioned the challenge of data being biased. If we speak about diversity in areas like clinical development, this topic has not been on the health agenda for very long. How do you see this factoring into the regulatory system and going beyond just a talking point?

I feel gratified that DE&I are squarely on the agenda in health care. We must all ensure that considerations such as race, ethnicity, gender, sexual orientation, and other elements of diversity remain front and center to address longstanding health inequities. While we should contemplate why we were not addressing these issues before, the good news is that these conversations have become more mainstream. Diversity in clinical trial development is finally an important topic within our healthcare system. We see other organizations making progress: For example, FDA instituted the draft guidance *Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Subgroups in Clinical Trials* this past April. We have also seen the Multi-Regional Center of Brigham and Women's & Harvard initiate comprehensive efforts to increase diversity in clinical trials while simultaneously addressing some systemic barriers to clinical trial participation.

Engaging diverse communities can be a challenge for organizations. Building a sense of trust within systems and communities so that participants have a clear understanding of what to expect as well as the benefits of participating clinical research is one key. I have seen thought leaders in health and life sciences conduct outreach to their communities to educate on health care, clinical research, and why it is important to be engaged in one's health. These grassroots efforts are critical in moving people forward in their understanding and willingness to engage. Clinical development is more in the public dialogue than ever before, easing the adoption of clinical research. We need to support small and large efforts which together will help to propel representative populations in clinical development.

Many of those communities might face several barriers to accessing trials such as distance. Do you see the integration of remote trials as a feasible opportunity?

There is a lot of work going on right now to advance the practice and acceptance of decentralized trials, and for good reasons. We must ease the clinical trial burden to encourage participation for patients who live far from these health centers must deal with the burden of travel, as just one example, and consider factors such as the financial constraints of participation and develop perspective on how we can overcome these access challenges.

For example, trials would proceed more easily by establishing methods for patients to access therapies through local providers. Effective devices and technologies allow remote monitoring of physiological symptoms through wearable technologies that allow professionals to access needed data. Decentralized trials aim to create a more distributed system instead of a centralized operation to which participants must accommodate. The need to include diverse trial participants requires a complete rethinking of these considerations in the original protocol development.

The application of decentralized trials is evolving, and we are still facing questions on methodology, data collection, requirements of regulatory authorities, and ensuring patient-centric approaches are prioritized. There are many complexities that must be further developed, and DIA will play a role in convening stakeholders, sharing best practices, and offering educational opportunities to enable the advances.

Of course, large companies will be on board with generating data and considering diversity, but when you look at the medicines which have recently gained clearance by the FDA, a majority have been developed by small biotechs, which by their very nature have limited resources. With these additional considerations, is there is a risk of development becoming even more costly than it already is?

In most innovations, there is a need to thoroughly evaluate conventional methodologies in parallel with novel approaches to ensure benefits are realized. This work should culminate in more streamlined processes that are time- and more cost-efficient. This is where we are heading on the pathway to ensuring diversity in clinical trials and the adoption of decentralized processes.

Small biotechs have long dealt with the challenge of the time and cost elements of drug development, in particular clinical development which is highly resource intensive. Until new approaches are developed, proven, and adopted by early innovators, we must be patient. Details

are under development, and DIA is in the mix of this evolution. We were early in convening our community on the topic of *Diversity in Drug Development,* a conference we have held since 2020. We are also developing a training course on decentralized trials to help our community remain on the forefront of the evolution. Much more will emerge as the work continues.

Reflecting on yourself and the 10 years you have been with DIA, what are you most proud of? As you prepare your exit what will this transition bring for DIA after?

It has been the honor of my life to have been at the helm of DIA for such a significant period of our evolution. The work that DIA does in advancing therapies to patients is essential, and I could not be prouder of the enormous impact we have made over the past years. I have seen firsthand the benefits of open, trusted sharing and collaboration for the benefit of patients. No organization does this better than DIA.

When I joined DIA in 2013, the Board of Directors gave me an enormous challenge: To lead in the transformation of DIA. This challenge was very motivating to me but in no way were these many accomplishments my own. DIA is a community, a community of dedicated health and life sciences professionals who band together in many different ways to advance our mission. I am indebted to the many members of our Board of Directors over the years, the Advisory Councils, the Editorial Boards, our Fellows of DIA, and our members from around the globe for working together to set our strategic direction, supporting our mission, and for allowing me the opportunity to serve.

Most importantly, the DIA staff is comprised of a highly motivated and committed group of people who make DIA what our members and stakeholders experience around the globe. I feel incredibly lucky to have worked with this group of experts who are behind the scenes making DIA happen seamlessly, regardless of location, scale, and even in the face of a pandemic!

You asked me of what I am most proud. Without a doubt, it is the network of people that we have brought together under the umbrella of DIA, dedicated to bringing their best selves to the service of patients. I have long believed that those of us who have chosen to work in health-related fields are united by a common bond, and that mutually supportive bond is shown over and again through DIA’s volunteer community. I am enormously proud of this association of experts who have become my friends over the years, and I am confident that these friendships will persist long beyond my tenure in the DIA leadership role.

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and disseminate knowledge, reinforced by digital technologies, is a proven success story. I know that whoever takes the baton from me will bring new ideas and energy to continue to evolve our organization, and I hope that individual has the same amazing experience that I have had over the past decade.

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