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## DRUG INFORMATION ASSOCIATION

# ANNUAL REPORT 2003-2004



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Dear DIA Member,

Making progress in almost every field of endeavor means change and for DIA, 2003 and 2004 marked the greatest period of change the association has seen for many years.

The following Annual Report summarizes the association's activities for the years 2003 and 2004. The report illustrates the breadth of DIA's activities around the world and highlights new offerings that have been developed and delivered to meet the changing needs of our members; not just new topics, although these are obviously important, but new ways of exchanging ideas and information while taking advantage of new technologies.

The DIA Board and staff continue to provide strong leadership that will improve the value of your DIA membership by creating opportunities for you to participate in supporting the DIA mission and by providing relevant and timely information that can reach the largest number of drug development professionals

We thank you for your contributions to the Drug Information Association and invite you to take a moment to read the following Annual Report. It celebrates our mutual successes and reminds us that a group of dedicated professionals can achieve together what no individuals, no matter how talented, could accomplish by themselves. Through these efforts, we will continue to drive the development of better medicines that will enhance the well-being of people all over the world.

Sincerely,

David M. Maola, Esq.  
DIA Executive Director

Theresa Kane Musser  
DIA President

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David M. Maola, Esq.  
DIA Worldwide Headquarters

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## 1. DIA Mission and Vision

As part of its ongoing work, the Board of Directors has refined the DIA strategic plan to help chart the association's course for the future. In the course of developing this strategic plan, the Board redefined the DIA Mission and Vision statements to align them more closely with the intentions expressed in the plan. Although the Board approved new Mission and Vision statements in 2005, you will find that they set forth important ideas that reflect many of the activities described in this 2003 and 2004 annual report.

### **DIA Mission:**

DIA is a nonprofit, multidisciplinary, neutral forum for sharing information that optimizes the process of drug development and lifecycle management by providing

- Global and regional forums for the exchange of information, education, and training
- Extensive multidisciplinary networking opportunities
- Rewarding volunteer leadership experiences
- High-quality professional development opportunities

***Developed and approved by the Board of Directors, March 2005***

### **DIA Vision:**

DIA is the universally respected forum for quality information exchange leading to better medicines that enhance health and well-being.

***Developed and approved by the Board of Directors, March 2005***

This Mission Statement differs from the previous Mission Statement in several ways. First, it clearly defines the space in which DIA operates i.e. "the process of drug development and lifecycle management."

More importantly, it makes special mention of the volunteer experience. Although association leadership and staff play important roles, it is primarily the efforts of volunteers that enable DIA to create topical quality offerings while rewarding those who participate in their development. For DIA to continue to meet its Mission, the association MUST strive to ensure that the efforts of our volunteers are recognized and rewarded.

The bold new Vision Statement describes the impact that DIA aspires to create in the world, lifting the sights of DIA to broad horizons and noble purposes.

## **2. Report on Progress on DIA Strategic Plan**

Early 2004, the Board of Directors began work to redefine the original strategic plan formulated in 2002 – 2003. Major efforts included a SWOT (strengths, weaknesses, opportunities, threats) analysis and market research that fed into a high-level vision exercise to look beyond today's challenges to see what DIA should look like going forward.

The outcomes of the strategic review planning process have enabled the Board to define strategic milestones, goals, and initiatives that the association will use to monitor DIA's progress and use in the course of planning association activities in 2006 and beyond. The strategic plan builds on DIA's unique ability to bring together industry, regulatory agencies, and academia in an environment that promotes the free flow of information critical to the drug development process.

We continue to believe that DIA is multidisciplinary, with particular focus on the clinical and regulatory aspects of the product development and lifecycle process, and that, as the conduct of clinical trials extends globally, it will become increasingly important for DIA to extend its reach and scope to support members worldwide.

### **3. DIA Core Values**

In the course of refining and updating the DIA strategic plan and DIA Mission and Vision Statements, the Board of Directors also approved the following Core Values in September 2004.

DIA is an educational and charitable, nonprofit association, made up of individual members who volunteer to create innovative programs and provide leadership across a wide range of disciplines. Volunteers are DIA's strength. The knowledge, commitment and talent of the staff, directors, members and volunteers combine to drive DIA's success and future growth.

#### **DIA's Core Values:**

##### Passion for our Mission and Vision

DIA serves and develops members by providing a neutral, global forum that promotes the exchange of information critical to their performance as professionals in the pharmaceutical and related industries. DIA members, staff, and Directors are passionate about this mission and are deeply committed to its execution.

DIA benefits from the services of a large group of volunteer members who contribute significantly to the value of programs. We seek to instill in these volunteers the same passion for DIA, its mission and membership, in order to encourage those who serve, and may be interested to serve to become involved in DIA during the duration of their professional lives.

##### Integrity

DIA members, staff and Directors are committed to maintaining the highest levels of integrity and honesty in all that we do. We conduct ourselves at all times in a professional and ethical manner. We will deal fairly with our members, suppliers, collaborators, and staff. Honesty, openness, and transparency are essential aspects of the way we conduct our business. The staff and Directors recognize that it is a privilege to serve in this capacity, and as such, will not breach our fiduciary responsibilities in any way that might result in any actual or perceived personal benefit.

##### Accountability and Trust

The work of DIA is built on human relationships – with our members, staff, Directors, suppliers, and collaborators. We are committed to keeping those relationships strong by communicating openly about our business practices, being transparent about our performance, and remaining accountable for our conduct. We manage the organization responsibly in order to maintain the confidence, respect, and trust

of our customers, members, volunteers, partners and other audiences. We are reliable, dependable, and accountable for our actions.

#### Treating People with Respect and Dignity

DIA expects its members, staff, and Directors to treat people with respect and dignity. We deal with each other as colleagues. We respect each other enough to tell the truth. We listen to each other even when we disagree. We demonstrate fairness, consistency, and compassion in our interactions with others. Compassion is a way of acting that is mindful and supportive of individual differences and reflects concerns about the needs of others.

#### Diversity

We value diversity in our membership and our work force. Our aim is to provide a consistent worldwide standard of protection from threats, harassment, and discrimination based on race, national origin, gender, religion, age, sexual orientation, disability, or other factors that have no bearing on the outcomes of our work. We seek to create a diverse work force that reflects the skills we need to succeed. Incorporating a commitment to diversity will result in the delivery of higher quality services to our members.

#### Neutrality

DIA provides a neutral global forum for its members for the purpose of exchange and dissemination of information relevant to the professional education and development of its members. It does not lobby, and it does not take a partisan stance on any issue.

DIA does provide a forum (via conferences, workshops, teleconferences, publications) for government and regulatory agencies to present views on regulations, policies and programs, as well as for individuals and organizations holding contrary views to present them. In constructing these educational opportunities, DIA attempts to balance the agenda so that the audience receives a fair representation of all the relevant aspects of issues, and it does not attempt to manipulate the audience response in any way.

Preservation of the neutrality of this forum is essential to the success and continued existence of DIA.

#### Social Responsibility

DIA has a strong and demonstrated commitment to the improvement of society through the exchange of information and ideas that should lead to greater access and usage of ethical drugs, and a better understanding of the health and economic outcomes from drugs. We encourage the support of charitable, civic, educational, and cultural causes through our Foundation and by encouraging our staff to participate in public service activities that are consistent with our charitable purpose.

***Approved by the DIA Board of Directors, September 2004***

#### **4. Members Approve Amended Bylaws, November 2004**

Association bylaws were amended by the Board of Directors in September 2004 and were approved by the membership in November 2004. The key amendments were as follows:

**Purposes** of DIA modified to specifically address the regional and national aspects of the drug development industry.

**Officers and Board of Directors** of DIA modified to change the timing of "a DIA year" to begin at the September Board meeting and holding of offices to reflect revised election process.

**Standing and Other Committees** of DIA modified to change the names of Steering Committees to Advisory Councils; to modify the membership of the Nominations Committee to reflect the addition of one "DIA member-at-large"; and to provide the Board of Directors the ability to designate new Regional Advisory Councils.

The association bylaws were previously amended by the Board in 2003 and approved by the membership during the 2003 DIA election. The approved 2003 amendments included the formal creation of the DIA Foundation to conduct charitable, scientific and educational activities consistent with the overall mission of DIA, and the creation of global, discipline-specific member subgroups; Special Interest Area Communities.

## 5. DIA Collaborations and Partnerships

### 5a Programs co-sponsored with US Food & Drug Administration

In 2003 and 2004, DIA sponsored the following programs in collaboration with the FDA.

#### DIA / FDA Collaborative Programs 2003

Assessing Treatment Impact Using PROs	CBER 101 Workshop: An Introduction to the Center for Biologics Evaluation and Research
CDER 101 Workshop: An Introduction to the Center for Drug Evaluation and Research <i>(two offerings)</i>	CDER Live: Drug Quality Regulation for the 21st Century <i>(satellite video conference)</i>
Electronic Submissions Review Best Practices	FDA's Proposed Rule on Safety Reporting for Human Drugs and Biologics: "The Tome"
Overview of the Pharmaceutical Industry: An FDA-Industry Dialog on the Drug Development Process	Pharmacogenomics in Drug Development and Regulatory Decision Making
The Electronic Common Technical Document	

#### DIA / FDA Collaborative Programs 2004

CBER 101 Workshop: An Introduction to the Center for Biologics Evaluation and Research Co-Development of Drug, Biological, and Device Products	CDER 101 Workshop: An Introduction to the Center for Drug Evaluation and Research Combating Counterfeit Drugs
Good Dose-Response: Rewards of Success, Cost of Failure: A Critical Path Opportunity to Focus on Optimizing Benefit/Risk	Improve Agency/Industry Communication Throughout the Drug Development Process
Overview of the Pharmaceutical Industry: An FDA-Industry Dialog on the Drug Development Process	The FDA's Continuous Marketing Application (CMA) Pilot 2 Program
Update on FDA's Critical Path Initiative	

### 5b Programs co-sponsored with European Medicines Agency

DIA serves as conference organizer of the only EudraVigilance training officially recognized by the European Medicines Agency. In addition, DIA proudly served with the EMEA as co-sponsor of the following programs, presented in London in 2003 and 2004:

4th Pharmacogenetics Workshop: Moving Toward Clinical Application

DIA/EMEA Joint Meeting on Gene Therapy & Cell Therapy Products

## DIA/EMA Joint Workshop on Preclinical Safety Assessment Update

**5c Programs co-sponsored with Other Groups or Associations**

In addition to collaborations with the FDA and EMA, DIA also presented the following programs in concert with these other associations and groups.

<i>Agency for Healthcare Research and Quality</i> 5th Annual Workshop on Pharmaceutical Outcomes Research <i>Tucson, AZ USA</i>	<i>BFarm – Federal Institute for Drugs and Medical Devices, Germany</i> Enlargement Summit <i>Bonn, Germany</i>
<i>Canadian Association of Pakistani Pharmaceutical Professionals</i> Manufacturing Controls, Validation and Stability <i>Karachi, Pakistan and Lahore, Pakistan</i>	<i>Centre for Medicines Research International</i> <i>Institute for Regulatory Science, UK</i> Key Issues in Global Drug Development <i>Tokyo, Japan</i>
<i>Clinical Data Interchange Standards Consortium</i> e-Clinical Interchange <i>Arlington, VA USA</i>	<i>Council for International Organizations of Medical Sciences</i> 1st Annual Japan Workshop for Pharmacogenomics <i>Tokyo, Japan</i>
<i>European Regulatory Issues on Quality of Life Assessment Group</i> Assessing Treatment Impact Using PROs: Challenges in Study Design, Conduct and Analysis <i>Paris, France</i>	<i>Institute de Formation des Industries de Sante, France</i> 7th Annual European Scientific and Regulatory Affairs Conference <i>Paris, France</i>
<i>Massachusetts General Hospital Center for Biomarkers in Imaging</i> 5th Annual Workshop for Medical Imaging in Clinical Trials <i>Boston, MA USA</i>	<i>National Cancer Institute, US</i> Advances in Health Outcomes Measurement: Item Response Theory, Item Banks, and Computer-Adaptive Testing <i>Bethesda, MD USA</i>
<i>National Institute for the Control of Pharmaceutical and Biological Products, China</i> Drug Development and Quality of Pharmaceuticals <i>Beijing, China</i>	<i>North American Society for Pacing &amp; Electrophysiology</i> The Clinical Evaluation of QT Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs <i>Rockville, MD USA</i>
<i>State Food and Drug Administration, China</i> International Workshop on Multicenter Clinical Trials <i>Beijing, China</i>	

**5d Academic Affiliations**

To help members advance their educational and professional development, DIA maintains the following academic affiliations:

**Drexel University (PA)**

DIA members may enroll in the Drexel MS Research Management and Development program at a 20% discounted registration fee.

**Massachusetts College of Pharmacy**

Annually serves as host for DIA Regulatory Affairs I and Regulatory Affairs II combined training course.

**University of the Sciences of Philadelphia (PA)**

The University of the Sciences of Philadelphia (USP) offers an MBA in Pharmaceutical Business in an evening MBA program, an Executive MBA program offered on weekends, and other formats. DIA members may receive a 15% discounted registration fee in these programs. In addition, DIA and USP have identified ten DIA CC&PD training courses for which DIA members may receive "life credits" eligible for transfer into the MBA and Executive MBA programs.

**University of Southern California**

The University of Southern California's Masters Program in Regulatory Science incorporates the DIA CC&PD Combined Regulatory Affairs I and Regulatory Affairs II training courses as a key introductory course. Structured to accommodate part-time students who are already in the workplace, this is the first formal collaboration between a CC&PD training course and a university degree program.

**West Chester University (PA)**

West Chester University (WCU) hosts the annual collaborative WCU / DIA Pharmaceutical Product Development Scholarship Conference as part of the university's Pharmaceutical Product Development undergraduate program, and applies proceeds from this conference to scholarship funds for this undergraduate program.

## 6. New and Renewed Continuing Education Accreditations

DIA's continuing education program provides members with opportunities to increase and maintain their professional knowledge and skills. All DIA programs offering continuing education credits include a program overview, clearly defined learning objectives, and the target audience to allow potential participants the opportunity to determine if the program will meet their needs.

### Accreditation Council for Continuing Medical Education

In 2004, DIA was reaccredited by the Accreditation Council for Continuing Medical Education as a provider of continuing medical education for physicians for four years. ACCME awards accreditation status to providers to assure physicians, the public, and the CME community that continuing medical education activities meet the ACCME's criteria for compliance with the Essential Areas.



### Accreditation Council for Pharmacy Education (ACPE)

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. DIA programs offering continuing pharmacy education credit are identified with the appropriate approved provider statement and the ACPE logo. Participants attending these programs earn credits acceptable by all boards of pharmacy that recognize ACPE-approved providers.



### International Association for Continuing Education and Training (IACET)

DIA has been reviewed and approved by the International Association for Continuing Education and Training to offer continuing education units (CEUs). The CEU is available to all national and international participants in DIA programs and is also recognized and accepted by various state licensing boards for nursing.

### **Nursing Credit**

DIA collaborates to offer continuing education credit for nurses with Corexcel, accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation.

### **Project Management Institute**



DIA has been reviewed and approved as a provider of project management training by the Project Management Institute, which allows DIA to offer professional development units to project management professionals.

## **7. New and Enhanced Products and Services**

### **7a EudraVigilance and EVMPD Training**

In 2004, DIA began serving as conference organizer to assist the EMEA with the launch of its EudraVigilance training program. These jointly conducted sessions provide the only training in EudraVigilance that is officially recognized by the EMEA and is regarded as one of the main pillars of European risk management strategy.

DIA and EMEA also initiated training in the EudraVigilance Medicinal Product Dictionary with a dedicated tutorial conducted at the 2004 Annual Meeting in June and at the First DIA Multitrack Meeting on Clinical Trials and Pharmacovigilance, presented in Paris in November 2004.

### **7b Webinars**

To provide time-sensitive information to worldwide customers as expeditiously as possible, DIA introduced an innovative new meeting format in 2004. Webinars, or online seminars, allow participants to access up-to-date, expert discussion on industry issues from almost any Internet-equipped location. DIA webinars have attracted a global audience, with participants located in America, Europe, Asia, Africa, Australia, and the Middle East.

Attendees view slide presentations on their computers while listening to the audio presentation via telephone in their own home or office. As information is presented, attendees can submit questions to the moderator via a live chat feature. The moderator reviews these questions and presents them to the speaker. Many webinars offer continuing education credit.

### **7c eLearning**

DIA eLearning is Internet-based courseware that can be accessed from anywhere at anytime. eLearning provides access to the same expert knowledge and resources that are available in DIA's standard training courses. DIA expanded its eLearning offerings in 2003 and 2004 to include the *Certified Clinical Investigator eLearning Program*, the *Navigating HIPAA eLearning Program*, and the *Medical*

*Communications eLearning Certificate Program.* The *Navigating HIPAA* program was updated in April 2004 with important new content based on HIPAA's impact on clinical research plus updated regulations and compliance dates.

## **7d New Training Courses**

DIA presented its first *Project Management* training course in September 2003. This training course describes the four phases of the project management lifecycle and their specific applicability, using real-world examples from the pharmaceutical industry.

In October 2004, DIA presented the first offering of the new training course *Overview of Drug Development for Administrative Staff*. This course gives administrative support staff better understanding of how their roles fit into the overall picture of pharmaceutical development by presenting an overview of the roles and interactions among marketing, clinical operations, regulatory affairs, and manufacturing.

## **7e In-company Training**

In 2004, the Board of Directors approved a policy that allows DIA to conduct in-company training, training courses taught on location by the same faculty who deliver the traditional classroom training course, thus providing a more cost- and time-effective way for participants to receive professional education and training. DIA has successfully conducted in-company training courses in US and European regulatory affairs, clinical statistics, GCP and auditing, and the fundamentals of clinical research, for such companies as Amgen, Inc., Boehringer-Ingelheim, DAIICHI, the Otsuka Maryland Research Institute, NABI Biopharmaceuticals, and Pfizer.

## **7f CDs, CD-ROMs, etc.**

In response to customer demand, in 2003 DIA began to offer individual sessions from the Annual Meeting and EuroMeeting recorded on audio CD and CD-ROM with audio synchronized to the actual PowerPoint

presentation used in the session. The availability of these products enables people who could not attend these programs to access their content.

## **7g Job Bank**

DIA upgraded the online Job Bank in 2004 under the auspices of the Center for Career & Professional Development. This offering connects potential employers with the largest and best-qualified group of candidates, from the broadest cross-section of disciplines in the industry. Upgraded functionality provides companies with a single Web page from which they can edit or update their job posting, monitor the number of page views, email responses to each posting, and monitor their active, pending, and expired postings, all online.

## **7h Certified Clinical Investigator Program**

DIA launched its *Certified Clinical Investigator Program* in 2003 under the umbrella of DIA Certification, Inc. This flagship program provides qualified physicians, pharmacists, nurse practitioners, physician assistants, and research scientists within the framework of the need to conduct safe, effective, and compliant clinical trials. The Certified Clinical Investigator Examination is administered at various locations across the United States and can be requested at specific sites. DIA has developed many educational products to help support this program, all of which offer both continuing medical education and pharmacy education credits:

- Core Content for Certification handbook
- CCI examination review course
- Good Clinical Practices for the Clinical Research Professional training course
- eLearning program with two modules: Study Preparation and Initiation, and Conducting the Study

Earning the Certified Clinical Investigator designation demonstrates a commitment to excellence in the field of clinical trial management, and is a mark of distinction for clinical investigators worldwide.

## 8. New and Expanded Programming in Europe

In addition to serving as conference organizer for the EudraVigilance training DIA has brought new and expanded programming to serve its European members:

In May 2003, a new program dedicated to *Clinical Trials in Central and Eastern Europe* was presented in Sofia, Bulgaria and marked DIA's first comprehensive overview of the steadily increasing significance of Central and Eastern Europe's contributions to the development of new medicines examined against the background of legislative, guidance, and research conditions within this region. This program relied primarily on local expertise, supported by experts from leading international research organizations.

Two CC&PD training courses celebrated ten-year anniversaries as European offerings in 2003: *Practical GCP Compliance Auditing of Trials and Systems*, and the *Medical Approach in Diagnosis and Management of Adverse Drug Reactions*.

In 2004, the CC&PD conducted the first European offering of its *Clinical Statistics for Non-Statisticians Training Course* in Paris, France and a special *US Regulatory Affairs Training Course*, an introductory course for professionals who require enhanced knowledge of US regulatory procedures, in Heidelberg, Germany.

In November 2004, DIA presented *Three Worlds, One Voice: 14th Annual European Clinical Data Management Conference, 4th Annual European Validation Conference, and 1st European Information Technology Conference* in Amsterdam, the Netherlands. This was the first program of its kind to explore the interface and integration of clinical data management, information technology, and validation. It offered attendees the option to join one of four parallel tracks dedicated to their core discipline, or to attend specific talks or sessions covering different disciplines. A special "regulatory day," with an FDA tutorial and agency plenary session was offered, so that professionals from regulatory affairs could join their colleagues from other disciplines.

The *1st DIA Multitrack Meeting on Clinical Trials & Pharmacovigilance: European Directive on Clinical Trials (Practical Implementation, Lessons Learned, and Areas for Future Clarification) and Hot Topics in Pharmacovigilance* was held in Paris in November 2004, where Peter Arlett of the European Commission, Belgium, and Dr. Daniel Brasseur, Chairman of EMEA Committee for Proprietary Medicinal Products, Ministry of Public Health, Belgium, delivered the keynote addresses.

## 9. New and Expanded Programming in Japan

DIA introduced its first training course as well as two new workshops in Japan in 2004. The *US Regulatory Affairs Training Course* held in July presented a modified version of two, three-day regulatory affairs courses combined into one extended three-day course that encapsulated all the essential information from the individual courses. In September, DIA presented the *1st Workshop in Japan for Drug Regulatory Affairs: Role of Regulatory Affairs in Global Drug Development*, and co-sponsored the *1st Annual Japan Workshop for Pharmacogenics* with the Council for International Organizations of Medical Sciences.

## 10. New and Expanded Programming in North America

In November 2003, DIA presented the *1st Canadian Annual Meeting: The Canadian Pharmaceutical Scene into the 21st Century* in Ottawa, Ontario. This new two-day, four-track program offered plenary sessions featuring Canada's regulatory, industry, and research leaders, providing insight into national and provincial strategies for the future of healthcare delivery in Canada.

The *2nd Canadian Annual Meeting: Leading and Responding to International Initiatives*, also presented in Ottawa in November 2004, overviewed and analyzed Canada's participation in the development, modification, and implementation of international standards, guidelines, and other initiatives, and helped participants learn more about Canada's involvement in the global pharmaceutical environment.

In the US, DIA presented the new program *West Coast Drug Development Forum: Challenges in the Development of Therapeutic Products*, which focused on such strategic and tactical challenges as preclinical/clinical issues and GCP compliance, in October 2004 in San Francisco, CA. DIA's first multi-track meeting on the US West Coast was the first of its kind to bring together the two main areas of strategic and tactical challenges in developing therapeutic products.

In November 2004, DIA presented its first conference on e-Archiving, *Best Practices in Records Management and e-Archiving*, dedicated to the need for and methods of achieving comprehensive and robust e-Records management strategies and techniques, in Philadelphia, PA.

## 11. New and Expanded Programming in Other Locations

In September 2003, DIA presented *Latin American Herbal Medicines: Harmonization of Regulatory and Drug Development* in Santiago, Chile. This international workshop provided a forum for discussing changes and bridging studies that must transpire to achieve harmonization, and to promote partnerships that facilitate the development of herbal drugs and their marketplace integration.

*Drug Development and Quality of Pharmaceuticals* was jointly presented in Beijing, China, by DIA and the National Institute for the Control of Pharmaceutical and Biological Products (NICPBP), China, in December 2003. This interactive discussion forum explored topics from manufacturing and control of active pharmaceutical ingredients to marketing supervision, and was co-chaired by the Deputy Director-General of the NICPBP and the Deputy Director-General of the Chinese Pharmacopoeia Commission, China.

Also in December 2003, DIA and the Canadian Association of Pakistani Pharmaceutical Professionals presented two two-day workshops, *Manufacturing Controls, Validation, and Stability* in Karachi and in Lahore, Pakistan. This follow-up to the first such workshop presented in December 2002 was instructed by expatriate Pakistanis living abroad in Canada and directed by the Director of the Bureau of Pharmaceutical Sciences, Therapeutic Products Directorate, Health Canada.

In Sao Paulo, Brazil, the September 2004 *Workshop on Clinical Trials in South America* provided follow-up to the *1st DIA International Symposium on Practical GCP in Latin America* (August 2002) by reviewing the progress of clinical research and drug development in South America, notably in the Mercosur countries, since that first symposium.

In October 2004, in tandem with the State Food and Drug Administration, China, DIA presented the *Multicenter Clinical Trials* workshop in Beijing, China, to help advance increased pharmaceutical R&D activities by multinational companies conducting clinical trials in China within the context of global drug development.

## 12. Continued Success of Annual Meeting and EuroMeeting

The DIA EuroMeeting and Annual Meeting remain DIA's flagship offerings in their respective regions, with the number of attendees and sessions offered at each year's annual meeting consistently surpassing those numbers from the previous year.

In 2003, the 39th DIA Annual Meeting held in San Antonio, TX, saw two historic advances in global cooperation: Mr. Thomas Lönngren, MPharm, Executive Director of the EMEA, and Dr. Mark M. McClellan, Commissioner of the US FDA, spoke together publicly for the first time by sharing the platform for the special "Ask the Regulators" session. Also during this meeting, the US FDA and Mexico's Ministry of Health, Federal Commission for Protection from Sanitary Risks, signed a Memorandum of Understanding covering the safety and quality of certain exports from Mexico to the US. Dr. Bob Arnot, former Chief Medical Editor and Special Foreign Correspondent for the NBC network, delivered the Keynote Address.

At the 40th Annual Meeting held in Washington, DC, in 2004, Dr. Arthur L. Caplan, Chair of the Medical Ethics Department at the University of Pennsylvania, delivered the Keynote Address. A special "Ask the Regulators" session allowed attendees to interact with four senior regulators: Dr. Philippe Brunet (Head, Pharmaceuticals and Cosmetics Unit, European Commission, Belgium); Mr. Thomas Lönngren, MPharm (Executive Director of the EMEA, UK); Robert G. Peterson, MD, PhD, MPH, (Health Canada); and Janet Woodcock, MD (Acting Deputy Commissioner for Operations, FDA; Director, CDER, FDA; US).

Dedicated to the theme *e-ternal Medical Progress*, the 15th Annual DIA EuroMeeting presented in Rome, Italy, in 2003, featured two plenary sessions dedicated to the theme of medical progress in light of new European regulations and the upcoming European Union enlargement. These sessions were led by Vittorio Silano, Director General of the Italian Ministry of Health, and Paul Weissenberg, Director of Directorate F, Single Market, Management & Legislation for Consumer Goods, European Commission, Belgium.

In 2004, DIA presented the 16th Annual EuroMeeting in Prague, Czech Republic. To commemorate the European Union's historic expansion to include ten new Member States in 2004, DIA titled this programme *Expanding Horizons – Hopes and Challenges* and devoted a specific meeting track to the subject of EU enlargement. Phillipe Brunet, Head of Unit "Pharmaceuticals: Regulatory Framework and Marketing Authorizations" Directorate F, of the European Commission, served as Plenary Speaker. Ernesto Bertarelli, CEO of Serono International S.A., Switzerland, and America's Cup winner in 2003, delivered the Keynote Address. Attendees were able to ask questions of a distinguished "Ask the Regulators" panel that included Mr. Brunet; EMEA Executive Director Thomas Lönngren; Dr. Daniel Brasseur, Chairman of the EMEA Committee for Proprietary Medicinal Products, Belgium; Dr. Milan Smid, State Institute for Drug Control, the Czech Republic; and Professor Josep Torrent-Farnell, Chairman of the EMEA Committee for Orphan Drug Products, Spain.

### 13. Enhanced Website, Publications, and Communications

The DIA website continues to evolve as an integral tool for facilitating communications and transactions among DIA members. One of its more transformative enhancements was the creation of the SIAC WebBoard, as part of DIA's focus on career and professional development. Created as an online tool for members to share experiences and ask questions about DIA events, interest areas, or other topics related to their professional discipline and career development, the WebBoard promotes the free exchange of ideas, opinions, and information on these and related subjects. The immediate success of the SIAC WebBoard led to further improvements at the end of 2004 that were designed to enhance communication among members by dedicating a WebBoard to each SIAC, streamlining website navigation, and making information easier to find and use.

Through licensing content from a third party, DIA has also introduced two new ePublications to members. The ***DIA Global Regulatory Activity Digest*** provides a weekly review of all the texts of a regulatory nature published in over 30 countries. The ***DIA Dispatch*** provides comprehensive summaries of US FDA drugs and biologics Advisory Committee Meetings just hours after their completion. These ePublications are delivered to members who "opt in" to receive them and are also archived on the website for members' future reference.

DIA upgraded the online Job Bank in 2004 under the auspices of the Center for Career & Professional Development. This offering brings together potential employers and the largest and best-qualified group of candidates, from the broadest cross-section of disciplines, in the industry – DIA members.

In direct response to member feedback about receiving too many emails, DIA premiered the electronic weekly update, ***DIA @ a Glance***, in 2003. This easy-to-read electronic digest delivers weekly updates on association news and new DIA products and services, plus reports on current and upcoming conferences, workshops, training courses, and other programs. ***DIA @ a Glance*** provides a quick and

reliable way for members to get a look at what is current each week, combining the timely delivery of new information with overviews of all DIA products and services. It also forms the basis for the weekly update of the DIA homepage.

## 14. Drug Information Journal Report

The official publication of the Drug Information Association, the international, multidisciplinary, peer-reviewed, scholarly *Drug Information Journal* disseminates information on the discovery, research, development, regulation, utilization, and marketing of drugs, devices, biologics, and related products. It fosters communication between educational, research, industrial, and governmental personnel engaged in the above activities by providing an international, neutral forum dedicated to improving methods related to these efforts.

The *Drug Information Journal* implemented a new look and feel with the first issue of 2003 (Volume 37, Number 1), switching to a larger physical format more consistent with other major scientific and medical journals. The cover was redesigned to include a list of each article in that issue, helping readers identify articles of interest before they even opened the publication. The articles were redesigned to present the abstract in a shaded block on each articles' first page, to immediately draw the readers' attention, and the front matter was also redesigned.

A special supplement to the *Drug Information Journal* dedicated to global drug development and ICH in Asia was published in 2003. This supplement analyzed the penetration of the ICH spirit, in the context of drug development, into specific regional issues in Asia; the growth of the drug development infrastructure in the Asia Pacific region; the use of bridging studies; and an overview of the current status of clinical trials in each country in the region. Herng-Der Chern, MD, PhD, Center for Drug Evaluation, Taipei, Taiwan, served as guest editor for this special supplement.

Kenneth I. Kaitin, PhD, served as *Drug Information Journal* Editor-in-Chief for 2002, 2003 and 2004. Effective January 2005, Michael Hamrell, PhD, former Editor-in-Chief of the *DIA Forum*, began serving as *Drug Information Journal* Editor-in-Chief.

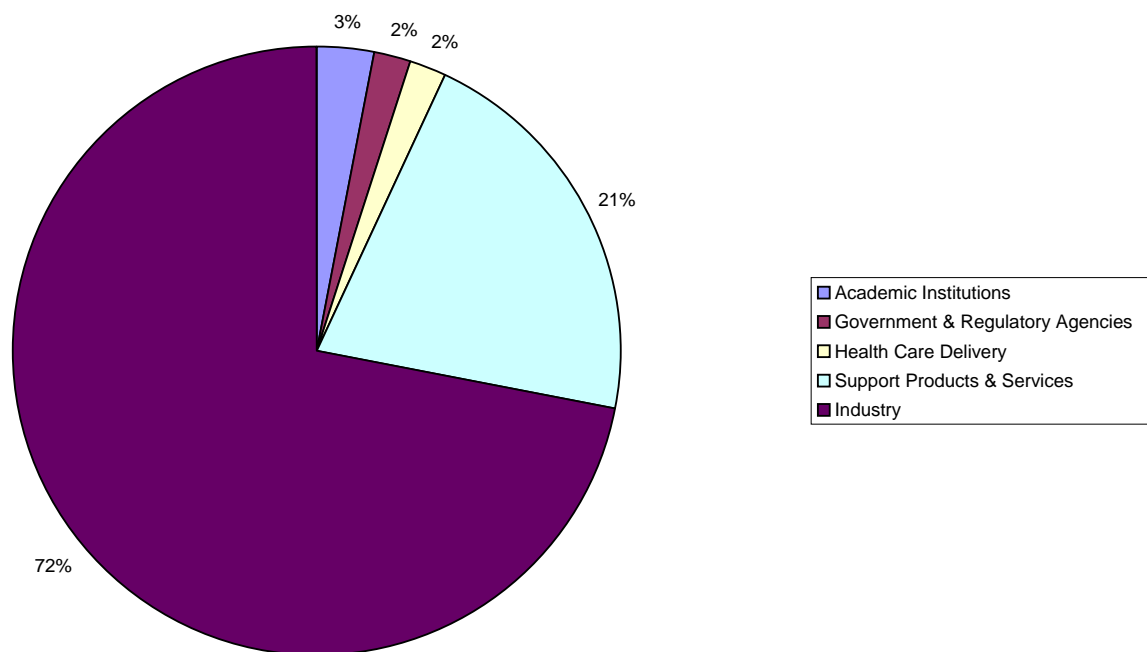
## 15. Membership

Now in its fifth decade as an association, DIA continues its commitment to providing members with access to industry and regulatory information, career and professional development resources, and professional networking opportunities.

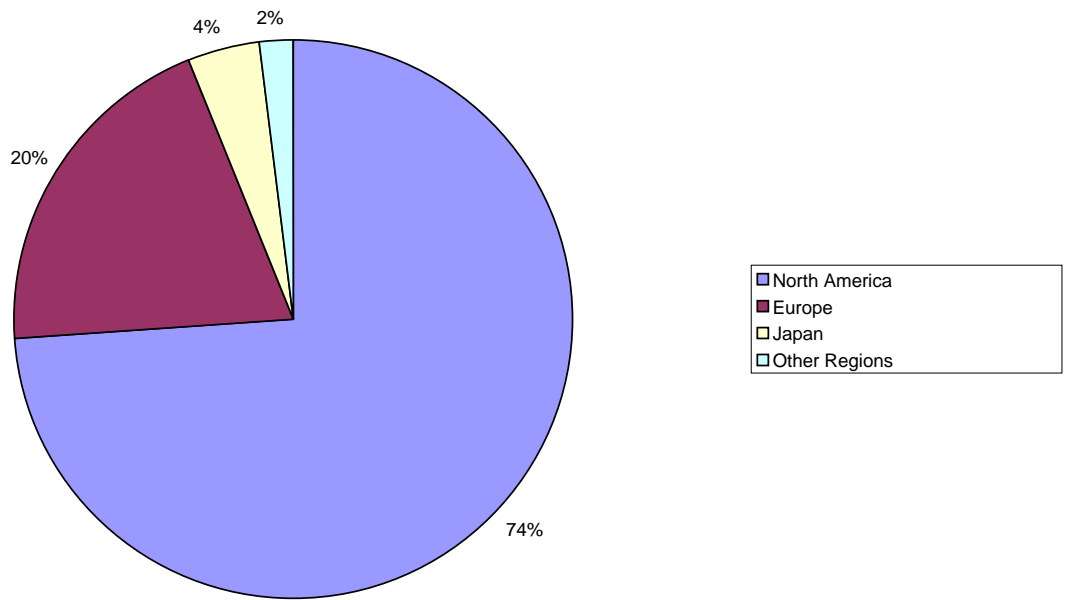
DIA members work in every facet of the drug development and related healthcare industries, including the pharmaceutical industry, government and regulatory agencies, academic institutions, contract service organizations, biotechnology firms, device manufacturers, and related organizations.

At the end of 2004, DIA membership comprised approximately 24,000 members in countries all around the world.

**Members' Professional Setting End of 2004**



Regional Distribution of Membership End of 2004



## **16. Operational and Financial Stability**

DIA operates in each of the three ICH regions, with its worldwide headquarters located in Horsham, PA, USA, and branch offices in Europe (Basel, Switzerland) and Tokyo (Japan) to better meet the needs of members and customers in these regions. . From an operational perspective, DIA consists of four legal entities: The Drug Information Association that was incorporated in Maryland in 1972, the legal entity in Japan, DIA Japan LLC, the DIA Foundation that was created to serve as the official conduit for DIA philanthropic activities and, and DIA Certification, Inc., created to administer testing for DIA certification programs

Strategic technology investments have been made to accommodate this growth and ensure future stability. New online technology products such as Webinars, the Job Bank were launched that will deliver new professional resources that will continue to meet members' needs in the future. In addition, our new membership management system allows for more comprehensive management of information associated with each member (such as professional interest area, geographic region, etc.), so that DIA can better identify and respond to their professional development needs.

Significant progress has also been made in improving the financial management and infrastructure of the organization. Changes to the financial reporting environment have greatly improved transparency and accountability across all levels of the organization. Monthly financial reporting now provides faster access to decision-making financial data. These new early financial indicators give us the ability to identify ways to contain costs much more aggressively.

This annual report highlights many of the important changes that occurred at DIA during 2003 and 2004. One thing that has clearly changed is the improvement in DIA's financial position. This improvement has been the result of DIA's commitment to providing a neutral forum for sharing information that optimizes the process of drug development and lifecycle management. In 2004, DIA achieved total revenues of \$24,279,674 which represented a 12% increase over 2003. DIA's net assets increased 7.4% over 2003 to \$9.8 million in 2004.

Moving forward, association leadership remains committed to the continued pursuit of appropriate new revenue opportunities.

## 17. DIA Foundation

DIA has supported students, governmental agencies, research training programs, and educational activities, both within and in support of the pharmaceutical and related healthcare industries, around the world since 1964. In 2001, the DIA Foundation was established as a not-for-profit corporation in the Commonwealth of Pennsylvania to serve as the support entity for the charitable efforts of DIA.

The mission of the DIA Foundation is to provide research grants to health and educational authorities throughout the world, for the purpose of expanding training, knowledge and practice, and contributing to improved availability and utilization of safe and effective medicines. The Foundation awards one-year grants of up to \$25,000 for quality research which contributes to the goals and objectives of DIA. The Foundation is designed to be self-sustaining, receiving revenue generated by investments to ensure that there will always be a means for DIA to provide funds for grants and fellowships, independent of the association's day-to-day operations.

Association bylaws were amended in 2003, in part, to recognize the formal creation of the DIA Foundation as an entity. This amendment was approved by membership vote.

In 2004, the Foundation provided financial support to *The International Conference on Promotion and Development of Botanicals Through International Coordination*, jointly organized and presented by the School of Natural Product Studies, Jadavpur University, and the Indian Institute of Chemical Biology, presented in Kolkata, India, in February 2005.

In 2004, the DIA Research Grant program administered by the DIA Foundation awarded research grants totaling \$55,652 for three projects selected from nearly forty submitted proposals.

## **18. DIA Certification, Inc.**

DIA Certification, Inc. was incorporated in 2003 for the purpose of providing strategic direction for professional credentialing programs. DIA Certification, Inc. currently administers the certification examination for DIA's first certification program: the Certified Clinical Investigator Program.