

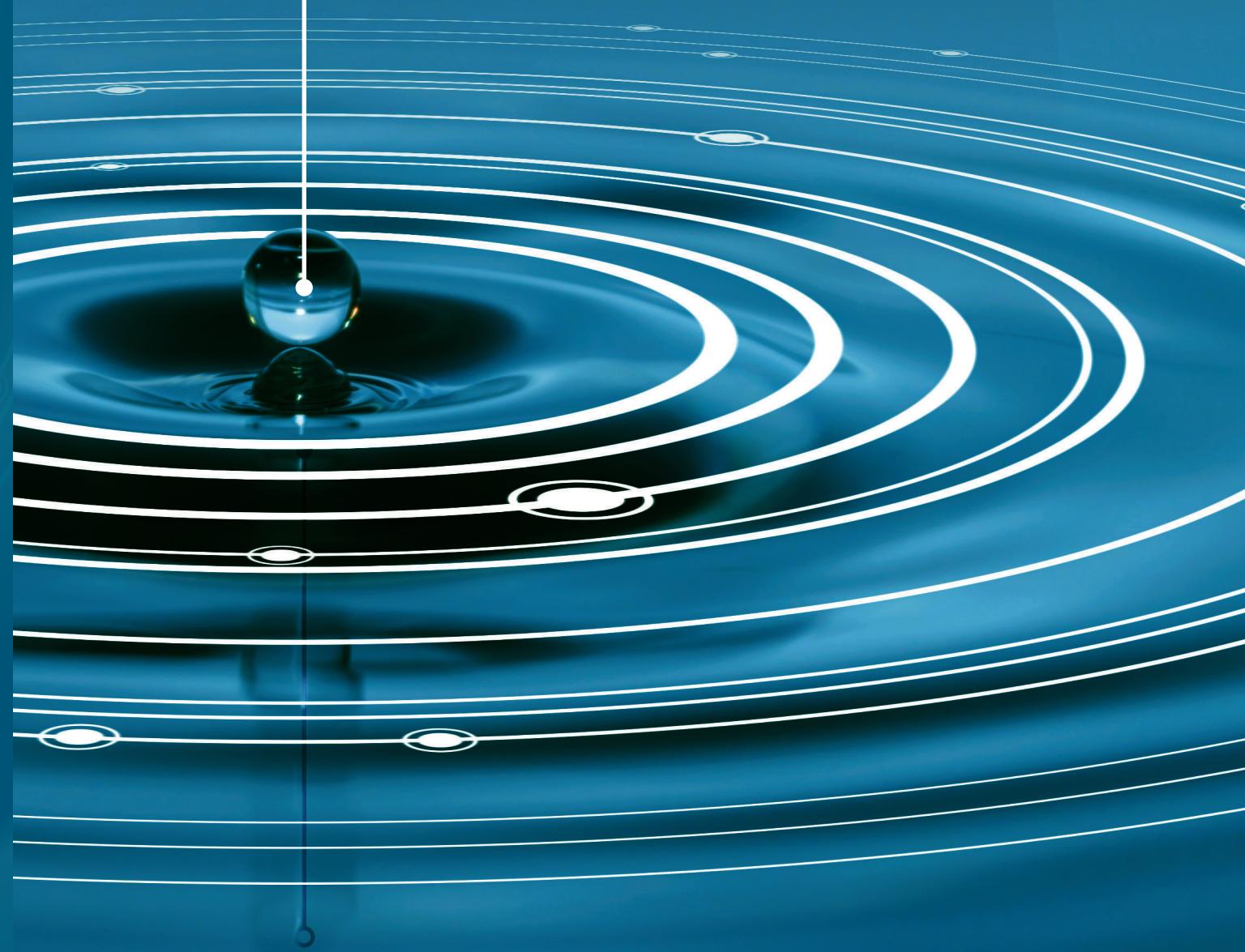


DIAGlobal.org

- Members get involved.
- Issues are resolved.
- Health care evolves.

Conversations and Innovations

Annual Update, June 2015



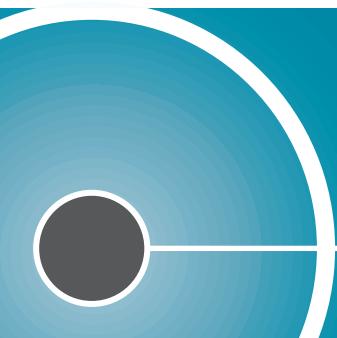


50 Years of conversations & innovations

DIA was founded in 1964 by a dedicated group of professionals with one goal in mind—to improve health care product development. Fifty years later, this essential work continues.



Jamie Heywood
Keynote, DIA2014 Annual Meeting



1960s

Thalidomide, used for nausea in pregnancy, is found to cause birth defects in babies born throughout Europe and is barred from the US market. In response, Congress passes legislation establishing a framework that requires drug manufacturers to prove scientifically that a medication was not only safe, but effective.

The Drug Information Association (DIA) was founded on the heels of the thalidomide disaster to further the standardization and sharing of information among health care professionals.



1970s

Over-the-Counter (OTC) drug review and medical device amendments enhance the safety, effectiveness, and appropriate labeling of OTC drugs, as well as medical devices and diagnostics.

DIA holds stakeholder conferences on the need for specific, understandable, and accurate information in drug package inserts and publishes the *Drug Information Journal (DIJ)*, DIA's official peer-reviewed scientific publication.



1980s

The advent of personal computers sparks the creation of new ways to gather and store data, and creates opportunities for global collaboration.

DIA recognizes the need for increased education and offers courses and workshops on clinical data and records management. DIA expands its reach beyond the US by hosting its first *DIA EuroMeeting*.



1990s

Regulatory and industry associations in Europe, Japan, and the US convene the International Conference on Harmonisation (ICH) to rationalize and harmonize health care product registration controls, and to usher in new global laws, regulations, and guidelines.

DIA enters a period of global growth and expansion to support ICH and the scientific evaluation of medicines efforts, establishing formal offices in the US, Switzerland, and Japan. The launch of the DIA website in 1996 enables greater global sharing of knowledge, while the first DIA discipline-specific Community (then SIAC) is formed in 1998.



2000s

Globalization and technological advances continue to change the world of health care product development.

DIA opens offices in India and China. On-site training and certification programs on a widening array of topics are offered in a variety of locations. DIA recognizes the importance of patient involvement with the creation of *EuroMeeting* patient fellowships and includes the patient voice in programs. Both DIA annual meetings in Europe and US attract high levels of attendance and top quality speakers. Regional annual meetings are added in China and Japan, and Japan introduces the *Annual Conference in Japan for Asian New Drug Development*. Leadership from the FDA, WHO, Bill & Melinda Gates Foundation, International Vaccine Initiative, Developing Countries Regulatory Network, and BIO Ventures for Global Health convene at DIA's first *Global Vaccine Development for World Health Symposium*.



2010s - Current

New trends emerge in health care product development, including patient-centric initiatives, pre-competitive partnerships, big data, novel clinical trial design, precision medicine, and Bayesian statistics.

DIA responds to changing needs with the inaugural *Annual Canadian Meeting*, a series of conferences in South Korea, and the *Asia Regulatory Conference*, as well as the First Steering Committee of Latin America. Recognizing the value of patient input and building on success in Europe, the North America Patient Advocate Fellowship Program is launched. DIA's educational platform is expanded to include the new trends emerging in health care product development such as clinical trial transparency, adaptive pathways, and biosimilars, and new ways of reaching stakeholders with online learning opportunities. DIA reaches out to the next generation with expanded student initiatives. DIA retires the *Drug Information Journal (DIJ)* and launches *Therapeutic Innovation & Regulatory Science (TIRS)*, expanding content to include the full spectrum of converting biomedical science into practical solutions to advance human health.

The world of health care product development has changed considerably in the past 50 years—and it will continue to change in the years ahead.

DIA has played a key role in these changes.

In 2014, DIA celebrated 50 years of leadership as the global, neutral forum for health care product development and regulatory science. It's always useful to reflect on how far we have come, but also to think about the future of DIA.

DIA's new branding and focused mission are part of a larger effort to clearly define the direction of DIA. The new tagline—Develop, Innovate, Advance—embodies our continued commitment to serve as a neutral convener, focused on connecting you and your fellow thought leaders.

Now we look ahead to what can be accomplished in 2015 and beyond. In this annual update, we cover some of the key issues in health care product development, and the role DIA is playing to advance those issues.

DIA aims to be the essential resource for those advancing biomedical and regulatory science and enhancing patient engagement. When you are looking to progress your personal and professional development, and increase your ability to establish groundbreaking collaborations, DIA wants to be your partner.



Barbara Lopez Kunz, MSc, MBA
Global Chief Executive



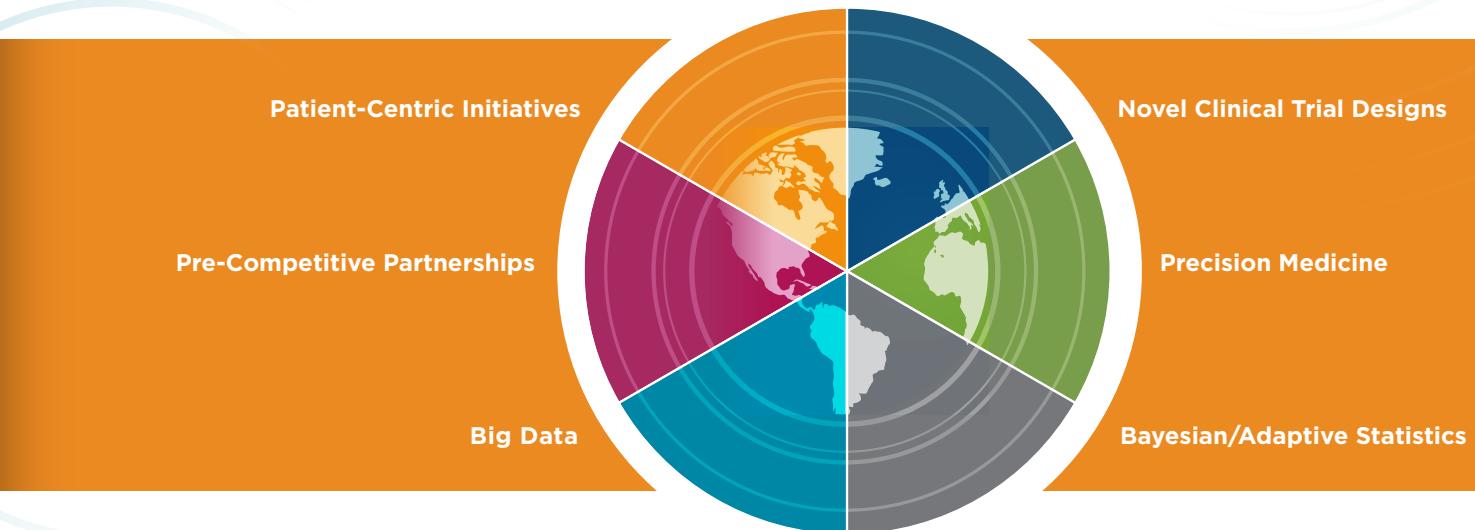
Per Spindler, DVM, MBA, MSc
President and Chair, Board of Directors

Making innovation work for everyone



Stephen P. Spielberg, MD, PhD
DIA Publications Editor-in-Chief

The last decade has indeed been a time of rapid changes in the global discovery and development of new health care products.



The rate of change will only accelerate. DIA plays a crucial role in creating a continuum of discourse and knowledge sharing to help its members lead the way forward. The ultimate driver of all these changes is advances in science—understanding the etiology and pathogenesis of disease at a molecular level has opened new horizons for the development of new therapies. The age of personalized therapeutics is indeed here. We have seen new medicines with much larger “effect sizes,” enhanced benefit guided by molecular and other diagnostics. This leads to smaller, more efficient clinical studies to demonstrate efficacy, with new statistical approaches, and ever-advancing regulatory science. Clinical trials of the future will be very different than those of the past, but the goals of effective, safe therapeutics will remain.

New paradigms present challenges, however, and dealing with change requires new types of partnerships. Patient involvement in all phases of drug discovery and development is a critical one. Companies and regulatory agencies are increasingly working together in the “pre-competitive” space to validate new paradigms that will benefit all. Development of partnerships, the sharing and transparency of new knowledge, and continuous re-evaluation of all we do, are vital to sustain progress.

We need new financial models to drive investment in new science, technology, and products, and a pricing structure that assures access to all those who are in need of advances in therapeutics, without breaking the bank of the rest of the health care system. Not small tasks, but we need to address this together urgently. Ultimately, this is a time of information, in vast and almost unimaginable quantities. Sifting through, separating the validated from the rest, and developing new ways to assure quality in all that we do, are huge tasks. Communication, discussion, and collaboration never have been so vital.

Addressing the trends of today...

and tomorrow

Significant Trends

Patient-Centric Initiatives

Putting patients at the center of their health care decisions.

Pre-Competitive Partnerships

Bringing key stakeholders together to address global health concerns.

Big Data

Sharing results to better understand adverse events, recalls, labeling information, study design detail, data sets, and clinical trial results.

Novel Clinical Trial Design

Taking advantage of science and regulatory changes to conduct smaller, faster trials.

Precision Medicine

Understanding the factors that predispose patients to disease, leading to advancements in therapeutic treatments.

Bayesian Statistics

Improving study designs by allowing one or more adaptations based on information-to-date.

DIA Takes Action

FOSTER dialogue in a neutral environment

- Address key issues while enabling member interaction in DIA Communities
- Create networking opportunities at world-renowned regional and global Annual Meetings
- Convene thought leaders at more than 200 educational conferences, meetings, webinars, and workshops worldwide

COLLABORATE with leading organizations

- Actively participate with the European Patients' Academy on Therapeutic Innovation (EUPATI) and the Patient-Centered Outcomes Research Institute (PCORI) on patient initiatives
- Co-sponsored survey on patient engagement with Clinical Trials Transformation Initiative (CTTI)
- Build relationships with leading organizations, such as the Gates Foundation and TransCelerate BioPharma Inc. to facilitate innovation and encourage collaboration

ADVANCE thought leadership globally

- Publish peer-reviewed articles focused on converting biomedical science into practical solutions in *Therapeutic Innovation & Regulatory Science*
- Analyze key issues and trends in *Global Forum*
- Elevate the voice of the patient in health care product development by incorporating patient advocates in the planning of events and as speakers



ACCELERATE global innovation to reach patients throughout the world



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Jennifer Riggins, PharmD
Advisor, Digital Channels and eCapabilities,
Eli Lilly and Company

For fiscal year ended December 31, 2014, DIA's total revenue was \$26.4 million.¹

DIA's revenues were derived from various program offerings in the Americas; Europe, Middle East, and Africa (EMEA); and Japan, China, and India. Our operating revenue is primarily derived from meetings and workshops, training, membership dues and publications. The following two charts break down this revenue by type and geographic region.

DIA Revenue by Type, 2014 Audited



DIA Revenue by Region, 2014 Audited



¹ DIA is a not-for-profit and tax-exempt Maryland corporation organized under section 501(c) (3).