



*Drug Information Association
2006 Annual Report*

www.diahome.org

"This EuroMeeting takes place at a time when it is necessary to lay the foundations for the future of the pharmaceutical industry and pharmaceutical regulation. What was relevant twenty or thirty years ago, at a time of therapeutic optimism and before the range of public health crises we have witnessed, doesn't necessarily fit the requirements of present times."

- Jean Marimbert, Director General, AFSSAPS, France,
Welcoming attendees to the 2006 EuroMeeting, Paris

"India has demonstrated (the ability) to build on its several strengths to become a key player in this emerging model, recognizing the critical success factors among patients, physicians, hospitals, CROs, pharmaceutical professionals, government, regulatory agencies and technology, with DIA as the leading neutral platform for continuous educational opportunities and forums for solid scientific research in India."

- Mahesh Singh, PRTM,
"Transforming India into a Powerhouse" Session Chair,
Drug Discovery & Clinical Development in India,
Mumbai, India, October 2006

"There's no doubt that it's been a successful year for DIA and its members worldwide, a year that yet again demonstrates why DIA is the most respected forum for the exchange of ideas, education and training that is leading to better medicines that enhance the health and well-being of populations around the globe. That's happening because of each of us in this room. We should be proud of our contributions and proud of the collective difference we are making."

- Theresa Kane Musser, DIA President
Welcoming attendees to the 2006 Annual Meeting, Philadelphia

Table of Contents

Association Governance	1
2006 - 2007 Board of Directors Election	1
Membership Approves Bylaws Amendments	1
Volunteer & Member Services	2
DIA Awards Presented at EuroMeeting & Annual Meeting	2
Special Interest Area Community (SIAC) Initiatives	3
Other Volunteer Service Initiatives	3
Continuing Education & Certification	4
Publications Report	5
18th Annual EuroMeeting, Paris	6
42nd Annual Meeting, Philadelphia	7
Technology & Enhancements	8
Online Offerings	9
Regional Offerings - Europe	10
Regional Offerings - Japan	12
Regional Offerings - North America	13
Offerings in Rest of World (ROW)	16
Operational & Financial Stability	18
About DIA	19

Association Governance

2006 - 2007 Board of Directors Election

The results of the DIA Board of Directors election were announced in the week following the close of the 42nd Annual Meeting in June. Candidate biographies and responses to questions about the candidates' perspectives and positions on issues of importance to DIA constituents were published in the March 2006 *DIA Today*. Polls opened in March at the beginning of the EuroMeeting in Paris and closed on June 22. Please join us in congratulating our new Board members:

Ron Fitzmartin, President-elect 2006 - 2007

Three-year Director Marie Dray

Three-year Director Thomas Kühler

Three-year Director Cathy Stein-Izsak

Membership Approves Bylaws Amendments

DIA members approved amendments to DIA Bylaws in 2006. The approved changes include the following, along with minor editorial corrections:

Article VI, Officers & Board of Directors

Nominations Committee was changed to Nominations and Elections Committee to reflect its full scope and function

Article VIII, Standing & Other Committees

- The term "company" was changed to "Association"
- The description of the Audit Committee's role was revised to incorporate current standards of practice reflected in the Sarbanes-Oxley regulations and best practices in nonprofit management
- The description of the Compensation Committee was revised to specify its advisory role with respect to its responsibilities relating to the reasonableness of the total compensation of the Association's senior staff in compliance with legal requirements. The composition of this Committee was also modified.

Volunteer & Member Services

On December 31, 2006, DIA had approximately 18,000 members.

DIA Awards Presented at EuroMeeting & Annual Meeting

DIA volunteer service awards were presented at the EuroMeeting and Annual Meeting, just before the beginning of their respective plenary sessions. Please join us in congratulating:

Distinguished Career Award:

Harry A. Guess, MD, PhD

Fernand Sauer, PhD

Founders Service Award:

Michael R. Hamrell, PhD, RAC

Lifetime Membership Award:

Barry W. Burnstead, BSc

Dave Domann, MS, RPh

Outstanding Service Award:

Sabine Brosch, MSc, PhD

Herng-Der Chern, MD, PhD

Martin D. Hynes III, PhD

Truus (Geertruida Magrietha) Janse-de Hoog, PhD

Shigeru Kageyama, MD, PhD

Mohammed Razdar Khan

Ingrid Klingmann, MD, FFPM, MBCPM

Pulok K. Mukherjee, MPharm, PhD, FIC

Gary G. Walker

Drug Information Journal Donald E. Francke Award:

Investigating Drug-Induced QT and QTc Prolongation in the Clinic: A Review of Statistical Design & Analysis Considerations: Report from the Pharmaceutical Research & Manufacturers of America QT Statistics Expert Team

Pharmaceutical Research & Manufacturers of America QT Statistics Expert Team composed of: Scott Patterson, PhD, Chair; Marilyn Agin, PhD, Chair; Rich Anziano, PhD; Tracy Burgess; Christy Chuang-Stein, PhD; Alex Dmitrienko, PhD; Georg Ferber, PhD; Margarida Geraldes, PhD; Kalyan Ghosh, PhD; Ron Menton, PhD; Jaya Natarajan, PhD; Walt Offen, PhD; Jay Saoud, PhD; Brian Smith, PhD; Ram Suresh, PhD; and Névine Zariffa, MMath

Drug Information Journal Thomas W. Teal Award:

Development of Interactive Software for Bayesian Optimal Phase 1 Clinical Trial Design

William F. Rosenberger, PhD; Gerald C. Canfield, PhD; Inna Perevozskaya, PhD; Linda M. Haines, PhD; and Petr Hausner, MD

Drug Information Journal Student Award:

Examination of the Relationship between Direct-to-Consumer Advertising Expenditure & Price

Radhika Nair, MS, PhD; Anju Parthan, MS, PhD; Mapi Values, LLC; and Marv Shepherd, PhD

Special Interest Area Community (SIAC) Initiatives

At the 2006 EuroMeeting, DIA SIACs presented four special, simultaneous lunchtime sessions focused on crossover topics: *Open Discussion on the US & European Guidance on the Use of PRO Measures in Clinical Trials*, sponsored by the IMPaCT SIAC; *Key Considerations in Design and Reproductive/Developmental Toxicity Studies for Biologicals/Biopharmaceuticals*, sponsored by the Biotechnology and NonClinical SIACs; the *Joint CSP and CDM SIAC Lunch Session*; and *Validating: The Path from Patient to Sponsor to Agency*, sponsored by the Validation, Electronic Regulatory Submission, Document & Records Management, and eClinical SIACs. While many SIACs sponsor tutorials, sessions, and workshops at DIA meetings, these were the first lunchtime sessions offered at a DIA EuroMeeting by SIAC members.

In November 2006, DIA convened the first SIAC Leadership Summit in Dublin, Ireland. More than 85% of SIAC chairpersons from Europe and North America attended this meeting, which focused on providing opportunities to better engage SIAC members and to develop stronger communities toward the goal of advancing SIACs globally.

SIAC WebOffices, dedicated websites for SIAC members to share documents and other information and collaborate online 24 hours a day, were also launched in 2006.

Other Volunteer Service Initiatives

In 2006, for the very first time, members from all three Regional Advisory Councils convened prior to the Paris EuroMeeting. This was the first time that many Regional Advisory Council volunteers had the opportunity to meet their counterparts from other regions and discuss common themes.

Knowing that the students of today are the Association's members and leaders of tomorrow, the Advisory Councils in Europe and North America, with Board support, began integrating students into the DIA environment in 2006. The Paris EuroMeeting featured an *Overview of Pharma R&D* session for students, followed by a Career Development Roundtable.

Using this successful EuroMeeting Student Initiative as its model, the Annual Meeting in Philadelphia offered a similar *Student Forum*. A representative from the Tufts Center for the Study of Drug Development presented data on the characteristics of the current labor pool in clinical research and what the future job market might look like. A University of the Sciences representative discussed different types of academic programs that have been developed in recent years and how the education of clinical research professionals is changing. As part of this Student Initiative, DIA also reduced Annual Meeting registration rates for full-time students.

The 2006 Annual Meeting also played host to the first *Emerging Professionals Networking Reception*, a special forum that brought together individuals and students with six years or less of experience in their professional fields to share ideas and experiences.

DIA also unveiled a new *Get Involved* tab on its homepage that allows members and other volunteers to submit ideas for educational offerings, to respond to open Calls for Abstracts, and to submit article ideas for DIA publications, instantly and online.

Continuing Education & Certification

Many DIA educational offerings provide participants the opportunity to earn important continuing education credits, in accordance with approved accrediting bodies. In 2006, these continuing education accreditations were:

- DIA collaborates with Corexcel to offer continuing education credit for nurses. Corexcel is accredited as a provider of continuing education in nursing by the American Nurses Credential Center's Commission on Accreditation.
- DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. DIA programs that offer continuing pharmacy education credit are identified with the appropriate approved provider statement and the ACPE logo. Participants attending continuing pharmacy education programs earn credits acceptable by all boards of pharmacy that recognize ACPE approved providers.



- 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.



- DIA has been reviewed and approved as a provider of project management training by the Project Management Institute (PMI) to offer professional development units (PDUs) to its participants. Programs offering professional development units are identified with the appropriate approved provider statement and the PMI logo.



- DIA is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. DIA was reaccredited by the ACCME as a provider of continuing medical education for four years in 2004. 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. Many DIA programs offer continuing medical education credit. These programs are identified with appropriate accreditation and credit designation statements.

Effective June 1, 2006, the DIA Clinical Investigator Certification Program was integrated with the existing Certified Physician Investigator (CTI™) examination offered by the Academy of Pharmaceutical Physicians and Investigators (APPI) in conjunction with the Association of Clinical Research Professionals (ACRP). After the 2005 affiliation of APPI and ACRP, both certification programs were consolidated into APPI's CPI™ Program. Upon ACRP's acquisition of its Clinical Investigator Certification program, DIA has agreed to endorse CPI™ certification to its own members. DIA, ACRP and APPI have in total certified more than 650 physician-investigators since 2002.

Publications Report

DIA members receive all DIA print publications free of charge. These include the member newsletter *DIA Today*, which now includes professional development content formerly published in the *DIA Forum*, the *Contract Service Organization Directory* and the Association's official publication, the *Drug Information Journal*.

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 among 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. Michael R. Hamrell, PhD, former Editor-in-Chief of the *DIA Forum*, began serving as *Drug Information Journal* Editor-in-Chief in January, 2005.

Each issue of the *Drug Information Journal* contains an article that may be read for continuing education credit. The November 2006 issue featured a special section on Adaptive Design. Other special sections are planned for 2007.

The Editorial Board agreed that, beginning in January 2007, the *Drug Information Journal* will publish six times a year instead of four. This increased frequency will shorten the time between acceptance and publication, bringing information to readers in a more timely fashion and lessening the wait for authors to see their work in print. Additionally, with six journals and six issues of *DIA Today/DIA Forum*, advertisers will have the opportunity to reach DIA readers each month, making the DIA publications more desirable outlets for advertising.

DIA unveiled a new publication in 2006, the Annual Meeting *Show Daily*, and published the first four editions at the 2006 Annual Meeting.

18th Annual EuroMeeting, Paris

DIA convened the 18th Annual EuroMeeting in one of the world's most beautiful cities and against the backdrop of the revised Pharmaceutical Legislation effective November 2005. Attendees were welcomed to Paris by Jean Marimbert, Director General, AFSSAPS, France. EuroMeeting co-chairs Iman Barilero and Marie A. Dray introduced the first Plenary Session, which featured Keynote Speakers Georgette Lalis (European Commission, DG Enterprise and Industry, EU) and Jean François Dehecq (sanofi-aventis, France). These Keynote Speakers addressed the theme of innovation as a key part of the new Pharmaceutical Legislation, compared the cost of innovation relative to its value, and also presented an overview of the research-based European pharmaceutical industry and its role in the modern economy of the European Union.

The second part of the 2006 EuroMeeting Plenary Session offered an international expert panel discussion on *EU Innovation and Competitiveness: Practical Implications for and Involvement of the Stakeholders* co-chaired by Barilero and Phillip Brown. Jean Marimbert (Director General, AFSSAPS, France) was joined on this panel by Brian Ager (EFPIA, Belgium), Jacques Demotes (ECRIN, France), Yann Le Cam (EURODIS, France), Thomas Lönngren (EMEA, EU), and Martin Terberger (European Commission, EU).

Upon the request of the European Commission, DIA hosted a special EuroMeeting lunchtime session, *An Assessment of the Community System of Pharmacovigilance*. This European Commission-sponsored assessment was made public just before the EuroMeeting (February 2006) and the Commission requested this session to facilitate dialogue as part of its public consultation on the results of this study. Dr. Peter Arlett of the European Commission presented the study report, then invited EuroMeeting attendees to present comments and questions on its findings.

Another special, two-part Plenary Session addressed *Optimal Regulation--What it is, What it Costs, and How it Impacts Stakeholders*. During the first part, Thomas Kühler of the Medical Products Agency in Sweden served as video moderator for featured interviews with regulators from the EMEA, the Danish Medicines Agency, and the State Institute for Drug Control, Czech Republic, plus industry representation from the EFPIA, Belgium, all of whom described the "golden aim of regulation." Follow-up panel discussion, featuring members of regulatory agencies from The Netherlands, France, the EU, Switzerland, and the US, comprised the second part.

42nd Annual Meeting, Philadelphia

Thousands of attendees filled the Pennsylvania Convention Center for the Plenary Session and Keynote Address that formally opened the 42nd DIA Annual Meeting in Philadelphia. Welcoming remarks by DIA President Theresa Musser and DIA President-elect Cindy Kirk introduced Annual Meeting program chair Chuck Depew.

Chuck recounted a few of this program "firsts," such as the first appearance at a DIA Annual Meeting by the Drugs Controller General of India and the first public update on the FDA's *Human Subject Protection/Bioresearch Monitoring Initiative*, presented by Dr. Janet Woodcock, Deputy Commissioner for Operations and Chief Operating Officer, Office of the Commissioner, US FDA. Dr. Sanjay Gupta, on-air medical correspondent for the Cable News Network (CNN), delivered the Keynote Address.

Special plenary and other "Hot Topic" 2006 Annual Meeting sessions included:

- *Best Practices in Conducting Clinical Trials in India from Multiple Perspectives* focused on the advantages, challenges, risks, practical aspects, and logistical problems surrounding clinical trials in India, along with updates on environmental and government policy topics, such as pharmacovigilance and intellectual property issues; this session featured the first appearance at the DIA Annual Meeting by the Drugs Controller General of India
- In *CDER Hot Topic: Physicians' Labeling Rule*, the CDER team that developed and delivered the first major revision to the format of "the package insert" in 24 years, which was going into effect just days after the conclusion of the Annual Meeting (June 30), presented an overview of the background, development, and practical implications of the revised Rule
- *EU/FDA Confidentiality Arrangements: Current Status-What's Next?* identified achievements to date and future plans for the Confidentiality Arrangements signed by the EU, EMEA, and FDA in September 2003. During this session, Noël Wathion, Head of the Post-authorization Evaluation Unit of Medicines for Human Use, EMEA, outlined the Arrangements' key initiatives; Murray M. Lumpkin, MD, MSc, Deputy Commissioner, International & Special Programs, Office of the Commissioner, FDA, announced that the Agreement, originally created as a two-year arrangement, had been extended to September 2010.

The 2006 Annual Meeting also featured a special reception honoring the one hundredth anniversary celebration of the FDA, which provided a special update from the Office of the Commissioner on the agency's agenda for 2007 – 2010.

Technology & Enhancements

After months of design, development, and testing, our Association's new online presence, the new www.diahome.org website, was rolled out in January 2006. The primary objective behind the redesign was to streamline the processes by which visitors find information from, and conduct transactions with, DIA online. New and improved user-centric features of www.diahome.org now include:

- Consolidation of all DIA educational offerings into a single section of the website so that users can more readily identify and access detailed content and registration information about offerings
- Consolidation of all online member benefits into a single section of the website, so that it is easier for members to use their benefits
- Consolidation into a single resource the various opportunities for companies to reach DIA customers, such as advertising in DIA print publications and program guides, exhibiting at DIA programs, and listing in the online Job Bank and online and printed *Contract Services Organization Directory*
- Upgrades to the "shopping cart" so that customers can more easily purchase different product types (such as registration for a conference, an eLearning module, and membership renewal) in the same transaction.

Online Offerings

In addition to presenting regionally-specific and international educational programs onsite all around the world, DIA also delivered information instantly and simultaneously all around the world through its 2006 webinar series of online seminars.

DIA reprised as webinars two overflow sessions from the Annual Meeting in Philadelphia for those who were unable to attend their original presentations: *PIM & SPL: An Examination of the Two Standards* and *Recent MedDRA® Developments: Medication Errors & Labeling Considerations*, with the original speakers reprising their popular presentations.

DIA presented several 2006 DIA webinars based upon the "CDER Town Hall" model that has made such sessions consistently popular with Annual Meeting attendees. These included *CDER Town Meeting: Current Hot Topics Regarding eSubmissions*, *CDER Town Meeting: Current Hot Topics Regarding Drug Safety Oversight Board / Drug Watch*, and a three-part *Town Hall on eSource & Electronic Data Capture* series.

Many other webinars helped disseminate critical regulatory updates with the speed and convenience of the worldwide web, and brought professionals governed by these regulations together with the professionals responsible for developing and implementing them. These 2006 webinars included:

- *The Current Implementation Status of Electronic Case Reporting*, regarding paperless submission of expedited ICSRs in the three ICH regions, featuring the Deputy Head of Sector, Pharmacovigilance, EMEA; and the Director, Regulatory Affairs, Office of Drug Safety, CDER, FDA
- *New Patient Reported Outcomes (PRO) Guidance Issued by FDA* featured an array of agency panelists, including the Director, Study Endpoints & Label Development Team, Office of New Drugs; the Director, Office of Biostatistics; and the Lead Medical Officer, Antimicrobial Drug Development & Resistance Initiatives
- *Physician Labeling Rule* featured the Director, Office of Training & Communications, CDER; Deputy Director, Office of Medical Policy, CDER; and the Associate Director for Regulatory Affairs, Office of Medical Policy, CDER
- *PIM is Live for Product Information in the Centralised Procedure – Are You?*, regarding the new XML standard for product information in the centralised procedure in Europe, featured the Head of Sector, Project Management, EMEA & PIM Core Team Co-chair; and the Project Management, Communications & Networking, EMEA & PIM Project Manager.

Regional Offerings - Europe

By September 2006, the New Medicines Legislation in Europe had been in effect for nearly one full year. Working with regulatory, academic, and industry experts, DIA delivered several educational offerings that returned to many themes presented at the Paris EuroMeeting, each designed to help industry professionals understand the requirements of this Legislation and effectively plan to implement them.

The *DIA Workshop on Harmonisation Beyond Implementation of the Clinical Trial Directive* was presented in September in Copenhagen. This workshop compiled and disseminated detailed information on the Investigational Medicinal Product Dossier and Clinical Trials Authorisation; applications to Competent Authorities; impact of the Clinical Trials Directive on European ethics committees; GMP, compliance, monitoring and inspections; Electronic Data Capture; and EudraVigilance, EudraCT, EudraVigilance Medicinal Product Dictionary, and the Eudra Data Warehouse.

This *DIA Workshop on Harmonisation* was co-located with the *DIA Workshop on Pharma Legislation*, through which clinical study sponsors and regulators shared their experiences with the changed Centralised and Mutual Recognition Procedure and the newly introduced Decentralised Procedure.

These two workshops were based on the co-located workshops model developed and refined by three educational offerings simultaneously presented in Vienna in May: DIA workshops on *European Regulatory Chemistry, Manufacturing & Control*; on *Regulation & Self-Regulation of Marketing & Sales Activities*; and *New Vaccines Development*.

In November, DIA hosted an international clinical operations conference specifically designed to bring together all clinical development professionals in Europe, *The Changing World of Clinical Trials: European Clinical Research Conference; European eClinical Conference; 16th Annual European Clinical Data Management Conference & Exhibition*, in Basel, Switzerland.

Collaborative DIA offerings in Europe included *EMEA Excellence in Pharmacovigilance: Clinical Trials & Post Marketing*, the EMEA's definitive training course in pharmacovigilance, presented in Paris; and the *Joint DIA/HESI/SAPS Conference on Environmental Assessment of Human Medicines* on the impact of chemical substances on human health and on the environment, in collaboration with the University of Copenhagen (Denmark), the ILSI Health & Environmental Sciences Institute, and the Swedish Academy of Pharmaceutical Sciences, presented in Stockholm in May.

Another DIA collaboration with the EMEA celebrated a major milestone in 2006: The EMEA EudraVigilance training program, with DIA serving as conference organizer, had trained more than 1,000 users from pharmaceutical companies, European National Competent Authorities, non-commercial organizations, and contract research organizations with the skills and competencies required to efficiently manage the new concepts of electronic adverse reaction

reporting, which became mandatory in the European Economic Area (EEA) in November 2005. This significant accomplishment represents the importance and commitment organizations have made to ensure accuracy in the electronic reporting of safety data in the EEA in line with the standards agreed to at the ICH level. EudraVigilance training is offered at the EMEA offices in London and occasionally presented at various other European locations in Europe. The *EudraVigilance: Electronic Reporting* course was also offered in the US for the first time, at DIA headquarters, in 2006.

Other educational offerings presented in Europe in 2006 included the *7th European Electronic Document Management Conference: Electronic Records, Standards & the Submissions Continuum* in Berlin, December; the *Cardiac Safety Conference* also in Berlin in December; and *The International Workshop on Statistical Methodology in Clinical R&D: Developing a Common Understanding Through Discussion* in Heidelberg, December.

Regional Offerings - Japan

Second only to the US in per-country DIA membership, Japan hosted several educational offerings of regional and international interests to constituents in Japan and surrounding nations.

The 9th Annual DIA Clinical Data Management Workshop in Japan, *CDM Contributes to Business: Yes, You Can Open the Door*, was presented in January 2006.

DIA in Japan continued to recognize the increasingly interconnected, multidisciplinary, and international nature of drug development and lifecycle management by presenting two multi-track workshops. The second DIA multi-track workshop in Japan, *DIA Congress on Moving Toward a New Era in Drug Development*, was presented in April to overflow attendance. Keynote speakers Dr. Satoshi Toyoshima (Executive Director, Center for Product Evaluation/Pharmaceutical & Medical Devices Agency) and Dr. Hatsuo Aoki (President, Japan Pharmaceutical Manufacturers Association) shared their respective viewpoints of regulatory agency and industry on *Dreams and Expectations of New Product Development*. Following the Plenary Session, three parallel tracks explored pharmacogenomics, drug development strategy, and clinical trial management. These tracks incorporated additional hot topics, such as the concept of joint evaluation and leadership of Japan in the Asian region, and their practical implications for drug development in Japan.

The third DIA multi-track workshop in Japan, *How Could Companies, Regulators & Academia Better Collaborate in Pharmaceutical Development?*, was presented in October 2006. Dr. Koji Kawakami and Takeo Ozawa delivered keynote speeches that focused on how industry, academia, and regulatory bodies can collaborate in the areas of advanced medical fields, including investigator-initiated clinical trials and training for reviewers. Three parallel tracks devoted to content management, regulatory affairs and safety management, and biostatistics, followed this Plenary Session. This workshop also featured the first DIA webinar offering in Japan: Due to one speaker's inability to attend the meeting onsite, he delivered his presentation from the UK via the worldwide web.

Both 2006 DIA multi-track workshops in Japan were simultaneously endorsed by the Japan Pharmaceutical Manufacturers Association; the Ministry of Health, Labour & Welfare, Japan; and the Pharmaceutical & Medical Devices Agency, Japan.

Regional Offerings - North America

DIA presented several new offerings in North America in 2006. In March, a select group of international participants from industry, government, and academia were chosen to participate in *Computerized Systems for Nonclinical Safety Assessment: Current Concepts and Quality Assurance: A Follow-up to the Red Apple Conference* at DIA worldwide headquarters. These professionals gathered to review the reference guide *Computerized Systems for Nonclinical Safety Assessment: Current Concepts and Quality Assurance* written in 1987, to update the material for current challenges that nonclinical laboratories now face. Their updated reference text provides a seminal guide to implementing computer automation in nonclinical laboratories; due to the need for quality computerized systems in all aspects of the biopharmaceutical industry, its principles and practices can generally be applied to clinical and manufacturing systems. (Publication of this reference text is planned for fall 2007.)

Clinical Research & Drug Registration in China and India, presented in Princeton (NJ) in September, convened a two-day workshop dedicated to the clinical, logistical, and regulatory environments of two of the pharmaceutical industry's most expansive new markets, and featured a special address from Dr. David Lepay, Senior Advisor for Clinical Science, and Director, Good Clinical Practice Programs, Office of Science & Health Coordination, OC, US FDA.

Another DIA offering debuted in 2006. *The First International DIA Workshop: Developing Probiotics as Foods & Drugs: Scientific & Regulatory Challenges* overviewed the microbiology and human uses of these organisms, and also highlighted knowledge gaps potentially suited to funded research. DIA presented this international workshop with participation from FDA, the National Institutes of Health, and the Scientific Association for Probiotics and Prebiotics.

DIA's 4th Canadian Annual Meeting: What Will the Regulatory Landscape Look Like in the Next Decade? was held in Ottawa, Ontario, in October. Extended Plenary Sessions addressed Canada's future regulatory framework and biomedical ethics through presentations by Omer Boudreau, Director General, Therapeutic Products Directorate; and Dr. Pierre Charest, Director General, Biologics and Genetics Therapies Directorate. Both highlighted their visions for their respective organizations. These were followed by a presentation by David Lee, Director, Office of Medicines & Liaison, who leads the design of Health Canada's new Progressive Licensing Framework. Dr. Giorgio Fontana provided an industry perspective on this topic. The meeting was closed by Mr. Neil Yeates, Assistant Deputy Minister, Health Products and Food Branch, with his vision for the Health Products and Food Branch.

DIA teamed with the FDA to support and advance the agency's Critical Path Initiative. The *Medical Imaging Conference: Critical Path Opportunities List: From Opportunities to Action* (October) was held in collaboration with the FDA, the American Medical Informatics Association, the Biotechnology Industry Organization, the Council on Radionuclides & Radiopharmaceuticals, the Medical Imaging Contract Agent Association, and the Pharmaceutical Research & Manufacturers of America.

Other key collaborations with the FDA in 2006 included:

- *Key FDA Meetings: Success Strategies & Practical Approaches*, developed in response to suggestions by senior regulatory affairs personnel for a workshop that would benefit pharmaceutical professionals who possess limited FDA meeting experience
- *Best Practices & Development of Standards for the Submission of Genomic Data to the FDA*, which facilitated discussion of the FDA Concept Paper "Recommendations for the Generation & Submission of Genomic Data," also co-sponsored by the Pharmaceutical Research & Manufacturers of America and the Biotechnology Industry Organization
- *Satellite Video Conference: CDER Live! Understanding FDA's New Requirements for Prescription Drug Labeling* offered guidance and answered public questions about revising the content and format of prescription drug labeling
- *Webinar: Interactive FDA Presentation on Exploratory Investigational New Drug (IND) Requirements* facilitated industry-agency discussion of the newly-released "Guidance for Industry, Investigators, and Reviewers Exploratory IND Studies," part of the agency's Critical Path Initiative
- *Webinar: FDA Withdraw of Three Guidances for eSubmissions* brought agency representatives together with industry and other stakeholders to explain why these Guidances were withdrawn
- *One Day Hot Topic Open Forum: Creating Clinical Trial Efficiencies through Standard Data Collection*, presented with additional collaboration with the Association of Clinical Research Organizations and the Clinical Data Interchange Standards Consortium
- *FDA Hands-on Workshop: Implementing the Final Rule on the Content & Format of Prescription Drug Labeling*.

Other key collaborative offerings that DIA presented in North America in 2006 include:

- *Challenges & Practical Aspects of Assessing Clinical QT Prolongation / Proarrhythmia Risk and Implications for the Critical Pathway*, co-sponsored by the Heart Rhythm Society
- *Clinical Research Educational Conference & Career Fair*, presented in collaboration with the Northwestern Center for Clinical Research

DIA continued to produce its annual calendar of recurring offerings in North America throughout 2006, including:

- *21st Annual DIA Clinical Data Management Symposium & Exhibition, Delivering Quality Data Effectively in a Changing Environment*
- *19th Annual DIA Conference for Electronic Document Management: Transitions, Standards, eContent Lifecycle Management & Beyond*
- *18th Annual Workshop on Marketing Pharmaceuticals in a Time of Change*
- *17th Annual Workshop for Medical Communications: Medical Information, Medical Liaisons & Contact Centers*
- *5th Annual DIA Workshop for Contemporary Pharmacovigilance & Risk Management Strategies*
- *5th Annual Electronic Submissions Conference: eCTDs: Entering the Mainstream*

- *DIA Annual Workshop on Statistical Methodologies in the Biopharmaceutical Sciences*

DIA continued to offer the industry's "best in class" instructor-led training course calendar, which introduced a new course in 2006: *Pediatric Clinical Research*, training on how to operationalize clinical trials in pediatrics, in collaboration with Duke Clinical Research Institute.

Since 2003, DIA's training opportunities have included a Project Management offering. In 2006, a subcommittee of the Project Management SIAC undertook the development of a comprehensive Project Management training curriculum. The first component of this new curriculum was available in 2006: *Project Management: Planning, Executing & Controlling Projects in Pharmaceuticals & Biotechnology*. Additional Project Management-focused courses offered in 2006 included *Overview of Drug Development Lifecycle, Team Building & Dynamics* and *Budget Analysis*.

Another new training course developed in 2006 for availability in 2007, *Overview of Drug Development in Japan*, reviews the recent history of the pharmaceutical industry in Japan and identify key elements of the Japanese culture to help participants better understand the organization of the Japanese Regulatory Authority and the requirements for successful drug development in Japan.

DIA also continued to offer in-company training, instructor-led training courses conducted onsite upon the company's request, and completed nearly ten such offerings in 2006.

Offerings in Rest of World (ROW)

Drug Discovery & Clinical Development in India: Opportunities & Challenges, jointly organized by DIA and the Institute of Clinical Research (India) and with collaborative sponsorship from Biomedical Consulting International, Inc., was presented in Mumbai, India, in October 2006.

Academia and industry professionals shared perspectives on how India's end-to-end clinical trial development and drug discovery to market complies with the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

Two preconference tutorials, *Statistics for Nonstatisticians* and *Risk Management Assessment & Management: Challenges & Solutions*, were specially targeted at graduate postmedical students in clinical research and pharmacy, and were rewarded by sizeable percentage of attendees who were students from Delhi, Bangalore and Mumbai.

Dr. David Jacobson-Kram of the FDA opened the conference with a keynote presentation on *The Role of Preclinical Safety Testing in Clinical Development of Drugs*, followed by the Drug Controller General of India, M. Venkateswarulu, who covered aspects of *The Regulatory Landscape in India*. Professor Yoshinobu Hirayama, PhD, formerly with the Pharmaceuticals and Medical Devices Agency, addressed the mission of PMDA and the Amendment of Pharmaceutical Affairs Law. The Plenary Session was devoted to the mission of *Transforming India into a Powerhouse*.

In response to requests from several representatives of the region's Drug Regulatory Authorities to develop a better understanding of how certain regulatory terms are defined and regulated, DIA conducted a workshop in Dubai for these authorities in this region. This workshop focused on several aspects of the regulatory environment in the region. DIA presented this workshop in partnership with the Middle East Regulatory Network, a network of the EFPIA International Regulatory Affairs Group.

Themes discussed during this May workshop were advanced to the *7th Middle East Regulatory Conference: MERC 2006* conducted in November in Dubai, and attended by representatives from eleven different Middle Eastern regulatory authorities. Since its inception, MERC has become an important forum for matters related to providing health care in the region, with a focus on the evaluation of innovative medicines for human use. The *Regulators Workshop* offered regulatory authority delegates the opportunity to meet in a closed session with colleagues for a facilitated discussion on specific topics, while the *Industry Delegates Workshop* allowed industry delegates the opportunity to surface regulatory issues that impact them in this region.

In September, with co-sponsorship by the Sociedade Brasileira de Medicina Farmaceutica, DIA presented *The SBMF/DIA Workshop: 3rd Latin American Congress of Clinical Research: Topics in Clinical Research & Drug Development* in São Paulo, Brazil. This workshop comprised a one-day preconference training course on *Good Clinical Practices for the Clinical Research Professional* and a two-day conference with presentations including ICH and FDA updates, Latin American

regulatory guidelines and ethical issues, infrastructure and components of clinical research, and perspectives for the development of clinical research in Latin America, delivered by speakers from Brazil, Argentina, Chile, Germany, Mexico, Spain, and the US.

Operational & Financial Stability

DIA continues to operate in each of the three ICH regions. DIA worldwide headquarters and North

American operations are based in Horsham, PA, USA. DIA operates a European branch office in Basel, Switzerland, and a DIA Japan LLC office in Tokyo, Japan. These offices work with their respective regional Advisory Councils for North America, Europe, and Japan, to develop programs and services that anticipate and meet the needs of all DIA constituents in these regions. DIA operates as a not-for-profit organization.

In 2006, DIA continued to make strategic investments in technology and personnel to accommodate anticipated growth and ensure future stability. Many of these investments, such as development of the new www.diahome.org website and upgrading the membership / customer management system, are summarized within this Annual Report.

DIA also continues to make significant progress in improving the financial infrastructure, management, and transparency of our operations. Monthly financial reporting implemented in 2004 continues to provide faster access to decision-making financial data; these early financial indicators continue to identify ways to manage expenditures much more efficiently.

This sustained improvement in DIA's operational and financial stability has been the direct result of its commitment to providing a neutral forum for sharing information that optimizes the process of drug development and lifecycle management. This commitment is shared by association leadership, staff, members and other volunteers, and is summarized in our new association Mission and Vision statements, which you can also read in this Report.

In 2006, DIA achieved total revenues of \$28,819,486, representing a 4% increase over 2005 revenues. DIA incurred \$26,607,715 total expenses in 2006, representing a 4% decrease over 2005 expenses.

Net DIA assets increased 33% over 2005, to \$13.9 M in 2006. This includes a residual amount of \$3,442,961 from 2006, an increase of 361% over the 2005 residual.

DIA has committed to applying this residual to advance the DIA mission and vision through all regions, and remains committed to the continued pursuit of new, appropriate opportunities for revenues and savings in 2007.

About DIA

DIA is a professional Association of more than 18,000 members worldwide who are involved in the discovery, development, regulation, surveillance, or marketing of pharmaceuticals or related products.

DIA is committed to the broad dissemination of information among its members, with continuously improved professional practice as the goal. DIA serves its members in a neutral, global environment that operates independent of the influence of any one organization or authority.

DIA operates as a financially independent nonprofit organization that funds itself from meeting and membership fees. The voluntary efforts of DIA members and speakers allow DIA to provide programs and publications to members at a reasonable, competitive cost.

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; and
- High-quality professional development opportunities.

DIA Vision

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

For more information about DIA, please visit us online at www.diahome.org.



United States

Drug Information Association
800 Enterprise Road, Suite 200
Horsham, Pennsylvania 19044-3595
Tel: +1.215.442.6100
Fax: +1.215.442.6199
dia@diahome.org

Europe

Europe, DIA
Postfach
4002 Basel, Switzerland
Tel: +41.61.225.51.51
Fax: +41.61.225.51.52
diaeurope@diaeurope.org

Japan

DIA Japan LLC
Maruei Building 4F
2-19-9 Iwamoto-cho, Chiyoda-ku
Tokyo 101-0032, Japan
Tel: +81.3.5833.8444
Fax: +81.3.5820.8448
diajapan@diajapan.org

www.diahome.org