GLOBAL CONNECTIONS

Collaborations

Neutrality

ANNUAL REPORT 2013

FIFTY YEARS 1964-2014 DIA®

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DIA is an independent, nonprofit organization with our global center located in Washington, DC, US; and regional offices covering the Americas; Europe, Middle East and Africa; and Asia (China, Japan and India).

DIA gives people a chance to contribute to something greater than themselves.

Part of the value of being a member in a global organization comes from feeling that you are part of something larger, and seeing the impact that you and your work have globally.

It's harder to see that kind of impact as an individual, but when you're part of an organization, it's empowering to know that tens of thousands of people around the world are having these same conversations and collectively advancing medical science.

DIA is the global connector in the life sciences product development life cycle. Our association of more than 30,000 key stakeholders builds productive relationships by bringing together regulators, life sciences professionals and academics, patient advocates and other influencers to exchange knowledge and collaborate in a neutral setting. DIA's network creates unparalleled opportunities for the exchange of knowledge and brings together global interdisciplinary experience to help our members prepare for the future.

DIA is governed by an international Board of Directors. A new president is elected each year by the members of DIA during our global Annual Meeting in North America. DIA Global Chief Executive Barbara Lopez Kunz is based in the global center located in Washington, DC and oversees the activities of the Association's executive leadership to ensure cohesive, global efforts that support our strategic plan.

DIA convenes regional annual meetings for members, volunteers and other community members in China, Europe, India and Japan; annual clinical and regulatory conferences in Latin America; and a global annual meeting in North America. More than two hundred other educational programs, including online webinars and training, bring together smaller communities to exchange national, regional and global perspectives on clinical data management, medical and scientific communications, cardiovascular safety, benefit-risk assessments, personalized medicine, statistics and quantitative science, social media, rare diseases and orphan products, and other topics essential to the discovery, development and delivery of medical products to patients.

Regional Advisory Councils, cross-disciplinary member groups from each region, discuss pertinent regional issues to provide insight into topics that are important in their region, and ensure that the DIA message is heard by people who need us. The passion of these volunteers as they work to come up with solutions to issues with which they and their peers are struggling is inspiring. Our members view DIA as their home, and they view the people with whom they collaborate in DIA forums as their comrades in arms in advocating for an important shared cause.

DIA President's Award for Outstanding Achievement in World Health

EURORDIS
Yann Le Cam, MBA
Chief Executive Officer, France

National Organization for Rare Disorders (NORD)
Peter L. Saltonstall
President and CEO

Distinguished Career Award

Freda Lewis-Hall, MD, FAPA
Executive Vice President and Chief Medical Officer
Pfizer, Inc.

Odette Morin, MD
Director, Regulatory and Scientific Affairs IFMPA (NGO)
Switzerland

DIA Honorary Fellows

Richard O. Day, MD
Professor of Clinical Pharmacology
St. Vincent's Hospital, Australia

Marie Allison Dray, MBA
President, International Regulatory Affairs Group, LLC

Ron Fitzmartin, PhD
Senior Advisor, Office of Planning and Informatics
CDER, FDA

Yves Juillet, MD
Senior Vice President, Industrie Sante, France

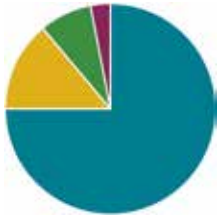
Jeffrey W. Sherman, MD
Chief Medical Officer & Executive Vice President
Development & Regulatory, Horizon Pharma, Inc.

DIA 2013 Financial Summary

Revenue by Region
(in millions)

The Americas	$16.0	58%
EMEA	7.7	28%
Asia	3.8	14%
	$27.5	**100%**

Revenue by Line of Business
(in millions)



Meetings & Workshops	$20.6	75%
Training	3.8	14%
Membership	2.1	8%
Publications	1.0	3%
	$27.5	**100%**

Top Left: *Annual EuroMeeting Student Poster Award Winners.*

Volunteer Recognition Awards

DIA 2013 Volunteer Recognition Awards recognize significant individual or group accomplishments in the discovery, development or life cycle management of pharmaceuticals, devices or related products, and to acknowledge significant volunteer contributions in the advancement of DIA's mission and vision.

Founders' Service Award

Françoise Auger de Cremiers, PharmD
FdC Consulting, France

Outstanding Service Award

James Xue Jun Cai, MD
Senior Vice President
Clinical Development, Roche, China

Nandkumar K. Chodankar, PhD
CEO, Excel Industries Limited, India

David B. Clemow, PhD
Senior Clinical Research Scientist
Eli Lilly and Company

Lawrence Bin Huan, MS
Executive Director, Regulatory Affairs
AstraZeneca Pharmaceutical Co. Ltd., China

Julianne Hull, BSc, MSc
CEO, WenStar Enterprises, UK

Angelika Joos, MPharm
Head, Regulatory Policy, EU and Most of World
Merck Sharp & Dohme, Inc., Belgium

Gustavo L. F. Kesselring, MD
Executive Director, Latin America
VIS Research Institute, Brazil

Yuichi Kubo
Vice President, Intellectual Property
Business Strategy Division, Daiichi Sankyo Co. Ltd., Japan

Haiyan Li, MD Professor of Cardiology
Director of Clinical Trial Center
Peking University Third Hospital, China

Joao Massud Filho, MD
CEO, Trials Consulting, Brazil

C. Latham Mitchell, MD
Managing Principal, Erudita Biotechnical LLC

Frances E. Nolan, MBA
Vice President, Quality & Regulatory Affairs
Medidata Solutions Worldwide

Toshiyoshi Tominaga, PhD Professor and Director
Center for Drug and Food Clinical Evaluation
Osaka City University Hospital, Japan

Toshi Yoshinaga
Manager, Regulatory Affairs Department 2
GlaxoSmithKline K.K., Japan

Global, Neutral Forum

Neutrality is DIA's most important strategic differentiator. It was a hallmark of our founding in 1964 and has been a core value ever since.

"DIA is the only environment where people who represent the various components of the knowledge generation required to deliver safe and effective medical products to patients can come together for open discussion without any fear of inappropriate representation. We are very careful that our educational activities are truly driven by problem resolution and scientific sharing."

"DIA's global, neutral forum provides a valuable meeting place for representatives of regulatory agencies, and of the industries they oversee, to work together on common challenges and mutually agreeable solutions. With this neutrality comes great global trust in DIA platforms and forums."

Barbara Lopez Kunz
Global Chief Executive

Regulators working together with those they regulate, from regional and global perspectives, was a highlight throughout our *DIA 2013 49th Annual Meeting: Advancing Therapeutic Innovation & Regulatory Science* in Boston. More than a dozen sessions gave attendees the opportunity to discuss key issues with representatives of national agencies in Latin America and Europe plus the European Medicines Agency, the Pharmaceuticals & Medical Devices Agency (Japan), the Korean Ministry of Food & Drug Safety, Health Canada, and the US FDA Centers for Devices and Radiological Health (CDRH), Drugs (CDER) and Biologics (CBER). *DIA 2013* also convened the first forum in which representatives from the Centers of Drug Evaluation (CDE) from Mainland China and Taiwan shared their respective regulatory review experiences. Forum moderator Dr. Ling Su, DIA's first Board President to be elected from China, noted the historic importance of this forum: "This is the first time ever to have both sides of the strait sitting in the same room to discuss the same topic."

DIA initiatives in China and India helped regulatory science keep pace with advances, and exchange information with colleagues, in other sciences and fields. In March 2013, the DIA Americas region hosted the China (SFDA) Drug GMP Inspectors Training Program, where inspectors received instruction in GMP law and enforcement, cold chain management and other topics. Through a 2013 agreement with the Gujarat Food and Drug Control Administration, DIA provides training in regulatory science to state inspectors and pharmaceutical industry professionals.

"As regulatory changes take place, the webinar platform is a good way of keeping our audience up to date on major changes of which they need to be aware to do their jobs better," observed Susan Cantrell, Senior Vice President and Managing Director, DIA Americas. "In February 2013, the US Centers for Medicare and Medicaid Services released their final rule for implementing the Physicians Payment Sunshine Act by August 1. In response, we presented the webinar *Preparing for the Physician Payment Sunshine Implementation* in April 2013; this not only overviewed the rule's basic requirements but its specific implications for research and educational activities and what manufacturers need to track, assign value to, and report. That is good use of our webinars: Bringing a group of knowledgeable people together for a very brief period of time to push out timely information on an issue that may very well still be evolving."

During the *Asia Regulatory Conference 2013*, which was jointly presented by DIA, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), and the Health Sciences Authority (HSA) in Singapore, the HSA signed an agreement with the Medicines Evaluation Board of the Netherlands. This agreement will move forward agency collaboration on pharmacovigilance and risk management strategies and practices, benefit-risk assessments, and joint regulator and student training, to improve access to the safe and effective medicines that their respective populations need. (In 2011, DIA and IFPMA co-presented the first *Asia Regulatory Conference* with the Asia-Pacific Economic Cooperation (APEC) Harmonization Center (AHC) in Seoul.)

"We strategically rescheduled our *DIA 2013 Japan Annual Meeting* in Tokyo to precisely one week before the ICH Steering Committee Meeting in Osaka. Several sessions examined ICH activities and Fernand Sauer, Honorary Director General of the European Commission and one of the founders of the ICH, was our keynote speaker," explained Ko Sekiguchi, Senior Vice President and Managing Director, DIA Japan. "It can be very difficult to get global regulators to come to Japan but because our meeting was so close, in date and location, to the ICH meeting, many regulators from FDA, EMA, Health Canada and other agencies were able to participate in our *DIA 2013 Japan Annual Meeting*. This is a very precious opportunity for Japanese professionals, not only those working in industry but also regulators and academia, to have a chance to interact with or listen to global regulators."

"DIA is THE *international forum for regulatory business and one of the few forums where regulators and the industry can talk to each other with a high level of understanding. Working for a regulatory agency, it is extremely important to reach out to a wide variety of industry and regulators and DIA offers a very good platform for that. This forum allows appropriate interaction between key actors to talk about the challenges and evolution of the health care system."*

Dr. Guido Rasi
Executive Director
European Medicines Agency

"I really believe *that your organization has embraced collaboration and synergy among the health care industry and the public and private sectors as well as patients and caregivers. What makes DIA important to the fight against Alzheimer's is your integrative approach that unifies disciplines and innovators across proprietary boundaries that were once unbreachable."*

Meryl Comer
President of the Geoffrey Beene Foundation
Alzheimer's Initiative and
DIA 2013 49th Annual Meeting Session Chair

Top Left: *Larisa Nagra Singh, Chair of DIA Advisory Council of India, welcomes attendees to our 8th DIA Annual Meeting in India.*

Right: *Associate Professor John Lim, CEO of the Health Sciences Authority, Singapore, addresses attendees at Asia Regulatory Conference 2013.*

Connections and Collaborations

People join DIA to connect and engage not just with peers focused on their specific area, but because they realize there is great value in connecting with people who look at things from a different perspective.

DIA presented nearly 250 onsite and online educational forums in 2013. These gave attendees the opportunity to hear from and speak with representatives from more than 60 global, regional and national organizations.

DIA offers more than thirty global online communities which allow our members to continue to connect and discuss these issues year round. These communities actively contribute to the knowledge base in their particular professional expertise, and then encourage members to think a little further to work across communities – at the interfaces of science – to create things that are perhaps not so obvious to practitioners in a separate field. DIA members consistently say that there's nowhere else that they could go to get this kind of perspective. It changes the way they personally look at their individual job – toward its global impact.

"Our DIA Japan 2013

Annual Meeting, our tenth, was presented on the theme 'Revolutionary Drug Development from Japan: The role academia, regulators and industry should play in the discovery and fostering of innovative drugs.' With Dr. Yasushi Saito, President of the University of Chiba, as program chair, we set a very clear target for 2013: To enhance collaboration between research professors at medical universities, medical doctors at universities, and other members of academia engaging in clinical research and drug development. We had three times as many participants from academia at our 2013 Annual Meeting, which will enhance and improve collaboration between industry, regulators and academia."

Ko Sekiguchi
Senior Vice President; Managing Director
DIA Japan

"DIA is the

pinnacle of collaboration around medical product development in the world. Our DIA Annual Meeting specifically focuses on bringing together professionals who are engaged in every aspect of medical product innovation for the purpose of sharing knowledge with one another. Scientists involved every step of the way come together in whatever city – we were in Boston in 2013, a perfect educational, science and technology hub – and share their knowledge. DIA offers the one forum where you can network with and learn from people who work in different areas across the medical product development life cycle."

"No other venue features such representation from global regulatory authorities. When you look at the content that we offer, as well as the regulators and the regulatory agencies that are represented, it really is a unique opportunity. This is what the Annual Meeting is all about: Bringing people together."

"As regulatory changes take place, the webinar platform is another good way of keeping our audience up to date on major changes of which they need to be aware to do their jobs better."

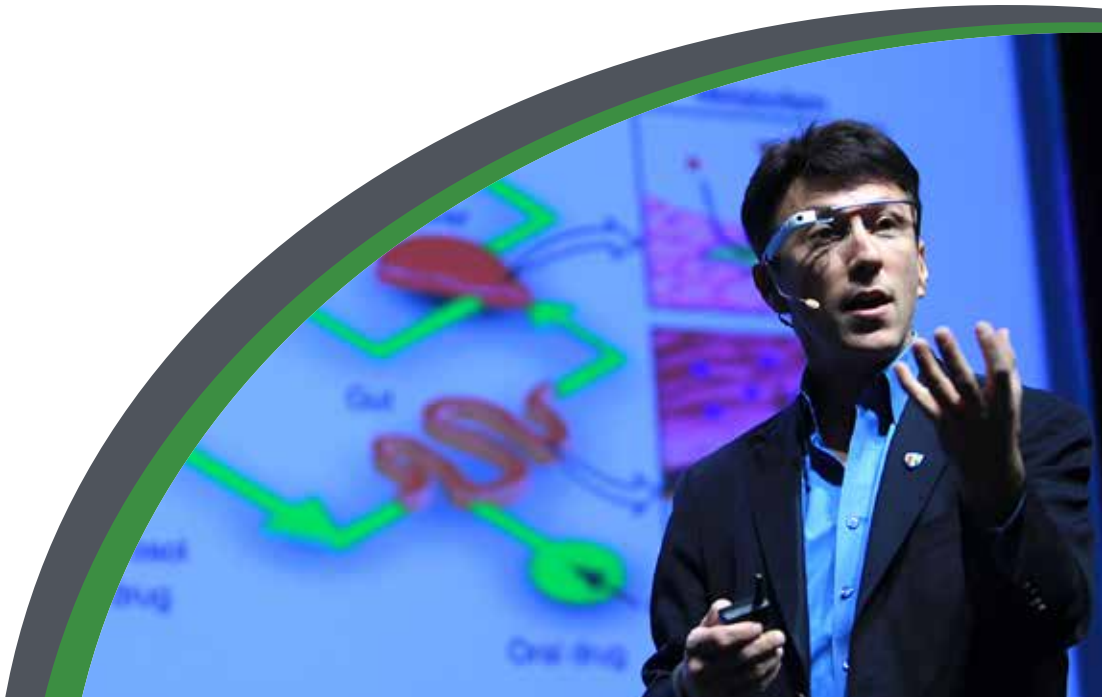
Susan Cantrell
Senior Vice President; Managing Director
DIA Americas

"In 2013, we

celebrated the tenth anniversary of our Middle East Regulatory Conference. This has become, much like our Annual Meeting and EuroMeeting, an important collaborative forum for many of these same stakeholders to share work under the basic premise of creating better medicines and quicker access to medicines for patients in the Middle East. The Middle East is different from Europe but countries in both regions are interested in collaborating and cooperating. Health care is now a global enterprise, and we work to expand knowledge so that we can discover more efficient processes and less time in misunderstandings and unnecessary hurdles."

"DIA is serving as the coordinator of the content production for EUPATI, the European Patient Academy on Therapeutic Innovation, a consortium of thirty member groups from industry, patient organizations, academia, non-government organizations and nonprofit organizations, across many different European countries. The whole purpose of EUPATI is to create, through education and training, informed patient involvement, early and more often, in health care R&D and regulatory processes across Europe. In 2013, we finalized the syllabus and began production of these educational materials. This benefits not only patients but health care systems: Better medicines, more relevant medicines, more quickly, is by definition good."

Jytte Lynvig
Senior Vice President; Managing Director
DIA Europe, Middle East and Africa



Top Left: *Plenary debate at DIA 2013 Clinical Forum in Europe.*

Right: *DIA 2013 Keynote Speaker, Dr. Daniel Kraft.*

"The impetus

for forming DIA was communication – communication between professional colleagues about the benefits and risks of medications. DIA members consistently cite our publications as one of the best benefits of membership, and publications are deeply rooted in DIA's history; in fact, the Drug Information Bulletin was the first product that DIA offered after our 1964 founding. This Bulletin was one of the first to disseminate, and to open up discussion of, such critical information. The Drug Information Bulletin grew into the highly-respected Drug Information Journal, which was rebranded in 2013 as Therapeutic Innovation & Regulatory Science (TIRS).

Now we're in our 48th year of peer-reviewed, scientific publishing and the need for this type of communication and information is stronger than ever. TIRS connects our members, digitally and in print, to peer-reviewed scientific research on a truly global scale so they can keep pace with evolutions and innovations in product development and regulatory approval. We also publish and deliver our Global Forum industry and association newsmagazine to provide members with more general but still timely news and information on these topics."

Judy Connors
Associate Director
Editorial Services

"The integration

of exponentially growing technologies is beginning to empower the patient, enable the doctor, enhance wellness and begin to cure the well before they get sick. In an age where a simple iPhone can be used as a diagnostic tool, I'm excited that DIA invited me to share the significance of leveraging technology to advance health care with such a collaborative community."

Dr. Daniel Kraft
Keynote Speaker
DIA 2013 49th Annual Meeting

DIA also publishes and delivers monthly publications that keep members connected with advances in science, technology, regulation and legislation. In 2013, we re-launched our peer-reviewed scientific *Drug Information Journal* as a new journal, *Therapeutic Innovation and Regulatory Science*, and appointed Dr. Stephen P. Spielberg, former FDA Deputy Commissioner for Tobacco Products and Alcohol, as Editor in Chief. "DIA is unusually well-situated to be able to use all of our resources – our journal, our educational activities throughout the world – in an integrated way to bring together all of those who have a stake in the future of human health," Dr. Spielberg said. "We have a challenge of determining how best to inform one another about science and how that converts into the discovery, development, regulation and use of new medical products. *TIRS* will bring together members of all sectors that have a stake in the future of human health to discuss key issues facing the industry and regulatory affairs and to translate human brilliance and discovery into real products."

DIA members also receive our *Global Forum* industry and association newsmagazine, which provides international regulatory and industry updates, news about upcoming educational events, interviews with industry and regulatory leadership, and a special INFORM section devoted to a specific topic of emerging or new importance; in 2013, special INFORM sections were devoted to clinical drug development in emerging markets, supply chain integrity, pharmacovigilance in the European Union, clinical research in the elderly, indigenous American and other special populations, and an AIDS at 30 retrospective on the impact of patients on clinical research.

Regional Mosaic

Karen L. Ball, President and CEO of the Sturge-Weber Foundation, was among the patient advocates who attended our *DIA 2012 Annual Meeting*.

Although approximately 10,000 individuals in the US live with Sturge-Weber syndrome (SWS), there are few clinical trials available for SWS patients, so one of the immediate goals of the Sturge-Weber Foundation (SWF) was to facilitate and increase clinical research into this disease by creating ten connected SWS Centers of Excellence throughout the US. "*DIA 2012* was beneficial in helping me understand even more about the clinical trials process and the benefits of telemedicine, and getting to meet vendors in this area," she said.

"Since our attendance at that meeting, we started a campaign and enrolled almost three hundred families in the SWS registry that we host online at Patient Crossroads/Innolyst, and combined with our Access database of over 5,000 patients with over 25 years' worth of data," Karen subsequently explained. "The registry data was crucial to the SWS Project portion of the consortium grant we received through the Rare Diseases Clinical Research Network."

In May 2013, the *New England Journal of Medicine* published the discovery, by researchers from the Kennedy Krieger Institute in collaboration with a team at Duke University Medical Center, of the genetic mutation that occurs before birth to cause SWS and port-wine stain birthmarks.

"Without gathering that data for the last 25 years and having the statistics to prove there was a trend worthy of study, we would not have found the gene as quickly as we did. Without DIA investing and truly partnering with the patient advocacy group, I wouldn't have been thinking downstream toward the drug development side of it, and DIA gave me the education to understand that process," Karen suggests. "By partnering together and by sharing ideas and by doing exactly what DIA has done for all of us – by bringing the scientists, the clinicians, the advocacy groups, the FDA, all the key stakeholders together – that model has propelled us in finding the gene."

> ***"We listen to the voices of all our members but we are especially attuned to the voice of the patient. Many DIA educational programs offer patient fellow and scholarship opportunities for the sole purpose of connecting patients with regulatory and industry professionals so they can learn how to become more involved and helpful in the medical product innovation process. 2013 also featured our annual collaborative conferences with EURORDIS, the European Organization for Rare Diseases, in Europe, and with the National Organization for Rare Disorders in the Americas. DIA has become deeply ingrained in the global patient community because we share the same mission: Improving research, discovery and development, and the delivery of safe and effective medical products to patients who need them."***
>
> **Elizabeth Lincoln**
> Global Director of Engagement

Above: *Award winner Yann Le Cam at the 2013 EuroMeeting.*

To help members navigate the challenges of changes in science, technology, regulation and legislation, DIA expanded our educational programming with these new offerings in 2013:

- *1st Biosimilars Workshop: European Experiences & Challenges*
- *1st Clinical Operation & Monitoring Workshop in Japan*
- *1st Conference on Development of Live Biotherapeutics (Americas)*
- *1st DIA/China CDE Quantitative Science Forum*
- *1st DIA/ISPE Joint Conference on API: Advantage India - Building a Sustainable & Regulatory Compliant API Life Cycle*
- *1st EMA MedDRA Information Day*
- *1st EMA Information Day on Periodic Safety Update Reports - ICH E2C(R2) Periodic Benefit-Risk Evaluation Reports*
- *1st Joint Regulatory Forum by CDE Mainland China and CDE Taiwan (at DIA 2013 Annual Meeting)*
- *First Collaboration on Medical Writing and Ethics with All India Medical Writing Association and Forum for Ethics Review Committees in India (at DIA India Annual Meeting)*
- *First Initiaitve by DIA Student Tri-State (CT, NJ & NY) Student Consortium, "Countering Counterfeit Medication in Africa" (Americas)*
- *First Joint Student/Patient Representative Session at DIA 2013 EuroMeeting*
- *First Patient Representative Keynote Address at DIA China Annual Meeting*
- *First Student Sessions at DIA 2013 Japan Annual Meeting*
- *First Therapeutic Innovation & Regulatory Science Journal Podcast*
- *New Advanced Clinical Vendor Oversight: Vendor Life Cycle Management Training Course (Americas)*
- *New Key Considerations for the Development & Marketing of Biosimilar Products Training Course (Americas)*

"In 2013, DIA

members came together to establish several active Communities around data management, statistics and other vital industry functions in China. Our working relationships with leading industry, regulatory and academic groups helped us to provide workshops and training, such as our first collaborative Quantitative Science Forum with the Center for Drug Evaluation, on these and other important topics. Our 5th DIA China Annual Meeting was not only focused on the theme "Patient Safety – A Sustained Focus from Scientific Ideas to Innovative Medicines," it was our first China Annual Meeting to formally incorporate the patient viewpoint throughout the program, including a patient representative Keynote Speech. It was also the first to feature the China FDA interactive Town Hall, where participants posed questions to, and received clarifications directly from, our regional regulatory leadership. This is a most unique opportunity for industry and research professionals in China."

Haijun Dong
Senior Vice President; Managing Director
DIA China

"Latin America

has a specific profile within the global health care enterprise, with many branches of large pharmaceutical companies and many CROs that are native to Latin America. Many CROs from larger countries such as Argentina, Brazil and Mexico, are setting up operations in smaller countries. This CRO network is expanding more rapidly than regulations can keep pace, so it is very important for industry and regulatory professionals in these smaller countries to work with the latest regulatory dynamics. Our annual Latin American Regulatory Conference (LARC) is an effort on behalf of civil society by non-governmental organizations, industry, academia and other stakeholders, to dialogue with these regulators. LARC is the region's only impartial forum devoted to fostering regulatory convergence throughout the Americas. It provides a forum for these agencies to learn from each other and for other stakeholders to dialogue directly with them, without any intermediary."

Alejandro Bermudez-del-Villar
Project Coordinator, Latin America/
Global Program Development

DIA volunteers, members and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials, throughout the year, all around the world. DIA connects people around their unifying passion for improving the overall medical product development process in a way that makes the world safer and better.

Associations are built around one simple premise: ***We are stronger together than we are apart***. DIA is a global community representing thousands of stakeholders working together to bring innovative, safe and effective products to patients.

For more information, please visit **diahome.org**

Above: *DIA 2013 booth display.*

Right: *Latin American Regulatory Conference (LARC) 2013.*

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