GLOBAL FORUM

JUNE 2011 • VOL 3 | ISSUE 3

DIA Oxford Debate and the Future of Medicines

ANDRZEJ CZARNECKI
EDITOR-IN-CHIEF

DIA serves its members as an excellent independent forum for the exchange of knowledge, information, and experience in all areas of interest. Over the past 20 years, this platform has established its position for members from different professional and "employment" circles, and has proved to be very useful not only for the industry that started our association, but also for academia and regulators from across the world. Over the last 10 years, our activities and meetings have managed to attract even larger external interest, and we experience the active participation from individual patients and patients' associations, students of different faculties, the media, and the legal profession, no matter whether it is working with us or against the pharmaceutical sector. It is clear that such wide participation is evidence of the added value and impact of our activities on the health care environment and on many professional groups, which is also reflected in cross-participation by members of other societies in our meetings.

During the 2011 EuroMeeting last March, participants attended many "hands-on and purely scientific sessions. On the Monday afternoon just after the opening plenary session, DIA's independent forum reached out to the strictly academic form of the Oxford Debate, which created a great start to the subsequent two days of the meeting. The debate had a theme, "The current regulatory system does not support timely access to beneficial medicines" and

proved to be challenging for the presenters arguing both "for" and "against" from the four perspectives (patient, academia, regulators, and industry) and the moderator, who requested that the audience expresses their view by registering a telephone vote. Excellent presentations by the speakers and discussions resulted in the strengthening of the view of the substantially large audience on the efficiency of the regulatory system. The discussion from the podium and the floor raised many aspects of the environment seen from several perspectives. It was refreshing to hear so many topics of importance being raised, such as the need for/to

- greater involvement of patients in regulatory and industry decision making
- regulators to take media on board, explain better, and help them understand the complexity so that the message passed by the media would serve the patients better
- tackle the legal profession to stop them having a negative impact on patient health
- industry to work more closely with patients and their needs
- regulators to create a framework supporting the development of innovative medicines, and medicines clearly needed by society
- increase the scientific basis of decisions in the three main streams, ie, industry, regulators, and academia, that may have such a great impact on future medicines.

These and many other topics were mentioned during the session, despite the limited time available. Their importance was very clear since they could be discussed, however briefly, in such a short period of time.

As a participant in the eight sessions of the following two days of the EuroMeeting, I heard many repercussions from the Monday debate from speakers and chairpersons. The future is being built on such debates, so let's hope that there will be a continuation of interest in the topics discussed in the everyday activities of all involved in the years to come so that science, and patient/and public health, can benefit fully.

Over the years, the *Global Forum* has covered many of the topics raised during the 2011 EuroMeeting debate. However, the focus of this issue, Medical Devices, is an area that may be new to many of us, and I would like to thank its guest editor, Dan Schultz, for his excellent work in bringing these articles together.

After such a high-quality experience at the EuroMeeting, I eagerly await the Annual Meeting in June, which will bring even more food for thought for a more exciting future. ■

Looking BACK, Looking FORWARD

RICHARD DAY

The DIA Annual Meeting each June, our industry's largest and most respected annual gathering, is the culmination of thousands of volunteer hours spent by our program chairperson, the program committee, track and session chairs, panelists, speakers, student poster presenters, professional poster presenters, and other contributors, all working toward one common goal. *DIA 2011: Convergence of Science, Medicine, and Health*, provides us with a snapshot in time, as we work through current issues toward our vision of the future, together.

Each year's Annual Meeting seems to grow more global. This year, *DIA 2011* presents the first Annual Meeting track devoted exclusively to global regulatory and associated health agencies. Our recent *Asian Regulatory Conference: Asia's Role in Global Drug Development, our 3rd DIA China Annual Meeting: Quality & Standards: Elevating China Pharmaceutical Development, our 3rd Latin American Regulatory Conference: Harmonization of Regulatory Requirements in Drug Development & Registration*, along with our upcoming *6th Annual Conference on Drug Discovery & Clinical Development in India*, are hallmarks of an association with truly global vision and scope.

Building on the heritage of our association's past, working together in the present to build a better future for the world's patients, caregivers and health care providers, is the legacy shared by every DIA member and volunteer. It is this legacy, and the role that I have been fortunate to play in it, that I treasure most as I write my final *Global Forum* message as President of DIA.

In reflecting upon a President's term that seems to have passed too quickly, it is most gratifying to consider how we have collectively elevated the voice of the patient in our association's global endeavors. Economic and social circumstances make it more important than ever to heed this voice in the "bench to bedside" model of drug development, where innovations begin with basic scientific research at the "bench," progress through development and clinical testing, and arrive at the "bedside" of the patient. Our recent 23rd Annual EuroMeeting in Geneva celebrated the sixth year of the Patient Fellowship program that supports the participation of patient organization representatives in our European flagship offering. We remain grateful for and encouraged by the continual leadership provided by, among other organizations, EURORDIS, "The Voice of Rare Disease Patients in Europe," and look forward to presenting programs with EURORDIS and similar organizations as a hallmark of future DIA educational offerings in Europe.

Or we can turn toward Chicago, where *DIA 2011* will inaugurate our Annual Meeting Patient Fellowship program. Representatives of 15 different patient advocacy organizations will share their challenges and accomplishments and those of the patients they represent, from their own booth in our exhibit hall, and through formal sessions and informal conversations, with us. In October, we will turn toward Washington, DC, where we will present our *First Annual Rare Diseases & Orphan Products Summit*, co-sponsored by the National Organization for Rare Disorders (NORD), to consider how we can better serve patients with rare disorders and diseases.

In closing, I wish to thank many colleagues for sharing adventures and accomplishments during my tenure as DIA President. I extend special thanks to Dr. Jeffrey Sherman, from whom I accepted the DIA Presidency and who generously assisted me as I transitioned from President-Elect, and to Dr. Yves Juillet, to whom I will turn over the DIA Presidency at our transitional Board of Directors meeting at the Annual Meeting. I was honored to be the first

DIA President to serve from outside the US. Dr. Juillet will be the first DIA President to serve from Europe. Looking forward, Dr. Ling Su is the first nominee for DIA President to come from China. It is an honor to serve this international company at this pivotal juncture in DIA's history.

I wish to thank Paul Pomerantz, DIA Worldwide Executive Director, whose leadership, advice, and business and association expertise has provided invaluable and constant support. To the Directors of our regional offices in Europe, China, India, and Japan, a special thank you for representing your regional needs and opportunities so well, and for the regional perspectives with which you continually nourish DIA's global mission and vision. Our programming and training, members and volunteer services, and interactions with constituents in your part of the world enrich DIA globally.

I also wish to thank our special section editor for this issue, Dr. Daniel Schultz, who put together the special section on the critically important and rapidly evolving topic of medical devices.

Most of all, I thank all of you. One day, we will look back at the work we've done together as incremental but essential steps in building a better future for our industry and every patient and practitioner whose lives our work will touch. We have done, and will continue to do, great things together. I look forward to continuing this journey, and thank you for walking alongside me.

One partner.
Four product-critical services.
Complete peace of mind.

Trust our industry experts to support your products with seamless customer service and full regulatory compliance. Individual or integrated solutions available.

ddnmedicalaffairs.com 414.434.8400

DDN Medical Affairs
A Dohmen Company

connect protect succeed

GLOBAL FORUM JUNE 2011, VOL 3 ISSUE 3

CONTENTS

70

www.diahome.org

Publishing Information

Global Forum Staff

Paul Pomerantz

Executive Director

Andrzej Czarnecki, MD, PhD, DSc, *Editor-in-Chief*
Lisa Zoks, *Editor*
Fran Klass, *Managing Editor*
Chris Slawecki, *Senior Copywriter*
Joe Krasowski, *Marketing Communications Manager*
Pat Friia, Joyce Litwin Zimmerman
Freelance Writers

Mission

The *Global Forum* provides a multidisciplinary, neutral forum for communicating information related to drug development and lifecycle management on a global basis. The *Global Forum* disseminates content that is relevant to members' professional experiences, including international industry and regulatory updates and news of the association and its programs. The magazine is circulated six times a year as a benefit of DIA membership.

Publishing, Subscription, and Advertising Offices:

Drug Information Association (DIA), 800 Enterprise Road Suite 200, Horsham, PA 19044-3595, USA.

Contact Information

Worldwide Advertising Sales, Michael Boucher 267 419 8735
Subscription Information, Customer Service 215 442 6100
Membership Services, Mike McGovern 215 442 6129
Senior Marketing Manager, Mike Keller 215 442 6173

The ***Global Forum*** (ISSN: 1944-1991) is a publication of the Drug Information Association. Editorial Office: Drug Information Association (DIA), 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA; phone: 215 442 6100; fax: 215 442 6199.

The ***Global Forum*** (ISSN: 1944-1991) is published six times a year, in February, April, June, August, October, and December. Periodical postage paid at Horsham, Pennsylvania, and additional mailing offices. Thirteen dollars of each member's annual membership fee is for a year's subscription. Prices include postage and are subject to change without notice. Notify DIA eight weeks in advance of address change with a copy of the mailing label. Back issues of most previously published issues are available from DIA.

PUBLICATIONS MAIL AGREEMENT NO. 41103506 RETURN UNDELIVERABLE CANADIAN ADDRESSES TO CIRCULATION DEPARTMENT, PO BOX 1051, FORT ERIE, ONTARIO L2A 6C7

Postmaster: Send changes of address to ***Global Forum,*** 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA.

Cover Illustration: Copyright © istockphoto.com

Devices, Innovation, & Alliances: DIA 2011

PAUL POMERANTZ

This year's Annual Meeting, chaired by Ken Getz, is shaping up to be both innovative and exciting. I would like to take this opportunity to illustrate how this meeting is also reflective of DIA's strategic direction.

DIA programming in Medical Devices is not new. For many years, we have provided sessions on this topic, including a well attended CDRH Town Hall in 2010. In addition, devices have been the focus of programming in Europe, most notably a theme at the EuroMeeting, but also through other training courses and conferences.

At the same time, *DIA 2011: Convergence of Science, Medicine, and Health* represents a new beginning, so to speak, for medical devices as an area of focus within DIA, and will be our first Annual Meeting to dedicate a specific track to medical devices. But DIA has provided educational leadership while the scientific and regulatory environments for medical devices have continued to evolve throughout the year: DIA hosted an online seminar on the impact of parallel review of drugs and devices by the FDA and Centers for Medicare & Medicaid (CMS) in February, and on the FDA reclassification of medical device data systems in May. More programming, including a dedicated conference, is planned for 2012.

In 2009, the DIA Board undertook a deep review of its vision and strategy. As part of this, the Board examined trends in the industry, in health care, and in technology, and noted the increasing role of advanced medical devices in therapy, the convergence of devices and drugs (devices as drug delivery systems or in diagnostic-drug combinations), the growing participation of traditional pharmaceutical firms in medical devices, and increasing regulatory requirements for clinical studies and safety management.

DIA's vision statement does not limit us to any one type of technology. Rather, our focus is on innovation: *DIA is the global forum for knowledge exchange that fosters innovation to raise the level of health and well-being worldwide.*

It was felt that DIA's neutral multistakeholder forum and scientific focus could provide a unique resource to this emerging area.

In 2010, DIA established a Medical Devices Task Force to help guide our association's offerings in this important area. Chaired by DIA Board member Steven Caffé, MD, the Task Force scanned the broad environment for Medical Devices, emerging challenges, and offerings by DIA and other organizations. The group suggested that DIA focus on combination products and advanced technology, areas that could benefit from DIA's expertise in clinical studies and regulatory science. The Task Force recommended the device content that has been put in place for 2011.

The task force also recommended this special focus of your *Global Forum*, for which I thank all of our contributing authors and especially Dr. Daniel Schultz, who served as section editor for this timely and informative group of articles. On behalf of our entire association, I thank the Medical Devices Task Force for all their efforts behind these and other initiatives, and look forward to new programming on this timely topic.

Technological innovation is another critical component of DIA's future, both operationally and strategically. Operationally, our recent EuroMeeting and upcoming Annual Meeting were the first of these offerings to provide mobile device agenda apps to attendees. We have also launched mobile device apps so

that members can download and access our *Drug Information Journal* and *Global Forum* publications on the go, as well as our daily industry newsletter, our *DIA Daily.*

Strategically speaking, DIA 2011 will also be our first Annual Meeting to present the HIMSS Interoperability Showcase℠, a unique collaboration between DIA, the Clinical Data Interchange Standards Consortium (CDISC), the Healthcare Information & Management Systems Society (HIMSS), IHE (Integrating the Healthcare Enterprise) International, and IHE USA vendors and organizations. This event will offer the opportunity for researchers to collaboratively demonstrate the benefits of using standards-based interoperable health IT solutions for effective and secure health data information exchange. For all of our exhibitors and attendees, this is an important addition to our Annual Meeting program.

At the same time, the HIMSS Interoperability Showcase℠ illustrates how DIA 2011 marks another step forward in DIA's alliances with like-minded organizations and associations. We are pleased to announce the first DIA Annual Meeting Patient Fellowship program, through which 15 representatives of patient groups will share their experiences in sessions and at their booth in our exhibit hall. DIA worked with a committee consisting of representatives from NORD (the National Organization for Rare Disorders), EURORDIS (The Voice of Rare Disease Patients in Europe), CISCRP (the Center for Information & Study on Clinical Research Participation), and the NHC (National Health Council) to secure nominations and select these 15 Patient Fellows for this program. We welcome representatives of the Bill & Melinda Gates Foundation to DIA 2011, and thank them for developing their session on *Vaccines for Low- and Middle-Income* Countries, which also features representation from the World Health Organization (WHO). We are grateful for and energized by working with all these and other groups who share our goals and vision, so that we can move forward together.

Collaborate to Innovate will be the theme of DIA 2012, our 48th Annual Meeting in Philadelphia next June, and the 2012 Program Committee, chaired by Craig Lipset, is already at work to develop new content, and new ways to deliver that content, to benefit the patients, caregivers, and health care providers that we all ultimately serve.

Devices, innovation, and alliances are just some of the high points of DIA 2011. Did I mention that we'll convene in Chicago, one of my hometowns? I know from experience that Chicago hosts some of the finest educational, sports, and musical institutions in the world. It's a great location for our DIA Annual Meeting. We'll see you there! ■

THOUGHTS ABOUT THE NEW EUROPEAN PHARMACOVIGILANCE LEGISLATION:

The pharmacovigilance master file and supervisory authority for pharmacovigilance inspections

Arthur P. Meiners

The new European pharmacovigilance (PV) legislation, which was published by the European Commission on 31 December 2010 and will go into effect in July 2012, has major implications for the pharmaceutical industry. While the aim of updating the legislation was to reduce the administrative burden, only consultation on very high-level proposals for changing the old legislation occurred. The result is a possible gap between the actual legislation and a full understanding of the practical implications thereof for industry and by extension for regulatory authorities and inspections.

One area where this may be the case is the replacement of the requirement for a (product-specific) detailed description of the pharmacovigilance system (DDPS) by a pharmacovigilance master file (PV MF). The DDPS needs to be submitted with new drug applications, variations, and with any updating of the DDPS. The PV MF would be located at a specified office of the marketing authorization holder and would only need to be submitted at the request of a regulatory authority. The location of the PV MF will determine the supervisory authority for pharmacovigilance, in particular for pharmacovigilance inspections. There are two areas which may result in implementation issues with respect to the PV MF: the content and layout, and the location.

The content and layout of the PV MF is not described in the new legislation. It is highly likely, however, that it will extend the DDPS and be closer to the level of the UK MHRA's Summary of Pharmacovigilance Systems (SPS), which is required prior to MHRA pharmacovigilance inspections. The latter document requires more detail on the pharmacovigilance system as present within the UK affiliate, and a lot more variable data from live data sources in attachments, including listing of ongoing studies in various parts of the world, lists of local and global contracts, and current compliance figures for various types of submissions. Both the DDPS and SPS have so far suffered from a lack of clear modularity.

With respect to the DDPS, there has also been insufficient agreement on whether attachments generated from live databases are part of the core document. In case the first is assumed, then any change to these attachments results in a change to the DDPS as a whole. If however, it is accepted that the attachments reflect information subject to continuously ongoing change, and therefore are to be seen as attachments to be supplied in up-to-date format when requested, then the changes to the attachments cannot be considered as changes to the core document.

Without clear definition of the general layout and contents of the core PV MF, and proper agreement on the way to handle certain attachments originating from live data sources, there is a very high likelihood that the practical implementation of the PV MF will cause significant problems.

Currently the legislation does not foresee, and thus does not require, definition of some standard for a "Pharmacovigilance Local File" (PV LF) which extends the description of a company's global PV system in the PV MF with additional information relevant to how the different locally performed aspects of pharmacovigilance are covered. This could be a fixed set of attachments to the PV MF to be maintained within each separate local operating company, or it could be a separate PV LF. The latter approach most likely is the better solution as it aligns with the location where the PV LF should be maintained.

Issues with definition of content and layout may well be further complicated by the linking of the location of the PV MF within the company to the supervisory authority for PV. This assumes that only that supervisory authority will do PV inspections in the future. That

is both highly unlikely, and from a national authority perspective, most likely unacceptable. The national authority remains responsible for the supervision of the safe and effective use of medicinal products on its national market. Such supervision requires assurance that the MAH is fulfilling the regulatory requirements also within that national jurisdiction. The new PV legislation does not exclude national authorities to continue to do PV inspections if they feel this is needed. It would have been helpful if the legislation had explicitly acknowledged the needs of the national authorities and had specified clear distinction between an inspection by the supervisory authority and those by other national authorities. This could have allowed explicitly limiting the remit of national authorities to inspecting the local implementation of the PV system to be in line with the PV LF. Only the supervisory authority should perform full systems inspections of the global PV system against the PV MF and the PV LF of the local operating company being inspected, and provide the other authorities with information about its findings.

The above discussion on the supervisory authority does not highlight the fact that in larger companies the PV MF will most likely be a virtual document. It will exist on servers which may be located anywhere in the world and only exist in a physical state where and when requested for submission or inspection. The location where the company indicates it to be located may well be tied to the location of either the Qualified Person for Pharmacovigilance (QPPV), or a regional PV center. As more than 50% of the QPPV and regional centers for global companies are located in the UK, this would result in a highly unbalanced workload among inspectorates and resultant imbalance in knowledge and experience. The latter would undoubtedly result in continued disharmonization between the approach to and outcome of inspections across the region.

A much more practical way forward might be that, in consultation between companies and regulatory authorities, a work-sharing occurs where by mutual agreement a particular regulatory authority accepts being the supervisory authority for a particular company for a given period of years. Once that agreement has been reached, the authority in question should request the company to submit a copy of the PV MF. Thus it will not be the location within the company, but the first presence within an EU regulatory authority, which determines the supervisory authority. Once every 4, 5, 8, or 10 years, depending upon agreement among the EU regulatory authorities, there should probably be a reshuffling of the supervisory authorities to ensure continued balancing of workload and occasional re-inspection of the same company by a different inspectorate for a next period. This would reduce any risk of perception that any particular authority's inspectorate and company were becoming "too comfortable."

Such an approach would result in a good distribution of the workload across inspectorates in the region. All inspectorates would retain adequate experience with full systems versus only local PV inspections. The requirement to communicate the results of full systems PV inspections to the other inspectorates in the region would stimulate a harmonized approach to inspections. No single authority would control more than 50% of the PV inspections. The limitation of other authorities to do only local PV inspections of the company in question would result in a very significant decrease in burden for inspectors and industry.

Acceptance of the fact that the most current PV MF should be seen as a virtual document and that significant attachments to the PV MF are to be considered variable data subject to continuously ongoing change, should result in excluding those variable data for the 7-day submission rule if the supervisory authority suddenly asks for an updated PV MF. Such attachments should have a longer allowed time from request to submission. From experience, it is clear that ensuring all data are up to date and validated appropriately within large organizations can take up to several weeks. A 30-day timeframe would be a more realistic minimum timeframe for generating up-to-date attachments. Possibly even the 60-day timeframe allowed for the DSUR and PSUR should be considered. ■

Arthur P. Meiners, *is a Senior Medical Advisor Pharmacovigilance, Perspektivo PV Consulting Services, Hoofddorp, Netherlands. You can contact him at a.p.meiners@ameiners.nl.*

Effective Clinical Research Training

Rani Abraham

Before the regulation of clinical trials, control, compliance, and uniformity of practice were primarily achieved by restricting trial activities to a couple of key personnel. Most frequently these personnel were also the investigators who came up with the study hypothesis, which ensured that compliance in all aspects of trial conduct was achieved.

Today, as trial procedures have markedly evolved in line with the regulations governing trial activities, clinical trials are no longer conducted by a small number of individuals. While this ensures the involvement of a wide array of experts with the required experience and qualifications, there is the need to ensure that all participants, irrespective of their geographic location and experience, follow uniform procedures. Training therefore has been acknowledged as a key requirement prior to clinical trial conduct for the experienced clinical researcher as well as for those new to the industry. Training is particularly relevant, since no two trials are alike and the regulations governing clinical trials are constantly being updated and refined.

With a fixed objective and an expected outcome, trainers have, however, had the opportunity to experiment and implement the most effective methods to ensure optimal learning. Irrespective of the functional area of clinical research involvement, it becomes essential to ensure that personnel are provided with an overview of the drug development process and clinical trial methodology, as well as important information on regulations and guidelines. This forms the basis for further training and development within the chosen functional area.

As ICH and most country-specific regulations mandate clinical researchers to be trained, experienced, and qualified in the areas of their clinical trial involvement, currently offered clinical research training falls under three broad categories:

- Long-term courses resulting in a degree or a diploma
- Short-term accredited/certified courses
- On-the-job training

Degree and Diploma Courses

The degree and diploma courses within clinical research usually are offered or accredited by a university and have a broad curriculum that is covered over two to three years. Such courses are best suited to provide a comprehensive foundation in clinical research and a good understanding of the clinical research procedures, principles, guidelines, and regulations. They also offer the possibility of focusing on a chosen functional vertical, such as regulatory affairs, data management, or biostatistics.

One of the most commonly cited disadvantages of such courses is the inadequate exposure to actual clinical trial procedures within the curriculum. It is therefore important to ensure that all such courses are closely integrated with practical training within a clinical trial setting to ensure that the knowledge gained is relevant.

Accredited or Certified Short-term Courses

Within the emerging clinical trial markets, short-term courses are becoming increasingly popular among professionally qualified personnel. These courses offer the opportunity for focused learning and development leading to a recognized certification. Considering that there are only a couple of certified and recognized courses within various clinical research functional areas, it would be prudent to identify such courses before enrolling in any program.

On-the-job Training

The most commonly practiced method of learning is on-the-job training, which is very effective as the trainee receives hands-on experience in the clinical setting. However, being adequately qualified is usually

a prerequisite for such training, making it unavailable for many novice trainees.

Training Delivery

While each of the three categories of training and education listed here targets different objectives, there are varied approaches employed in the delivery of training. The most common mode of training has been classroom-based training; however, we now see more creative and less resource-intensive training solutions evolving with time.

Classroom-based training encourages active learning with the possibility of interaction between participants and the trainer, while distance learning programs provide flexibility with respect to the pace and location of training. Web-based training in recent years has offered the same flexibility, while offering the opportunity to interact and actively learn. Interactive workshops and on-the-job training have been and continue to be preferred choices for effective learning.

The identification of training requirements and consideration of the credentials of the trainee therefore play an important role in the selection of the training mode best suited to ensure effective training.

Key Learnings

Training in the emerging markets has been characterized by the need to build capabilities and provide a foundation with basic training for all clinical research stakeholders – sponsors, regulators, ethics committees, investigators and CROs. The training requirements in other regions have been focused on updating participants on regulatory changes and training on advanced topics within biostatistics, medical writing, project management, and data management.

Other than the varied training requirements across the experienced and the emerging clinical trial markets, there have been many important observations that are unrelated to the training content. Some of these key observations are as follows:

- Need for trainer(s) fluent in local language
- If English is acceptable as the medium for training in a non-native English speaking country, the need for trainers to speak simple and clear language
- Requirement to adapt training time to the local working hours and days
- Need to evaluate if positive interaction is feasible in countries with hierarchical social structures
- Requirement for evaluation of participants prior to training to understand awareness and conduct a post-training evaluation to assess learning
- Periodically query participants to evaluate comprehension
- Allow for adequate "interaction-time" for the trainer to individually talk to trainees and respond to their queries
- To ensure key information and messages are available in a written format (such as slides, handouts, etc) to facilitate trainee comprehension
- To allow trainee views and experiences to be shared interactively

Most of these observations stem from cultural and social differences rather than training content. When designing training programs, much attention is paid to the course content rather than the delivery, often resulting in a poor learning experience, despite an excellent curriculum. It is therefore recommended that non-local trainers have the chance to benefit from some cultural awareness training before they provide training to participants from other geographic locations.

Conclusion

As the number of trials being conducted each year grows steadily, including substantial growth in the emerging markets, all stakeholders involved in clinical research should extend their support of learning and development to support the local training requirements in these regions. ■

Rani Abraham *is ClinTec's Associate Director, Regulatory Affairs & Operations.*

Quality First—Implementing Quality in Times of Change

Nicky Dodsworth and Sherri Hubby

Building quality into an organization, such as a pharmaceutical company or a contract research organization (CRO), requires recognition of economy change indicators in addition to having the right people and processes to be successful. Quality Assurance (QA) can contribute greatly to the success of an organization by ensuring that the processes in place incorporate the federal, state, and country/local requirements as well as providing smart concepts for streamlining and achieving best practices.

Building quality into any system takes time. One way to make quality a part of your ongoing business is to design and monitor it. A checklist like the one presented below can be designed into your quality system by identifying upfront critical parameters that could affect your business early on to minimize the chance that they will occur.

An example of risk parameters that QA could monitor based on the analysis of the work conducted before, during, and after a clinical trial includes the following:

Step1. Prior to Accepting Work on a Clinical Trial

QA Assessment/Questions
If contracting to vendors such as CROs and central laboratories, prior to signing the contract, contact QA to ascertain whether the CRO been audited prior to use.

Points to consider/Questions to ask:
Audits are needed to assess suitability of the vendor.

Example of Questions to Ask:

- Has the vendor been audited within the past 2 years?
- If the vendor was audited, were there significant findings associated with the audit?
- Were all audit findings resolved and corrective action accepted by QA so that the report could be closed out?

Note: The industry standard for re-audit is every 2 years. However, this depends on use, business, and regulatory risk. Also, any issues detected while working with a vendor need to be fed back to QA.

QA Assessment/Questions
An independent review by a quality unit should be conducted to look at the vendor's processes and procedures to determine whether there are any gaps which may have an effect on the vendor's performance in the study as well as regulatory risk for the company.

Note: It is important to assess whether there is sufficient documentation in place to demonstrate that audits were conducted and resolved and that training records have been reviewed and found to be acceptable.

Points to consider/Questions to ask:
Critical factors to identify include:

- Do procedures exist for all work that will be performed?
- Have all individuals to be involved in the study met their training requirements?
    - Does the vendor's team list identify everyone working on the study?
    - Are there job descriptions, CVs, and training records for individuals working on the study and is the individual's job background appropriate for the work being performed on the study?
- Is any of the work going to be further subcontracted to another vendor?

QA Assessment/Questions
Prior to signing the final contract, it is important for individuals from the sponsor and CRO to discuss issues which could affect the client deliverables, procedures used on the study, and overall regulatory impact on the study. Often, the decision on whether to waive or combine the prestudy and site initiation visit are frequent areas which need to be addressed. In addition, there are times in which the sponsor may request that telephone visits/assessments be conducted.

Points to consider/Questions to ask:
Examples of questions to ask prior to signing the contract for clinical services:

- Is there a plan to waive or conduct via phone any pre-study site qualification visits or site initiation visits?
    - Is there sufficient documentation/reason documented to justify waiving the visit?
    - Has the investigator site been used for the same indication within the last six months?
    - Does the vendor have procedures to support conducting visits by phone or waiving visits?
- Are there policies in place for home-based CRAs? Will documents be stored or destroyed according to set procedures?
- Who will be conducting translation of relevant clinical trial documents? What are the processes for back-translation?

Step2. After Sgning the contract and Before the Sponsor/CRO has Begun Work on the Study

QA Assessment/Questions
Conduct a GCP/GMP/GLP assessment early in the study to assess vendor compliance.

Points to consider/Questions to ask:
Areas to assess for a GCP assessment include:

- Have any modifications been made to sponsor-approved documents without sponsor approval which would include:
    - Monitoring visit reports or other templates
    - Change in procedures used by the vendor
    - Change in computerized systems used for the trial
- Current status of study team member's adherence to required regulatory and study-specific training.
- Documentation of list of procedures (including version dates) used to conduct work on the study. This should be a living document.
- Signed documents by sponsor and CRO prior to performing work include:
    - Data Management Plan
    - Clinical Monitoring Plan
    - Safety Management Plan

Tip: The sponsor/CRO should have a list of procedures that will be used on the study for all services that are contracted along with a written plan for services such as project management, monitoring, data management plan, safety monitoring plan.

QA Assessment/Questions
Request from the sponsor/CRO the following documents on an ongoing basis during the study.

Points to consider/Questions to ask:
Request updated documents, for example:

- Trial Master File (TMF) Structure/and or access to documents (if applicable) including whether electronic files are maintained and location of files.
- Recent changes in procedures associated with work performed on study.
- Team Member List, including CVs, JDs, and training records.
- Company Organogram.
- A list of regulatory inspections/ sponsor audits and whether major or critical issues were noted.
- Ongoing trackers and access to the TMF for ensuring that the TMF and investigator site files contain the required essential documents as per ICH GCP and applicable regulatory requirements.

Tip: The above documents should be reviewed on an ongoing basis. Changes in any of these areas could indicate areas which need to be audited or followed up closely. Too frequent changes in personnel can indicate issues within the company and can have an effect on the management of the study.

QA Assessment/Questions
Sponsors should ensure that they are reviewing the CRO and their own internal deliverables on a timely basis (for example, monitoring visit reports).

Points to consider/Questions to ask:
Review of Monitoring Visit Reports:

- Do the monitoring visit report templates contain all the required information including an area to indicate what was not able to be covered during the visit, and have these templates been reviewed by the sponsor?

- Are the monitoring visit reports finalized with approval signatures and filed in the TMF as required?
- Do the monitoring visit reports carry over any noncompliance issues to the next report until resolution?
- Do the monitoring visit reports contain serious noncompliance issues that would require action on the part of the sponsor, such as an enrolment hold or suspension due to repeat protocol violations or non-reported serious adverse events?
- Do the monitoring visit reports contain documentation that the IRB or ethics committee was notified of all issues subject to reporting?

Tip: Timely review of internal deliverables can prevent issues from escalating later in the study, when corrective action will be less effective.

QA Assessment/Questions
The sponsor/CRO should ensure that quality checks are being performed as required.

Points to consider/Questions to ask:
Questions to ask include:

- How often is the TMF being reviewed and are the results documented?
- Have any internal audits been performed on the study and what were the results? Were any critical issues or findings that affect the study being conducted noted?
- What are the current systems being used to run the study, eg, Oracle Clinical, Oracle AERs, Electronic Data Capture System, Interactive Voice Response System (IVRS).
    - Are the computer systems currently being used for the study validated? If yes, when were the systems last validated?
    - Are any home-grown systems being used (as opposed to off-the-shelf software) and are they validated?
    - Are all systems being used 21 CFR Part 11 compliant?

Step3. After Completing the Trial

QA Assessment/Questions
The sponsor/CRO should conduct a final review of documents. Examples of some of the critical documents to review include the following:

- Final monitoring close-out report for each investigator site
- Final report by investigator to the IRB for study closure
- Close-out of queries prior to database lock
- Close-out of all sponsor/CRO audit findings with corrective and preventative action and copies of audit certificates as applicable
- AE/SAE reconciliation tracker
- Final audit or QC check of TMF prior to transfer to sponsor

Points to consider/Questions to ask:
Questions/follow-up per category:

Final Monitoring Visit reports:

- Have all adverse events been reported to the sponsor/CRO, IRB/IEC and regulatory authorities as required and followed to final resolution?
- Was the principal investigator available for final resolution of any issues noted, and is this documented?
- Was a 100% investigational drug accountability performed and all drugs either returned to the sponsor or disposed of per protocol?
- Have all case report form pages been verified and pulled prior to study termination?
- Has the IRB/IEC been notified of site closure per local law/regulations?
- Was a final investigator site reconciliation performed to verify that all essential documents are present?
- Was a final check performed to ensure that source documents, data correction forms/queries, monitoring notes, all approved/signed informed consents and any HIPAA/Data Protection documents are present for each subject?
- Have all lab reports been reported and analyzed?

Query Process:

- Have all outstanding queries been resolved or a plan agreed to for resolving any remaining queries including database lock procedures?

AE/SAE Tracker:

- Have all SAEs been recorded on the SAE Tracker and has the tracker been compared to the clinical database tracker?

- Were any discrepancies noted in comparison of the trackers resolved?

File Transfer Process:

- Is there a process in place to ensure that all original study documentation is returned to the sponsor after close-out at the end of the study?
- Does the transfer of files include a quality check for missing documents by the CRO?
- Are the files returned to the sponsor inventoried and organized to include a list of all documents provided?

What Do We Find During Audits?

Internal process audits which focus on training requirements frequently show that although individuals have met the training requirements, they fail to meet regulatory requirements because they do not understand them. As resources for professional training courses can be expensive, QA can be utilized as a resource to teach managers how to self-audit, perform employee gap analysis on training requirements, and provide information to set up proficiency testing programs. Utilization of these types of programs can go far in giving assurance to sponsors that vendor selection is appropriate and repeat business is warranted.

As an example, QA should take the lead in ensuring that systems are in place to assure that individuals who perform key roles in the company have met the ongoing training requirements and have the relevant background. This is the number one finding in many sponsor audits.

While online test questions help in assessing an individual's understanding of procedures, this is no guarantee since tests can be retaken and answers can be memorized. Only through conducting review of documentation, interviews, and observation of processes can the true picture of an individual's understanding be ascertained.

An area which frequently goes unnoticed, but can result in significant impact for the company, is audit or inspection readiness. QA is adept in knowing the skills necessary and documentation requirements to ensure that individuals are prepared at a moment's notice. This includes holding a question-and-answer session to provide training on routine questions asked during a sponsor audit or FDA inspection. The best way to prepare for these is to have unannounced audits/inspections and have individuals respond to questions and receive immediate feedback on their performance.

Where Else Can QA Add Value?

Another area where QA can add value is by assisting the organization in understanding root cause analysis. By really understanding the issues, by peeling back the layers like an onion, you reach the key reason why something has gone wrong. This problem-solving process is something that has to be taught. When the real issue is identified, the organization is on its way to prevent re-offending, thereby saving potential time and cost. As part of this process, it is important to gain consensus rather than rushing in to fix the problem.

It is important that QA continue to build collaboration within operational teams and management. In QA, we have the enviable position of overseeing most of the activities of the organization and can easily determine issues and trends. Our strength is assisting teams in working together at interfaces where issues are most often found.

Summary

Conducting more audits does not improve compliance within an organization; this has been proved many times. We need to consider further ways in which QA can work with teams to improve quality. By improving the quality culture within an organization and the involvement of QA as a "change agent," the organization will be best placed to work effectively in this ever-changing environment. ■

Nicky Dodsworth *is Senior Director Global Quality Assurance, Premier Research Group Ltd.*

Sherri Hubby *is Director, US Quality Assurance, Premier Research Group Ltd.*

Not Your Parents' Medical Devices

Daniel Schultz, Section Editor

Full disclosure: I am a device guy. My clinical background includes three years of family practice followed by roughly 20 years of general surgery. My FDA career, which started in 1994 and ended in 2009, was spent in various capacities at the Center for Devices and Radiological Health (CDRH). So imagine my surprise when DIA asked me to serve as section editor an issue of their *Global Forum*.

Then I realized, the idea couldn't make more sense and the timing couldn't be better. The distinction between drugs and devices used to be quite sharp; most of us would have little trouble distinguishing a surgical clamp from an aspirin tablet, or an x-ray machine from an intravenous infusion.

Today, those borders are becoming much less clear and really looking much more arbitrary. Examples abound in every clinical and technological domain, where devices are looking and acting more like drugs and vice versa; where treatment modalities are combined into a single product; where device needs drug to enhance its clinical benefit; or drug needs device to get to its target.

When people talk about personalized medicine, the focus is typically on the need to customize therapeutics to meet individual patient needs. Companion diagnostics are often mentioned parenthetically in this discussion. In actuality, it is the diagnostic component that will determine if and when this concept becomes reality. The basic science of genomics, proteomics, and functional imaging must be translated into clinically useful products that can distinguish subpopulations and individual patient characteristics that can accurately guide appropriate therapeutic regimens.

Novel drug delivery systems enable higher levels of drug to get to the site where they are most needed and allow patients to enjoy the benefits of therapeutically powerful molecules without having to endure the risks of systemic distribution. Whether it's a smaller, longer catheter carrying chemotherapy to a liver tumor or a nanoparticle coupled with an antibody that can cross the blood/brain barrier, the result is the same… the potential for greater benefit and lower risk.

Antibacterial coatings on medical devices have been utilized for many years, including nonspecific agents like silver and targeted antibiotics like rifampin; however, use of these coatings has proliferated dramatically for a wider range of products. While antimicrobial activity can easily be demonstrated on the bench versus microbes of interest, the issue of clinical utility remains uncertain for many of these applications, and the ability to define and prove clinical benefit remains elusive for many sponsors.

And what has happened to those familiar metal plates and screws that have been the mainstay of orthopedic surgery for decades? Increasingly, those appliances for both spinal and peripheral applications are being supplemented with bone growth-stimulating substances designed to enhance healing and avoid the need for painful and debilitating bone graft procedures.

So, clearly these are not your father's medical devices! These new products are providing enhanced patient care today and have the potential to transform medical practice in the future. But there are challenges: scientific and technological, fragmented business models and financing, a siloed regulatory process, and a reimbursement system that reflects quantity of care rather than quality of outcomes. These challenges will require new approaches, new thinking, and most of all the ability of all of the different players to listen, learn, and ultimately work together to create the substrate needed for these innovative products to develop, undergo appropriate testing and evaluation, and succeed or fail based on merit, not misunderstanding.

Any novel approach to diagnosis or treatment must be based on sound science and a valid technological assessment. During my time at FDA, there were many instances where we were presented with a promising new technology, an enthusiastic sponsor, an unmet medical need, and minimal or marginal data. This scenario typically leads to a lack of progress and frustration for all the interested

parties. So why does this happen? Deciding what an appropriate data set looks like for a novel product is not always easy. Unlike the nth of a kind of product that can rely on recognized test methods, endpoints and regulatory requirements, the product with a novel mechanism of action may not be amenable to these tried and true methods which may necessitate the development, validation, and execution of a totally new and different R&D program. Developing metrics for local drug delivery, biocompatibility models for different tissues and novel materials (eg, drug/polymer), and designing statistical methods to evaluate customized products intended for multiple subsets of traditional populations are among many difficult problems that must be resolved in order to seize opportunities for innovative solutions.

To make matters more complex, what about the situation where key components of a novel clinical approach are designed and manufactured by separate entities? This may be two different pharmaceutical companies, two different device companies, a pharmaceutical and a device company, different management, different stages of development, or different visions of how to develop and commercialize their products. This scenario is commonly seen with companion diagnostics but has also hampered progress in the development of imaging modalities that rely on multiple contrast agents for a variety of clinical applications. Traditional business models are simply not adequate to optimize the development and facilitate the regulatory pathway for these nontraditional combinations.

How do regulators contribute to the problem and how can they become part of the solution? As technology and clinical practice advance, and particularly as the rate of change and the magnitude of those changes continue to accelerate, the challenge for regulators to accurately assess safety and effectiveness and facilitate the review of innovative drugs and devices becomes increasingly daunting. In addition to effectively and efficiently applying existing scientific and regulatory principles, regulators endeavor to recruit and retain cutting-edge scientists, develop appropriate regulation and guidance, and evolve organizationally to address the changing world around them.

With respect to FDA, the regulatory process and corresponding organizational structure have developed incrementally over the last century, primarily in response to imminent public health challenges. In the absence of a specific threat, forcing change at an agency as large and complex as FDA is difficult.

The Office of Combination Products (OCP) at FDA has provided a rational framework and oversight to a process that heretofore was defined by uncertainty and stagnation; however the mission is far from complete. The fundamental scientific, regulatory, and cultural divides between the Centers remain. Coordination and teamwork as was seen during the review of the drug-eluting stent (DES) technology unfortunately remains the exception and not the rule. But the collaborative paradigm created for these game-changing device/drug combination products can serve as a model for similar efforts and justifies a degree of optimism for the future.

Another lesson learned from the DES experience is that with good data, appropriate planning, and a willingness to communicate early and often with public and private payers, timely compensation commensurate with performance is achievable. Once again, this can only happen if all the pieces are in place, and for the majority of medical innovations, reimbursement remains a major challenge.

Clearly, in this exciting time for medical technology, a key component will be educating members of the different communities regarding issues of mutual concern, providing a common language for interaction, and an accessible format for dialogue. It is hoped that the information and perspectives provided in this and future issues, including premarket review, quality systems and compliance, global harmonization, and device tracking, will begin to address those needs. ■

Daniel Schultz, MD, *is Sr. Vice President, Medical Devices & Combination Products, Greenleaf Health, LLC. Readers can contact him at Daniel.Schultz@greenleafhealthllc.com.*

Why 510(k)?

Heather S. Rosecrans

There has been a lot of attention in recent months directed at the Premarket Notification program for medical devices, commonly referred to as 510(k), from within and outside the FDA. If you believe what you read and hear about the 510(k) program, the studies, the reports, the proposals, you might question how Congress could ever have authorized, and how FDA could ever have implemented, such a "flawed" concept.

Unfortunately many of the people writing and talking and criticizing the 510(k) program have never prepared, submitted, reviewed, or made a decision regarding substantial equivalence for a 510(k); and most device users probably never realized that the devices they have used were devices cleared through the 510(k) process. They simply want devices that work as intended and meet their needs. And while there are certainly improvements that are both necessary and feasible, in order to understand what needs to change, it is necessary to first understand what the program is, how it started, how it has evolved, and what it has accomplished over the 35 years it has been in existence.

The 510(k) Program, enacted by section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), is not a form nor a retirement program nor a race! It is in fact the classification program based on risk, using the Food and Drug Administration's (FDA's) regulations on valid scientific evidence, to determine whether a device to be marketed after May 28, 1976 can be put into commercial distribution in the United States. In other words, FDA must determine if that new device is substantially equivalent (at least as safe and effective) to another device(s) legally marketed in the United States–that does not require Premarket Approval (PMA) under the statute (a predicate). In fact, this program has become the pathway under which greater than 95% of devices are on the market in the US today.

Approximately 130,000 510(k) submissions[1] for devices have been cleared for marketing and made available to health care professionals and patients as prescription devices and to consumers as over-the-counter devices following 510(k) review. This program is considered to be the "gold standard" for device review in the world and is still used by a number of foreign governments as their review process for marketing of devices in their own countries.

It is highly unlikely that the committee drafting the Medical Device Amendments (MDA) to the FD&C Act in the mid 1970s thought that this piece of legislation would become the way the majority of devices would be marketed in 2011. In fact, in the legislation authorizing 510(k), there was no mention of what substantial equivalence meant. Fortunately, the Congressional Record[2] for the 1976 Medical Device Amendments (MDA) did provide a sense of how they envisioned the concept being implemented:

The term "substantially equivalent" is not intended to be so narrow as to refer only to devices that are identical to marketed devices nor so broad as to refer to devices which are intended to be used for the same purposes as marketed products. The committee believes that the term should be construed narrowly where necessary to assure the safety and effectiveness of a device but not narrowly where differences between a new device and a marketed device do not relate to safety and effectiveness. Thus, differences between "new" and marketed devices in materials, design, or energy source, for example, would have a bearing on the adequacy of information as to a new device's safety and effectiveness, and such devices should be automatically classified into class III. On the other hand, copies of devices marketed prior to enactment, or devices whose variations are immaterial to safety and effectiveness would not necessarily fall under the automatic classification scheme.

The 510(k) Program was, and is, a device classification program at its core. FDA staff collaborated with "classification" advisory panels to identify the legally marketed devices on the market prior to the MDA, and, through rulemaking, established approximately 1700 classification regulations[3] for generic types of

devices. Each device type was placed into class I, II, or III, based on its risks and how well the mitigation of those risks was understood.

Since that time, most new indications for use and most new technologies for devices have been reviewed prior to market through the 510(k) process.[4] By the mid-1980s, it was clear that the 510(k) program was here to stay and would continue to be the mainstay for review of devices and, if it was determined by FDA that a reasonable assurance of safety and effectiveness was demonstrated, the 510(k) would be found substantially equivalent and the subject device could enter the marketplace. During this period FDA staff established through guidance a four-part process for the review of 510(k)s—"The 510(k) Substantial Equivalence Decision-Making Process"[5] to expand upon the concept outlined in the Congressional Record. This process was codified into law in 1990 with the Safe Medical Devices Act.[6] FDA's four-part review process begins with comparison to a predicate(s) device, secondly review of the new device's use and next, the review of the device's technology. If FDA determines the new device has a predicate(s), the new device has the same intended use, same technology, or a different technology that does not raise a new type question of safety and effectiveness, the device is subject to review as a 510(k). If the new device is found to be not substantially equivalent for any of the above three decisions, the device must be reviewed as a PMA or perhaps would be eligible under the "de novo" program.[7] If the FDA 510(k) review does find that the device is eligible for review as a 510(k) based on a positive determination of the first three decision points, at that time the performance of the device is evaluated to see if the 510(k) holder has established that the new device is at least as safe and effective as other legally marketed devices of the generic type—ie, substantially equivalent. Performance can be evaluated with bench testing, animal studies, clinical data, or any combination thereof. The majority of 510(k)s do contain performance data, including approximately 10% of which have included review of clinical data.

Throughout its history, the 510(k) Program has received much scrutiny, beginning with FDA's Center for Devices and Radiological Health's own 510(k) Criticism Task Force in the mid-1980s, followed by Government Accountability Office reviews, the Department of Health and Human Services' Office of the Inspector General review, and most recently FDA another internal FDA review as well, as contracted with the Institute of Medicine in 2009 to study the ability of the 510(k) program to adequately assure the safety and effectiveness of medical devices in the US. While past studies have provided varying degrees of process improvements to the 510(k) program, the studies to date have, for the most part, shown an understanding and recognition of the validity of the determinations regarding substantial equivalence through the 510(k) Program. Those who have spent the time to review the regulations, guidances and policies, read the review memos, and meet with the staff have recognized that this program is not a "fast-track" nor a "rubber stamp"! It is a data-driven program that provides the FDA and the industry with the flexibility to require the type and amount of information necessary to evaluate a particular device in relation to similar devices that are currently marketed and whose use, technological characteristics, and functionality demonstrate reasonable assurance of safety and effectiveness.

The fact is that even many implants, life-supporting and life-sustaining devices, are reviewed via the 510(k) process. This is appropriate because the risks of the devices are known, methods to mitigate these risks are understood, and FDA can evaluate whether a 510(k) submitter has adequately addressed those risks using guidance, standards, and thorough scientific review.

It should be clearly understood that while 510(k) plays an important role in the premarket process for the evaluation of medical devices, it is only one part of the regulatory system. Devices are also subject to other requirements under the FD&C Act, such as the Quality System, postmarket surveillance, adverse event reporting, and the Investigational Device Exemption rules. Additionally, there certainly are devices where FDA review staff determine their novelty and risk profile designate them as class III and mandate Premarket Approval as the appropriate pathway for review prior to market.

The 510(k) Program has evolved over time through statutory and

regulatory changes, as well as through guidance. The current program covers a wide variety of device types and a wide range of technological complexity. The program's success is highly dependent upon the ability of the review staff at CDRH to use good science and sound judgment to make decisions that are in the best interest of public health. The 510(k) Program has allowed technology to advance over time in a manner that parallels the evolution of clinical practice and has provided health care practitioners and patients with the tools needed to offer the high level of medical care that we enjoy in the US today. ■

References

1 Over 150,000 510(k)s have been received since 1976.
2 Report by the Committee on Interstate and Foreign Commerce on the Medical Device Amendments of 1976 (House Report).
3 The classification regulations are found in 21 CFR 862-892.
4 Those devices with no predicate, a new intended use or a new technology that raised a new type question require review through the PMA process or the de novo process.
5 See FDA guidance K86-3 entitled, "The 510(k) Decision-Making Process for Substantial Equivalence."
6 See section 513(i) of the FD&C Act.
7 See section 515 of the FD&C Act for PMA and section 513(f)(2) for de novo.

Heather S. Rosecrans *is Senior Advisor, Regulatory Affairs, atGreenleaf Health LLC, and as Vice President of Regulatory Affairs, Medical Device Manufacturers Association. Readers can contact her at heather.rosecrans@greenleafhealthllc.com.*

The Importance of Complying with Quality Systems in a Global Environment

Steven Niedelman

Medical devices continue to play an increasingly vital role in today's health care system by providing a spectrum of safe and effective technologies that range from cutting-edge, technologically sophisticated life-supporting, life-sustaining devices to those that are less techno-savvy, yet equally important, in our daily lives. These devices range from critically important automatic implantable defibrillators and heart-lung machines, to orthopedic implants, infusion pumps and contact lenses, to in-vitro diagnostics, and to the simplest devices such as canes, crutches, and tongue depressors. As our current health care policy evolves and hospital stays shorten, many of even the most sophisticated, software-driven devices that were envisioned at the time of their introduction for use by specifically trained individuals in hospital settings are being used in the home health care setting, placing increased importance on human factors in the design of these devices to ensure safety and ease of use by many who have never had the formal training in the use of these devices. Many of the devices currently on the market have become more sophisticated, their therapeutic indications have expanded, and we have become more dependent upon them to provide safe and effective treatments and therapies that just a decade ago were unheard of. Many of these complex devices have become miniaturized and more portable for use in environments not originally envisioned, all of which requires more robust design and increased importance of manufacturing devices in accordance with the requirements contained in FDA's Quality Systems regulation. Contributing to those challenges, device manufacturers have become increasingly dependent upon global sources of parts, components, technical expertise, and even finished devices, many of which are located in remote areas of the world, which makes their oversight difficult and costly.

Manufacturers who offer their devices for sale in the United States are required to manufacture their devices in accordance with the Quality System regulation (21CFR Part 820). Failure to comply with the Quality System regulation renders a device adulterated in accordance with the requirements of the Federal Food, Drug and Cosmetic Act. The Quality Systems regulation is an umbrella type, non-prescriptive regulation that applies to the full spectrum of devices from the simplest to the most complex. The Quality System regulation identifies requirements for management controls, design control, production and process controls, documentation, facilities and equipment, corrective action and preventive action (CA/PA), and materials controls. Compliance with these requirements is not optional, and FDA, through its cadre of investigators located in District Offices and Resident Posts, conducts inspections to assure conformance with these requirements. Certain Class I medical device manufacturers are exempt by regulation from all but the general records and complaint-handling requirements of the Quality System regulation, while six select categories of Class I device manufacturers (tracheobronchial suction catheters, surgeons' gloves, protective restraints, manual radionuclide system applicator, and radionuclide teletherapy sources) require design controls to be implemented and followed. Wherever possible, FDA has harmonized the Quality System regulation with internationally recognized quality systems such as ISO. To provide for harmonized requirements wherever possible, FDA maintains an ongoing dialogue with international counterparts to maintain open lines of communication and share information. As one of the founding members of the Global Harmonization Task Force (GHTF), representatives from FDA serve on the Steering Committee as well as the various Study Groups to develop Guidance Documents that once implemented by regulators and the medical device industry will lead to increasingly harmonized quality systems requirements.

FDA has a variety of administrative and judicial actions available in its enforcement toolbox for failure to comply with the Quality System regulation. At the conclusion of an inspection, significant findings made by the investigator are prepared on a List of Observations, FDA Form 483, that is presented and discussed with top management at the conclusion of an inspection. Under FDA Commissioner Hamburg's enforcement policy, firms have 15 working days to respond to FDA about those observations or risk FDA not considering the firm's response in their decision to pursue any subsequent actions. Depending on the significance of those findings and

their potential impact on safety and efficacy and public health, FDA may exercise any of several administrative or enforcement actions with the goal of attaining compliance and ensuring that safe and effective devices are being manufactured. Typically, judicial actions are not undertaken without providing the firm an opportunity to voluntarily correct the observations. FDA may simply provide untitled correspondence to top management about its concerns, or issue a Warning Letter to top management about the findings, and that failure to correct in a timely manner may result in enforcement action such as seizure, injunction, civil money penalties, or even prosecution. Other tools available to FDA to attain compliance and assure the quality and safety and efficacy of the devices in commercial distribution are import alerts to stop the importation of violative products from a foreign source; recalls (voluntary as well as mandatory in imminent risk situation when a firm will not voluntarily take action to remove violative products from the market); safety alerts; and lastly administrative detentions when FDA needs to "freeze" devices in place for up to 30 days while it seeks more permanent control of the violative devices with a seizure action. Judicial actions available to FDA include seizure of adulterated and/or misbranded products, injunction action to stop further manufacturing, shipping, processing, storing, packaging of product, and lastly prosecution for violating the Food, Drug and Cosmetic Act.

The medical device industry has become increasingly dependent upon globally sourced suppliers for parts, components, sub-assemblies and even finished devices. The medical device industry persuaded FDA through their comments to the proposed Quality System regulation that vendors and suppliers would be an extension of their quality system, and it would be their responsibility to monitor conformance with adherence to requirements. Based on those comments, FDA revised the Quality System regulation to create Purchasing Controls requirements (21CFR 820.50) as an alternative to imposing full requirements on suppliers. As global outsourcing has increased, the challenges of assuring conformance to the quality system requirements have increased dramatically. The increasing dependence upon third-party suppliers, some of which are located in third world countries that are difficult and costly to visit, creates a new variable for device manufacturers and potentially increases their liability should a problem develop with their finished device as a result of these outsourced components/devices.

We have all read about or personally experienced the recent spate of supplier quality issues in products used in our daily lives—from lead-based paint on toys to melamine in pet food, ethylene glycol (anti-freeze) in toothpaste, heparin purposefully contaminated with over sulfated chondroitin and even contaminated peanut butter—all of which continually serve as a reminder of the importance of assuring a robust, compliant supply chain. Dr. Margaret Hamburg, Commissioner of the Food and Drug Administration, expressed her concerns about the globalization of complex supply chains as one of her top priorities during a presentation on her enforcement philosophy in August 2009. This past year alone, approximately 20 million lines of FDA-regulated product was offered for import into the United States. The volume of FDA imports has tripled in the past decade, and doubled in the past five years alone. A decade ago, nearly all imports were food, where today better than 25% are medical devices. Despite recent budget increases, FDA does not have adequate resources to assure the quality of each of the products as they arrive on our shore and has long understood the value of having inspectional intelligence about foreign manufacturers generated from onsite inspections to assure compliance with the Quality System regulation, rather than the "whack a mole" approach to sampling imported products upon entry. Unfortunately, establishing an adequate foreign inspection program is also extremely resource intensive, so it is incumbent upon medical device manufacturers to establish their own risk-based supplier quality program that is grounded in proper due diligence, robust contractual quality agreements, and is supported by a vigorous audit program to assure conformance to FDA requirements and the firm's specifications. As part of the Quality System regulation, the Purchasing Controls requirements are not prescriptive, but need to provide for an effective risk-based program to meet an individual company's needs. Manufacturers who choose to use off-shore suppliers should visit those suppliers to evaluate the actual physical site that will be manufacturing their products and determine their current state of compliance. If necessary, utilize third-party providers to perform those audits, to avoid the potential trap of "show and shadow" operations that serve as "shells" for manufacturing sites, while actual operations are taking place at other, less pristine facilities. Many firms have resisted outsourcing in off-shore locations unless they have a permanent presence, or are doing business with a firm that has a permanent presence in the foreign

country to provide the assurance that oversight can be easily accomplished.

To reduce any risk associated with outsourcing, and to maintain compliance with the Quality System regulation, a formal, risk-based supplier quality program should be established. This program should comprise six strategic elements: initial suppler selection, contractual supplier quality agreements, risk management stratification program, risk- based audit program, maintaining supplier data and corrective action planning and follow-up. During initial supplier selection an assessment of the supplier's knowledge of FDA's requirements needs to be made to ascertain the level of oversight needed to obtain a quality product and determine a supplier's ability to meet capacity needs, both large and small. Supplier quality agreements are critical to identifying expectations and requirements about conformance to regulations, need for audits, sharing in investigations, and shouldering costs should a problem arise.

Risk management stratification provides the tools to determine the highest-risk products being outsourced and determine the level of controls and oversight needed. Vendors that provide product with little or no impact on the quality of overall operation of the finished device should not require the same attention as a critical component supplier whose failure may have safety implications. Establishing an effective audit program is critical to the success of any supplier quality program. However, it is important to remember an audit is only as good as the auditor performing the audit, and the audit program being followed. Companies should resist the temptation to create a simple "check the box" checklist that does not encourage adequate description of what was audited and the findings. Maintaining current supplier data is equally critical to the success of the program to assure awareness of the current status of suppliers, ie, which are acceptable and which are on probation or have been disqualified. Suppliers should only be approved for specific commodities/services. When a supplier is providing products with various risk factors, firms should always audit to the highest requirement.

Special attention needs to be focused on those suppliers that either as a result of an onsite audit, or perhaps a recent increasing rejection rate upon incoming acceptance testing, may require increased oversight to provide a comfort level about the quality of products being provided. Firms should attempt to keep the number of their suppliers manageable and refrain from having too many providers of the same product or service. That being said, firms should also shy away from depending solely on one provider who may develop a problem or develop financial problems leaving no alternatives and possible product interruption. Last but not least, firms must plan for problems before they take place, so corrective action planning is a critical element of a successful program. It is important to remember industry's commitment to FDA that suppliers are an extension of the regulated company's quality system. Responsibility for any problems that may develop, and the firm's name and reputation are at stake, so acting responsibly, promptly, and in the interest of the public health is the best policy.

For the reasons discussed above, it is increasingly important that medical device manufacturers adhere to the Quality System regulation- not simply because it is an FDA requirement and expectation, but rather because it makes good business sense. As devices become more complex and new technologies come to light, it is essential that devices are appropriately designed, production and process controls validated or verified, and systems are in place to identify and investigate issues, establish root causes, and develop effective and sustained correction. As the use of outsourcing grows, especially at off-shore suppliers, meeting those fundamental requirements becomes more of a challenge. It is critical in today's environment that manufacturers establish a sound, risk-based supplier quality program to assure that the quality of the products they are purchasing will not have a deleterious effect on their finished devices. The industry committed to FDA that they would monitor their suppliers and consider them an extension of their quality system. Based on recent supplier quality issues, FDA is ramping up its oversight of supplier quality programs to assure those commitments are being fulfilled. ■

Steven Niedelman is Lead Quality System and Compliance Consultant at King & Spalding, LLP, Washington, DC. Readers can contact him at sniedelman@kslaw.com.

Unique Device Identification

Jay Crowley

In 1972, Congress amended the Federal Food, Drug, and Cosmetic Act with The Drug Listing Act. This required registered drug establishments to provide FDA with a current list of all drugs manufactured for commercial distribution. More importantly, the listed drugs are identified and reported using a unique, three-segment number, called the National Drug Code (NDC). Though the writers and implementers of this law could not have foreseen the technology explosion of the last two decades, the ubiquitous use of the NDC number laid the groundwork for an important tool to improve patient safety.

In response to the Institute of Medicine's report "To Err is Human: Building a Safer Health System" and the patient safety initiatives that followed, FDA published the Barcode Rule on February 26, 2004. This rule requires manufacturers to encode the NDC number in a linear barcode on the package of drug and biological products. The barcode enables health care professionals to use barcode scanning equipment in conjunction with computerized medication administration systems to reduce medication errors in hospitals and other health care settings. Essentially, use of the barcode verifies that the right drug, in the right dose, is being given to the right patient at the right time.

The Barcode Rule, however, does not apply to medical devices. In this rule, FDA stated that, unlike drugs, medical devices do not have a standardized, unique identifying system comparable to the NDC number, and that the absence of such a system complicates efforts to put barcodes on medical devices.

Establishing a Unique Device Identification System

Current medical device identification, if used at all, is inconsistently applied and often uses non-standard device identification systems or incorrectly uses standards in different ways. The identifiers used are not necessarily unique or unambiguous – and do not include all necessary levels of uniqueness (such as lot or serial numbers). Because stakeholders cannot rely on the codes applied by device manufacturers, many stakeholders, such as distributors and hospitals, create their own (proprietary) numbering systems, which severely limits our ability to identify devices.

To address this shortcoming, section 226 of the FDA Amendments Act of 2007 requires FDA to promulgate regulations to develop and implement a Unique Device Identification (UDI) System:

> The Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number.

It is important to note that medical devices cover an extremely wide range of products – including traditional hospital-based devices (beds, ventilator), implants, in vitro diagnostic devices (IVDs) – both clinical lab and Point of Care (POC), Health Information Technology (HIT) – eg, EHRs, stand-alone software, convenience kits, certain combination products, and a host of devices used in alternate care environments (dental, home) – which makes implementing such a requirement a challenge.

There are numerous potential patient safety and public health benefits to a properly implemented UDI System. The purpose of UDI is to allow all stakeholders to unambiguously and consistently identify medical devices – throughout the supply chain (to at least the point of patient use) – and throughout the device's life cycle for nondisposable devices (eg, IV pumps). UDI is the foundation for a host of benefits, including more efficient and effective device recalls, improved postmarket surveillance, and better adverse event reporting. There are also a number of other benefits – including improvements to tracking and tracing, supply chain security, identifying devices for disaster/terror preparation and

device shortages, anti-counterfeiting/diversion, reducing medical errors, better device identification in registries, the ability to document specific device use in patient's Electronic Health Records, and the collection of device information in population-based data sets. In addition, FDA believes that UDI will be central to its ability to use the Sentinel Initiative to identify relevant device safety information.

All of these efforts require various systems and processes to be successful. However, the one underlying, fundamental requirement for all these efforts is the need to unambiguously and consistently identify the medical device. Though few people will physically touch or use a device, all stakeholders need consistent, unambiguous identification information about medical devices.

There are three major parts to the development and implementation of a UDI System: 1. Creating the unique device identifier (the UDI code); 2. Applying the UDI to medical devices and their packaging; and 3. The development and population of the UDI Database.

1. The UDI Code:

The Unique Device Identifier (UDI) is a standardized, unambiguous, unique identifying number (code), which identifies a specific device, or one from a specific lot (batch) of devices, and its packaging. The UDI is constructed by concatenating two pieces of identifying information: 1) the [static] Device Identifier, which is analogous to the National Drug Code (NDC) number for pharmaceutical products, unambiguously identifies a specific medical device and its packaging (individual catalogue number), and 2) the [dynamic] Production Identifier, which includes the device's lot or serial number (however the device is currently controlled by the manufacturer), and the expiration date if the device/packaging currently contains one.

A separate Device Identifier is required when it is necessary for the user to differentiate between the various characteristics of a device or when any of these predefined characteristics change or are different in any significant or relevant way. The UDI will be developed and maintained by the device manufacturer (or repackager, relabeler, etc), according to global device identification standards (eg, GS1, HIBCC, ICCBBA). The UDI has no inherent meaning nor can it be parsed. It is also important to note that we expect to phase out the use of NDC/NHRIC numbers on those devices that currently move through the retail pharmacy, such as diabetes care devices.

2. Application of the UDI

The "default" location for the UDI will be on the device's label (the device itself or its packaging) and on all higher levels of packaging. For example, FDA would expect the UDI to be on a box of latex exam gloves, on an infusion pump, and on a sterile catheter's package. The UDI will be both human-readable and encoded in a form of automatic identification technology (eg, linear or two-dimensional barcode, RFID tag). FDA expects to remain technology neutral–that is, not identify a specific technology that must be used (as opposed to only a linear barcode as in the pharmaceutical barcode rule)–but rather allow device manufacturers and their stakeholders to determine which technology works best for specific applications/environments/situations. It is envisioned, however, that the global device standards organization will mange the use of these standards from which device manufacturers would choose – so that we do NOT see a proliferation of proprietary or obscure technologies.

However, there are some devices and situations that require another approach. For example, reusable surgical instruments and some implants would also have the UDI on the device itself – to facilitate traceability of the device over its life.

This requires two changes

- The UDI would need to be directly marked on the device itself (direct part marking through engraving or etching)
- In most situations it would be impractical to have the UDI be human readable, so only 2-D barcodes or other similar small marking technologies could be

used. Conversely, there could be devices or situations, such as home care, where the lack of scanners would necessitate only a human-readable UDI. Additionally, there remain issues to be resolved with how UDI will be developed, applied, and used for kits and convenience packs; combination products; and complex, multisystem ("capital") devices such as imaging devices.

3. UDI Database

As previously mentioned, the UDI is an unintelligent number – the device's "license plate"– which points to more information about the device. To be used, the meaning of the UDI must be knowable to FDA and other stakeholders. Therefore, a critical component of the UDI System is the UDI Database, which will contain static device identifying information and other attributes. The database would contain only "labeled," publicly available information (it would contain NO proprietary or commercial confidential data). Moreover, it would not contain dynamic or market share information (eg, specific lot or serial numbers).

For each device identifier; the database could contain the following types of identifying information:

- Manufacturer
- Brand/Trade Name
- Make/model (unique catalogue number)
- Device model number (or reference number)
- Contact information
- Clinically relevant size information
- Description
- GMDN classification code/term
- Control mechanism – that is, is the device controlled by serial or lot number and/or expiration date?
- Packaging level/number (eg, number of items in the package)
- Labeled as single use or reusable
- Sterility (eg, non-sterile, packaged sterile; needs to be sterilized before use)
- Contains known, labeled allergen (eg, latex)
- Storage conditions (eg, needs to be refrigerated)
- 510k/PMA number
- Listing number (would not be made publically available)

FDA envisions that this list could evolve over time – and could contain specific information for certain device types (eg, specific information for implants).

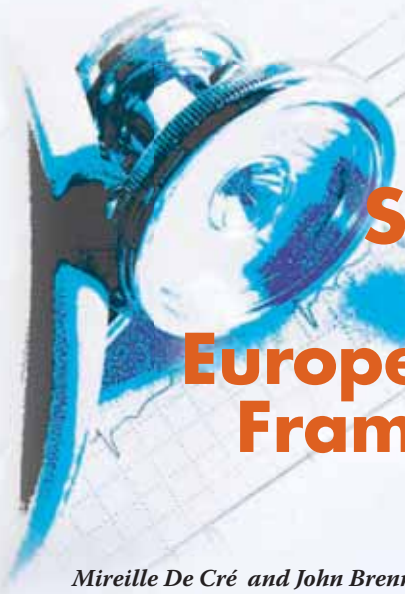
Device manufacturers would be responsible for populating and maintaining the data in the database. There is no cost to the manufacturer to enter data into the database – and data can be submitted either in bulk submissions (via the HL7 SPL standard) and single entry (via web-interface). Third parties (eg, GDSN data pools) may also submit data on manufacturer's behalf. There will be business rules to assure that the UDI is unique and the record is complete.

All of the data in the database would also be freely publicly available and will allow users to download the data for use in their systems.

Summary

FDA believes that a comprehensive Unique Device Identification System will greatly improve the safe use of medical devices. The UDI can help reduce device-related medical errors, improve medical device postmarket surveillance, enhance the effectiveness of device recalls and tracking, facilitate the inclusion of device information in patient electronic health records and other health-related information systems, and promote better device utilization and interoperability. A UDI system can also facilitate inventory control and electronic commerce in devices and assist in combating the counterfeiting of devices. ■

***Jay Crowley** is Senior Advisor for Patient Safety , Food and Drug Administration.*



The Future of STANDARDIZATION in the Context of the European Medical Device Legal Framework and Regulatory Globalization

Mireille De Cré and John Brennan

European Medical Device Framework – Where do we go from here?

The European legislation governing medical devices is constantly evolving. After the relatively recent changes in 2010 that followed the implementation of amending directive 2007/47, the Commission is in the midst of preparing for a new overhaul of the framework.

With the introduction of the Medical Device Directives (medical devices, in vitro diagnostic devices, and active implantable medical devices) in 1993, Europe aimed to achieve better access to safe devices and eliminate obstacles to the free movement of products in the Member States of the European Union. Manufacturers are to follow the appropriate conformity assessment route and demonstrate compliance to the essential requirements (Annex I) relevant to the devices they are placing on the market. The Directives are clear but very general at the same time, and compliance specifics are very much deferred to other tools such as Standards and Guidance documents (the so-called MEDDEVs). This new approach to European legislation was introduced more than 25 years ago. Since then, we have witnessed great industrial growth and competitiveness in Europe, thanks largely to this flexible but solid approach.

All regulatory models have the same fundamental goals of safety. The EU model of implementing those objectives, however, differs significantly from the FDA approach and most other regulatory settings in the world.

In Europe, a large part of the responsibility is placed on the manufacturer. In the case of Class I devices, manufacturers can follow a conformity assessment route leading to CE marking without any intervention of a third-party verifier. In most cases though, notified bodies (NB) play a crucial role in verifying the quality management system and the technical files. Documentation is focused on quality assurance, safety performance, and, to a lesser extent, on demonstrating clinical efficacy. Although the need for clinical evaluation has been more emphasized in the most recent version of the Directive (Annex X), there remains a need for better guidance.

Besides the approval procedure itself and the focus on clinical performance, another main difference between FDA and EU regulations comes in the perception of risk and how to manage it. The FDA reviews specific data about complaints and uses a quantitative method of risk assessment. The EU regulatory system's risk assessment process employs a more qualitative method, based on the entire set of available data. Licensed officers carry out the FDA's risk assessment, while the EU holds companies responsible for it.

The decentralized European model has resulted in a situation where, in particular for higher-risk devices (Class IIb and III), manufacturers can generally enter the market more quickly. This approach is an economic driver and offers industry an advantage that the European legislator is not inclined to abandon.

Since its inception, the European framework has been compared, analyzed, and criticized, not in the least by the European medical device industry itself. A stakeholders consultation organized in 2008 in preparation for the anticipated recast, revealed some shortcomings in the current legislation that are to be addressed in the forthcoming recast. One of the outcomes is the need to achieve a more uniform level of protection across the EU Member States. There are national variations in how the Directives are applied, and these lead to an inconsistent and fragmented approach. Further, there will be a focus on the monitoring of notified bodies. The 80-some notified bodies are appointed by competent authorities and have a wide spread in expertise. Central

oversight and improved information exchange between the NBs should lead to a decrease in forum shopping. Although the decentralized model is overall appreciated, some centralization is asked for when it concerns the regulation of new technologies that have difficulty finding a home under the current legislation. With regard to market surveillance and the centralized bodies, the long-awaited publicly available Eudamed database is expected to hold all information on CE marked devices, notified body assessments, and device vigilance issues.

Where Do Standards Fit in This Current and Future Framework?

The requirements for safety and performance are laid down in the European medical devices Directives and are given a technical, state-of-the art, translation into specific technical solutions to these requirements via harmonized standards. Thus, standardization in the medical device sector must not only be seen in the technical sense but also in the political sense, as a key component of European and national public health policy. Standards provide the translation of the legislative text of the Directives into defined and measurable technical requirements based on state-of-the-art and technically feasible solutions, ie, standards define the technically feasible level of safety.

Manufacturers and other stakeholders, such as notified bodies and regulators, benefit from standardization as compliance to standards facilitates the conformity assessment process. From the consultation effort, it appeared that the two-fold foundation of Directives on the one hand and supporting documentation on the other, will not be affected. In fact, the system should even be strengthened in order to reinforce flexibility and adaptability. Technical standards can be modified more readily in response to technological development, and their role should remain solidly anchored in the compliance process.

We are at a crossroads and need a strong reaffirmation of the political commitment to standardization and the strategic importance of standards. Lately, however, it seems that the strategic importance of standards and standardization is less evident in policy making in Brussels. In certain areas it is even under threat by a desire to return to the "old approach" with prescriptive legalized technical standards. In such an innovative and technically diversified area as medical devices, this is a step firmly in the wrong direction.

Sustainable Cost Model for Standardization

We need to define a sustainable, if possible even global, cost model for standards development and further encourage public funding to support academic and medical device user involvement in the development of standards. There is an increasing trend towards canvassing only industry and industry trade associations to fund Technical Committees and Secretariats of Technical Committees. Industry recognizes that standards development is also in their interest and contributes its fair share through direct participation and the sponsorship of meeting venues and meeting events. In the US, regulators and user groups participate more readily in the standardization process thanks to a concerted funding effort. We have to investigate how that model could be applied to ISO and CEN.

The European "begging bowl" cost model to develop standards does not seem transparent, appropriate, or sustainable.

International versus European Standards

With more and more standards being developed at ISO level (and becoming European Standards via the Vienna agreement) how do we ensure that these International standards still support the European Directives? The future role of CEN would need to be discussed in this regard.

The medical device industry is a global industry; the device sold in Italy is the same as the one sold in China. The New Approach Directives were written in an era of European development of standards to support European Directives, which is not the case now.

Global Regulatory Trends

The European approach in standardization and regulation is a paragon for the global trend. We need our European approach in standardization and regulation to be championed within global regulatory developments.

The activities of the Global Harmonization task force for medical devices (GHTF) are taking a greater

interest in liaison with standards programs and other groups such as WHO. This is to be enthusiastically welcomed since standardization is an important pillar that supports many regulatory systems. Indeed, in a highly regulated sector such as medical technologies, standardization and regulatory processes are fundamentally intertwined.

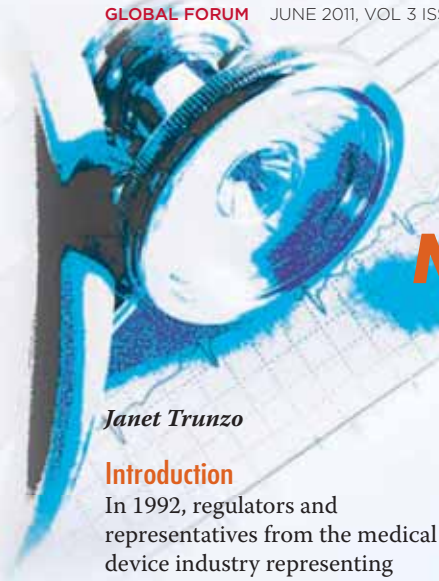
The successful EU-China standards program is a good example and starting point.

We need to reform the way we develop standards and publicly fund the participation of authorities' experts. The same constraints on industry are also apparent for public health authorities. Direct European Member State participation in standards development, technical committees, and working groups is declining. This is of a particular danger in our sector, as it is key that public health policy and requirements are built into standards at the development stage. Without this valuable and necessary input, a standard runs a high risk of non-harmonization at the final stage.

It is important that the reaffirmation of the importance of standards and, in particular, medical device standards, is accompanied by a strong plea that Member States and the Commission increase their participation in the development phase of standards.

Furthermore, harmonized standards and standardization in the medical device sector must not only be seen in the technical sense but also as key components of European and national public health policy. Therefore, the Commission should consider creating subvention mechanisms for national authorities´ expert participation. ■

***Mireille De Cré**, PharmD, is CEO of MDCPartners, and **John Brennan** is the Director, Regulatory Affairs, at Eucomed. Readers can contact Mireille at mireille.decre@mdcpartners.be.*



Global Harmonization Task Force: A History of International Medical Device Regulatory Cooperation

Janet Trunzo

Introduction

In 1992, regulators and representatives from the medical device industry representing three geographical regions of the world–North America, Europe, and Asia-Pacific– established a voluntary organization called the Global Harmonization Task Force (GHTF). Geographical regions were represented by five founding members: European Union, United States (US), Canada, Australia, and Japan. The chairmanship of the GHTF is rotated among the geographical regions every three years. The chairmanship currently resides with Australia and was transferred to Japan in May 2011.

GHTF Purpose

The purpose of the GHTF is threefold. The first is to promote regulatory convergence among the founding members in their practices to ensure the safety, performance, and quality of medical devices. The second is to foster technological innovation and facilitate international trade by minimizing redundant regulations. And the third goal, to serve as an information exchange for countries developing regulatory systems, has emerged as having the most impact in recent years.

GHTF Governance

The GHTF is governed by a Steering Committee (SC) comprised of 24 representatives– eight from each of the three geographical regions with equal numbers of regulators and industry representatives. North America, as an example, is represented by three representatives from the US Food and Drug Administration (FDA), three from the US industry, one from Health Canada, and one from the Canadian industry.

The development of GHTF guidance documents that form the basis for the "GHTF regulatory model" is accomplished through the work of five major Study Groups and various ad hoc working groups. The documents are developed by consensus and then posted on the GHTF website for stakeholder consultation. The five Study Groups and their areas of focus are:

- Study Group 1 - Regulatory Systems Premarket Assessment
- Study Group 2 - Vigilance Reporting And Market Surveillance
- Study Group 3 – Quality System Requirements
- Study Group 4 – Quality System Auditing
- Study Group 5 – Clinical Evidence

Ad hoc working groups have been established by the SC for specific work projects. Such projects could include either the development of a guidance document or a position statement and are expected to be completed within 18 months. Ad hoc working groups on topics such as software, combination products, training, global medical device nomenclature, and the regulatory model have been created over the last several years. In 2009, the GHTF recognized the need for prospective harmonization in the area of unique device identification (UDI) and established an ad hoc working group to address this need. Global regulators including the US FDA are planning to establish UDI regulations and as such recognized the importance of having a common framework to ensure a globally harmonized approach.

Expansion of Membership

Under the current GHTF Roles and Responsibilities procedural document, the founding members have the decision-making capability for assignment of work projects and approval of final guidance documents. Other entities may become involved through the regional member, participating member, or liaison member pathway; each allows participation in GHTF activities at varying degrees. For example, current liaison bodies are the Asian Harmonization Working Party (AHWP) and the International Organization for Standardization (ISO).

Within the last several years, interest in harmonization and the work of the GHTF has escalated as countries have begun to develop their own medical device regulatory systems.

The GHTF has struggled to identify a way to expand membership such that it does not make the Steering Committee too cumbersome to conduct its operations in an efficient manner.

Additionally, other regional harmonization organizations such as the AHWP have recently emerged as major harmonization groups with global membership at 22 countries, including Chile and South Africa.

GHTF Accomplishments

Since its inception in 1992, the GHTF study groups have published over 30 guidance documents covering the basic elements of a medical device regulatory system. Topics include: a risk-based classification system, common definitions and vocabulary, format and content of marketing applications commonly referred to as the Summary Technical Documentation (STED), assessment and review practices, adverse event reporting, quality management system requirements, auditing strategies, use of international standards, common definitions for clinical evidence, and conducting clinical evaluations.

Of particular significance is the establishment of the National Competent Authority Report (NCAR) exchange program. This program allows for the exchange of information regarding serious adverse events among participating members. In order to participate in this information exchange program, a prospective member must meet certain criteria, including the existence of a national adverse event reporting program and successful completion of the NCAR training program. The NCAR training program is managed by the NCAR Secretariat, currently residing with Health Canada.

Recognizing the importance of international standards and their applicability to the GHTF regulatory model, the GHTF has also entered into Memoranda of Understanding with ISO Technical Committees 194 (biocompatibility) and 210 (quality management).

GHTF Challenges

As the GHTF has continued to mature and gain recognition, it has also confronted many challenges. Expanding membership to other countries and regional organizations beyond the five founding members has proven to be particularly challenging. As stated earlier, expansion of membership beyond regional organizations to individual countries remains difficult.

Another challenge is the adoption of GHTF guidance documents by all founding members. For countries with very mature regulatory systems, such as the US, complete adoption of GHTF guidance documents is not straightforward. In these cases, regulatory convergence to the fullest extent possible may be the more appropriate goal.

Long-term maintenance of guidance documents and the GHTF training program also present noteworthy challenges. As with any regulatory guidance document, it may be necessary to regularly update the document to account for changes in regulatory thinking. Guaranteeing that a group of experts with knowledge of the GHTF regulatory model are available to ensure that guidance documents remain current will be a difficult objective to attain going forward. Similarly for GHTF training, development of a training curriculum with a cadre of expert trainers to conduct training for the long term is equally challenging. Partnering with training organizations may be the solution and the GHTF is exploring this possibility.

The concept of prospective harmonization as new medical device regulatory issues arise has always been a challenge for the GHTF. The GHTF has attempted to address these issues by establishing ad hoc working groups. In cases where a founding member has a defined regulatory approach in place, the ad hoc working group may not be the appropriate vehicle to achieve harmonization. This became evident with the Ad Hoc Working Group on combination products where several regulators had established systems involving both their drug and device regulatory units for combination product regulation. As stated earlier, the Ad Hoc Working group on UDI

may be the test case for prospective harmonization.

Future Direction

The future of the Global Harmonization Task Force as it exists today is unknown at present. In February 2011, senior officials from the GHTF regulatory authorities met in Washington, DC, to decide on the future of the GHTF. While acknowledging the significant accomplishments of the GHTF, the group agreed that the next phase in the evolution of the GHTF was to form a regulators-only group to oversee harmonization activity. This regulator-led group will allow for input from all stakeholders including industry, health care professional groups, academia, and consumers.

According to a statement on the GHTF website, "the regulatory officials noted that uniform implementation of the GHTF model at an operational level among founding member regulators had not been fully achieved, and that the current GHTF membership is not reflective of the changing global market in 2011 and beyond." The group further noted that "achieving harmonized regulatory requirements remains a highly desirable objective…" and "…that the best way to achieve such an outcome was to develop a regulator-led harmonization and collaboration group that would allow for more detailed discussion between members."

Achieving a smooth transition from the current GHTF structure to the new regulator-led harmonization group will be vital to ensuring that the GHTF harmonized regulatory model will continue as the global aspiration for medical device regulatory harmonization. ■

***Janet Trunzo** is Executive Vice President, Technology & Regulatory Affairs at Advanced Medical Technology Association (AdvaMed). You can contact her at JTrunzo@AdvaMed.org.*

PROFILE OF

KEN GETZ

Ken Getz is a Senior Research Fellow and Assistant Professor at the Tufts Center for the Study of Drug Development (CSDD) and is the Founder and Board Chair of CISCRP. Ken serves as Program Chairperson for DIA 2011, the 47th Annual Meeting, June 19-23 in Chicago, IL

When did you first think you might be interested in this industry?

As an undergraduate in college, I participated in several phase 1 studies. I remember one in particular when a group of college students were fed a meal and put on a boat in choppy seas around Boston Harbor. Half of the passengers were given an investigational motion sickness drug; the other half received a placebo. I never found out what I received although I probably confounded the results since I grew up sailing with my family in Buzzard's and Narragansett Bays. This initial experience piqued my interest in the industry.

Like most people, I had no prior exposure to clinical research and would have continued on with no connection if not for my stumbling upon these phase 1 studies. The clinical research enterprise desperately needs to create awareness and relevance among not only the adult general population but also among child and young adult populations if it is to engage these communities as potential study volunteers and partners in the research process.

What was the first step in your career in the pharmaceutical development arena?

I worked as an analyst and a project manager at top management consulting firms for seven years. During that time, I focused extensively on projects related to pharmaceutical development. In the mid-1980s and early 1990s, I assisted drug development companies in fast-tracking clinical research study cycle times; reengineering development planning and execution functions; and in integrating more strategic insights into clinical research programs.

One particular project really stands out in my mind: my team assisted a major pharmaceutical company in launching a new drug for treatment-resistant schizophrenics. The investigational drug was very well received by the medical community as it was highly effective, but it caused agranulocytosis–a serious blood disorder–among a very small percentage of patients. The sponsor was planning to shelve the NME. My team advised the sponsor company to bundle drug prescriptions with a blood monitoring service–one of the first times in our industry's history. The drug went on to generate hundreds of millions in sales annually. That is one of the few times I can say that, as a management consultant, we created "real" and measurable value for a client. Don't get me started on management consulting…

What is your undergraduate and graduate training?

I majored in psychology at Brandeis University and took pre-med classes. I majored in managerial economics, management strategy, and marketing at the Kellogg Graduate School of Management at Northwestern University.

What advice would you give to people who want to begin a career in this industry?

I know of few industries that offer as much career opportunity, diversity, and change as this one. Be proactive and get involved. Be opportunistic. Join DIA and become active in Special Interest Area Communities (SIACs), network, attend and participate in DIA programs. Find a passion–there is no shortage of interesting, complicated, and important issues that ultimately will benefit patients and public health.

What is the single most amazing change that you have witnessed while working in this industry?

The single most amazing thing that I have witnessed is that drug development conditions have NOT

been measurably altered in spite of dramatic and profound changes in technology solutions now available; the integral and growing role of outsourcing and new partnering models across the R&D and commercial arenas; new management philosophies, operating structures and practices; globalization; a changing regulatory landscape and bioethics reform; new approaches to training and accreditation; the growing role and need to empower patients and the public.

Yet with all of these profound changes, drug development costs continue to rise 8-10% annually; success rates are consistently low; overall cycle times have not improved; patient recruitment and retention rates are getting worse; the incidence of conflicts-of-interest and the rate of noncompliance and fraud is increasing; and the industry's public image is the worst in our history.

Q&A Are there any job experiences that you have had that you think are especially interesting/ inspiring?

I have the unusual privilege of pursuing my passions in all of my job experiences – from management consulting and CEO of for-profit ventures serving the industry, to principal investigator at the Tufts Center for the Study of Drug Development and chair of a nonprofit organization. I've had the honor and responsibility of dedicating myself to observing and analyzing the clinical research enterprise for nearly 25 years, directing projects examining drug development trends, evolving markets, newly launched companies and ventures created, emerging technology solutions and changing management strategies and practices. I've had wonderful and rich experiences reporting and publishing journalistic stories on all aspects of drug development at CenterWatch; conducting primary and secondary research; authoring peer-reviewed and trade-press articles, books, and book chapters; presenting at conferences, workshops, and meetings at government agencies, foundations, associations, and corporations; serving on a variety of nonprofit and for-profit boards including DIA and roundtable committees at the National Academy of Sciences' Institute of Medicine. I am extremely proud of founding and serving as board chairman for the Center for Information and Study on Clinical Research Participation (CISCRP) – an eight-year-old nonprofit organization dedicated to raising public awareness and understanding of the important role that clinical research plays in advancing public health.

Q&A You have found time to contribute in a major way to DIA. Why?

Throughout my career, DIA has played an essential and central role in providing an invaluable forum for learning, exchanging information, sharing ideas and insights, and for networking. DIA has been my primary "portal" to interacting with global colleagues on every level in every year of my career. I fondly look back at my early career as an analyst in management consulting. I attended a DIA Annual Meeting where Dr. Louis Lasagna gave a presentation at the plenary session. I introduced myself to him and we began an ongoing dialogue and relationship over many years. Who knew that I would join the faculty here at the Tufts Center– Dr. Lasagna's academic group–two decades later.

Q&A How are you able to balance life and career?

Cloning would be immensely helpful. If that is not feasible then will-power and time management are key. It's been a challenge, given the high energy that I put into all that I do, but I set this balance as a top priority in my life. I believe that if I'm working long into the evening or on the weekend, then I must not be managing my time effectively. And frankly, my colleagues all know that family comes first for me. Despite the number of hats that I wear at any given time, I make sure that I play a very active part in all aspects of my family life. And for more than 10 years, I've been able to move my entire base of operations up to northern Maine where my family has a summer residence.

Q&A How does your job impact patients and consumers or others?

I contend that all professionals in the drug development industry ultimately impact patients, consumers and help advance public health. I'd like to think that my original research at the Tufts Center and journalistic reporting at CenterWatch have provided information, insights, and best practice examples that have helped companies better manage development operations. CISCRP's mission is focused entirely on public outreach and education with the goal of assisting patients and the public in making informed decisions about clinical research and engaging the public and patients as active partners in the clinical research process.

Q&A Is mentoring and teaching important to you?

My career in this industry can be characterized in large part by my ability to educate and persuade others to think and act based on evidence and data that I have collected and analyzed.

Mentoring and teaching are critical ways to help others grow, to share ideas, and to ensure continuity. Teaching and lecturing are major responsibilities for me as a faculty member at Tufts CSDD, and Tufts Medical School. And at CenterWatch, CISCRP, and Tufts CSDD, we routinely mentor our staff and provide internship opportunities.

Q&A If you had to do it over again, would you take the same path?

Absolutely. I wouldn't do it any other way. I'm so grateful and appreciative of the path that I've taken. I have deeply enjoyed the ride. ■

Continuing Education at the Annual Meeting

The DIA Annual Meeting is the premier event for professionals involved in the discovery, development, and life cycle management of pharmaceuticals, medical devices, and related products. The program offers a variety of continuing education opportunities to help strengthen professionals' understanding of the value of cross-discipline integration and to foster innovation for better health outcomes.

Participants may receive up to 19 *AMA PRA Category 1 Credits*™ and pharmacy contact hours; 19 nursing contact hours; 19 professional development units, and 1.9 IACET CEUs for attending the 47th Annual Meeting program offerings (including sessions, forums, workshops, symposia). The program offerings designated for credit will be clearly identified in the final program with the statement of CME, Pharmacy, Nursing, or PMI credits offered. IACET continuing education units (CEUs) are offered for all program offerings, except the opening plenary session on Monday morning.

Participants who would like to receive continuing education credits for the Annual Meeting **must scan their DIA name badge at each program offering** to record their attendance, and complete each program offering evaluation form. Participants may scan their badges within 45 minutes after the start of each program offering. **Attendees who do not scan their badge within the allotted time will not be eligible to request the available continuing education credits for that program offering.**

To request a statement of credit for your attendance at the DIA 2011, the 47th Annual Meeting, be sure to scan your badge as described above and after the meeting go to the DIA website at **www.diahome.org**. Select "Continuing Education" from the left menu bar, and then select "My Transcript." You will be prompted for your user ID and password, which will then take you to your transcript. Select the "Annual Meeting" from the grid and choose "Credit Request" in the bottom of the right pane. "My Transcript" will be available for all Annual Meeting participants to request credit on Tuesday, June 28.

New this Year! DIA will be implementing an online evaluation system to collect feedback on all of the program offerings. At the end of each day during the Annual Meeting, participants will receive an email with a link to the evaluation for program offerings attended. Participants are required to scan their name badge to record attendance at each program offering. If participants attend multiple program offerings with the same time frame, the last scanned entry will be recorded. **Additionally, if you would like to receive continuing education credit, you must complete each program offering evaluation form.**

Keep in mind, to receive continuing education credit you must:

- Scan your DIA name badge at each program offering
- Complete an evaluation form for each program offering you attend
- Request a statement of credit by visiting www.diahome.org

If you have any questions about the continuing education credits for this meeting, please talk with a representative at the DIA booth. ■

One of AMERICA'S Best Kept SECRETS:

CHICAGO

The first thing you'll notice upon approaching Chicago is one of the world's tallest and most beautiful skylines. The city stands along the southwest edge of Lake Michigan at the mouth of the Chicago River. Close to 3 million people occupy its 77 diverse neighborhoods, forming a remarkable patchwork. It has been called the Windy City, Chi-Town, and Second City. It's the home of the original deep-dish pizza as well as the birthplace of the skyscraper and of writer Ernest Hemingway (Oak Park).

Chicago has been the proving ground for the sharp improvisational wit of Second City comedians like Tina Fey, Steve Carrell, and countless other comic talents. It has also given rise to the low-rise architectural style of Frank Lloyd Wright and the high-rise style of German transplant Mies van der Rohe.

Like the razzle dazzle of *Chicago*, its theatrical namesake, the South Side of the city still sizzles with excitement in its jazz clubs and bellows with the haunting sound of the Blues. But the raucous underbelly of 1920s Chicago and famed gangsters like Al Capone have long disappeared from the scene.

Today's Chicago boasts 120 miles of bike routes and an 18-mile stretch of asphalt trail along its lakefront as well as 26 miles of lakefront beaches. And shoppers can head to Chicago's north side where the "Magnificent Mile" boasts 500 stores, galleries, and boutiques. In fact, here, shopping reaches new heights with four vertical malls!

When it comes to entertainment, you can enjoy the Joffrey Ballet, watch an avant-garde theatrical performance at the Steppenwolf Theatre, see the Chicago Cubs in full swing at famous Wrigley Field or just for laughs head to The Second City comedy club. Or you can enjoy Chicago's many museums, parks, gardens, and beaches.

FAMOUS CHICAGOANS

include Hemingway, Benny Goodman, and Ray Kroc—the visionary who saw an America on the go and built the world's first-ever McDonald's. Visitors to Chicago can see the original restaurant—now a museum—in Des Plaines (15 mi/24km west of Chicago). And, let's not forget Chicago's "honorary native" Oprah Winfrey.

When it comes to food, chow down on a genuine Chicago-style hot dog with all the trimmings, order a deep dish pizza at Pizzeria Uno, or treat yourself to an Italian beef sandwich drenched in au jus and covered with sweet peppers, all held together by a crisp Italian roll. If you're looking for fine dining, there is definitely no shortage of that either. From the gastronomic delights of Alinea's pricey 12- or 20-course tasting menu to the pure decadence of Hot Doug's chipotle chicken sausage and duck-fat fries, there are literally thousands of restaurants and hundreds that will match your mood and budget.

A City Rises from the Ashes

Long before Chicago became a modern-day city, the area was a trading post and hunting ground for Native American Indians. It was discovered in 1673 by French-Canadian explorer Louis Jolliet, and French missionary Jacques Marquette—however it was not until 1779 that Jean Baptiste Point du Sable, a "free negro" and a trader, built a permanent settlement here. Others soon followed.

Chicago earned city status in 1837. Then, in 1871, the landscape of the Chicago was to change forever following a three-day inferno in which 18,000 buildings and most of the city burned to the ground. During its reconstruction, a new type of building arose: a steel-framed structure that could tower more than nine stories above ground. In 1885, the first skyscraper, The Home Insurance Building, was completed and opened the door to a new age of skyward building!

Rebuilt and stronger than ever, in 1893 Chicago grabbed the attention

Chicago Airport Concourse

of the world with the World's Columbian Exposition.

The 1920s ushered in the Jazz age with greats like Louis Armstrong dominating Chicago's music scene—and, after the Second World War, the Blues came to town and stayed.

FACTOID

Since 1900, the Chicago River has flowed away from Lake Michigan. Thanks to a cleverly engineered 28-mile (45 km) canal, the main and south branches of the river drain away from the lake and into the canal thus protecting the city's principal water source from contamination.

Getting There, Getting Around

Chicago is served by two international airports: O'Hare which is 19 miles northwest of downtown and Midway which is 11 miles southwest of the downtown Loop. Keep in mind when planning that O'Hare is an extremely busy air transportation hub.

Visitors landing at **O'Hare** are 30-90 minutes from downtown by taxi depending on traffic—the ride will cost around $45 plus tip. Public transportation offers an inexpensive option. The Blue Line of the "El" elevated trains, will land you in the downtown Loop in just under 45 minutes and cost just $2.25. Purchase a transit card at the automated vending machines at the station. Look for "TRAINS TO THE CITY" signs and take the Blue Line from the underground concourse. Get off at a stop near your hotel or exit at Washington and Dearborn and take a cab straight to your hotel. The Airport Express Shuttle splits the difference in cost at $27 ($49 roundtrip), and DIA offers a $2 ($4 roundtrip) discount to members making an advance reservation. Call 888-284-3826 and use code DIA. Also, if you are traveling with multiple passengers, the per-person price drops.


Chicago El Train

If you are flying Northwest, Delta, Continental, Southwest, AirTran or Frontier, you will probably land at **Midway.** The cab ride to downtown runs 30-60 minutes and costs $35 plus tip. If you choose to use public transportation, hop on the Orange Line of the El with your transit card and get off at Adams Street and Wabash Avenue, which is not far from the hotels. Once again, the Airport Express Shuttle is a good option—the one-way fare from Midway costs $22 ($39 roundtrip). The same DIA and multipassenger discounts mentioned above apply.

Getting Around

Chicago streets are laid out on a grid, so it's easy to get around—only three streets run diagonally through Chicago: Elston, Lincoln, and Milwaukee. A simple way to maintain your bearings is by keeping an eye on three distinct landmarks: Lake Michigan lies to the east, the Willis Tower is downtown, and the

John Hancock Center is on Michigan Avenue in northern (uptown) Chicago.

Depending on where you are going, water taxis can offer a scenic way to get there. You can board Chicago

Water Taxis

Water Taxis operated by Wendella Boats at their docks along the Chicago River on Madison or LaSalle Street, or at Michigan Avenue or Chinatown. Or look for Shoreline Water Taxis which runs a river taxi between the Willis Tower and Navy Pier, as well as a harbor taxi on Lake Michigan between Navy Pier and the Museum Campus. Tickets are available at the docks or can be purchased on their websites: www.wendellaboats.com or www.shorelinesightseeing.com.

A more traditional means of getting around is via the elevated trains or El with eight lines that crisscross Chicago. The Red Line which runs north-south through Lincoln Park, the Gold Coast, the Loop and the South Side, is popular with tourists. While most of its trains are elevated, the Red Line is an exception and runs underground. Get yourself a free CTA system map at any station or visit www.transitchicago.com, and you should have no problem getting to your destinations.

If you plan on seeing the sights while in town, pick up a copy of the handy "Downtown Transit Sightseeing Guide" at any station. Also, consider purchasing a 1-day ($5.75), 3-day ($14) or 7-day ($23) fun pass that offers unlimited use of the train and bus system. Otherwise, simply use a preloaded transit card that acts like a debit card when using public transportation. Cost with transit card: bus $2.00; train $2.25; train with transfer $2.50.

When heading to the suburbs, the Metra commuter trains are your best bet, Visit www.metrarail.com for more information.

You'll find plenty to see and do while in Chicago including entertaining attractions that may bring back pleasant childhood memories.

Feel Like a Kid Again

Navy Pier (600 E. Grand Ave. at Lake Michigan; 312-595-7437), Chicago's most popular attraction, features a 150-foot tall Ferris wheel and other amusement rides. Here you'll discover a year-round playground for adults as well as kids with a carousel, bike paths, beaches, paddle

RIDE FOR FREE

From Memorial Day to Labor Day, free daytime trolley buses run on four routes from downtown El and Metra stations to the Museum Campus, the Art Institute of Chicago, State Street, Michigan Avenue shopping, and Navy Pier. Look for the green and red Free Trolley signs.

boating, and more. View scientific documentaries in 3D (IMAX Theater; 312-595-5629) or enjoy 150 examples of colored glass art at the one-of-a-kind Smith Museum of Stained Glass. Relax in a greenery-

filled atrium, Crystal Gardens, or enjoy the water's breeze at Olive Park, a nearby respite on the lake.

A wide variety of animals live amidst waterfalls, climbing structures, and other natural settings at the **Lincoln Park Zoo** (2001 N. Clark St.; 312-742-2000; www.lpzoo.org). Here you'll witness the entertaining antics of penguins and one of the world's largest polar bear exhibits. The McCormick Bird House features an array of beautiful birds, including approximately 20 exotic and endangered species. It's the nation's oldest free public zoo.

See glimpses of river, lake, and ocean life at the **Shedd Aquarium** (1200 S. Lake Shore Dr.; 312-939-2438; www.sheddaquarium.org). It's one of the world's largest indoor aquariums. Arrive early for the scheduled dolphin and beluga whale shows in its *Oceanarium*, which replicates the beauty of the Pacific Northwest. Visit the *Caribbean Coral Reef's* sea turtles, glinting tarpon, and barracuda, and get up-close views of predators in the *Wild Reef–Sharks at Shedd*, a re-created Philippine coral reef.

Interested in architecture or art? Learn and see more about each within the city's historical context.

More to See and Do

The Chicago Cultural Center (78 Washington St.; 312-744-6630; www.chicagoculturalcenter.org) is an 1897 building with a Gilded Age interior filled with marble, brass, and mosaics. (Pick up a copy of the *Loop Sculpture Guide*, which lists outdoor art by major names, such as Picasso, Chagall, and Miró.) You'll notice the Art Deco style of the **Chicago Board of Trade** (141 W. Jackson Blvd), adorned with Ceres, the Roman goddess of agriculture. The building has landmark status as does **Macy's** (111 N. State St.)–formerly Marshall Field's Department Store–with its iconic clock. The picturesque courtyard of the Greek Revival-styled **Fourth Presbyterian Church** (126 E. Chestnut St.; 312-787-4570; www.fourthchurch.org) is a great place to rest.

If you would like to view an example of modern residential architecture, visit **The Robie House**. This Frank Lloyd Wright Prairie-style home can be seen in Hyde Park (5757 S. Woodlawn Ave.; 708-848-1976). **The Glessner House Museum** (1800 S. Prairie Ave.; 312-326-1480) is a National Historic Landmark located in the **Prairie Ave Historic District**; this neighborhood was filled with millionaire mansions in the 19th century.

Polar Bear at Lincoln Park Zoo

John Hancock Building

Do you think you might enjoy another vantage point from which to view the city?

Get a birds-eye view of Chicago from the 110 story **Willis Tower** (233 S. Wacker Dr., entrance on Jackson Blvd; 312-875-9447; www.theskydeck.com), formerly the Sears Tower. It provides a panorama of the city as well as views of four states as far away as 50 miles! Feeling adventurous? Enter one of four glass booths protruding from the building to get a view straight down from the 103rd floor! Or you can ride up to the 94th floor observatory of the **John Hancock Center** (875 N. Michigan Ave.; 312-751-3681; www.hancock-observatory.com). It offers the same expansive views, as well as a bar and a restaurant!

Want to "shop until you drop" Chicago-style? Originally named for outstanding turn-of-the-20th-century architecture, the **Magnificent Mile** is now known for its stores: four malls; numerous designer shops; art and antique galleries; and branches of national chains.

Adler Planetarium

While on Michigan Avenue, why not see the famous clock tower on the **Wrigley Building** (410 N Michigan Ave; http://www.thewrigleybuilding.com). It was inspired by the bell tower of Spain's Grand Cathedral in Seville. Or go on a "treasure hunt" and look for pieces from the Parthenon, Westminster Abbey, and the Taj Mahal that are embedded inthe exterior wall of the **Tribune Tower** (435 N. Michigan Ave.; www.Chicagotribune.com).

Two historic landmarks located in the **Gold Coast**, Chicago's expensive residential area, somehow survived the Great Chicago Fire of 1871. The **Water Tower** (806 N Michigan Ave. at Pearson St.) built in 1867 which today houses a small art gallery and, across the street, the still-operational **Water Works Pumping Station** (163 East Pearson St. at Michigan Ave.) which houses a theater company (312-337-0665; www.lookingglasstheatre.org) and a visitor center (877-244-2246).

DISCOVER CHICAGO'S SPECIAL INTEREST TOURS

www.chicagochocolatetours.com

www.gangstertour.com

www.ghosttours.com

www.tourblackchicago.com/blog

Chicago's Museums

Chicagoans have been in the forefront of developing and maintaining world-renowned cultural institutions. See for yourself!

The innovative **Adler Planetarium & Astronomy Museum** (1300 S. Lake Shore Dr; 312-922-7827; www.adlerplanetarium.org) opened in the 1930s. Today, see the constellations

The Clock at Marshall Field

Kids of all ages also enjoy the "Great Train Story" model railroad exhibit.

If you like modern art, visit the **Museum of Contemporary Art**, (www.mcachicago.org) which offers rotating exhibits. Other specialized museums in Chicago include:

- www.dusablemuseum.org - African-American history
- www.nationalmuseumofmexicanart.org
- www.spertus.edu - Jewish history and culture
- www.swedishamericanmuseum.org

Chicago's parks house many of its museums and outdoor sculpture.

as they appear at night, experience how it would feel if a meteor hit earth, or take a virtual reality trip through the Milky Way. Fascinating exhibits include "From the Night Sky to the Big Bang," which features instruments of astronomy, and "Galaxy Wall," a 140-foot-wide photographic composite made of images taken from a space telescope as it orbited the earth.

The **Art Institute of Chicago** (111 S. Michigan Ave.; 312-443-3600; www.artic.edu) possesses the largest collection of Impressionists and post-Impressionists outside of France. Also, don't miss modern American masterpieces ("Nighthawks" by Edward Hopper and "American Gothic" by Grant Wood) or the light-filled modern art wing with works by Picasso, Matisse, and Pollock. The museum offers many choices: Japanese ukiyo-e prints, ancient art from Egypt and Greece, miniature rooms filled with historically accurate furnishings and even a 19th century glass paperweight collection.

Learn about the city's evolution from its days as a trading post at the **Chicago History Museum** (1601 N. Clark St., Lincoln Park; 312-642-4600; www.chicagohs.org). The fascinating Hall of Dioramas includes a re-creation of an 1890s El train station, while the Costumes and Textile Gallery highlights historic period clothing, including couture gowns by designer Christian Dior. Learn more about the World's Columbian Exposition of 1893 and view portraits of national leaders, including the state's own Abraham Lincoln.

Learn and observe the interrelationships between living things and objects at the world-renowned **Field Museum of Natural History** (1400 S. Lake Shore Dr.; 312-922-9410; www.fieldmuseum.org). These include a 67-million-year-old Tyrannosaurus named "Sue," 5,000-year-old hieroglyphics, mummies, and a re-created Egyptian marketplace as well as jade artifacts from China that span 8,000 years.

The **Museum of Science and Industry** (57th St. and Lake Shore Dr.; 800-468-6674 or 773-684-1414; www.msichicago.org) is one of the largest of its kind in the world and was the first to offer interactive exhibits. Here, take a trip through a re-created 1930s coal mine and walk through the replicated chambers of a 20-ft (6m) heart. Watch in amazement as twelve robots assemble 300 toy tops in one hour.

Lincoln Park

A City of Parks

Business people and city planners used their influence to preserve the Lake Michigan waterfront from commercialization. As a result, there are more than 7300 acres of parkland and 552 parks in Chicago.

Grant Park (www.chicagoparkdistrict.com; 312-742-7529) is one such urban oasis.

Grant Park

Visitors enjoy the water displays of the Versailles-inspired Buckingham Fountain (Columbus Dr. and Lake Shore Dr., east of Congress Plaza), outdoor art, and the park's "museum campus" which includes the Adler Planetarium, the Shedd Aquarium and the Field Museum.

The path along the six-mile waterfront strip of **Burnham Park** connects Grant Park at 14th street and Jackson Park at 56th Street. This area, named for Chicago's influential architect, offers a chance to enjoy a wonderful view while strolling by the lake.

The 24.5 acre **Millennium Park** (201 E Randolph St., between Michigan Ave. and Columbus Ave.; 312-742-1168; www.millenniumpark.org) was reclaimed from industrial blight and completed in 2004. It includes **Lurie Garden** (http://luriegarden.org/; E. Randolph St. between Michigan Ave. and Columbus Ave.; 312-742-1168), **Cloud Gate** (Washington St. and Madison St.), Anish Kapoor's kidney shaped sculpture, affectionately known as the "bean" which reflects the city skyline and **Crown Fountain**, Jaume Plensa's interactive, interdisciplinary must-see sculpture, consists of two 50-ft-high glass towers, a fountain and live video images.

Lincoln Park is the city's largest park with 1200 acres. It runs along Lake Michigan north of the Magnificent Mile and includes a zoo and other entertaining diversions, including:

- the late 19th-century Lincoln Park Conservatory (Fullerton Ave. at Stockton Dr.; 312-742-7736), filled with palm trees and rubber trees, ferns and century-old orchids
- **Montrose Beach** (4400 N. Lake Shore Drive) and **Kathy Osterman Beach** (W. Hollywood Dr. and N. Lake Shore Dr.; 312-742-3224)
- **Café Brauer** (now a catering hall), a 1908 historic landmark, and an example of the Prairie School of architecture, with a wonderful city view, refreshment concessions, and a pond with rental boats
- **Peggy Notebaert Nature Museum** (http://www.naturemuseum.org; 2430 North Cannon Dr.; 773-755-5100), known for its outstanding butterfly house, also displays wildflowers, prairie grass and native Chicago birds from 1900

Sports

If you're a sports enthusiast, you won't be disappointed. Here's a rundown of where you can go and what you can do in the Windy City.

Tennis – If you feel like hitting a few tennis balls, get into the swing at Chicago parks public tennis courts. Go to www.chicagoparkdistrict.com

Buckingham Fountain

and click on the tennis icon under CPD Resources to learn more.

Golf – Chicago has several nine-hole and 18-hole golf courses. Visit www.cpdgolf.com to learn more.

Kayaking – Feel like paddling? Kayak Chicago (630-336-7245; www.kayakchicago.com) offers beginning lessons and lakefront paddles. It's located at Montrose Beach in Lincoln Park.

Biking – Do you prefer to get around on two wheels? Start by getting a biking map from the City Dept. of Transportation (www.chicagobikes.org). To rent bikes visit www.bikeandroll.com/Chicago or call 866-736-8224.

Baseball – Watch the **Chicago Cubs** in action at Wrigley Field (1060 W. Addison Street; 773-404-2827 or 866-652-2827; www.cubs.com). Buy tickets in advance or try the box office two hours before the game (standing room only). Want to get a view of the game from atop neighboring buildings; then visit www.goldstar.com. **White Sox** fans pack the stands in **US Cellular Field** (formerly Comiskey Park) at 333 W. 35st Street; for tickets to a game, visit www.whitesox.com, call 312-674-1000 or go to www.ticketmaster.com

Touring Chicago

Looking for some interesting ways to see the city? Visit these websites to learn more:

- www.cruisechicago.org/tours -- the Official Chicago Architecture Foundation River Cruise (112 E. Wacker Drive) or call 1-847-358-1330 for reservations
- www.tallshipwindy.com -- take a Chicago sailing adventure aboard a schooner ship; for more information call 312-451-2700
- www.chicagoneighborhoodtours.com – Motorcoach walking tours (Chicago Cultural Center; 77 E. Randolph Street; 312-742-1190)
- www.chicagotrolley.com – self-guided; hop-on, hop-off tours
- www.bobbysbikehike.com – bike tours (312-915-0995)
- www.bikeandroll.com – bike tours and rentals (located within McDonald's Cycle Center in Millennium Park; 866-736-8224 or 312-729-1000)
- www.wateriders.com – kayak tours and rentals (312- 953-9287)

Chicago Nightlife

Planning a night out on the town? Make your first stop a visit to these helpful websites:

- www.choosechicago.com – check out what's happening during your stay in Chicago
- www.chicagoplays.com – get a comprehensive list of live Chicago theater performances
- www.hottix.org – unsold tickets go for half price the day of the show; you must pick up tickets in person at 163 E. Pearson St. or 72 E. Randolph St. (312-751-1876)
- www.secondcity.com – if you're in the mood for laughs, this renowned comedy club is a must-see

If you're searching for the sound of the Blues, head to the Southside of Chicago and go to **Buddy Guys Legends** (754 S. Wabash Ave., Loop; 312-427-1190; www.buddyguys.com) or visit the **Checkerboard Lounge** (5201 S. Harper Ct.; 773-684-1472). If it's jazz you're looking for, then head uptown to **Green Mill** and step into a former Roaring 20s speakeasy with '30s and '40s inspired jazz sounds (4802 N. Broadway, Lakeview; 773-878-5552; www.greenmilljazz.com). Or, find more top ten jazz and blues venues by visiting: http://www.10best.com/destinations/illinois/chicago/nightlife/jazz-blues-clubs/.

If you plan to extend your stay after DIA 2011, be sure to get over to Grant Park for the **Taste of Chicago** which runs June 24-July 3 (dates are subject to change). It's the world's largest outdoor food festival. Or take in a free concert any Wednesday, Friday or Saturday in June at the Jay Pritzker Pavillion in Millenium Park at the north end of Grant Park.

Let's Get Together

We hope you'll join your fellow industry professionals at DIA 2011, the 47th Annual Meeting, June 19-23, at Chicago's McCormick Place. Visit Chicago, home of medical product innovation, and enjoy an exchange of knowledge that can have a positive impact on future patient care and outcomes. Click on the Chicago meeting icon at www.DIAhome.org for further details. See you there! ■

Executive Roundtable Highlights

Innovative Outsourcing Track

Executive Roundtable Highlights No matter how long you've worked in the pharmaceutical or biotech industries, you've seen tremendous evolution and growth in the practice of outsourcing. This year's program committee has correspondingly expanded and refined our Annual Meeting outsourcing track to more fully reflect this evolution and growth, and will debut the new **Outsourcing Strategies & Innovative Partnering Models track at DIA 2011: Convergence of Science, Medicine & Health** in Chicago.

This retooled track includes *A Close Look at Clinical Outsourcing Strategies: An Executive Roundtable* scheduled for the afternoon of Wednesday, June 22. In this forum, executives from three companies will present their company's respective clinical outsourcing strategies, the circumstances and rationales that culminated in these strategies, and how they expect their strategies to evolve over the next several years. This executive roundtable will be chaired by Patricia Leuchten (The Avoca Group, Inc.), and feature Peter A. Carberry, MD, MBA (Astellas Pharma Global Development, Inc.), Craig Coffman (Endo Pharmaceuticals), and Mitchell A. Katz, PhD (Purdue Pharma L.P.) as panelists. Patricia will also present "the industry perspective" during the Tuesday June 21 afternoon session *An Innovative Strategic Partnering Relationship: Can This Approach Revolutionize Drug Development?*

"A big theme of this year's meeting is innovation. Our industry has moved into more mature and innovative approaches for outsourcing and partnering. I'm excited that we have speakers and executives who match up with this movement toward innovation," Patricia explained. "Certainly, since I started 20 years ago, but even within the past five to 10 years, the industry has really changed and evolved. Innovation is a great theme for the 2011 conference as a whole; we're going to be hearing about innovative and interesting approaches to partnering in the outsourcing track that are aligned with that theme." She spoke further about DIA 2011's new approach to outsourcing and partnerships in the following Q&A.

Q&A Why did you agree to serve as co-chair, and what do you hope to accomplish by serving as co-chair, for the DIA 2011 Outsourcing Strategies & Innovative Partnering Models track?

I started in the industry in 1987 and have been going to the DIA Annual Meeting for about 20 years. It's always been striking to me how the DIA organization is able to pull off such impressive events year after year. Part of me just wanted to see what happens "behind the curtain," so to speak. I was an attendee early on and learned so much by going to those sessions and I wanted to give back by volunteering. It's been very gratifying for me to have chaired a number of sessions, and to have had several presentation abstracts chosen, over the years. So it's a combination of wanting to volunteer and provide some of my own expertise to an organization that contributes such a great service to our industry.

So much of what I do in my profession is tracking trends in clinical outsourcing – staying on top of what's happening and what's important in the industry, and what pharmaceutical and biotech companies as well as CROs and other types of service providers are interested in. I wanted to transfer all this knowledge by providing input to DIA programming. I have a good handle on the hot topics, what is important right now in clinical outsourcing, and how the relationship dynamics between sponsors and CROs have changed over the years. Serving on the program committee provides an opportunity to share some of this information and knowledge. Obviously, DIA is a terrific vehicle for getting this information out there.

What new, expanded, or different topics are included in this year's Outsourcing Strategies & Innovative Partnering Models track that might have been part of a different track, or perhaps not even addressed, at previous Annual Meetings?

Track chairs have a pretty challenging job of having to pare down hundreds of abstracts into what we feel is going to be most interesting, most pertinent, and a well rounded track. I was told that, in years past, the outsourcing track was the "catch-all" for anything that was submitted by a CRO or had "outsourcing" in the title. We've spent time this year focusing the track and communicating this focus so that we would receive abstracts that fit specific themes.

And so we focused the track on outsourcing strategies, relationship dynamics and innovative alliance models, including models that are outside of the traditional sponsor-CRO partnerships. We included some sessions on biopharmaceutical alliances, alliance management between two pharmaceutical companies, or between a pharmaceutical and a biotech company, and best practices associated with those types of alliances. We also looked at the partnership dynamics between sponsors, CROs, and academic organizations.

We honed in on: "What are the innovative models that currently exist in the industry? How are different types of companies approaching partnerships? How has relationship management come into play in terms of partnering?" One theme of this year's track will be a comparison of the different types of partnering models; for example, the high-profile, big pharma model of working with large international CROs, compared to the approach that small- to mid-size companies and virtual pharma might take to outsourcing and partnerships. Attendees will see a good mix of very specific examples and case studies of the different types of innovative partnering models prevalent now in the industry.

We made sure that abstracts which came across our desk in the outsourcing track that did not fit with the themes of outsourcing strategy, relationship dynamics between sponsors and CROs, alliance management, innovative partnering, or issues around partnering, were considered in other tracks. So, for example, the project management, regulatory affairs, and quality assurance tracks, received abstracts from us for their consideration. In the beginning, when the abstracts start coming in, it feels a bit daunting for the track chairs, because we are literally reading hundreds of abstracts, so having clarity around the theme and vision of each track is essential. We work very closely with each other to make sure that all submitted abstracts are considered carefully

How does expanding this topic reflect current regulatory dynamics?

One of the big issues that our industry is focused on right now is CRO oversight and how the relationship dynamics between sponsors and CROs come into play with the quality of outsourced clinical trials and regulatory compliance. One of my colleagues from The Avoca Group, Dr. Denise Calaprice, will chair a session focused on quality and CRO oversight. Recent industry data will be presented and some of the questions that will be answered in that session will include: "Are there issues with the quality of outsourced trials? If so, how can they be characterized? And importantly, how can sponsors and CROs work effectively together to achieve their mutual goals of ensuring high quality and efficiency in outsourced clinical trials?" We believe that regulatory and QA professionals from sponsors and providers as well as the executive management from these companies would be very interested in that session. The session will be interactive and the audience will be engaged in asking questions and making comments about their own experiences. There will be senior executives on the panel from Otsuka, Lilly, and Covance, along with a representative from the FDA, answering questions from the audience, responding to Avoca's data, and providing their own viewpoints on how partnering and relationships between sponsors and CROs impact quality, and how close partnerships could actually help to avoid risk and achieve very high quality in outsourced trials.

You will also serve as chair for the special DIA 2011 "A Close Look at Clinical Outsourcing Strategies: Executive Roundtable" forum. May we ask you to describe the purpose, and preview anticipated discussion topics, for this forum?

Peter Carberry, Mitch Katz, and Craig Coffman will serve on this panel. Part of the reason that those particular individuals were selected is that each of these companies relies heavily on CROs, and the companies can be categorized as small- to mid-sized pharmaceutical or biotech companies, but they all have different philosophies for outsourcing and working with CROs. It will be interesting for the audience to compare and contrast these strategies, what these companies look for in CROs, and their preferences, to get a handle on how "one size does NOT fit all" when it comes to small- to mid-sized pharma and biotech outsourcing.

At Avoca, we've collected some data on the outsourcing practices of small- to mid-sized companies, comparing those to big pharma companies, which I will present to get a reaction from our panel and from the audience. The session will focus on what small- to mid-sized companies are looking for in CROs. I'll be asking the panel some provocative questions about their criteria for selecting companies, how they go about choosing a CRO partner, the thinking behind their strategy for outsourcing, and what has led them to take the particular approach that they're taking. We're going to make sure that we leave plenty of time for questions and comments from the audience.

A lot of CROs have a misperception about small- to mid-sized companies. Some CROs think that they're only looking at small- to mid-sized CROs, that they're small companies and want to work with companies of similar size and scope. It will be interesting to show that this is true in some cases but certainly not in all cases. When Peter Carberry presents his model for outsourcing, it will be eye-opening in terms of the strategy and what comes into play in the decisions about moving forward with a particular strategy.

We always gather perception data from both sides – from sponsors and providers – and sometimes there is alignment, but sometimes there's a real disconnect between perceptions. What I'll do is highlight areas where there seems to be a bit of a disconnect or a lack of alignment, have the panel address that, and get the audience talking as well. I'm sure it will be a lively and interesting session. ■

CISCRP Q&A with DIA

Although the "Voice of the Patient" will be heard throughout many of the educational opportunities available at our upcoming **DIA 2011** Annual Meeting, it will most profoundly resound through the session *Voice of the Patient: Stories That Touch Us* scheduled for 8:00AM on Tuesday June 21.

In this session, a panel of patients who volunteered to participate in clinical trials will share details about their clinical trial experience, what prompted their interest in participating, and the obstacles or challenges they encountered with friends and family when they told them about their participation.

This panel discussion will be chaired by Diane Simmons, President & CEO of the Center for Information and Study on Clinical Research Participation (CISCRP). At last year's Annual Meeting, CISCRP presented the special evening session *Voices of Medical Heroes: A Family's Journey of Hope* with John Crowley, whose children suffer from a rare and nearly always fatal neuromuscular disorder and whose family story was told in the film *Extraordinary Measures*.

CISCRP's collaborations with DIA include providing the special "Patient Perspective" feature articles that conclude each issue of the *Global Forum*. Closing each *Global Forum* with this "perspective" gives patients, our ultimate customers, the final word in every issue. Diane shared her thoughts on how DIA and CISCRP can continue to work together to advance medical science for the benefit of these and other medical heroes, in the following interview. "We're working shoulder to shoulder on caring about what happens to people, and that's why these are important conversations to have," Diane said. "It's based on relationship building, and sharing what we've learned."

For our readers who may be unfamiliar, would you please introduce and describe the purpose and activities of The Center for Information & Study on Clinical Research Participation – CISCRP?

We are an independent, nonprofit organization. Our mission is to promote greater awareness and understanding of clinical research participation and the role that it plays in public health. In order to make that happen, we educate, inform and empower all the stakeholders in the clinical research enterprise; that includes not just the public and the patients but also medical and research professionals, the media and policy makers, all those who are involved in advancing medical science.

You will serve as chair for the special "Voice of the Patient" Tuesday morning plenary session. Would you please also introduce and describe the purpose and presentations for this session?

This panel of patients will be diverse and represent different therapeutic areas. Most importantly, this is a chance for research professionals to see their world from another vantage point. Some professionals in attendance may have interactions with patients, but it's rare that a patient feels comfortable enough to really open up and give details about their experiences as a clinical research volunteer. This is "the whole truth, and nothing but the truth." This is the patient explaining the impacts of a protocol, or making suggestions about what could have been better from the volunteers' point of view. This provides a very important learning for these professionals, to sort of "stop the world" and listen to the voice of the patient.

Our panel includes Cindy Hahn, whose daughter Elena has Alagille Syndrome. She's quite impassioned about Elena's experience, and there are lots of lessons for professionals to learn directly from the mother of a patient. We're calling upon others who are part of your Patient Fellowship program. Dr. Jürgen Venitz from the Myasthenia Gravis Foundation, who was a healthy clinical study volunteer early in his life, will tell his story. He has a very interesting perspective – although he is a scientist, he is going to wear the hat of the patient, and his story is powerful. We are bringing in a number of therapeutic areas because different trials cause patients to have different experiences, and we can learn from all of them. It looks like we have a panel of five representatives and it will be nice to hear them interact with each other as well as with the audience.

Q&A CISCRP also provides a special "Patient Perspective" section to our *Global Forum* member newsmagazine. How are the subjects for these articles selected, and how are they written?

We know these patients because they've become part of our world through our grassroots educational programs known as "Aware for All: Clinical Research Education Day," which are offered across the United States. At each of these programs, patients tell the story of their participation in clinical trials – similar to the session we're presenting at **DIA 2011** – directly to the public and patients in various communities. Many of these stories have had such an impact that we're glad to repeat them and give them a wider audience through your *Global Forum*.

We have another way of helping the public and patients, through SeachClinicalTrials.org. There are people who have medical conditions and are looking for help in finding a trial that might be right for them. Through this service, we interact with a number of patients, and in the course of helping them find the trial that's right for them, we learn details about their lives and their search, and then follow up with them to gather more information about their experience. We have to be somebody that they trust in order to gather the kinds of details that they share.

Q&A Are there certain characteristics that patients who agree to participate in clinical trials seem to consistently share or is everyone's story more unique and different?

A number of focus groups have explored this, and we're very clear about the characteristics that are shared. Certain motivations serve as a blueprint for those who choose to be, and choose to remain, in trials.

First, they want to feel that they're taking control of their medical condition and their well-being, so they're very invested in their own wellness and care.

Beyond that, they want to build a personal relationship with the study staff. That interaction is critical and makes a difference in whether or not a person gets to the end of the protocol, which may be difficult to tolerate or may be very long. If they have that relationship with the study staff, they stay in there.

Plus other things that are so obvious that we take them for granted but they don't always happen: People want to be treated as human beings. Those who, in their experiences, have been referred to as a volunteer or they're recognized for their volunteerism, or they're thanked for their contributions to the trial, those are the ones who stay involved. But when they're treated like a word that is so commonly used – subjects – they don't want to be part of the process. They don't like thinking of themselves as "subjects." If it's been reinforced over and over again that their participation will make a difference, and they understand that, and when they realize that, "This trial might not help me personally but I know that I'm helping the next generation" – when they have that understanding, there's almost a glow. They really appreciate being part of the clinical research process.

Q&A What is the biggest common public misconception about clinical trials and drug development, and how can organizations such as CISCRP and DIA work to overcome this misconception?

I like to think of it not so much as a misconception as a real problem:

There's a lack of awareness, and the public is walking around with a distrust that gets in the way of greater participation in clinical research. So CISCRP has been an advocate of "education before participation" – that's our motto. It's going to take a level of education and outreach to increase public trust and their understanding.

There are ways that we can work together across the industry – DIA helping us with access to your annual meeting attendees in Chicago, and with access to your members through your *Global Forum*, for example. But there is a critical need for general, broadly based outreach and education to assist in reversing the erosion of public trust. CISCRP created the *Medical Heroes* public service campaign to encourage people to think differently about clinical research and to transform the image of the participant from "guinea pig" to Medical Hero. In the long term, improved recruitment rates depend on the implementation of this type of campaign.

As an industry, we need to embrace this. We need to do what the milk industry did with their "milk moustache" campaign that advocates for the value of milk. Shouldn't we stand together as an industry and advocate for the value of being a clinical research volunteer? ■

Join Diane at *Voice of the Patient: Stories That Touch Us* and hear from:

- Cindy Hahn, parent of a child with the genetic disorder Alagille Syndrome (appearing through DIA's Patient Advocacy Fellowship)
- Janet Pepitone, patient with the genetic disorder Friedreich's Ataxia
- Rosemarie Rogers, African American breast cancer survivor
- Dr. Jürgen Venitz, patient with the chronic autoimmune neuromuscular disease Myasthenia Gravis (appearing through DIA's Patient Advocacy Fellowship)
- Frances Waldynski, patient with the motor system disorder Parkinson's Disease

Diane Simmons

Devices Highlight ExpandedProgram

Months of effort coordinated by the Annual Meeting Program Committee and Medical Devices Task Force will culminate in Chicago, as *DIA 2011: Convergence of Science, Medicine, and Health* will be the first DIA Annual Meeting to dedicate a complete content track to medical devices and drug/device combination products.

"The Medical Devices track marks an important milestone in DIA's drive to expand resources beyond our traditional base in pharmaceutical and biopharma products to provide value in additional subject areas of key importance to our global constituents," explains Paul Pomerantz, DIA Worldwide Executive Director. "Many medical devices are currently used as drug delivery systems and as diagnostic companions to pharmaceutical treatment. These are closely related to pharmaceutical products, and fall increasingly under similar regulatory constraints. They also represent tremendous opportunities for our global stakeholders to develop and deliver innovations that can simultaneously benefit the world's patient populations and increase the value of their products."

"With a long-standing tradition of being a neutral forum for knowledge exchange between industry, government and academia, DIA is uniquely positioned to continue to bring these forces together to address the increasing complexity of the technology and the global regulatory and healthcare environments as they pertain to medical devices and combination medical products," said Steve Caffé, former Chair of the DIA Medical Devices Task Force. "I am delighted that DIA can play an important role in uniting all who strive to find solutions to accelerate the pace of innovation and improve patient access to medical products globally."

The medical devices component of DIA 2011 actually begins before the Annual Meeting, with the half-day tutorial *A Device Primer: 510(k)s, PMAs & IDEs* on Sunday 19 June, instructed by Barry S. Sall.

The Medical Devices track will feature sessions focused on specific product types and industry/regulatory regional perspectives:

Product Types:

- *Implications of Shifting Regulations for Combination Products: A Comprehensive Review,* will examine how regulations – and interpretations of these regulations – are changing how drug/device combination products are classified, along with the manufacturing and safety implications of these changes; Steven Cox will serve as chair.

- *Roadmap to Efficient Development of Companion Diagnostics* will explore the business, clinical, and regulatory aspects of companion diagnostics and combination products, and will be chaired by Libbie J. Mansell, PhD, MBA, RAC.

Regional Sessions:

- *Recent Reformation on Medical Device Regulatory Systems in the Asia Pacific Region* is planned to include regulatory representatives from the Korean Food & Drug Administration and the Food & Drug Administration, Department of Health, Taiwan; Dr. Chih-Hwa Wallace Lin will serve as chair.

- *Revision & Recast of the Medical Device Directives: Where the Pressures Lie for Change,* presenting competent authority and notified body perspectives on the most recent changes to the European Union's Medical Device Directives, chaired by Amanda Maxwell.

- *Understanding Medical Device Trial Regulation & Operational Challenges in Latin America,* a clinical and regulatory overview of timelines and guidelines for conducting medical device clinical trials in Latin America, chaired by Professor Cristina Nunes Ferreira, MBA.

International Harmonization?

How can clinical, industry, regulatory, safety, and related professionals navigate such a turbulent landscape of approval and postmarketing requirements for medical devices? *International Harmonization Pathways for Medical Devices* will share strategic perspectives on these and other key issues. Steve Caffé, MD will serve as session chair. ■

DIA 2011 SPOTLIGHTS

Promise & Problems of Social Media

Although new digital media and networking technologies seem to change the electronic landscape of the pharmaceutical, medical device, biotech, and related industries almost daily, one underlying premise remains unchanged: Social media – more specifically, the use of social media by these health care industries and communities – is here to stay. To help navigate this landscape, the DIA 2011 Annual Meeting Product Advertising & Communications Track will present a special discussion forum on *The Problems and Promise of Using Social Media to Improve Patient Care* on Wednesday, June 22. Through these discussions, marketing professionals will describe industry efforts to reach patients, caregivers, and doctors through various digital and social media. From their related perspective, legal and regulatory experts will overview the evolving social media regulatory environment including FDA policy, plus public and private legal concerns raised by the public, the plaintiffs' bar, and state and federal law enforcement agencies.

This panel will be chaired by John F. Kamp, JD, PhD (Coalition for Healthcare Communication), and will feature Sharon Callahan (The Vue Group, LLNS), Stuart P. Ingis, JD (Venable LLP), and Mike Myers, MBA (Palio, an inVentiv Health Company) as panelists. Christopher M. Schroeder (HealthCentral) will serve as the forum's special speaker. After his remarks, each panelist will make their own presentation; the session will conclude with questions from the audience. While preparing for this discussion forum, Christopher and John shared their perspectives on these topics with the *Global Forum*.

Q&A As CEO and a member of its board, may we ask you to introduce and overview HealthCentral.com for our readers who may be unfamiliar?

CS: HealthCentral empowers people to improve and take control of their health and well-being through more than 35 condition- and wellness-specific interactive health experiences, where people who have been through a health situation can share their stories and counsel others. While clinical and medical resources and exchanges remain important, by far the most important revolve around how we live our lives on a day-to-day basis as spouses, parents, loved ones, friends, employees, and so on. As we know, we all rely on medical professionals to help us with critical medical treatment and advice in the off-line world, but it's loved ones and folks who have "been there" that not only help us get through or rise to a circumstance, but help us to feel empowered and that the actions we take matter and have impact. This, in my view, is the real revolution in health: We are all co-pilots when it comes to our health care, with medical professionals and with each other.

Q&A Participants come from literally every skill/discipline and management level, from industry and academia and regulatory agencies, and from every region of the world, to attend our Annual Meeting. What messages do you hope to deliver to these professionals through your special forum presentation?

CS: To be the patient that they seek and, at some point in their life, are. So often we all desire –for very good and thoughtful reasons – to control how our organizations participate in health care. However, we now live in a world where other conversations are happening among hundreds of thousands and millions of patients all comparing notes and experiences and ideas to become more healthy. That genie will never go back in the bottle. All of us are using technology for these purposes ourselves! The key is for all of us to ask, "How would WE feel if our personal engagement with a given organization was this way?" This seems very simple, but it is very hard. Being the patient that we ourselves seek provides the perfect "gut check" for determining if the way our organizations enter these

conversations is truly impactful, as opposed to control-oriented or even defensive.

Q&A As Executive Director, may we ask you to introduce and overview the Coalition for Healthcare Communication for our readers who may be unfamiliar with it?

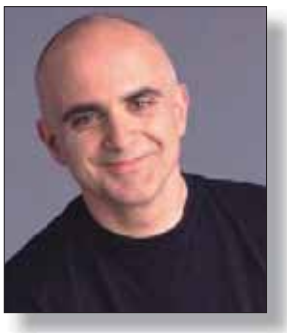
JK: We are a trade association of medical publishers and communication companies. Our members focus on the delivery of health care information to doctors and patients on behalf of drug, device, and bio companies. We believe that medical communication is key to the delivery of effective, efficient health care in America: A pill is just a poison unless delivered in an envelope of information on how to use it safely and effectively.

Q&A For numerous reasons, social media continues to be an industry and regulatory "hot topic." You will serve as chair for a special forum titled "The Promise & Problem of Using Social Media to Improve Patient Care." May we ask you to please briefly preview this forum and some of the topics that you hope to address?

JK: The Internet and social media are now the primary source of health care information for patients and caregivers, and are increasingly important communication vehicles for health care providers. We intend to focus on the promise and problems of these media, especially as consumers and health care providers depend upon them increasingly for information and social support. Panelists will trace the growth in use and types of use of these media, including the incredible growth among older citizens. Media experts will focus on uses and potential uses, and highlight some of the more creative, innovative, and effective recent programs. Other experts will explore barriers to use, including concerns about FDA and other legal restrictions, plus the difficulty of finding reliable, understandable sources of information.

Put most simply, communications made possible by the Internet promise to transform the way that doctors practice medicine and patients learn about and use their medicines. Consider, for example, the information available to a practitioner at the bedside who has access to the full medical record of the patient and a vast array of information, at the touch of a finger. Dr. Marcus Welby never had these tools. Meanwhile, consider the situation where a patient has just been diagnosed with a major disease, then sits down at a computer and enters a few words in a search engine. Before some of the words are fully entered, vast arrays of information on symptoms, treatments, and social support groups appear almost instantly. Patients can use that information to become a full partner in their care, to pose questions and suggest alternatives that would both please and perplex Dr. Welby's successors. But classic problems still remain. How do patients know the difference between facts and baloney? How do caregivers find the wherewithal to appropriately use the information? How do health care professionals decide and suggest the appropriate course?

Meanwhile, the law has not yet fully responded. FDA uses traditional concepts to regulate company-supported information online even though the context has largely changed. Plaintiff lawyers still seize on any fact that may further a lawsuit against doctors, hospitals, and drug companies. State regulators believe that they, too, should intervene to protect patients and others. How do patients, providers, and industry navigate these risks? This topic is immense, so we can only begin the conversation. But it will be lively, informative, and interesting! ■



***Christopher M. Schroeder** is the Chief Executive Officer and Board Member of HealthCentral.*

***John F. Kamp, JD, PhD**, is the Executive Director, Coalition for Healthcare Communications.*

The Problems & Promise of Using Social Media to Improve Patient Care will be presented on Wednesday, June 22, at 1:30pm.

www.diahome.org

UPCOMING EVENTS

In the Americas

Conferences

SEPTEMBER 14-17, 2011
13th International Paul-Ehrlich-Seminar-Allergen Products for Diagnosis and Therapy: Regulation and Science
Washington, DC

SEPTEMBER 15–16, 2011
Improved Development and Regulation of Transdermal Systems
Arlington, VA

SEPTEMBER 19-20, 2011
Optimizing Dosing for the Safe and Effective Use of Drugs in Patients with Renal Impairment
Washington, DC

SEPTEMBER 20-21, 2011
Sampling in the Future for International Clinical Trials
Philadelphia, PA

SEPTEMBER 2011
Clinical Trial Disclosure Workshop
Washington, DC

OCTOBER 11-13, 2011
US Conference on Rare Diseases and Orphan Products
Co-Sponsored with the National Organization for Rare Disorders
Washington, DC

OCT. 31-NOV. 1-2, 2011
DIA Canadian Annual Meeting 2011: New Models-New Frameworks-New Partnerships
Ottawa, Ontario, CANADA

In the Americas

Training Courses

AUGUST 8-11, 2011
Leadership Experience
Boston, MA

AUGUST 8-12, 2011
Regulatory Affairs: Part I: The IND Phase and Part II: The NDA Phase
Boston, MA

AUGUST 15, 2011
How to Prepare for a Safety Inspection
Boston, MA

AUGUST 15-16, 2011
European Regulatory Affairs
Boston, MA

AUGUST 16, 2011
Introduction to Signal Detection and Data Mining
Boston, MA

AUGUST 17-18, 2011
Regulatory Affairs for Biologics
Boston, MA

AUGUST 19, 2011
Overview of Drug Development
Boston, MA

AUGUST 22-24, 2011
Essentials of Project Management
Horsham, PA

AUGUST 23-24, 2011
Introduction to Portfolio Management and Performance Metrics
Horsham, PA

AUGUST 25-26, 2011
Executing and Controlling Projects
Horsham, PA

AUGUST 25-26, 2011
Cost and Resource Management in a Multiproject Environment
Horsham, PA

Europe

Conferences

JULY 4, 2011
1st Information Day on the Development Safety Update Report Guidelines ICH E2F
London, UK

SEPTEMBER 26-27, 2011
Joint DIA/EFGCP/EMA Paediatric Forum
London, UK

OCTOBER 10-12, 2011
5th Annual Clinical Forum
Basel, SWITZERLAND

Europe

Training Courses

SEPTEMBER 19, 2011
Advanced GCP Study Monitoring
Paris, FRANCE

SEPTEMBER 19-20, 2011
Medical Approach in Diagnosis and Management of ADRs
Paris, FRANCE

SEPTEMBER 23, 2011
2nd Information Day on the New Identification of Medicinal Products (IDMP) International Standard and ICH M5/M2
London, UK

OCTOBER 3-7, 2011
Excellence in Pharmacovigilance: Clinical Trials and Post Marketing
Zagreb, Croatia

OCTOBER 5-7, 2011
Clinical Project Management - Part I
Vienna, Austria

OCTOBER 6-7, 2011
Clinical Statistics for Nonstatisticians
Vienna, AUSTRIA

OCTOBER 26-28, 2011
Practical GCP Compliance Auditing of Trials and Systems
London, UK

Japan

Conferences

SEPTEMBER 5-6, 2011
2nd DIA Cardiac Safety Workshop in Japan
Tokyo, JAPAN

OCTOBER 27-28, 2011
8th DIA Japan Annual Meeting
Tokyo, JAPAN

In Other Regions

Conferences

JULY 17-19, 2011
DIA/ FDA Orphan Drug Designation Workshop
Mumbai, INDIA

JULY 18-19, 2011
Supply Chain Management Workshop
Suzhou, CHINA

JULY 21-23, 2011
DIA/ FDA Orphan Drug Designation Workshop
New Delhi, INDIA

SEPTEMBER 15-17, 2011
DIA-WHO-EDQM Quality of Active Pharmaceutical Ingredients
Hyderabad, INDIA

OCTOBER 15-18, 2011
6th Annual Conference on Drug Discovery and Clinical Development: Convergence of Science, Medicine, and Market Access Strategies to Benefit Patients
Mumbai, INDIA

October 19-21, 2011
8th Latin American Congress of Clinical Research Symposium
Buenos Aires, ARGENTINA

OCTOBER 23-24, 2011
Understating the statistical Thinking in Clinical Research for Drug Development
Shanghai, CHINA

OCTOBER 25-26, 2011
Quality and Integrity of Clinical Study Date in the Compliance with GCP: From Patient to Data Submission
Shanghai, CHINA

Webinars

July 26, 2011
11:30 AM -1:00 PM EDT
REMS and Scheduled Opioid Medications: A Review and Critique

Coming this July

Webinar Series: Electronic Submissions Basics
Part 1: eSubs 101: The Transition from Paper
September 15, 2011
11:00 -12:30 PM ET
Part 2: eCTD 101: Core Concepts of the eCTD Standard
September 22. 2011
11:00 -12:30 PM ET
Part 3: RPS 101: Introduction to the RPS (Regulated Product Submissions) Standard
September 29, 2011
11:00 -12:30 PM ET

Webinar Series: Pharmacovigilance
Part 1: Out with the Old, In with the New: Operational Implications for the New European Pharmacovigilance Legislation
October 20, 2011
10:00 -11:30 PM ET
Part 2: Closing the Gap between Safety Signaling and Confirmatory Studies
October 27, 2011
Time: 10:00 -11:30 PM ET

eLearning

Medical Communications eLearning Certificate Program

Clinical Investigator eLearning Program

Informed Consent Module

Kaplan EduNeering

Clinical Pharmaceutical eLearning Program

Clinical Medical Device eLearning Program

GMP Pharmaceutical eLearning Program

Validation and Part 11 Compliance eLearning Program

Basics of the PhRMA Code

Basics of the AdvaMed Code

Eucomed Guidelines on Interactions with Healthcare Professionals

Foreign Corrupt Practices Act

Introduction to Medical Device Compliance

Global Anti-bribery

Zenosis by Intellego

Variations to Marketing Authorisations in Europe

Registration of Monoclonal Antibodies

The ANDA: Requirements for Obtaining FDA Approval for Generic Product in the US

Pharmacokinetics and Pharmacodynamics (PK/PD) in Drug Registration

Online Training Series

JULY 7-28, 2011
12:00–1:30PM
Overview of Drug Development in Japan

JULY 11-19, 2011
11:30AM –1:30PM
Clinical Statistics for Nonstatisticians

JULY 25–AUGUST 2, 2011
12:00–2:00PM
Advanced Clinical Statistics for Nonstatisticians

SEPTEMBER 8-23, 2011
12:00–2:00PM
High Performance Biopharm Teams

SEPTEMBER 13-22, 2011
12:00PM–2:00PM
Introduction to Clinical Data Management

EudraVigilance
Electronic Reporting of ICSRs in the EEA

JULY 6-8, 2011

SEPTEMBER 5-7, 2011 – Zagreb, CROATIA

SEPTEMBER 14-16, 2011

SEPTEMBER 19-21, 2011

OCTOBER 3-5, 2011 – Vienna, AUSTRIA

OCTOBER 12-14, 2011

OCTOBER 24-26, 2011

Medicinal Product Dictionary (EVMPD)

AUGUST 31 – SEPTEMBER 1, 2011

SEPTEMBER 8-9, 2011 – Zagreb, CROATIA

SEPTEMBER 22-23, 2011

SEPTEMBER 28-29, 2011

Focus on Interoperability at DIA 2011

HIMSS Interoperability Showcase℠

Located in the Exhibit Hall at McCormick Place, the HIMSS Interoperability Showcase℠ is a joint effort of HIMSS, DIA, CDISC, and IHE. This event will offer the opportunity for research stakeholders to collaboratively present the benefits of using standards-based interoperable health IT solutions for effective and secure health data information exchange.

Attendees will first be escorted to the theater, where they will see a 10-minute introduction to the concept of the showcase. They will then be able to see complementary perspectives from US and European stakeholders, including FDA and EMA.

Confirmed Participants and Supporters as of May 16, 2011

- Outcome
- Medidata Solutions
- Allscripts
- Nextrials
- Greenway Medical Technologies
- Cerner Corporation
- CMIC Co., Ltd.
- IPL
- FDA
- Duke Clinical Research Institute
- Oracle
- Quintiles
- HL7 - Health Level Seven International
- Quintiles

The showcase demonstration will present a research information exchange (RIE). RIEs are unifying concepts for interoperability between health care and research, and each RIE comprises a set of services, such as data provision, management, privacy management, and monitoring and auditing.

Attendees will have the opportunity to learn first hand how standards-based solutions can improve the potential for health information exchange to optimize research and patient care.

Showcase Times

Monday, June 20, 9 AM - 6:30 PM
Tuesday, June 21, 9 AM - 4:30 PM
Wednesday, June 22, 9 AM - 4 PM

Interoperability Showcase Town Hall Tuesday June 21, 4:45-5:45PM

This session will present members of the FDA in an open panel to discuss technical solutions for using EHRs in conducting regulated clinical research and safety reporting, as shown in the DIA-CDISC-IHE-HIMSS Interoperability Showcase.

In addition, the panel will be open to taking questions related to the recent eSource Draft Guidance Document that was released by FDA in December 2010. As outlined by FDA in its Guidance for Industry Electronic Source Documentation in Clinical Investigations, the eSource Draft Guidance *"...provides guidance to sponsors, contract research organizations (CROs), data management centers, and clinical investigators on capturing, using, and archiving electronic data in FDA-regulated clinical investigations...It is intended to ensure the reliability, quality, integrity, and traceability of electronic source data and source records maintained at the site for FDA inspection.*

This guidance is intended to promote the capture of source data in electronic form, which will help to: eliminate unnecessary duplication of data, reduce the opportunity for transcription errors, promote the real-time entry of electronic source data during subject visits, and ensure the accuracy and completeness of data (eg, through the use of electronic prompts for missing or inconsistent data)." ■

Chairperson
Rebecca D. Kush, PhD
President and CEO
CDISC, United States

Panelists
Sean Y. Kassim, PhD
Pharmacologist, Office of Compliance, CDER
FDA, United States

Jonathan S. Helfgott, MSc
Consumer Safety Officer, DSI, OC, CDER
FDA, United States

Stephen E. Wilson, DrPH
Director, Division of Biometrics III, CDER
FDA, United States

Leslie K. Ball, MD
Director, Division of Scientific Investigations, Office of Compliance, CDER
FDA, United States

Terrie Reed
Associate Director, Informatics, CDRH
FDA, United States

DIA 2011 PREPARES for Patient Fellows

Discussions at our upcoming Annual Meeting will, more than ever before, feature the voice of those who advocate for patients and patient populations, through our first-ever Annual Meeting Patient Fellowship Program.

Elevating the voice of the patient in these discussions is a natural extension of the Meeting's theme: *DIA 2011: Convergence of Science, Medicine and Health*, said DIA 2011 Program Chair Kenneth A. Getz, MBA (Chairman, the Center for Information & Study on Clinical Research Participation [CISCRP]; Senior Research Fellow, Tufts Center for the Study of Drug Development, Tufts University). "We're trying to make sure that all of our sessions bring in the perspective of the public and the patient, the recipients of our innovations and perhaps the most important member in that convergence of science, medicine, and health," he explained.

Working in tandem with a committee comprising representatives from CISCRP, EURORDIS (The Voice of Rare Disease Patients in Europe), the NHC (National Health Council), NORD (the National Organization for Rare Disorders), and Mark Krueger & Associates, DIA selected 15 Patient Fellows to participate in this program. On Sunday afternoon, June 19, they will receive presentations on health care policy, reform, and related issues, from expert representatives of the National Health Council, the Center for Medical Technology Policy, the FDA Office of Special Health Issues, and the Tufts Center for the Study of Drug Development. Later that evening, they will be honored guests at a special networking reception that includes these presenters and the DIA Board of Directors Executive Committee.

These Patient Fellows will be provided special seating, and will be introduced to the audience at the opening plenary session on Monday, June 20. After this plenary, they will serve as speakers and panelists to share the experiences and insights of the patients they represent through our Annual Meeting sessions, forums, and workshops. You will also be able to meet with them at the special Patient Fellowship booth in the exhibit hall.

Please join us in welcoming these 15 Patient Fellows to Chicago for DIA 2011. ■

Alagille Syndrome Alliance:
Cindy Hahn, President & CEO: http://www.alagille.org/
This Alliance serves as the main networking resource and source of information for people with Alagille Syndrome, their families, friends, and health care providers. The Alliance is dedicated to increasing public awareness of Alagille Syndrome and supporting research efforts on behalf of the Alagille Syndrome Community.

American Kidney Fund:
Nikia Okoye, Director of Government Relations: http://www.kidneyfund.org/
AKF has become the leading source of direct, treatment-related financial assistance to people in the United States who are living with chronic kidney disease.

Asthma and Allergy Foundation of America:
Liana Burns, Policy & Programs Assistant: http://www.aafa.org/
Founded in 1953, the AAFA is the leading national patient and consumer organization helping people with asthma and allergic diseases through education, advocacy and research. AAFA is dedicated to improving the quality of life for people with asthma and allergies.

Autoimmune Diseases Association:
Virginia Ladd, President & Executive Director: http://www.aarda.org/
AARDA is a national nonprofit 501(c)(3) voluntary health organization dedicated to bringing a national focus to autoimmunity as a category of disease and promoting collaborative research efforts in order to find better treatments and a cure for all autoimmune diseases.

Hepatitis C Caring Ambassadors Program:
Lorren Sandt, Executive Director: http://www.hepcchallenge.org/
CAP-Hepatitis C is a national non-profit organization devoted exclusively to meeting the needs of the hepatitis C community. Its mission is to help improve the lives of those affected by long-term diseases through advocacy, information, and support.

International Pemphigus & Pemphigoid Foundation:
Molly Stuart, CEO: http://www.pemphigus.org/
Provides patients and doctors worldwide with information about pemphigus and pemphigoid, develops and maintains close relationships with doctors and leaders in the medical community, and cultivates relationships that may be able to encourage or provide research funding.

Myasthenia Gravis Foundation:
Dr. Jürgen Venitz: http://www.myasthenia.org/
The MGFA is the only national volunteer health agency in the US dedicated solely to the fight against myasthenia gravis. MGFA has over 20 Chapters around the US serving patients and their families and caregivers through support groups and programs.

National Alopecia Areata Foundation:
Richard Gilula, Senior Director, Treatment Development Program: http://www.naaf.org
NAAF is dedicated to overcoming this most prevalent of all autoimmune diseases by leading the effort to discover effective hair-restorative treatments and also supporting every person who experiences sudden or total hair loss.

National Ataxia Foundation:
Sue Hagen, Patient Services Director: http://www.ataxia.org/
A patient advocacy group representing patients affected by hereditary and sporadic ataxia, the Foundation is dedicated to improving the lives of persons affected by ataxia through support, education, and research.

Pancreatic Cancer Action Network:
Anitra Talley, Director of Patient Services: http://www.ataxia.org/
A nationwide network of people dedicated to working together to advance research, support patients, and create hope for those affected by pancreatic cancer.

Parkinson's Disease Foundation:
Veronica L. Todaro, Director of National Programs: http://www.pdf.org/
A leading national presence in Parkinson's disease research, education and public advocacy, the PDF works for the nearly one million people in the US who live with Parkinson's disease by funding promising scientific research while supporting people with Parkinson's, their families, and caregivers, through education and support services.

Spinal Muscular Atrophy Foundation:
Dr. Dione Kobayashi, Associate Director, Research: http://www.smafoundation.org/
The Spinal Muscular Atrophy Foundation is focused on preclinical and clinical research, which we execute through internal and external sponsored research programs and in a variety of research collaborations.

Susan G. Komen for the Cure:
Shelley Fuld Nasso, Director, Public & Medical Affairs: http://ww5.komen.org
Komen for the Cure is the world's largest grassroots network of breast cancer survivors and activists fighting to save lives, empower people, ensure quality care for all, and energize science to find the cures, and is the largest source of nonprofit funds dedicated to the fight against breast cancer in the world.

Uniting Against Lung Cancer:
Holli Kawadler, Scientific Program Director: http://www.unitingagainstlungcancer.org/
A nonprofit organization dedicated to finding a cure for lung cancer and raising awareness of the disease, UALC works with partners across the country to run awareness and fundraising events.

Women's Heart Foundation:
Bonnie Arkus, Executive Director: http://www.womensheart.org/
A 501c3 charity dedicated to prevention of heart disease, improved survival, and quality of life, the WHF implements effective wellness and prevention projects in schools, and has demonstrated positive outcomes for the past six years, strengthening communities, while lowering some of the risk factors associated with heart disease.

DIA 2011 EXHIBITORS

As of May 4, the following companies had reserved space in the Annual Meeting Exhibit Hall at McCormick Place, in Chicago, IL.

Abbott
Accel Research Companies
Accelovance
Accovion
ACM Global Central Laboratory
ACRI-Phase I, LLC
ActiGraph
Acurian, Inc.
Advanced Clinical
Advantar Laboratories, Inc.
Aerotek, Inc.
Akaza Research
Akos Ltd.
Alamo Medical Research
AliCRO Alliance
Almac
Almac
APCER Pharma Solutions, Inc.
Applied Clinical Trials
Aptiv Solutions
Aris Global
Arrowhead Electronic Healthcare
Asia Global Research Co., Ltd.
ASKLEP Inc.
Aspire IRB
Assign Group
Aureus Research Consultants
Axis Clinical Trials
B. McLaughlin Associates, Inc. (BMA)
BA Research India Ltd
BARC Global Central Laboratory
BBK Worldwide
Beardsworth
Beckloff Associates, Inc.
Benchmark Research
BioClinica
BioFortis
Biomedical Consulting International, Inc
Biomedical Systems
Bio-Optronics, Inc.
BioPharm Insight
bioskin GmbH
BioSoteria
BioStorage Technologies Inc.
Biotec Services International
Blue Chip Patient Recruitment
Brand Institute, inc.
Brillance Sp. z.o.o.
Buffalo Clinical Research Center, LLC
Burg Translations
Business & Decision
C&R Research Inc.
C3i, Inc.
Camargo Pharmaceutical Services
Canary Limited
CanReg Inc.
CANTOX - An Intertek Company
Cape Cod Clinical Research, Inc.
Cardiocore
Catalent Pharma Solutions
CDISC
Celerion
CenterWatch
Cerner Corporation
Cetero Research
Charles River Clinical Services
Chesapeake Research Review Inc.
Chiltern
Cincinnati Children's Research Foundation
CIRION Clinical Trial Services Inc.
Citeline, Inc.
CITI Program - University of Miami
ClearTrial, LLC
ClinAudits LLC
ClinDatrix, Inc.
ClinForce, Inc.
Clinical Financial Services
Clinical Ink
Clinical Reference Laboratory
Clinical Research Advantage
Clinical Research Malaysia
Clinical Research Management, Inc.
Clinical Research Services Andernach
Clinical Resource Network
The Clinical Resource Network
Clinical Site Services
The Clinical Trial Company
Clinical Trial Media
ClinicalConnection, Inc.
CliniCallRN
Clinigene International, Ltd.
Clinilabs Inc.
Clinipace Worldwide
clinIT AG
Clinlogix
ClinOps, LLC
ClinStar
ClinTec International Ltd.
Clinverse, Inc.
CMED
CMIC Co., Ltd.
Cognizant
Compass IRB
CompleWare Corporation
Comprehend Clinical
Comprehensive Clinical Development
Contract Pharma
Copernicus Group IRB
CoreLab Partners Inc.
Corporate Translations
CORRONA
Court Square Group, Inc.
Covance Inc.
CPC Clinical Trial Hospital, Medipolis Medical Research Inst
CRF Health
CRO Dokumeds Ltd.

Cromos Pharma
CROMSOURCE
CROS NT Srl
CTI Clinical Trial & Consulting Services
Cu-Tech, LLC
Cytel Inc.
DAC Patient Recruitment Services
DataCeutics, Inc.
Datapharm Australia
DATATRAK International
Datatrial Ltd.
DaVita Clinical Research
Delmar Chemicals
Delta Pharma
Delve
DiagnoSearch Life Sciences
Doctor Evidence, LLC
Dow Pharmaceutical Sciences
Dr. Ebeling & Assoc. GmbH
DreamCIS, Inc.
Drug Safety Alliance, Inc.
DrugLogic Inc.
DSG, Inc.
DUCK FLATS Pharma
Duke Clinical Research Institute
d-Wise Technologies
DZS Software Solutions, Inc.
EastHORN Clinical Services in CEE, Ltd.
eClinical Solutions
ECLINSO
Ecron Acunova
EDETEK, Inc.
Elite Research Network, LLC
EMB Statistical Solutions, LLC
endpoint
Entimo AG
ePharmaSolutions
EPS Co., Ltd.
ERT
Esoterix Clinical Trials
Ethicare Clinical Trial Services
EtQ, Inc.
European Medicines Agency
Eurotrials
Exco InTouch
ExecuPharm, Inc.
ExL Pharma
Experis
Explorys, Inc.
EXTEDO, Inc.
Falcon Consulting Group
Fast4wD Ogilvy
FDA/CBER
FDA/CDER
Firecrest Clinical
FORENAP Pharma
Foresight Group, LLC
Forest Laboratories Inc.
Forma Life Science Marketing
Formedix
Fortis Clinical Research Limited
Foundation for Biomedical Research
Frontage
Fujitsu Limited
Future Science Group
GE Healthcare
Glemser Technologies
Global Instrumentation LLC
Global Language Solutions
Global Vision Inc.
Globalcare Clinical Trials, LTD
Green Key Resources
Greenphire
Greenway Medical Technologies
H&J CRO International, Inc.
HCRAmerica
Health Canada
Health Decisions Inc
Healthcare Communications Group
Hewlett-Packard Company
HHS Supply Service Center
HRP Consulting Group, Inc.
HungaroTrial CRO
i3
iCardiac Technologies, Inc.
ICON plc
Idem Translations, Inc.
IFAPP
Imperial
Inamed GmbH
INC Research
Inclinix
IndiPharm
INNOPHARMA S.r.L.
Innovative Print & Media Group
Integrated Clinical Systems, Inc.
IntegReview IRB
Intermountain Clinical Research
International Dermatology Research, Inc.
IntraLinks, Inc.
inVentiv Clinical Solutions
Investigator Support Services
invivodata
IRB Services
Italian Medicines Agency
J&S Studies, Inc.
JANIX CRO
JCL Bioassay USA, Inc.
Johnson & Johnson
Joule Clinical Staffing Solutions
Jubilant Clinsys
The Judge Group
Kansas Bioscience Authority
Kaplan EduNeering
Kayentis
Kelly Scientific Resources
Kendle
Kforce Clinical Research
Klein Hersh International
KoNECT
Kuantum CRO and Logistics
LabConnect, LLC
Laboratorio Hidalgo
Langland
Lernia Training Solutions
Libra Medical

Lifetree Clinical Research
Lionbridge Life Sciences
Liquent
Logos Technologies Inc.
LORENZ Life Sciences Group
Lovelace Scientific Resources
MAJARO InfoSystems, Inc.
MaxisIT Inc.
McGuire Research Institute
McKesson
MD Events
MedAssurant, Inc.
MedDRA MSSO
MedFocus, LLC
Medical Research Network Ltd.
Medical Staffing Network Clinical Research
Medicines Evaluation Unit
Medidata Solutions Worldwide
MedNet Solutions, Inc.
Medpace
MedPoint Communications, Inc.
MedSource
MEDTOX Laboratories
MedTrials, Inc.
Merge eClinical
META Solutions, Inc.
Miami Children's Hospital Research Institute
Micron Research Ltd.
Microsoft Corporation
Microsystems
Mid*Lands IRB
Mission3
MMG, Inc.
Monitorforhire.com
Montrium, Inc.
Moravia
Mortara Instrument, Inc.
MPI Research
Myoderm Medical
National Pharmaceutical Council
New England Institutional Review Board
New Orleans Center for Clinical Research
NewCardio, Inc.
Next Generation Clinical Research
NextDocs
Nextrials, Inc.
Norwich Clinical Services
Nova Language Services Ltd.
Novella Clinical
November Research Group
Novotech
nSpire Health, Inc.
Ocasa, Inc
OCT
Octagon Research Solutions, Inc.
Odyssey Research
Omnicare Clinical Research
OmniComm Systems, Inc.
On Assignment Clinical Research
Online Business Applications
Ora
Oracle
Orlando Clinical Research Center
Outcome
Palm Beach CRO
Paragon Biomedical Inc
Paragon International, Inc.
PAREXEL International
The Patient Recruiting Agency
PCM TRIALS
PDR Network, LLC
Pegasystems Inc.
Penn Pharma
Perceptive Informatics, Inc
Pharm Med Alliance
Pharma Publications
Pharmaceutical Executive
Pharmaceutical Outsourcing
Pharmaceutical Safety Services LLC
Pharmaceuticals and Medical Devices Agency (PMDA)
PharmaNet Development Group, Inc.
PharmaSeek
PharmaSys, Inc.
PharmaVigilant
PharmaVOICE
Pharm-Olam International
Philips Respironics
Phlexglobal Limited
Phoenix Software International
PHT Corporation
Piramal Healthcare
PleaseTech Ltd.
POPSICUBE
PRA International
Praxis
Premier Research Group
Pretium
PrimeVigilance Ltd
PRL Central Laboratory Services
Progressive Impressions International
Projecis, Inc.
PROMETRIKA, LLC
PROSAR
ProTrials Research, Inc.
PRUDENTAS LLC
PSC Biotech
PSI
Qliktech, Inc.
QPS LLC
Quality and Compliance Consulting, Inc.
Quality Associates, Inc.
QualityMetric Incorporated
Quanticate Inc.
Queensland Clinical Trials Network
Quest Diagnostics Clinical Trials
Quintiles
QUMAS
Quorum Review IRB
R&D Directions
Radiant Research, Inc
Randox Laboratories
RCI & SSI
RDP Clinical Outsourcing
Real Staffing Group
Reed Technology
REGISTRAT-MAPI
Regxia Inc.
Research Across America
ResearchDx, LLC
ResearchPoint
Rho, Inc.
RPS, Inc.
RWD Technologies
Rx Trials Inc.
RxLogix Corporation
SAS Institute
Schlafender Hase GmbH
Schulman Associates IRB
SDL
Sentrx

SGS
Sharp Corporation
SIRO Clinpharm
Small Planet Meetings
Smith Hanley Consulting Group
SNBL Clinical Pharmacology Center
Soltex Consulting LLC
Sonic Clinical Trials
Southern Star Clinical Research
Sparta Systems, Inc.
Spaulding Clinical Research
Spectra Clinical Research
SRA Global Clinical Development
Statistics and Data Corporation (SDC)
STATKING Consulting, Inc.
StatWorks, Inc.
Stiris Research Inc.
Strata Company
Symbio, LLC
Synapse Labs Pvt Ltd
Synchron Research Services Pvt. Ltd.
Synowledge Drug Safety Solutions
Synteract Inc
TAKE Solutions
Target Health Inc.
Tarius A/S
Tata Consultancy Services Ltd.
TecHorizon S.r.l.
TechSol
TechTeam Global
TekVault Corporation
TFDA / Center for Drug Evaluation, Taiwan
That's Nice LLC
Therapak Corporation
Therapeutics Inc
Thomson Reuters
ThreeWire, Inc.
TIBCO Software Inc.
TKL Research, Inc.
Total Root Concepts, Inc.
TrainingCampus.com
TransPerfect
Trident Clinical Research
Trifecta Multimedical
Trio Clinical Research
TTC,llc
United BioSource Corporation
unithink nv
University Hospital Clinical Trial Alliance
University of Florida Center for Clinical Trials Research
University of Iowa Pharmaceuticals
University of the Sciences in Philadelphia
the Uppsala Monitoring Centre
Utah Clinical Trials, LLC
Veeva Systems, Inc.
Veridex, LLC
Veristat, Inc.
Virtify, Inc.
Virtual Clinical Solutions
VirtualScopics Inc.
Vitalograph
WCI Consulting Limited
WebbWrites, LLC
WebWise Learning, Inc.
WellCRO
West Coast Clinical Trials
Western Institutional Review Board
Whitsell Innovations, Inc.
Wipro Technologies
Woodley Equipment Company
World Courier
Worldwide Clinical Trials Drug Development Solutions
WriteResult
XClinical GmbH
Xerimis Inc.
Xybion Corporation
Yoh Clinical

In Memoriam

Dr. Thomas Willard Littlejohn III, a DIA member since 2008, was killed in a plane crash on March 30. Dr. Littlejohn served as a speaker for last year's 46th DIA Annual Meeting in Washington, DC. He was a graduate of the University of North Carolina at Chapel Hill, where he earned his bachelors and medical degrees. His lifetime of service included co-founding the nonprofit Greater Gift Initiative, whose mission is to advance global health and highlight the greater good of clinical trial participation by gifting a vaccine to a child to honor a clinical trial volunteer. Dr. Littlejohn was 62.

David A. Pitler, a DIA member since 2002, died at his residence in New Hope, PA, on May 8. David served as Executive Vice President, President of the Bioimaging Services Division, of BioClinica since 2009. He earned his degree in Economics from Colgate University. David was 56.

CLINICAL FORUM 2011

DIA's 5th Annual Clinical Forum will take place in Basel, Switzerland, 10-12 October at the Congress Center Basel. The title of this year's event, *Cross Functional Working for Better Results*, reflects the reality of today's business environment for many professionals working in the pharmaceutical and biotech industries, CROs, health regulatory agencies, and patient organizations.

The programme committee selected abstracts from 91 submissions from 14 countries, and authors of selected abstracts were notified of the decision in mid-May.

Programme Chair, Nermeen Varawalla, MD, PhD, MBA, Founder & CEO, ECCRO, UK answered questions about this conference for the *Global Forum.*

Q&A Why did you agree to serve, and what do you hope to accomplish, by serving as programme chair of the fifth annual DIA Clinical Forum?

I have served as the chair person of the Clinical Operations Theme and have been an active participant in the DIA Clinical Forum for the past four years. During this period the Clinical Forum has become an important multidisciplinary conference for those of us engaged in the delivery of high-performing clinical development programmes. The Clinical Operations track is increasingly important and relevant, not just for conference attendees engaged in clinical operations, but also for our colleagues in other disciplines. Given my expertise in global clinical operations, it was considered to be appropriate and timely for me to serve as the Programme Chair for the 2011 DIA Clinical Forum. I was invited shortly before the fourth annual Clinical Forum (Lisbon, October 2010) and was delighted to formally announce my acceptance there. It has been valuable to have had this advance notice and generous lead time which has greatly helped me and my programme committee develop a truly first-class programme.

Q&A How will this forum illustrate its theme, "Cross Functional Working for Better Results"?

The Clinical Forum is widely recognized as perhaps the only conference that brings together industry-leading thinking and practices across the key disciplines of data management, clinical operations, drug safety, and medical communication as they relate to the practical and operational aspects of drug development. The programme will have five concurrent tracks over two full days with sessions that address pressing and topical issues in eClinical, Clinical Research, Clinical Operations, Drug Safety, Peri- and Post-Approval studies, Validation, Medical Writing, and Medical Information. We expect conference attendees to select from the sessions on offer at any time, a customized programme that addresses the relevant topics for them across all the disciplines represented. In addition there are cross functional sessions with speakers from different

disciplines addressing topics such as ePRO and pediatric clinical trials. Plenary and networking sessions will also provide opportunities for informal interaction among colleagues working in different functions.

Basel, home to the world's leading large pharmaceutical companies and Europe's innovative biotechnology companies, promises to be an ideal venue for the exchange of ideas among colleagues who strive to achieve similar objectives, albeit in different organizational settings.

Q&A You will also serve as chairperson of Theme 2, "Clinical Operations." May we ask you to briefly preview or summarize some of the topics that this theme will address?

The second day of the forum will include a three-hour, double session addressing one of the most challenging and critical issues in clinical operations: the conduct of a reliable feasibility assessment. There will be presentations on the use of data mining tools, extrapolation of data across different ethnic populations, and best practices. These will set the stage for the practical part of the session where attendees will be invited to form breakout groups and develop a feasibility plan. Finally, these plans will be presented and critiqued by the rest of the audience. I will chair this session myself and endeavor to facilitate a productive discussion with the sharing of best practices so that attendees will leave with practical tools and insights on how to better address feasibility assessment of their clinical studies. The other highlight of the clinical operations theme will be a session on the operational aspects of adaptive clinical trial conduct. There has been a lot of discussion about study design and statistical analysis but relatively little guidance on the practical aspects of conducting such trials, such as the management of clinical trial supplies, study start-up in different countries, and early phase trials. A session chaired by Dr Johanna Schenk promises to highlight guidance on this very timely subject.

Q&A What are some of the "hot topics" that began to emerge in discussions at last year's Clinical Forum and evolved into more fully developed session topics for this year?

One of the hottest topics that the pharmaceutical and clinical research industry is facing is the loss of public confidence in us. We have been the subject of a number of high-profile, albeit poorly researched, media articles alluding to how we as an industry have failed to deliver the promise of safe, cost-effective and efficacious medicines. Given my expertise in clinical trial conduct in emerging countries, India in particular, I am regularly quizzed at social occasions about the ethics of my business. Strangely, it is rare that I am complimented on the positive contributions that my CRO makes to health care delivery in India. This is a reflection of how we as an industry

Nermeen Varawalla

have failed to communicate what we do and that in spite of all our efforts, the public doesn't trust us. To understand and address this growing lack of public trust and ignorance, the plenary session of the 5th Annual DIA Clinical Forum will be a debate on "This house believes that Clinical Research has lost Customer Confidence." The debate, which will follow Oxford Union debating rules, will be chaired by Julianne Hull with speakers representing the pharmaceutical industry, regulatory agencies, and patient support groups. As always, audience participation will be encouraged.

The final session of the conference will be a "mini-plenary" joint session on the "Impact of social media on the pharmaceutical sector." Social media has become an integral part of society and has diverse legal, regulatory and commercial implications on every aspect of the development and use of treatments. Speakers representing different viewpoints will share their experiences on this truly "hot topic."

The Congress Center in Basel.

Theme 1 | Clinical Data Management/eClinical

THEME LEADERS

Julianne Hull, Senior Director, Global Development Data Operations, Pfizer, United Kingdom

Pierre-Yves Lastic, Senior Director, Data Privacy & Healthcare Interoperability Standards, sanofi-aventis, France

Detlef Nehrdich, Director Statistics, Data Management & EDC Project Office Europe, Abbott GmbH & Co KG, Germany

PROGRAMME SUB-COMMITTEE

Nick Lucas, Vice President Global Data Management, INC Research, UK

Wolfgang Summa, Executive Vice President Europe & Asia/ Pacific OmniComm Europe GmbH, Germany

Peter Stokman, Head Global Data Management & Standards Oss, MSD, The Netherlands

This theme incorporates the 21st Annual DIA European CDM and the 7th Annual DIA European eClinical Conferences.

This theme will explore the evolving world of eClinical and CDM to include key insights from the global INCDMA community.

Jointly with our validation, clinical, and clinical operations colleagues we will explore getting ePRO right from validation through to inspection. How are companies implementing standards and how are they understood and used to best advantage cross functionally? We will explore the tools and processes to ensure data quality is both inbuilt and measurable in the eWorld. Finally, we will study how with maximum efficiency with data and timely data reporting implicit, we drive the artistic practice and the exact science of data.

Theme 2 | Clinical Operations

THEME LEADER

Nermeen Varawalla, President and CEO, ECCRO, UK

PROGRAMME SUB-COMMITTEE

Johanna Schenk, Senior Partner and Managing Director, PharmaProjekthaus GmbH & Co. KG, Germany

The conduct of a reliable feasibility assessment continues to be one of the most challenging and critical issues in clinical operations. This will be addressed in a workshop-style double session. The other highlight will be a session on the operational aspects of adaptive clinical trial conduct. There has been a lot of discussion about study design and statistical analysis but relatively little guidance on the practical aspects of conducting these trials such as the management of clinical trial supplies, study start-up in different countries and conduct of early-phase trials, which will be addressed in this session.

Theme 3 | Clinical Research

THEME LEADER

Ingrid Klingmann, President, Pharmaplex bvba, Belgium

PROGRAMME SUB-COMMITTEE

Wolfgang Eglmeier, Head Clinical Operations Germany, Grünenthal GmbH

Theme 4 | Drug Safety and Risk Management

THEME LEADER

Monika Pietrek, Managing Director, Pietrek Associates GmbH, Germany

PROGRAMME SUB-COMMITTEE

Liliana Hansen, Director Safety Surveillance Insulin & Devices Global Safety, Novo Nordisk A/S, Denmark

Our theme will deal with the new rules for safety reporting in clinical trials and also share practical experience in risk minimization and communication. The audience will learn the operational implications and challenges industry is facing during the adjustment of working practices. For example, given that the Development Safety Update Report (DSUR) is coming into effect

this year, the regulators have agreed to harmonized safety reporting at the aggregated level. However, at the same time, requirements for the individual SUSAR reporting in Europe and IND Safety reporting in the US are shifting apart.

Theme 5 | Peri- and Post- Approval Studies

THEME LEADER

Jens Reinhold, Head Global NIS, Bayer Schering Pharma AG, Germany

PROGRAMME SUB-COMMITTEE

Heike Schoen, Managing Director, CSG Clinische Studien GmbH, Germany

Theme 6 | Validation

THEME LEADER

Rolf Banholzer, Global Head CQA Computerized System Services, Novartis Pharma AG, Switzerland

PROGRAMME SUB-COMMITTEE

Breffni Martin, Director, Strategic Regulatory Services, i3, Ireland

Electronic Clinical Data Management was just the beginning of the journey towards a computer system- supported and technology-driven clinical development environment.

Clinical study design necessitates an ever-increasing technical expertise which is typically not well established in current pharma organizations. Ensuring data integrity requires a comprehensive, risk-based approach to the validation of a network of computerized systems. Concrete case studies of risk-based validation approaches of newest eTechnology as well as HA inspection experiences from a sponsor's perspective will be discussed.

Theme 7 | Medical Writing

Mary Gardner Stewart, Divisional Director, Medical Documentation, H. Lundbeck A/S, Denmark

Janet Stoltenborg, Senior Director, Scientific Communications, AstraZeneca Pharmaceuticals LP, USA

Theme 8 | Medical Information and Communications

THEME LEADER

Janet Davies, Director, International Medical Information, Gilead Sciences, UK

The Medical Information and Communications track provides a unique opportunity for European professionals working in Medical Information roles to meet and network. The programme will cover hot topics in the Medical Information world, including collaborating with internal colleagues, globalization and developments in Asia-Pacific, and changing information needs for patients. One session will be devoted to sharing best practices in Medical Information.

PROGRAMME ADVISORS

Lillian Auberson, Director, Global Medical Information, Actelion Pharmaceuticals Ltd, Switzerland

Nathalie Barrillon, Medical Information and Documentation Manager, Laboratoires MSD – Chibret, France

Aaron Cockell, Head of Medical Operations and Information, Pfizer Ltd, United Kingdom

Ainhoa Del Romero, Director Medical Information, International Scientific Affairs, Amgen (Europe) GmbH, Switzerland

Sarah Dunnett, Medical Affairs Manager, Baxter Healthcare Ltd, United Kingdom

Katie Gibson, Scientific Communications Director, Europe Middle East and Africa, Janssen-Cilag AB, Swede

Françoise Hanotte, Associate Director, Medical Information, Global Medical Affairs, UCB Pharma SA, Belgium

Sharon Leighton, Owner, Sharon Leighton Consultancy, United Kingdom

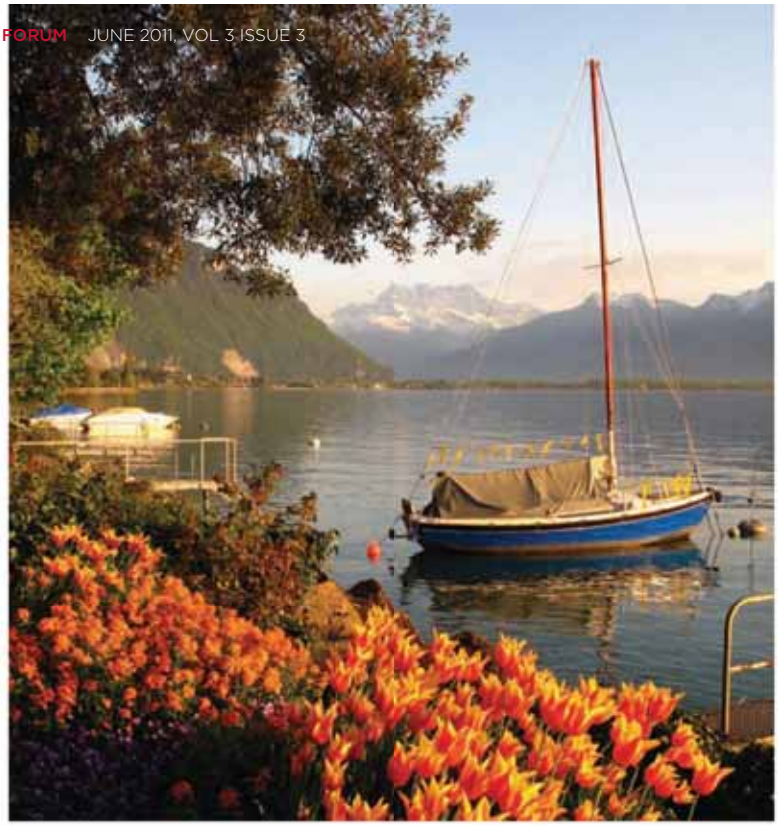
Victoria Vowles, Medical Communication and Information Manager, Merck Serono International SA, Switzerland

Ozgur Yuksel, Medical Director, NSO, AMAC Region, Novartis Pharma AG, Switzerland

Nermeen added a final comment for *Global Forum* readers, "My programme committee and I have crafted an exciting and stimulating programme for the fifth Annual DIA Clinical Forum and greatly look forward to the participation of our friends and colleagues from around the world. See you in Basel!"

For more information, go to www.diahome.org and click on the Clinical Forum icon. ■

GENEVA 2011



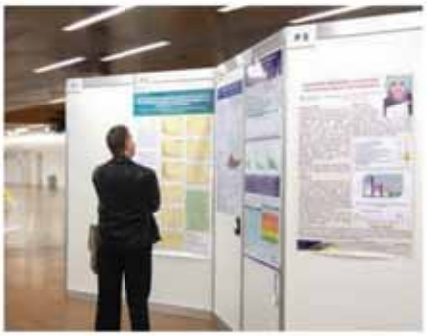
Images from the 23rd DIA EuroMeeting

EUROPE










Mr. John Dalli delivers the Keynote Address via videoconference.

John Dalli Keynote Address
Opens 23rd EuroMeeting

Historically regarded as one of Europe's most international cities, Geneva shared the beauty and culture of Switzerland with DIA's international array of panelists, speakers, DIA members and volunteers, exhibitors, and others who came to attend our **23rd Annual EuroMeeting**, presented from March 28-30 at the palatial Palexpo convention center.

This EuroMeeting marked the sixth anniversary of the DIA Patient Fellowship Program, through which DIA financially supports representatives of patient organizations to share the challenges and accomplishments of the patients they represent with EuroMeeting attendees. This year's Program supported the participation of sixteen Patient Fellows.

In their welcoming message for the EuroMeeting final program, co-chairs June Raine (Medicines & Healthcare products Regulatory Agency [MHRA], UK) and Valdo Arnera (PHT Corportation, Switzerland), wrote: "This EuroMeeting takes place at a critically important point in time in the evolution of drug development, post-authorization surveillance, and the nature of medicines regulation. The balance between prompt delivery of effective medicines and rigorous safety evaluation is in the spotlight as never before. How can this balance be optimized in the light of cutting-edge science, and at the same time meet patient expectations? How can value for the payers be maximized and how can public health outcomes be measured? Our goal is for everyone involved in the EuroMeeting, whether you are presenting or participating in the audience, whether you are in industry, authorities or academia, to feel actively engaged in how we meet these challenges."

Following a musical introduction and interlude by traditional Swiss Alpen Horn players, attendees were officially welcomed to the EuroMeeting by Director, DIA Europe, Brigitte Franke-Bray; DIA Worldwide Executive Director Paul Pomerantz; and Ric Day, DIA President.

"Over the next three days, I encourage you to take advantage of the DIA experience – learn, share and network with colleagues from around Europe and the world. But take advantage of the unparalleled opportunity to listen to and learn from patients," Ric said. "In closing, on behalf of DIA, I wish to extend my sincerest condolences to our colleagues in Japan who due to the tragedy that has befallen their country are unable to be here with us this week."

After presenting DIA's annual Volunteer Service Awards for 2011, Ric introduced Keynote Speaker John Dalli, European Commissioner responsible for Health & Consumer Policy.

John Dalli began his service as a Cabinet Minister in the Maltese Government in 1987, having been first elected to the House of Representatives of Malta on behalf of the Nationalist Party in 1987. He served as Parliamentary Secretary for Industry (1987-1990), Minister of Economic Affairs (1990-92), Minister of Finance (1992-96, 1998-2003), Minister of Finance & Economic Affairs and Minister of Foreign Affairs & Investment Promotion (2004). Between March 2008 and February 2010, John Dalli served as Minister for Social Policy which includes the health, housing, employment, and industrial relations portfolio. In February 2010, John Dalli was appointed European Commissioner responsible for Health & Consumer Policy. Due to urgent business, Mr. Dalli delivered his Keynote Address, reflections upon his first year as

Commissioner responsible for health and pharmaceutical policy, via videoconference.

Health must remain a top political priority, and citizens must be at the heart of EU health policy, he began. This means working toward better availability, and overcoming today's inequalities, of health care services and products in Europe. But, in today's economic climate, how can we ensure access to health care for all European patients while keeping expenditure levels under control?

Mr. Dalli referenced recent legislation that will strengthen the safety of medicines and correspondingly increase confidence in the safety of the pharmaceutical development, review, authorization, and postmarketing systems for consumers in Europe. 2010 legislation on pharmacovigilance will facilitate more intelligent use of the vast pharmacovigilance data collected in Europe, and enable pharmacovigilance surveyors to concentrate on those medicines which require special attention. In addition, political agreement has been reached on legislation to combat falsified (counterfeit) medicines that is rapidly moving toward implementation.

New legislation on the application of patients' rights to cross-border health care will not only give patients a coherent set of rules for choosing the most appropriate health care across the entire European Union, but also initiates a new phase of cooperation between national health systems. Furthermore, another new legal proposal on information to patients will allow citizens throughout Europe to make better informed decisions about their own health, he explained.

Volunteer Service Award winners: Martin Terberger, Sabine Brosch, Gesine Bejeuhr, and Pierre-Yves Lastic

While recognizing that health budgets in many member states are under considerable strain, Mr. Dalli emphasized that member states wishing to reform health services must balance economic outputs against patient outcomes. He noted the importance of health technology assessments in this balance, and that Hungary, which currently holds the EU presidency, has chosen this topic as its main health priority.

Mr. Dalli next turned to a familiar but no less important theme for DIA's many stakeholders: The need to maintain a robust regulatory framework that simultaneously ensures the quality, effectiveness, and safety of health products, while encouraging and rewarding innovation. He referred to recent medical device legislation and noted that there is a very strong link between medical devices and pharmaceutical innovation. Personalized medicine also presents opportunities to reward industry for innovation and genuinely change the lives of patients; the recently launched European Innovation Partnership on Active and Healthy Aging promises to help patients and industry make the most of these opportunities.

The challenge of building synergies that enable the more effective and faster transfer of clinical research results to the consumer market, a market that offers innovative therapies and treatments that meet the needs of Europe's citizens, and their carriers and care providers, is certainly ambitious, Mr. Dalli concluded. But it is a challenge that he is confident is within our collective grasp.

After Mr. Dalli's Keynote Address, the EuroMeeting plenary session shifted to the Oxford Debate, in the spirit of the university's eminent

tradition, on the statement: "The current regulatory system does not support timely patient access to beneficial medicines." In a debate moderated by Hans-Georg Eichler, panelists presented arguments either against or in favor of this statement. Before the panelists presented their viewpoints, the audience was asked to vote in favor of or against this statement; in that voting, 53% of attendees were in favor, 38% were opposed, and 9% were undecided. After the panelists' lively exchange of ideas and positions, attendees' view of this statement dramatically changed: . 80% agreed with this statement, 16% were opposed, and 4% were undecided.

Upon the conclusion of this plenary, attendees enjoyed the EuroMeeting Networking Reception at the Crowne Plaza Hotel. ■

Oxford Debate

"The current regulatory system does not support timely patient access to beneficial medicines"

Debate Moderator:

Hans-Georg Eichler
Senior Medical Officer, European Medicines Agency (EMA), EU

Debaters:

Mary Baker, MBE
President, European Federation of Neurological Associations (EFNA); President, European Brain Council, UK

Peter Bonne Eriksen
Senior Vice President, Global Regulatory Affairs, Novo Nordisk, Denmark

Stephen Evans
Professor of Pharmacoepidemiology, The London School of Hygiene & Tropical Medicine, UK

Agnius Kalis
Executive Director, Medicines Evaluation Board, The Netherlands

The student poster winners with Brigitte Franke-Bray and Ric Day.

Poster Winners Recognized at GENEVA 2011

Student Poster Winners

On Tuesday, 29 March, the 2011 Student Poster Award Ceremony took place at the DIA booth on the Exhibition Floor at 5:30PM. Full-time university students, residents, and fellows were eligible to submit abstracts for this session, and the 20 accepted abstracts were published in the March 2011 issue of the *Drug Information Journal* (volume 45, number 2, pages 213-219). During the EuroMeeting, the posters were on display in front of Room F. The students were available to discuss their work during the coffee and lunch breaks on 29 March.

The poster committee comprised Dagmar Stara, Faculty of Pharmacy, Comenius University, Slovak Republic, Sergio Guerrero, Director, OCA Hospital/ Monterrey International Research Center, Mexico, and Lembit Rägo, Coordinator, Quality Assurance and Safety, Medicines, Policy, and Standards, WHO, Switzerland.

Professional poster winners with Ric Day

Brigitte Franke-Bray, Director, DIA Europe and Ric Day, President, DIA, spoke about the importance of students to DIA's future. Brigitte and Ric then presented the awards to the students.

The winning authors and posters are as follows:

First Prize of €1000
Hans Ebbers, Utrecht University, The Netherlands
Determinants of Safety Related Regulatory Actions of Biopharmaceuticals

Second Prize of €500
Elise Mai, Sabine Marteil, Margot Chalaye, Mathilde Gaultier, and Marion Blanc, Eudipharm, France
Experimental Designs in Small Sample Size Phase-III Clinical Trials: A Decision-making Tool

Third Prize of €300
Sandra de Bie, Erasmus University Medical Centre, The Netherlands
Prediction of the Masking Effect of Vaccines within Paediatric Signal-Detection

Professional Poster Winners

Thirty-two professional posters were on display in front of Room A. The prizes were presented by on Wednesday, 30 March at 1:00PM at the DIA booth on the Exhibition Floor.

The members of the poster committee were Vincenzo Cannizzaro, International Regulatory Manager, Qualitecfarma, Spain, Olivier Chassany, Professor, Clinical Research & Development Department, Assistance Publique-Hôpitaux de Paris, France, and Katrin Rupalla, Senior Director, Celgene R&D, Switzerland.

The winning authors and posters follow.

First Prize
Pasi Korhonen, EPID Research, Oy, Finland
Rehospitalisation Risk and Discontinuation of Initial Antipsychotic Treatment after first Hospital Episode of Schizophrenia

Second Prize
Peter Cornelisse, Cedric Marchand, Elisabetta Verdun di Cantogno, and Stephane Marzbal, Merck Serono S.A, Switzerland
Comparison of Statistical Models for Analysis of Historical Magnetic Resonance Imaging (MRI) Data in Multiple Sclerosis (MS)

Third Prize
Mazhar Thakur, Lia Mclean, Swapu Banerjee, Popewoodhead & Associates Ltd., UK
Can public communication of the benefit-risk of medicines be improved?

Chris Kula-Przezwanski, Mediguard, USA
Expanding a Patient-centric Safety Registry from the US to Europe: Year 1 Learnings. ■

Monitor **www.diahome.org** for information on the student and professional abstract processes for Copenhagen 2012.

EPSA Holds Annual Reception

On the 28th of February, the European Pharmaceutical Students' Association (EPSA) held its Annual Reception in the European Parliament, which had as topic for this year "The Pharmacist of tomorrow – developing new roles to meet professional challenges." This event was hosted by Ms. Oana Antonescu, a member of the European Parliament, with the participation of EPSA's main partners such as the Pharmaceutical Group of the European Union (PGEU), the European Association of Faculties of Pharmacy (EAFP), the European Association of Hospital Pharmacists (EAHP), and the European Industrial Pharmacists Group (EIPG), among others. More than 20 students from several countries were also in attendance.

Two of EPSA's most successful projects, the Individual Mobility Project (IMP) and the Training Project, were presented in this event, where Mr. Jürgen Tiedje, Head of Unit of the DG Internal Market and Service of the European Commission, was also a speaker. Mr. Tiedje explained the challenges of the recognition of pharmacists' professional qualifications within the EU space and the changes which are currently being developed in the legislation at that level. Once more, EPSA provided to its partners and members a unique event to show the Association's main projects and outcomes, as well as an opportunity to voice the students' opinion on such an important topic as the pharmaceutical profession.

"GREENEST EXHIBITOR" Award Presented in Geneva

Ric Day, Saurabh Joshi, Neetu S., and Paul Pomerantz at the DIA booth.

For the third year in a row, DIA presented its Greenest Exhibitor Award to the exhibitor who best incorporated an awareness of the importance of this movement in the conferences and exhibitions industry.

The location of the 2011 EuroMeeting in Geneva was fortuitous, as that city takes its responsibility to the environment quite seriously, from renewable energy production to its efficient public transportation system. The Palexpo Convention Center shares DIA's and Geneva's commitment to an environmentally friendly EuroMeeting. Waste recycling for some events at the Palexpo has reached 80%. All of Palexpo's energy needs are met by hydroelectric power and/or solar panels on the roof of one of the halls and an electrical charge port for two-wheeled vehicles in the parking area which may be used free of charge.

In recent years, the EuroMeeting has successfully reduced its carbon footprint by adhering to the 3Rs: reduce, recycle, and reuse. Attendees were offered environmentally friendly conference bags, and their badges were recycled at the end of the meeting. The meeting was paperless wherever possible, and all EuroMeeting publications were printed on FSC-certified paper.

European office staffers traveled to Geneva by train. DIA offset the air miles of other staff with a Swiss nonprofit foundation, "myclimate"-The Climate Protection Partnership. All participants staying at a hotel in Geneva received a free public transport card.

This year's Greenest Exhibitor is Superior Document, based in Mumbai, India. As an example of the measures they took to be environmentally friendly, Superior Document did not ship their booth. They brought it with them on the plane. In addition, they used recyclable material for printing their booth display, had a lighter-weight stall decoration, used LED lights to save power, distributed no plastic giveaways, maximized their in-booth area by avoiding stands, and their business cards doubled as product information cards, referring potential customers online for further details.

On Tuesday, 29 March at 13:30, Ric Day, DIA's President, presented the Greenest Exhibitor award to Saurabh Joshi and Neetu S., who accepted it on behalf of Superior Document. ■

3rd DIA China Annual Meeting Held in Beijing

The 3rd DIA China Annual Meeting Quality and Standards—Elevating China Pharmaceutical Development was held on May 15–18, 2011 in Beijing with great success. Compared to the previous Annual Meetings, this year's meeting had more participants, exhibitors, workshops, and program tracks and features. The Annual Meeting was again jointly hosted with the China Center for Pharmaceutical International Exchange (CCPIE) of State Food and Drug Administration (SFDA), China.

James CAI, MD, President, Pangu Biopharma Ltd., member of the DIA Advisory Council of China (ACC), co-chaired the event, together with ZHAO Yajun, Director-General, China Center for Pharmaceutical International Exchange. John J. HU, PhD, Vice President, General Manager, USP-China, also a member of the ACC, was Vice-Chairperson of the meeting.

Under the theme of "Quality and Standards—Elevating China Pharmaceutical Development," the Annual Meeting provided a unique international and neutral forum to discuss and explore the latest developments within the China pharmaceutical industry, and ideas that will impact global health.

The first day featured an opening session with a keynote address by Mr. Mingli SHAO, Commissioner, State Food and Drug Administration, China. The plenary session also featured a high-level opening debate on *Positioning China-The Strengths and Challenges in Innovative Drug Development,* moderated by Ling SU, PhD, Senior Vice President, Head of Development Greater China, Beijing, and Chair of the ACC.

The excellent program featured 35 sessions and 7 interactive tracks, covering the topics of Clinical Research and Development, Drug Safety/Pharmacovigilance, Regulations and Practices, Data Management and Statistics, CMC/cGMP, Clinical Capability and Capacity Building, Medical and Scientific Affairs, Quality Assurance, and Control. Over 130 expert speakers and panelists attended the meeting from SFDA, US FDA, and other regulatory bodies throughout Asia and Europe, WHO, industry, academia, and medical institutions.

Preconference workshops were held on 15 May, and provided in-depth skill training and knowledge enrichment. New to this meeting were an unprecedented town hall, three standalone/hot topic sessions on the WHO Prequalification Program for medicines, translational medicine, ethnicity and drug development, as well as a student poster session. Over 30 students from six Chinese universities submitted posters for this session, with topics ranging from clinical data management, drug approval and release to quality and safety and standards.

Save the Date

The 4th DIA China Annual Meeting will be held May 2012, in Shanghai, China. For more information and exhibiting opportunities contact Ms. Runshan Chen at dia@diachina.org. ■

Upcoming DIA Events in China:

Supply Chain Management Workshop, July 18-19, Suzhou

2011 DIA China Statistical Workshop: Understanding the Statistical Thinking in Clinical Research for Drug Development, October 23-24, Shanghai

DIA China Annual Workshop for Clinical Data Management-Quality and Integrity of Clinical Study Data in the Compliance with GCP: From Patient to Data Submission, October 25-26, Shanghai

4th Regulatory Conference Held in India

Sultan Ghani

The 4th Regulatory Conference: Quest for Quality-Changing Global Regulatory Landscape was held at the Hotel Courtyard Marriott, Ahmedabad, from April 7-9. This conference provided a dynamic forum for interaction, and sharing ideas, knowledge, and expertise.

Three tutorials were held prior to the conference opening on April 7. Attendees had the opportunity to participate in tutorials on the global perspective and overview of CTD to eCTD, current updates on packaging and labeling requirements, or cold chain management.

There were also exhibits and a Student Poster Session. The student posters were assessed by a panel of judges, and the top three posters were awarded prizes.

The pharmaceutical manufacturers in India are facing many challenges within their domestic and global regulatory environments. This conference addressed many of these issues, in addition to presenting a grand opening ceremony which included a video presentation from the Hon. Jay Narayan Vyas, Minister of Health & Family Welfare, Government of Gujarat, and a keynote address from the Vice Chancellor of the University of Vadodara, Mr. R.K. Goyal. Mr. Paul Pomerantz, DIA Worldwide Executive Director, and Mr. H.G. Koshia, Commissioner, FDCA, Govt. of Gujrat, also offered remarks. The outgoing Advisory Council of India chair, Dr. Nandkumar Chodankar, received a DIA service award from Paul.

Two other important events took place at this conference: a special lecture on "Emerging Regulatory Mandates for Serialization, Track and Trace and ePedigree: An Operational Framework of Indian Pharma" delivered by Dr. Avi Chaudhary, Director, Kezzler AS, followed by a Regulatory Industry Conclave: Building bridges between Regulators and Industry. This interactive session focused on the regulatory and quality challenges and opportunities surrounding the pharmaceutical industry and regulatory authorities and was moderated by Dr. Shoibal Mukherjee, GVK Bio, India

Gujarat is a state which is regarded by many as a pharmaceutical industry hub. The state has approximately 3500 manufacturing units and is a net exporter of pharmaceutical products. About 95% of API and formulations are produced locally, which represents 40% of national pharmaceutical production over the past two decades. The state has ancient roots and has been ruled by many dynasties. Although the principle language of Gujarat is Gujarati, other languages are spoken throughout the region, and casts and traditions make Gujarat rich in culture. A social cultural evening which was highlighted by the folk dances of Gujarat was another highlight of the program. The closing of the conference included a special lecture from Mr. Pankaj Patel, Chairman & MD, Zydus Cadila.

The conference was well attended, with more than 260 delegates and received wide media attention. In Ahmedabad, it was part of the national news telecast. ■

***Sultan Ghani** serves as Director, DIA India.*

Program Co-chairpersons
H.G. Koshia
Pankaj Patel

Program Committee
Nandkumar Chodankar
Chetan Majmudar
Vinay Nayak
Arun Mishra
Kamlesh Udani

Organizing Committee
Nirav Chokshi
Shrenik Shah
Alpesh Chudasama
Pratik Vora
Jigar Patel
Apexa Patel
Rakesh Patel
Nilesh Patel

DIA JAPAN HOSTS DRUG DEVELOPMENT CONFERENCE

When the 9.0 magnitude earthquake and resultant tsunami struck northeast Japan on Friday March 11, the scheduling of DIA's **5th Annual Conference in Japan for Asian New Drug Development** in early May seemed very much in doubt. But the volunteer conference program committee and DIA Japan, working together amidst some extraordinary circumstances, presented this Conference as scheduled, May 10-11 at the Tokyo Dome Hotel.

"We really thought about whether to postpone this meeting or to keep it as originally scheduled. This was not an easy decision," explained Ko Sekiguchi, Director, DIA Japan LLC. "While I was in Geneva to attend the EuroMeeting, I discussed the nuclear power plant situation with our program chair, Dr. Hironobu Saito, who is also from Japan, and whether we should have the conference or not. The week after the EuroMeeting, Dr. Saito expressed a very strong wish to hold this conference as scheduled as a sign that Japan is still okay, because, outside of Japan, there seemed to be almost too much concern from excessive reports about the situation. These reports sounded worse than what actually happened."

"The program committee for this conference had roughly 20 people; of those 20, about half were from Japan and the others were from China, Korea, or Taiwan," Ko continued. "At that point, we asked the Japanese program committee members whether we should hold it or postpone it. It was surprising to me that the majority – almost everybody – was positive about holding it because it would point Japan in the direction of recovery."

This decision to continue as scheduled was not without its challenges. "The biggest challenge was whether or not we could expect enough speakers from overseas to attend because at that moment there was international concern that Japan was very chaotic," said Ko. "So, each program committee member contacted a speaker, asked if they would kindly come to Japan as scheduled, and tried their best to explain what the situation really was. Tokyo, 250km away from the nuclear plant in serious trouble, was pretty safe. Of the twelve speakers we invited, seven responded that they would come. Some companies did refrain from sending their employees to Japan during this time."

"For instance, one of the speakers from Taiwan could not come. In this situation, Dr. Herng-Der Chern very kindly accepted our offer to speak in replacement because he is really committed to helping Japan," Ko said. "This was a great opportunity for Asian people from Korea, Taiwan, China, and elsewhere, who were really willing to help support Japan. It was very encouraging to see Asia unite around Japan and become even stronger."

This spirit of cooperation and unity also meant that the exhibit hall and networking opportunities offered by this conference were minimally impacted by this calamity. "We had planned this meeting with the expectation of having 26 exhibitors, and ended up with 24 even after this earthquake," Ko explained. "Exhibitors might also have been discouraged about this event from reports about the Japan situation but this was very encouraging to us and I am very thankful to our exhibitors."

"When I attended the Asian Regulatory Conference in Seoul late April, a number of people from China, Korea, Taiwan, India, and elsewhere, expressed concern and care about what's happening in Japan. I felt great encouragement through them," Ko concluded. "We had a very difficult, very tragic, disaster, but we've learned how people care about us, and that we are not alone: We are not isolated but very much part of a global network through DIA." ■

Upcoming DIA Events in Japan

2nd DIA Cardiac Safety Workshop in Japan
September 5-6 in Tokyo

8th DIA Japan Annual Meeting: New Trend for Global Pharmaceutical Development
October 27-28 in Tokyo

Earthquake and Tsunami in Japan

A Personal Perspective

Dr. Tatsuo Kurokawa

It was a lazy, still chilly afternoon. I was at home preparing a lecture for the Japan Pharmaceutical Manufacturers Association (JPMA) later in the day. I had my bag at my side and was checking my tie, feeling a certain amount of tension rising from within, when I felt a vertical shake at my feet. As a Japanese accustomed to earthquakes, I looked around and prepared myself for a horizontal shake that I thought would follow. I was even starting to think this earthquake could not be that serious since there were more than several seconds between the vertical and horizontal shakings, which indicates the epicenter is likely rather distant. But I was totally wrong. The horizontal shake that followed was as powerful as I had never experienced in my life, which would have been a 5 on a Japanese quake scale. It was almost impossible to keep standing in my home, as its wooden frame shook, throwing boxes and bottles off shelves. It lasted an entire three minutes.

The March 11 earthquake and tsunami in East Japan killed nearly 15,000 people, and 11,000 are still missing. Much of the coastal and inland areas of northeastern Japan were destroyed. Japanese medical care and related industries suffered serious damage and are still struggling to recover with an enormous effort spanning widespread resources. Northeastern Japan was home to many sales offices, a number of distribution centers, and production facilities for pharmaceutical companies. Without exception, all sales offices in Sendai city, the center of the region, were hit by strong shakings from the 9.0 magnitude quake. Damage to buildings and infrastructure was followed by a prolonged loss of electricity, water supply, transportation modes, telecommunications including cell phones, and other so-called "life lines." Live video footage of massive tsunami swallowing towns and the subsequent explosions at Fukushima Dai-ichi nuclear power plant horrified everyone who could possibly imagine what was befalling the people of the region.

People working for the pharmaceutical and related industry immediately thought of the safety of their employees. But, at the same time, they worried about hemodialysis patients and diabetes patients who need regular, essential medical treatment. The continuation of hemodialysis was expected to face major obstacles because of power blackouts that were widespread over the prefecture, as well as the lack of transportation. According to media reports, some patients were transferred by helicopter to remote hospitals to receive the necessary medical care.

There was also the problem of providing care for patients who were unable to move on their own. The administration of parenteral fluids for hemodialysis was almost certain to run into serious problems within several days, if production were to halt, because it needs massive transportation support in addition to being manufactured in a sterile environment. In anticipation of possible natural disasters and to prepare against risks of damage, Fuso Pharmaceutical Industries, one of the major manufacturers of large-volume parenteral drugs including fluid for hemodialysis, had built its production facilities in two locations far apart from each other– Osaka city and north Ibaragi. It reported on its homepage that its north Ibaragi factory was severely damaged, but the company essentially survived during this difficult time in terms of drug supply. A number of pharmaceutical companies had taken similar precautionary policies for production site locations, but the damage to the production capacity was reported as extremely serious.

Secondary damage also set off inconveniences unimaginable under normal circumstances. Prolonged and/or unpredictable power shortages caused contamination to the sterile drug-production even at facilities that had luckily survived physical damage; halted cooling led to discarding finished drugs; and the disruption of fermenting and other chemical reactions led to damage to equipment at the facilities. Some warehouses for pharmaceuticals, which are usually high-rise rack types controlled by computers, could not start their operations even after the restoration of electricity because of the droppage of containers and distortion of railings for elevators. In research and development,

the progress of clinical trials was hampered as patients found it difficult to commute to clinical sites for follow-up. Damage to Hitachi Group companies, which are mainly located in the Ibaragi prefecture and are known for manufacturing equipment for R&D affected R&D because there was no place to make needed repairs.

One week after the disaster, it was still difficult for pharmaceutical companies to assess the extent of the damage, but signs of recovery are gradually emerging. Government offices were making concerted efforts for the proper administration of the relevant laws to deal with the situation, with top priority on saving lives and improving the quality of life for patients. The pharmaceutical industry is making contributions in both goods and in spirit toward the recovery, despite having sustained significant damage from the disaster, by collecting donations and providing aid as an individual company or through the Federation of Pharmaceutical Manufacturers Associations of Japan (FPMAJ) and other organizations. The worst crisis seems to be over in the medical field.

About 4 o'clock in the afternoon on March 11, sometime after the quake, I headed by car to the lecture, as public transportation had stopped The lecture room was on the twenty-first floor, and since the elevators had all stopped, I was asked to please come up the stairs. By that time, traffic jams were making car travel impossible, and rows of commuters could be seen walking home from the city. The lecture was eventually postponed. I recently received word that the lecture was being rescheduled for May, and that I was to get ready.

Japan is in very difficult times, but it is making a gradual yet certain way back to recovery. We were greatly encouraged and consoled by the aid and moral support the world sent to Japan after the quake. I thank you for all your warm thoughts and wishes. I hope you will be with us, perhaps giving us encouraging words now and then, as we continue to tackle this nation's recovery. ■

Dr. Tatsuo Kurokawa is a member of DIA's Board of Directors.

ASIA REGULATORY CONFERENCE
Held in Seoul, Korea

DIA partnered with IFPMA and APEC to host the *Asia Regulatory Conference: Asia's Role in Global Drug Development*. The conference took place April 26-28 at the Grand Hilton Hotel in Seoul, Republic of Korea and attracted more than 620 attendees, speakers, and exhibitors, including 158 from the international community and 460 from Korea.

Planning for the conference began about 18 months ago, when representatives from DIA and IFPMA decided it would be advantageous to members of both organizations to do a joint conference in the Asia region. During the early planning process, the APEC Harmonization Center, based in Seoul, came on board as a partner also and added their local knowledge to the vision.

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) works toward understanding between the research-based pharmaceutical industry and other global health stakeholders.

Asia-Pacific Economic Cooperation, (APEC) is a forum for facilitating economic growth, cooperation, trade and investment in the Asia-Pacific region.

The Program Committee, chaired by Dr. Andre Broekmans, Vice President, Most of World Regulatory Policy & regulatory Affairs, MSD, the Netherlands, was made up of 25 professionals from our industry, with a balanced cross section from DIA, IFPMA, and AHC.

"This was one of the toughest exercises I have managed in recent memory, what with all the different time-zones, cultures experiences and language barriers influencing the conversations. However I am extremely proud of what we were able to accomplish collectively in such a short planning timeline. I had the most amazing Committee to work with, as the end result proved," stated Dr. Broekmans.

The most powerful part of this conference was by far the content delivered by the wide range of speakers. Using a combination of plenary and panel sessions, as well as a series of break-outs, the attendees sometimes had to make difficult decisions about which sessions to attend. Collectively there were more than 70 speakers and presenters.

The conference began with an Opening Ceremony, featuring remarks from Dr. Sun Hee Lee, Director, Drug Evaluation Department, KFDA, Dr. Broekmans, and Opening remarks from Dr. Seung Hee Kim, Director General, National Institute of Food and Drug Safety Evaluation, KFDA. Congratulatory Remarks were

delivered by Dr. Yun Hong Noh, Commissioner, KFDA, and Dr. Bup Wan Kim, President, KHIDI. Dr. Odette Morin, Director, Regulatory and Scientific Affairs, IFPMA, presented a welcome from that organization, and Dr. Yves Juillet, DIA President-elect welcomed the attendees on behalf of the association.

Key themes of the conference were as follows:

- Update on ICH Activities
- Regional Harmonization Initiatives
- Early Clinical Development in Asia
- Late Clinical Development in Asia
- SBPs in Asia
- Electronic Submisisons and eCTD as Vehicles to Reconcile Differences in Technical Regulatory Requirements
- Pharmacovigilance: How Do Regulatory Agencies and Industry Work Together to Protect Patients?
- Good Regulatory Practices, Including Assessment Report, Efficient Use of CPPs amd Transparency

"I'd like to thank all the Program Committee members and speakers who made tremendous contributions to the success of Asia Regulatory Conference which ended just last week.

The AHC will continue to commit itself to providing good training programs for advancing regulatory harmonization and regulatory science. So, I ask for your continued attention and interest in our future activities.

Once again, thank you all for your contributions to the success of this meeting and will be looking forward to more opportunities to deepen our relationship and cooperation in the future."

Kui Lea Park
Director of Center for Drug Development Assistance
KFDA

A number of parallel tracks offered attendees choices between presentations on important topics such as counterfeit medicines, practical uses of the CTD, and establishing the Asia-Pacific region as a partner in global pediatric development.

After the conference, the KFDA offered the attendees an opportunity to visit the GCP facilities at the Seoul National University Hospital. Recently, the hospital has carried out a clinical research project-Korean National Enterprise for Clinical Trials (KONECT)- run by the Korean government. The objective of the visit was to promote better understanding of the current status of clinical trial research in Korea. ■

3rd Annual DIA Latin American Regulatory Conference Held in Panama

DIA presented the **3rd Annual DIA Latin American Regulatory Conference (LARC): Harmonization of Regulatory Requirements in Drug Development and Registration** on April 12 -15, 2011 at the Panama Marriott Hotel, Panama City, Panama. Its goal was to maintain continuity between the Pan American Health Organization's biannual conferences of the Pan American Network for Drug Regulatory Harmonization (PANDRH) and to focus on key areas of harmonization. PANDRH is an initiative of the national regulatory authorities within the Americas Region that supports the processes of pharmaceutical regulatory harmonization in the Americas, within the framework of national and subregional health policies and recognizing pre-existing asymmetries.

Dr. Eric Conte, Director of Panama's Directorate of Pharmacy and Drugs of the Ministry of Health (MINSA), provided the opening welcome, and program co-chairpersons Justina Molzon and Mike Ward offered opening remarks describing the three-day program. The Keynote Address was delivered by, Dr. Felix Bonilla, General Secretary of Ministry of Health from Panama.

Speakers from the pharmaceutical industry, drug regulatory authorities and experts from academia, the World Health Organization (WHO), the Pharmaceutical Research & Manufacturers of America (PhRMA), Central American Federation of Pharmaceutical Laboratories (FEDEFARMA), and other allied working groups fostered genuine discussion of key topics promoting the advancement of collaborative goals and objectives across the Latin American region.

The following international regulatory authorities participated in these fluid and transparent discussions: US FDA and FDA Latin American Office, Health Canada, ANVISA (Brazil), ANMAT (Argentina), CECMED (Cuba), MINSA (Panama), and WHO (Switzerland). Attendees from the following Latin American countries also participated: Argentina, Brazil, Colombia, Chile, Costa Rica, Cuba, Ecuador, Guatemala, Mexico, Panama, Peru, and Puerto Rico, along with representatives from the US, Canada, and Europe.

Panama was selected as the site of the 3rd LARC due to its central location in the Americas. The program included presentations concerning the advancement of regulatory science, pharmacovigilance, biotechnological products, good clinical practices, evaluation of drug efficacy, and various viewpoints on harmonization initiatives.

Mike Ward, International Programs Division, Health Canada, delivered a key message in his presentation on Asia-Pacific harmonization efforts, where working together will promote public health and innovation and also strengthen drug regulatory authorities in the process.

"What we seek, for instance, is for Latin American countries to speak the same regulatory language. Also, the experiences in other countries can be applied to Panama and vice versa. A positive change in health is everyone's commitment," commented Dr. Eric Conte, Director of Pharmacy and Drugs, Ministry of Health, Panama.

The 4th LARC will be scheduled for May 2012 in Brazil. ■

Session 1, Current Environment for Regulatory Authorities and Industry for Latin America. ***Dr. Eric Conte****, Director of Panama's Directorate of Pharmacy and Drugs of the Ministry of Health (MINSA) and LARC participants.*

Program Committee Members

Justina Molzon, MS Pharm, JD, CAPT. USPHS,
Dr. Eric Conte
Mike D. Ward
Mark Paxton
Dr. Honorio Silva
Sergio Guerrero, MD

TEAM BULDING 2.0:
SEVEN STEPS TO SUCCESS

The point of business is to produce goods or services, and this is accomplished through the skills and talents of employees. How higher management chooses to reach its goals can vary. One way is to group employees into a business team. Like an athletic team that coordinates individual player's actions in order to win the game, individuals on a business team work in tandem to complete an objective devised by management.

Team environments often produce remarkable results–not only for the company, but for the employees as well. This is demonstrated in a research study cited in The Orange Revolution by Adrian Gostick and Chester Elton. A business team of health care workers took the time "to identify goals that aligned with members' personal competencies, as well as with the team, company, and customer needs." The results were overwhelmingly positive: a 10% increase in job satisfaction, a 17% rise in workplace morale, and more than a 50% reduction in absenteeism.

Would your company like to try the team approach on its next project? Once management determines it has a task to undertake–and it studies the essential differences between teams and departments–select team members and a leader based on the specific goal you have in mind and follow the seven steps to success.

STEP #1: GOAL SETTING

How does the work begin? A kick-off meeting helps the members become acquainted with each other, as well as the team's purpose. To define your goal to the team, answer the question: "What are we trying to achieve and why?" says Catherine Mercer Bing, CEO of ITAP International, Inc., a team building consultancy.

To achieve timely, on-target results, all team members need to understand the aspects of the above goal. "Goals must be specific with quantitative, measurable outcomes," says Gostick. "Your team cannot just improve customer service, for instance. Instead, a realistic goal would be to have company representatives answer all calls in fifteen seconds." Or the team needs to know how many widgets it needs to sell.

"Qualitative data is required as well," says team strategist James Berkley of Berkeley Burke International in London. He points out, "The team

VIRTUAL TEAM TOOLS

Courtesy, Nancy Settle-Murphy, owner, Guided Insights, a virtual collaboration consultancy

Although most companies already use team building, and do so with virtual teams, here are some tips to maximize the process:

During "phone team sessions" give non-native English speaking members time to translate into their own language. And, to avoid misunderstandings, "paraphrase and validate meanings." For example, you might want to say, I had a hard time understanding. May I repeat back to you what I think you said?"

Always treat people as individuals, but, in place of in-person meetings, team members should learn about the cultural backgrounds of team members (www.culturegram.com). What level of detail do they like? How do they process information? Do they prefer to talk or listen?

To facilitate team building at the outset, leaders need to investigate the best virtual collaboration tools for all members based on the infrastructure. Also, some cultures may prefer anonymity because of hierarchal issues, so using a virtual collaborative tool where an electronic blackboard is available may suit these individuals.

needs to establish a framework for decision-making–known as the strategy–to get those widgets to market." He suggests that if the goal is to reach West 72nd Street, the strategy options might include riding "the 'A' subway line or boarding the M4 bus."

To determine which tactics to utilize, answer the following questions:

- What are the needs of the customers? "Team members are invited to stretch their imaginations to brainstorm for exciting ways to deliver a great product or service beyond the expectations of the consumer or client," offers team performance expert Darelyn Mitsch of Pyramid Resource Group.

- Berkeley says the team leader should, "Find out what really matters to my team members and how do I appeal to their self-interests?" How can their individual goals help achieve the overall team goals? For example, "Jane" can incorporate her personal goal of helping those with infirmities into the organizational goal of helping her employer, a hospital, to improve its patient services.

- "Are the team members passionate about their achievements? Is there an extraordinary goal or noble cause that the team can get excited about?," Mitsch suggests. Likewise, *The Orange Revolution* gives the example of a medical facility with a cause; instead of just providing medical care, it increased the number of patients by making them "raving fans." This even included improving the cafeteria food, providing valet parking, and allowing patients' families into the emergency room surgery.

STEP #2: OPERATING GUIDELINES

How will the team know how to operate? The best way is to set up a series of rules. Team leaders can make suggestions and ask for team reactions. Or just ask for initial input from the outset. Either way, members will feel as if these are "their" processes–as long as their opinions are discussed and included.

Here are some of the areas to discuss:

Communication will help the members form relationships as they work on the chosen strategy. Start by outlining the preferred method of communication (phone, email, team Intranet). Also, determine the expected response time so that things keep moving forward.

Meetings are not necessary if the message can be encapsulated into an email. Otherwise consider:

- Conduct daily "huddles" held while members stand (to promote brevity) and at off-hours, such as between 9:05 AM and – 9:20 AM (to promote being on time), suggests performance coach John Brubaker.

- "Determine how often and who shall attend which other types of meetings," offers Rosemary McGuire, Vice President of Human Resources at PharmaNet, Inc. "Always send an agenda to explain the meeting's purpose and to help attendees prepare for the meeting."

- Start and end meetings on time. Set this norm and if you deviate, point it out, advises Baltimore, Maryland management consultant executive coach Joni Daniels: "We said we were going to keep on target." Also, if a new topic is introduced, immediately set up a different time to discuss it.

- Make sure everyone's opinion is heard. If team members don't speak up on their own, the team leader has the responsibility to encourage their participation and elicit their contributions, says

Anne Thornley-Brown, president of team building consultancy Executive Oasis.

Other ground rules can include how to set up a confidential meeting and how to handle emergency situations. Thornley-Brown feels it is equally important to determine how to make decisions and resolve conflicts.

STEP #3: ROLE CLARITY

All team members need to understand what each does—and why. Then, co-workers can assist one another with hands-on work and in problem solving. And Brubaker suggests that a member can best propel the team to success by embracing the task of doing "the one thing nobody else wants to do." Lawrence Polsky of PeopleNRG adds, "Knowing what they are '*not* supposed to do' prevents co-workers from stepping on each other's toes."

While many individuals are pre-selected based on specific capabilities, some team members can be given "stretch" assignments so they can develop new skills; this can help the individual as well as the company develop, says Bing.

Jim Willis, president of Executive Edge, Inc., a team building consultancy, states that the team leader should guide members to balance team responsibilities and existing functional tasks–a common difficulty. "Team leaders also need to be sure in the beginning that there are no handoff gaps or gaps in responsibility between different processes," emphasizes Bing. Productivity will suffer and valuable time will be lost if there is no one to perform a forgotten action between "Step A" and "Step B."

STEP #4: COMMUNICATIONS

Experts agree that good communication is the foundation for team success. This includes listening – as well as talking. In a 2007 study of health care professionals cited in *The Orange Revolution*, employees report that superior team leaders are seen as listeners who also asked about the status of current projects. Also, when leaders put team members' ideas into action they give them ownership which motivates them to accomplish the team goals.

"Communication should be taught, and body language can be more important than the verbal message," Brubaker emphasizes. He stresses the importance of eye contact.

Here are some other important communication tips:

- Those who share interdependent tasks should communicate directly, points out Polsky. There is no sense in the team leader carrying a message between "Bob" and "Joe" who are coordinators of a team sub-committee. "Direct communication between team members results in direct relationships," reports Willis, which begins building communication/relationship trust."
- Match your communication style with the person to whom you are talking; if your teammate is analytical, don't present an idea without supporting statistics, according to Polsky.
- Daniels advises teammates to be diplomatic. Instead of "That is a stupid idea," say, "I don't see how your idea will achieve the objectives we agreed upon."
- When a talkative member overtakes a meeting, it is beneficial to have someone from the group speak to this individual later in private.

DECISION MAKING

Willis advises that when members change the way they look at conflict, decision making can become streamlined. This happens when team members realize that they do not need to "win" or defeat each other, but rather make decisions that are congruent with the team's core values. For example, a salesperson may become the top producer if a particular order goes through on the condition that it is rushed through, without time for a quality check. Members of the manufacturing team might refute the order, though, because it is at odds with the company's core value of meeting high product quality standards.

- Team members should feel free to ask each other for help at any time.

STEP #5: TRUST

Gostick reports that "open communication is the biggest lever to pull to ensure trust." Bing suggests that to build this important element, "team leaders need to closely oversee projects by regularly sharing, 'How far we have gotten?' Here is where much of the work needs to be completed." In addition, the team leader should report changes in a project's status. "This was a high priority, but has been downgraded in importance since 'Joe' left the company last week."

McGuire suggests leaders build trust by speaking individually with members: "Do you understand what we are working on? Do you have any questions?" Give them the opportunity to give feedback. She adds, "Trust takes time; at first people may not be willing to tell you

ACCOUNTABILITY THROUGH THE STAGES

Willis explains how accountability shifts as the team develops in line with Tuckman's model. In the "forming" stage, members feel individually accountable, as they do in the "storming" stage, when they begin to carry out autonomous roles. In the "norming" stage and in the "performing" stage, the group moves towards accomplishing mutual goals while defining accountability from a group perspective.

what they are thinking. Hopefully over time the team members will see that you 'walk the talk' and slowly trust will build." Bing says that during both in-person and virtual meetings, members should express a personal, professional, or team goal that was met during the past week.

Gostick agrees that leaders have to be "promise keepers." They need to respect team members' ideas, admit to making mistakes, and "speak of the team in only the most flattering terms outside the team environment." For example, if you say you will respond to an email in three days, make sure you do it. Importantly, leaders need to be ethical. Unfortunately, *The Orange Revolution* reveals that many team leaders and supervisors take credit for employees' ideas.

Likewise, members need to be trustworthy; they should maintain a positive representation of themselves and the firm, says Polsky. "Spending time with team members and mutual disclosure builds trust," adds Daniels.

STEP #6: ACCOUNTABILITY

Accountability is knowing what needs to be done–and doing it. There is individual accountability–when each team member knows what is expected, including client commitments and team project deadlines. When members understand their roles, it is easier for them to be accountable, especially if they are clear on the task details, including the deadline. If there is a problem, it is advisable for team members to say, "I am running late" rather than later lamenting, "I didn't have time to get that done."

Effective team leaders can help team members be accountable by coaching them to break large goals into more manageable pieces. If "Sally" needs to make 20 sales calls, including several that require extra time, who should be called–and when–in order to meet the completion date?

Willis says that to increase feelings of accountability, leaders should give authority to team members. If "Joe" is responsible for maintaining five machines, he needs the authority to call in a mechanic to fix a broken unit. Experts agree that accountability–along with reasonable deadlines–engages people.

The team as a whole is also accountable for mutual goals. Team accountability should replace fault finding and placing blame with problem solving and brainstorming. The attitude becomes, "if the team wins, we all win," points out Daniels. And high-performing teams thrive with accountability. Most often they not only set a goal and achieve it. They usually exceed it!

Unfortunately, many team members feel they are "held accountable" only when they do something wrong. "During these tough economic times, there is too much emphasis on the negative," feels Brubaker. He says team leaders can enhance performance and morale by "catching members doing something right on a daily basis."

STEP #7: RECOGNITION

Role clarity and straightforward objectives are needed for the company to recognize the accomplishments of the team. Polsky advises team leaders to start this important process at the project's outset by asking members, *What do you want to learn?* and *What are your career goals?*

Once management knows what matters to the employee, Anne Thornley-Brown says it can ask members to choose from a "cafeteria-style range of options," which might include time off, money, or a convenient parking space. Daniels suggests some may enjoy public praise, while others may prefer a "pat on the back in private."

Gostick suggests these types of **recognition** for completed accomplishments:

- **Day-to-day recognition:** verbal praise, a handwritten note, movie tickets
- **Above-and-beyond recognition:** significant achievements (eg, helping clients over the weekend) should be acknowledged by top management
- **Career recognition:** retirement certificate or length-of-service award

- **Event recognition:** celebrate a big team project

When peers recognize each other it means a great deal. This creates a cohesive team because praised individuals don't want to disappoint co-workers. Gostick points out that the shoe company Zappos uses "snap" awards; co-workers recognize each other by snapping their fingers instead of clapping during staff meetings.

Most companies don't recognize effort, points out Brubaker, but many employees learn much from this important process. He points out that according to a Harvard Business Review study "Appreciation for effort is the number one workplace motivator."

(Willis suggests that to minimize competition, individuals should be rewarded during the beginning stages of the team process, and the entire team should be reward during later stages.)

BRUCE TUCKMAN'S 1965 "FOUR STAGES OF TEAM DEVELOPMENT"

Provided courtesy of Jim Willis, Executive Edge, Inc.

1. "Forming" stage: the team is established: goals, roles and leadership emerges

2. "Storming" stage: ideas are criticized; conflict occurs over roles, priorities and leadership

3. "Norming" stage: agreement on rules; acceptance of differences; collaboration and mutual adjustment emerge

4. "Performing" stage: collaborative work begins: members begin to value others' contributions and work with autonomy to achieve team goals

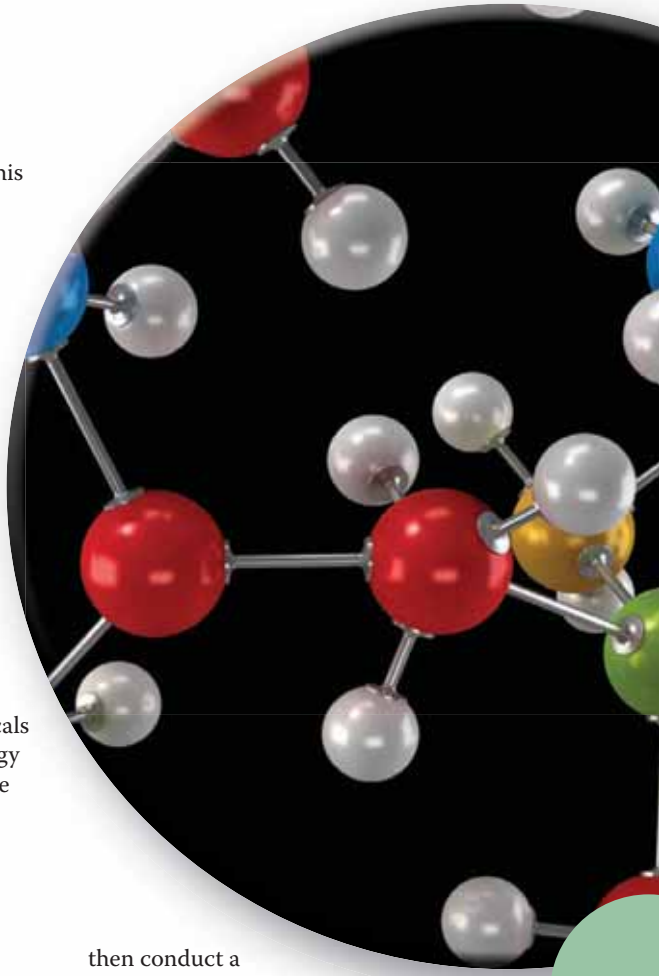
HAVING WHAT IT TAKES

For teams to succeed, individuals need to be cognizant of their roles and perform them in concert with the interrelated tasks of teammates. While striving toward a predetermined management goal, members should communicate frequently–and with respect and honesty. While following a set of self-prescribed guidelines, members ideally support each other and put the good of the team, as well as the company's core values, ahead of ego.

Real success occurs not only by meeting the target goal but when employees feel valued. This happens when the team leader communicates how each member helped reach the overall goal, and when both efforts and accomplishments are recognized in a way that is meaningful to those individuals.

Good luck to your company and the teams that can lead you to ongoing success. ■

FDA/DIA CONFERENCE TO INFORM ICH M7



Dr. John K. Leighton, PhD, DABT (Associate Director, Pharmacology & Toxicology, Office of Oncology Drug Products, Office of New Drugs, CDER) served as chair for DIA's recent workshop **DIA/FDA Quantitative Structure-activity Relationship (Q)SAR Approaches to Assessing Genotoxic Impurities in Pharmaceuticals**, presented in Rockville, Maryland, on April 7. The Keynote Address was delivered by David Jacobson-Kram, PhD, DABT (Associate Director, Pharmacology & Toxicology, Office of New Drugs, CDER).

This workshop was timed so that its discussions could help inform the June 2011 meeting for ICH M7 (Mutagenic Impurities) in Cincinnati. Upon this workshop's conclusion, Dr. Leighton shared the following insights with the *Global Forum*.

"I'm no expert in computational toxicology. I'll start with that," he began. "So, why am I interested in this topic? Why did we push forward for this workshop, and why did we engage DIA in the process?"

As a way of introducing the topic, what does (Q)SAR stand for and what does it mean or do?

(Q)SAR stands for "Quantitative Structure-Activity Relationship." There are various types of (Q)SAR programs, and I would hesitate to provide a description of them all. (Q)SAR takes known chemicals and correlates their chemical structure to an outcome of an assay – in this particular case, we're interested in the Ames assay. The Ames assay comprises five bacterial strains that are used to identify the mutagenic potential of compounds. This workshop was about using (Q)SAR to predict the outcome of an Ames assay, using computer modeling, built on very sophisticated mathematics to break chemicals apart into fragments. These models then identify potential structural parts of the molecule that may indicate the risk of mutagenic potential. We're specifically looking at DNA-reactive chemicals because of a concept in toxicology that assumes a linear to low-dose relationship. The risk is linear – there is no threshold.

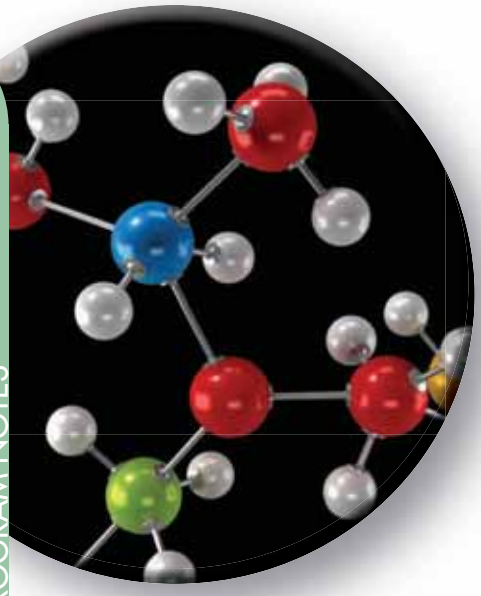
Using (Q)SAR to predict the outcome of an Ames assay is important, because if you can predict that the compound is negative using (Q)SAR, and we all accept the outcome of the predictive model, then the company doesn't have to synthesize an impurity and then conduct a separate assay. They CAN do that but that could be very resource intensive and if it's not needed, then we can push clinical development forward. This is a tool – and it's only one tool – that we can use to perhaps bring newer scientific tools to the drug development process. The workshop was specific to pharmaceutics in this regard.

John K. Leighton

We keep talking about using in silico approaches and using computer models to predict the outcome of quality testing. This is probably one of the first attempts to actually apply it in practice rather than in theory in a regulatory setting.

May we ask you to explain some of the background and context for this workshop?

In December 2008, FDA published a draft guidance which called for (Q)SAR analysis of genotoxic impurities. I read that guidance and thought to myself that I really don't know what that means. So I consulted with our internal pharm-tox group and suggested that we form a work group to educate the pharm-tox reviewers about what that guidance meant, so that we could actually understand what constituted an appropriate (Q)SAR analysis. At that time, we were doing (Q)SAR consults but it was sort of vague: We were running a (Q)SAR consultative service here within CDER, but the consults weren't in a form that we felt could be used for regulatory purposes. We formed this work group to engage those who were actually doing the consults so that we could understand what they were doing, and they could much better understand what we were looking for in a consult. If we were going to apply the principles of this draft guidance, we should know what we're talking about.



In this process, we found out that our internal (Q)SAR database was more geared toward predicting true positive, which is really not what we're looking for in a regulatory analysis. We're really interested in the negative predictive value of a (Q)SAR analysis. Let's say that you had a pharmaceutical with an impurity, and you wanted to know whether or not the impurity suggested risk to human health. If it was positive, then you would have to reduce it below a certain level. Predicting positives wasn't helping us. You had to reduce it regardless of the results. But if it's negative, and we felt confident that the negative predictive value was appropriate, then the company wouldn't have to do any more qualification. We were actually interested in something different than what the consults were providing.

We looked at various options for engaging commercial vendors trying to design their databases for what we felt we needed for regulatory purposes, and the option that we came up with was a public workshop. We approached DIA and DIA graciously agreed to provide all the logistical support behind the workshop. We thank you very much for that.

May we ask you to please share a few highlights from Dr. Jacobson-Kram's Keynote Presentation?

David stated the history and current state of (Q)SAR. Before (Q)SAR, we had what's called the Ashby-Tennant Structural Alerts, which was a chemist eyeballing a structure and saying that this one or that might be a problem. Different chemists may have had different opinions about what those structural alerts meant, or there may be modulating chemistry that would minimize the potential for the alert to be problematic. David talked about the FDA draft guidance and the EU guidance on this topic. Europe published guidance in 2006 and a question-and-answer guidance in 2010, documents considered by our workshop. (Q)SAR is really an attempt to bring some consistency to what is now a purely human evaluation.

This workshop's second session overviewed the different regulatory perspectives - the FDA in the US, the European Union, and the MHLW in Japan - of using (Q)SAR for Ames test predictions for regulatory purposes. May we ask you to share highlights from this session?

The different regions proposed different approaches for (Q)SAR analysis, but there was recognition among all three regions that a harmonized approach would be best. You don't want to do one analysis for the United States and then maybe have to repeat something for Japan and then have to do something else for Europe. Peter Kasper, Scientific Director for the German regulatory authority BfArM, noted that they have used two different programs in Europe, MultiCASE and DEREK. Their algorithms are slightly different so they don't have exactly the same call.

The Japanese reviewer, Dr. Masamitsu Honma (Japan National Institute of Health), talked about how the Japanese view the FDA and the EMA guidances on this topic. They're very interested in becoming part of the process, too. I'd also like to mention that Dr. Honma started his presentation by thanking the people of the United States for their concern, generosity and prayers for the people of Japan. That was very nice and was very warmly received.

How will the discussions from this workshop inform the upcoming meeting for ICH M7 (Mutagenic Impurities) in June?

Last November, the ICH started a new work group which met for the first time in Japan on M7, on genotoxic impurities. We felt that if we were going to have this workshop, for the information and discussion to be most useful, it should be held prior to writing a guidance document, so we pushed the timing of our workshop up, so that the workshop discussions could then impact the thinking and the recommendations of the ICH guidance document. It turned out that several workshop participants are also representatives from the M7 expert working group. We brought experts together who presented case studies about what the companies' challenges were for (Q)SAR analysis and how we would bring an in silico analysis to the forefront of testing for genotoxic impurities.

The design of the conference, who attended, and the fact that it was an open discussion, allowed the discussion to influence the people who were developing the ICH guidance. Members of the expert working group that I talked to felt that it would help speed up development of guidance and that it would be a more robust and more useful guidance.

What emerging "hot topics" will continue to shape the future of (Q)SAR?

Most of the participants felt that (Q)SAR was ready for incorporation into regulatory systems; we may not totally agree on all the details but most people felt that the technology was sufficiently robust to rely upon its results. Another point was that one program plus an expert cerebral analysis was probably the best approach to (Q)SAR, although not all participants were in agreement on this.

There is a real need for transparency: Communication from industry to regulatory agencies, and then back from the agencies to industry, about our mutual concerns is very important. Education of reviewers was also considered important because differences in how reviewers actually look at the data, and differences of opinions between a company and a regulatory agency, could be based on the fact that it's a newer technology and people may not be familiar with it.

The appropriate comparators in a (Q)SAR were an important topic, as well as the chemical space that needed to be covered. What exactly does it mean for compounds to be similar? If we're basing it on similar structures, what exactly does that mean at a molecular level? We are very interested in negative predictive value, but some of other things such as sensitivity and specificity and how well databases are constructed are also important topics.

There were also some concerns expressed by smaller companies who may not have the technological or financial resources that big companies have. What if you're a 20-man virtual company? Another point expressed was that we can't shut out vendors who bring new technology into this. Even though the FDA and EMA guidance mention specific programs, there are many programs that could be just as if not more robust than existing technologies. There is concern about mentioning specific products so that we don't pick favorites.

We really want to see this field push forward, which will require a multidisciplinary approach involving chemists, computer modelers, and toxicologists, to help integrate and understand the data. It's going to require many different disciplines to bring this all together. ■

Program Committee

In addition to Dr. Jacobson-Kram, who delivered the Keynote Address, Dr. Leighton thanks all the other members of the workshop program committee for their collaborative efforts:

R. Daniel Benz, PhD, CDER, FDA

Paul C. Brown, PhD, CDER/FDA

Krista Dobo, PhD, Pfizer

Sheila M. Galloway, PhD, Merck Research Laboratories

Abigail Jacobs, PhD, CDER/FDA

Peter Kasper, PhD, BfArM (Federal Institute for Drugs & Medical Devices, Germany)

Stephen Miller, PhD, CDER, FDA

Mark W. Powley, PhD, CDER, FDA

To learn more about genotoxic impurities and related subjects, plan to attend the DIA 2011 session on ICH Guidelines on *Genotoxic Impurities and Residual Metals: CMC and Safety Issues*, offered within the Non-Clinical and Early Clinical Translational Development Track (Track 04).

MERC 2011 HELD IN AMMAN

The 9th Middle East Regulatory Conference was held at the Le Méridien Hotel in Amman, Jordan, 1-2 February, in partnership with the Middle East Regulatory Network (MERN). The conference attracted more than 250 participants from 32 countries.

Attendees in the coffee break area.

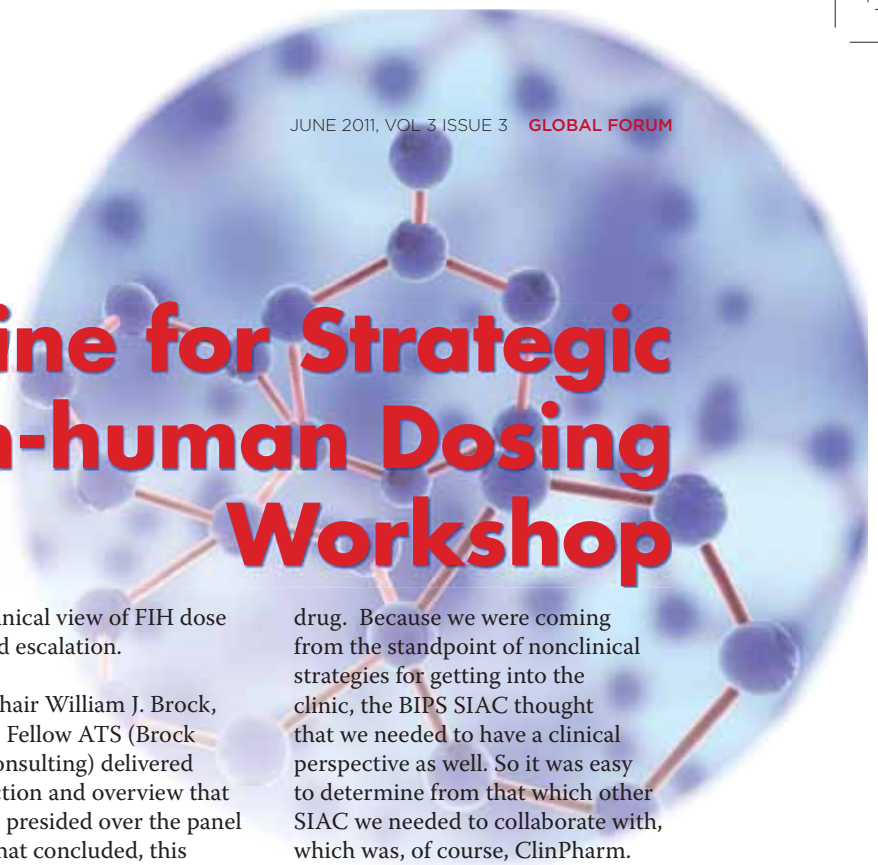
Since its inception 14 years ago, MERC has become an important forum to discuss providing health care to the region, specifically focusing on evaluating innovative medicines for human use. It again offered an opportunity for key stakeholders from this region to meet and exchange views on increased patient access to new and improved medicines and treatments, as well as other related topics.

The opening session offered welcome remarks from Brigitte Franke-Bray, Director DIA Europe and Yves Juillet, DIA President-Elect. Prof. Trevor Jones, CBE, WHO Commissioner, CIPIH, UK, conference chair, as well as Dr. Mohammad Said Rawabdeh, Director General, Jordan Food and Drug Administration, Jordan, also welcomed the attendees, and Angelika Michaelis-Gilles, Senior Regulatory Affairs Manager, Global Regulatory Affairs, Grünenthal GmbH, Germany, chair of the Programme Committee, delivered an introduction from EFPIA/MERN. Angelika summed up the 9th Middle East Regulatory Conference in this way, "It was a great experience to have over 250 delegates from most of the Middle East authorities, some EU authorities, and the WHO, as well as from pharmaceutical companies from around the world, together at this 9th MERC for networking and exchange of experiences and visions. This was a valuable and fruitful conference with excellent lectures that addressed important topics. Attendees seemed to be engaged with the content throughout this meeting. The local authorities' views, their key issues and activities towards harmonization of regulatory procedures and documentation, the topics on the global regulatory environment including variation management and the CTD, the role of research and development in patient access to complex biological and biosimilar products and its interaction with regulatory development in the Middle East, as well as pharmacovigilance as a tool to monitor drug safety for patients, were very well received. The inclusion of the topic of falsified medicines in the agenda "hit the mark," and the lectures and interactions from authorities and industry, which are key to the goal of eradicating falsified medicines, provided significant debate during the conference for one of the most critical safety issues all over the world. The delegates seemed to be really committed to follow up on the important subjects discussed during the 9th MERC 2011, and further events are planned for the near future."

Days 1 and 2 of the conference were filled with seven well attended sessions covering such areas of interest as "Local Regulatory Authorities Views and Key Issues," "Falsified Medicines," and the "Changing Regulatory Environment."

Prof. Trevor M. Jones provided an end-of-conference review and next steps. Discussions on the 10th MERC are currently ongoing. Please monitor www.diahome.org for updates on this conference. ■

Members of MERN, and the programme committee with Ministry of Health delegates and Brigitte Franke-Bray and Yves Juillet.



SIACs Combine for Strategic First-in-human Dosing Workshop

Two DIA Special Interest Area Communities came together to collaboratively support the program committee that developed and presented DIA's workshop on **Nonclinical & Clinical Strategies in First-in-Human Dosing of Large & Small Molecules**, April 4-6 at the Hilton Washington Embassy Row in Washington, DC.

This workshop comprised speaker-led workshop sessions and intensely interactive breakout sessions in which attendees were organized into groups, assigned large or small molecules, and were asked to develop nonclinical programs that would get their assigned molecule into a clinical trial. Speaker-led sessions on the first day explored the current regulatory environment – including current regulatory guidance and regulatory submissions – for nonclinical programs, along with CMC and clinical pharmacology considerations for FIH dosing and the process of developing a lead small molecule compound through a nonclinical program. Day two sessions examined nonclinical development of biopharmaceuticals, and first-in-human (FIH) dose setting in pediatric patients, oncology patients, and other special populations, and concluded with the workshop networking reception. Sessions on the third and final day were devoted to clinical designs and statistical evaluations for large and small molecules, and also presented the FDA's clinical view of FIH dose selection and escalation.

Workshop chair William J. Brock, PhD, DABT, Fellow ATS (Brock Scientific Consulting) delivered the introduction and overview that opened, and presided over the panel discussion that concluded, this workshop. Afterwards, Dr. Brock shared his thoughts on the promise and progress of this workshop with the *Global Forum*.

Q&A This workshop was collaboratively developed by the DIA Biotechnology & Innovative Preclinical Sciences, which you serve as Chair, and the DIA Clinical Pharmacology Special Interest Area Communities (SIACs). How did their different perspectives come together in this workshop?

I had attended a meeting of the DIA Advisory Council of North America that raised the issue of developing workshops, meetings, and the like, by collaborating with other SIACs. As chair of the Nonclinical SIAC at that time, I took this to heart.

The topic of interest out of the Biotech & Innovative Preclinical Sciences group – BIPS – was this first-in-human dosing concept, principally because it is one of the more important concepts in early stage drug development – generally speaking, if you can't get into the clinic, you're not going to have a drug. Because we were coming from the standpoint of nonclinical strategies for getting into the clinic, the BIPS SIAC thought that we needed to have a clinical perspective as well. So it was easy to determine from that which other SIAC we needed to collaborate with, which was, of course, ClinPharm. Ultimately, I ended up working with Royce Morrison, who represented the ClinPharm group. Dr. Morrison brought to the table phase 1 clinical experience from the physician's perspective, which the rest of our committee wouldn't necessarily have.

Our committee had been working on this for the better part of a year before this workshop actually took place. The interactions between those of us in nonclinical sciences – toxicology, pharmacology – and those with clinical experience such as Dr. Morrison really made this entire program so worthwhile. All members of the committee worked very hard to develop this workshop, and I appreciated their enthusiasm and energy to make this work.

Q&A How are small molecular entities differentiated from large molecular entities?

Small molecules are the drugs that you think about every day: The aspirin tablets or drugs that you can easily get by going to your pharmacy, common pills or capsules or liquids that you will generally take orally. Large molecules, for example,

proteins or monoclonal antibodies, are very large, complex molecules.

Think of it this way: Small molecules will have a molecular mass or weight of about 1000 daltons or less, whereas a large molecule may have a molecular mass of several thousands of daltons. They're a heavier molecule, if you will, but they're also very complex in their three-dimensional orientation.

Q&A For our readers who may have been unable to attend the workshop, could you briefly walk through and summarize its program?

We talked about nonclinical and clinical strategies – that is, what nonclinical data are needed in order to enter a clinical trial and how those data might be viewed not only from the perspective of the scientists who reside within the sponsoring drug company but also how those data may be viewed by a regulatory authority, which is why we invited speakers from the FDA. Sometimes, the sponsor's toxicologist may view the data entirely differently from the toxicologist at FDA. There are a multitude of reasons why, but we discussed how to interpret these data in such a way that you can get into a clinical trial. These discussions applied to both small and large molecules.

We also offered breakout sessions where attendees were given basic information about a drug – for both small and large molecules – and were asked to come up with a nonclinical program that would potentially allow them to get it into a clinical study. I thought those breakout sessions would go very quickly. It turned out that there was lots of discussion in those breakout sessions, and the principal reason is that there's not necessarily a standard way for one to do a nonclinical program to get into a clinical trial. There may be variations on how you can develop that program.

Subsequently, after we dealt with some of the nonclinical strategies, we explored the concept of different populations. There were presentations on juvenile toxicology, because there's a need to do certain types of studies for pediatric indications. There was a talk on oncology because drugs being developed for oncology are sometimes developed much differently than a drug, for example, for a CNS indication or for a cholesterol-lowering indication.

Then there were discussions about the clinician's point of view on first-in-human dosing. We as nonclinical scientists have our views on how to get there. But the clinician sometimes has a different perspective in terms of what signals seen in nonclinical studies are important for monitoring within the clinic. That perspective is important, and this was shared with attendees by some first-rate clinicians who are intimately involved with phase 1 clinical trials.

For our third and last breakout session, we said: Okay, you've developed your nonclinical program. Here are the results of that nonclinical program. Now, recommend a first-in-human dose. This was done for both large and small molecules. It was really interesting how different groups approached setting these first-in-human doses. It was not always straightforward – and it shouldn't be. That became very interesting.

These breakout sessions focused on drugs that were administered primarily orally. But the large molecules that were provided would have been injected – for instance, subcutaneously – so they would have a different nonclinical program than their respective small molecule. Plus, we had an example of a drug that was given intravenously. So we discussed a variety of examples throughout these breakout sessions, and all these topics culminated in the panel discussion at the conclusion.

Q&A Would you please share some of the highlights of those panel discussions?

We initially reviewed the breakout session outcomes so that people who did not deal with the IV drug, for instance, saw how that was handled, or someone who was dealing with a large molecule that was intended for MS could see that IV drug development program and outcome. This generated several questions about how could you have done this, that, or something else, within that program.

The other important thing in this discussion was other routes of administration. How are the first-in-human doses set for those? I asked a question about dermal drugs, because I'm working on a couple of dermal drugs. Setting the first-in-human dose for a dermal drug is a little more complex than for a small molecule that is given by the oral route of administration. Likewise, someone asked about setting a first-in-human dose for an inhalant, which is not something that I've worked on but which generated questions and discussions.

The entire panel discussion was not only about what was covered within the workshop and variations on those themes but also topics that were not covered within our workshop. Prior

to the meeting, we sent an email to attendees asking them to bring their own examples of things that worked and things that did not. The experts on the panel have been doing this for a long time, and here was our opportunity to ask for their help. That also worked out reasonably well.

Q&A What topics were raised at this workshop that you anticipate will evolve into more robust conversations at DIA's next first-in-human dosing strategies workshop?

One of the topics that we did not get to cover at all was first-in-human dosing for gene therapy products or cell therapy products. There's been a lot of work on those materials in the last couple of years, but there has not yet been an approval of one in the US that I can think of. How do you approach a gene therapy product for first-in-human dosing? I don't know. I suspect that over the next couple of years we'll get a better handle on that, and this topic would clearly be a very useful addition to such a workshop.

What is the next generation of biologics? How do you deal with biosimilars in first-in-human dosing? I don't know. Vaccines were not included in this at all. Should they be? Vaccines are a rather interesting therapy whether used as a preventive or therapeutic vaccine. The nonclinical program for a vaccine can be very limited but tends to be very complex. Likewise, even the clinical study for those is rather unique. I can even envision an entire workshop just on first-in-human dosing of the next generation of biologics and vaccines. ■

William J. Brock

Dr. Brock thanks all the other members of this workshop program committee for their collaborative efforts:

Lorrene A. Buckley, PhD, DABT, Research Fellow, Eli Lilly & Company

Joy Cavagnaro, PhD, DABT, Fellow ATS, AccessBio

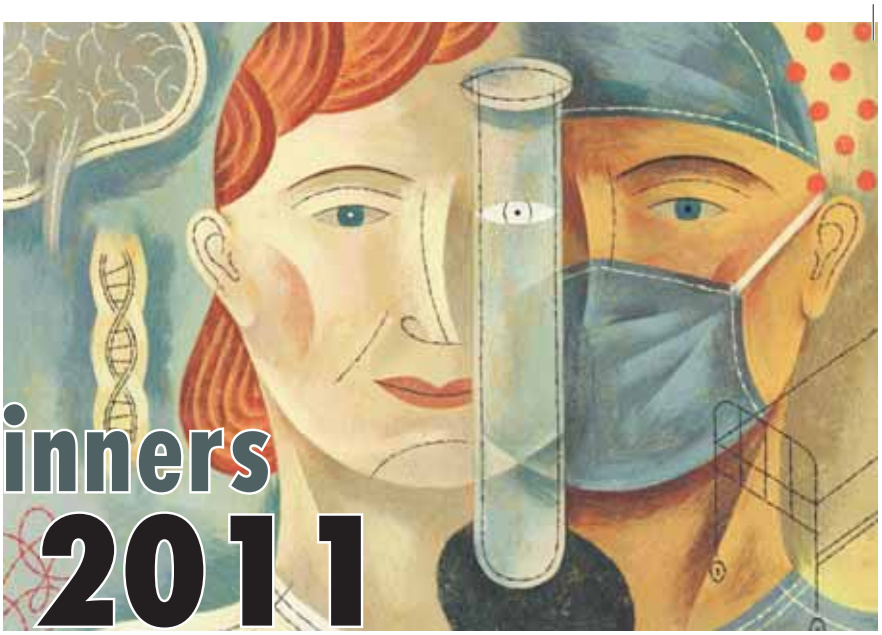
Bert Haenen, PhD, 3-D PharmXchange

Melanie Hartsough, PhD, Biologics Consulting Group

Kenneth L. Hastings, DrPH, DABT, Fellow ATS, sanofi-aventis

Royce Morrison, MD, CPI, Charles River

Drs. Brock and Buckley are also scheduled to present First-in-Human Dosing for Small & Large Molecules: Similarities & Differences during the **DIA 2011 SIAC Showcase** on Tuesday June 21. This showcase will offer a discussion-based approach to understanding small and large molecule drugs in development strategies, and the issues facing project teams in early first-in-human dosing concepts that result in "go or no-go" decisions. This showcase was developed by the Biotechnology and Innovative Preclinical Sciences SIAC.



Award Winners at DIA 2011

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

These awards will be presented in Chicago at the Awards Dinner at DIA 2011, and the winners will be recognized at the Plenary Session on June 20.

President's Award for Outstanding Achievement in World Health

This award recognizes the significant, innovative contributions of an individual, group of individuals, or organization to the improvement of world health.

CAPRISA 004 Team

The CAPRISA 004 trial, led by the Centre for the AIDS Programme of Research in South Africa and funded by USAID, was a proof-of-concept study that demonstrated the effectiveness of the tenofovir microbicide gel in preventing HIV in the women who used it.

CAPRISA 004 has been recognized by *The Lancet* as one of the top two published research studies of 2010; by observers and activists as "groundbreaking," "a major turning point," "a breakthrough," and a "gamechanger"; and by the women study participants as "a gift to all women."

CAPRISA 004 Team

The CAPRISA 004 partnership – led by South African researchers with South African participants – included USAID, FHI, and CONRAD as implementing partners, as well as TIA and Gilead Sciences. Gilead provided the microbicide gel for the trial.

The CAPRISA 004 Team includes

Salim S. Abdool Karim, MBCHB, PhD
The Director of the Centre for the AIDS Programme of Research in South Africa, Salim Abdool Karim was the co-principal investigator of the CAPRISA 004 tenofovir gel trial.

Quarraisha Abdool Karim, PhD
The Associate Scientific Director of the Centre for the AIDS Programme of Research in South Africa, Quarraisha Abdool Karim was the co-principal investigator of the CAPRISA 004 tenofovir gel trial.

Willard Cates, Jr, MD, MPH
Willard Cates is President, Research, at FHI, a global health and development organization; FHI was an implementing partner in the CAPRISA 004 tenofovir gel trial.

Henry L. Gabelnick, PhD
Henry L. Gabelnick is a member of the leadership team for the CAPRISA 004 trial, and the Executive Director of CONRAD, whose mission is the improvement of reproductive health, with an emphasis on developing countries. CONRAD was one of the two implementing partners for the CAPRISA 044 trial.

Carl Montague, PhD, MBA
Currently, Carl Montague is the General Manager of Health at the Technology Innovation Agency (TIA) in South Africa. In this role he is responsible for managing TIA's involvement in the development of the tenofovir gel microbicide.

James F. Rooney, MD
James F. Rooney is currently the Vice President of Medical Affairs at Gilead Sciences He was the Gilead representative on the CAPRISA 001 Trial Oversight Committee.

Jeff Spieler, PhD (Hon), MSc
Jeff Spieler is the Senior Technical Advisor in Science and Technology in Population and Reproductive Health (PRH) at USAID. USAID funded 90% of the $18 million budget for the CAPRISA 004 tenofovir gel trial.

Excellence in Volunteer Leadership Award

Teresa Pete Dowling

This award is given to recognize the individual who has demonstrated outstanding effective leadership during their dedication and extensive voluntary service to DIA. For 10 years or more, this individual has made consistent and significant contributions to the Association, not only as a volunteer, but as a volunteer leader in various DIA roles. Some of these roles should include leadership positions in the following areas: meetings/workshops, communities, special committee positions, advisory council, editorial board, author, or DIA board membership. The breadth and depth of their service as a leader to DIA should have a lasting, positive effect in contributing to the fulfillment of the mission and vision of the Association.

Teresa Pete Dowling, PharmD
Teresa Pete Dowling is Senior Director, Promotional Regulatory Affairs, at AstraZeneca. Teresa began her career in academia, joined the industry in Medical Communications, and moved to Promotional Regulatory Affairs in 2000.

In the 1990s, Teresa was an active participant and leader in DIA's Medical Communications SIAC. She felt that both the networking opportunities and what she learned from other DIA members was an invaluable experience. While active in the MC SIAC, Teresa was elected as a Director to DIA's Board of Directors. Subsequently, Teresa was elected Vice President and then President-elect. After serving as DIA's President, Teresa served as Immediate Past President and finally as Foundation Director. All of these opportunities opened new discussions and projects with members all around the world.

Teresa noted, "I can say that the presentations and sessions planned, the debates at the Board of Directors, the exposure to worldwide issues, the decision to build our headquarters, all helped me develop. While DIA continues to move forward and grow, we continue to be an association whose members share their experiences to help others grow both professionally and personally. We are good people who do good things. It was easy to give and to lead when you are surrounded by people who are doing the same. Thank you for this honor."

Founders Service Award

The Founders Service Award is named after the group of 30 professionals who founded DIA in 1964 with a fundamental value that the Association is member driven and fueled by the pharmaceutical industry's need for a neutral forum. Having previously received the Outstanding Service Award, this next award level would be given with the highest recognition and appreciation for volunteerism in the DIA organization. It recognized those individuals who have contributed to the advancement of the mission, vision, and values of DIA and fostered its growth and development through their dedicted and sustained volunteerism.

Stephen E. Wilson

Stephen E. Wilson, DrPH (Biostatistics), CAPT USPHS

Stephen Wilson, a Captain in the US Public Health Service Commissioned Corps, is currently the Director for the Division of Biometrics III at the Center for Drug Evaluation and Research, FDA. He has worked as a Statistical Reviewer and Supervisory Mathematical Statistician in FDA's Center for Drug Evaluation and Research (CDER) for 24 years. Steve received his doctorate in Biostatistics from the University of North Carolina, Chapel Hill, in 1984. His professional experience includes statistical research / management positions with the East West Center in Hawaii, the Indonesian Central Bureau of Statistics (Biro Pusat Statistik), the University of North Carolina, the Federated States of Micronesia, and the World Bank.

His professional interests and activities have been focused primarily on issues related to improvements in clinical trials science and practice, review of new pharmaceutical and biological products, the development of data and information standards and the application of new technology in the regulatory environment.

Steve has been a speaker at many DIA meetings and conferences, and has served on the core committees of the CDM and ST SIACs.

Steve, a California native and an avid/lifelong surfer, has two great children, Sam and Suzanne, and a wonderful, beautiful wife of 37 years, Barbara.

Outstanding Service Awards

The DIA Outstanding Service Award is given to recognize those individuals who consistently, through their volunteer efforts, have made contributions to the DIA mission and vision over the past several years. These individuals have exceeded expectations in their volunteer activities with DIA.

Carol H. Danielson, MS, DrPH, RAC

Carol H. Danielson has provided regulatory expertise and leadership for more than 25 years for drugs, biologics, and devices from discovery through postmarketing. Her areas of specialization include regulatory strategy and submissions, clinical affairs and compliance, and quality assurance. Her background includes both extensive "hands-on" experience and corporate level strategy activities from partnering due diligence to serving as an expert witness in the drug development process.

Carol is an active member of DIA. She serves as Chairperson for the DIA Editorial Board for Regulatory Training and is on the DIA faculty for Regulatory Affairs for Biologics, Regulatory Affairs IND & NDA, US Regulatory Affairs for EU and DIA-sponsored in-house training courses.

Carol manages and serves as president of her own regulatory and clinical consulting firm, Regulatory Advantage International LLC, based in Tucson, Arizona.

Carol H. Danielson

Her prior industry experience includes senior positions at the director and vice president level in Regulatory and Clinical Compliance for ALZA Corporation, Biocryst Pharmaceuticals, Meridian Biosciences, Colgate Palmolive, MediQuest Therapeutics, Global IQ, and others. She has an MS in Biology from Samford University and a Doctorate in Public Health from the University of Alabama.

Carol previously served on the Board of Directors for the Arizona Biotechnology Organization, is currently on the Advisory Board for the Clinical Research Program at Pima College, and is an adjunct professor in clinical and regulatory affairs.

Lisa D. Mulcahy

Lisa Mulcahy has worked as a study coordinator at a CRO and at a biotech/large pharma company.

Lisa D. Mulcahy

Lisa held positions with increasing responsibilities, growing in project management skills in both Clinical Trial Management and Clinical Quality Management. In 2007, she became an independent consultant, focusing solely on document management to improve processes and the management of paper and electronic records of the trial master file.

Lisa became a member of the Document and Records Management (DRM) SIAC in March 2008 She quickly thereafter became a member of DIA's cross-SIAC DRM initiative, the "Electronic Document Management Reference Model." Within one year of joining the DRM SIAC Lisa, along with a co-leader and industry representatives gathered together a group of volunteers with the common goal of creating the TMF Reference Model, a single, unified interpretation of the regulatory requirements for trial master file documentation.

Community Award

In recognition of an Outstanding Community which fosters the professional growth of their constituents while advancing the mission of DIA.

Electronic Document Management Reference Model Working Group (EDM)

The EDM Reference Model is a document management initiative aimed at developing a taxonomy/metadata reference model that can ultimately be shared by biopharmaceutical organizations as a common starting point for building sustainable, shareable EDM repositories.

In February 2008, members of the Documents and Records Management SIAC decided to form a working group to develop an electronic document management reference model to help companies design systems for authoring, storing, and publishing documents and data intended to be submitted as an application for drug marketing authorization and other types of submissions. The group – a team of subject matter experts on submission, content management and publishing from industry, consulting/professional services, and submission publishing services vendors – had this goal: to develop a "flexible, open, free and sustainable model for document management for the industry from the industry and by the industry." Evolution of the model continues and a sustainability plan is in place to preserve the model through the coming years. ■

DIA **Philanthropy** Program Update

The Philanthropy Program is the means by which DIA supports charitable causes that benefit the public and help to fulfill the mission, vision and social responsibility of the association as a nonprofit section 501(c)(3) tax-exempt charitable, educational, and scientific organization.

As of this issue's press date, the Philanthropy Program had identified the following recipients of its 2011 research and event grants.

Herald Cancer Care Network, for **Training Workshops for Cancer Caregivers**

EURORDIS (European Organisation for Rare Diseases), for the **EURORDIS Summer School in Drug Development and Health Technology Assessment**

Tufts Center for the Study of Drug Development (CSDD), for the **Tufts CSDD Forum on the Impact of Comparative Effectiveness Research on Innovation and Access**

Ohio State University, for **Decision Path-A Powerful Method for Analyzing Multiple Endpoints Clinical Data**

Monitor www.diahome.org for updates on the 2012 Philanthropy Program with its focus on patients.

Philanthropy Program Committee Members

Tatsuo Kurokawa, Chairperson

Karen Arts

Prem Bajaj

Nandkumar K Chodankar

Harold E Glass

Kelley Hill

Gautam Shah

Per Spindler

Jean A Yager

Drug Information Journal AWARD WINNERS

Early in 2011, members of the journal's editorial board began the evaluation and selection process for this year's winners. All of the articles published in volume 44 of the journal were eligible in one of the three categories, the Donald E. Francke Award, the Thomas W. Teal Award, and the Student Award. The following are the winning articles. These authors will be recognized in Chicago at an awards dinner and at the opening Plenary Session of DIA 2011. Congratulations to the winners.

The Donald E. Francke Award for Overall Excellence in Journal Publishing

How a Data-driven Quality Management System Can Manage Compliance Risk in Clinical Trials (DIJ 44:4;359-374)

Sina Djali, Stef Janssens, Stefan Van Yper, Jan Van Parijs

Sina Djali

The Thomas W. Teal Award for Excellence in Statistics Publishing

From Adaptive Design to Modern Protocol Design for Drug Development: Part II. Success Probabilities and Effect Estimates for Phase 3 Development Programs (DIJ 44:3;333-342)

Frank Bretz, Sue-Jane Wang

Sue-Jane Wang

The Drug Information Journal Student Award

Overview and Comparison of Postmarketing Drug Safety Surveillance in Selected Developing and Well Developed Countries (DIJ 44:5;519-534)

Sampada S. Vaidya, Jeff Jianfei Guo, Pamela C. Heaton, Michael Steinbuch

DIA thanks the members of the journal's editorial board for their participation in the awards selection process.

Sampada S. Vaidya

Drive to DIGITAL Continues

Our flagship meetings in Europe and North America bookend this update on DIA's Digital Initiative.

Our recent 23rd Annual EuroMeeting in Geneva was our first EuroMeeting to feature a free mobile agenda app that enabled attendees to receive up-to-the-minute event information on their mobile devices, delivered through a digital infrastructure that interconnected exhibitors, speakers, and registrants. After downloading this app, attendees could review the conference program, schedule the events that they wished to attend on their personal calendars, search the program by keyword or colleague name, and receive updates to the EuroMeeting program, on their personal mobile devices. This digital alternative to the paper EuroMeeting program and other supplemental meeting materials also advances DIA's "green" movement toward sharing ideas and information without consuming paper.

Behind the scenes, our Digital Initiative Team has begun to design a new look and feel for our online home, DIAhome.org, and to refurbish it with more powerful search capability and other functionality. Our Digital Initiative Team has begun the interview process for selecting a vendor who will analyze, organize, and migrate DIA's vast content resources, and will program the new and enhanced functionality that will work – and, in many cases, work better – with this content on our new website.

Simultaneously, we have engaged a design firm whose body of work, and expertise with modern web browsing, is most impressive. They bring to this engagement considerable association experience, plus experience with websites that must search, sort, and deliver a great deal of information both logically and quickly. These are critical qualifications for our online user community. This vendor will also work with our team on search engine optimization; this optimization will help users to more efficiently identify and find information on our website, thereby increasing the usefulness of these resources.

"DIA continues to invest significant resources and effort toward delivering a better experience and better value to members by making DIA content easier to find and access," explains DIA Worldwide Deputy Executive Director Carlos Fulcher. "As the Digital Initiative unfolds, our technology team has worked diligently through the rollout schedule, and now we are starting to see the deployment of early Digital Initiative deliverables, such as the EuroMeeting and Annual Meeting mobile agenda apps, DIA ConneX, and our mobile *Drug Information Journal* and *Global Forum*, to name a few."

DIA ConneX, our website's professional networking and collaboration tool, was previously rolled out for our discipline-specific Special Interest Area Communities. Now we're developing use of this tool for other DIA user communities, such as our program committees, members who have not yet joined a SIAC, and other user groups, too. These are scheduled for testing and rollout later this year.

Future *Global Forum* Digital Initiative updates will include deployment of our new DIA website taxonomy and mobile *DIA Daily*. We are also refining and enhancing the mobile agenda app from the EuroMeeting for your use at our upcoming DIA 2011 Annual Meeting. We hope to see you–digitally and in person–in Chicago! ■

Patient Sees Clinical Trial as Burdensome but Empowering

Cathy Fornabaio isn't the type to succumb to self-pity.

In 2001, Cathy was blindsided by a diagnosis of Behçet's disease, an autoimmune disorder that results from damage to blood vessels throughout the body.

Cathy went to bed on a Sunday night a healthy, 31-year-old working mother. When she woke up on Monday morning, she felt a painful heaviness in her chest.

Despite a trip to the doctor and a subsequent chest x-ray and a lung function test, both of which were normal, Cathy's pain worsened. By Friday night it had become so extreme that she ended up in the ER, where she was diagnosed with a heart attack. Doctors later changed their diagnosis and told her she hadn't suffered from a heart attack but from pericarditis, a condition in which the sac-like covering around the heart becomes inflamed—which had been brought on by lupus.

It was five months before Cathy learned that lupus was a false diagnosis as well and that she really suffered from Behçet's (pronounced Bish-ETTEs) disease, a rare, chronic, autoimmune condition that causes the blood vessels throughout the entire body to become inflamed.

Because Behçet's disease can involve blood vessels of nearly all sizes and types, it can manifest throughout the body including the eyes, mouth, skin, lungs, joints, brain, genitals, and GI tract.

Cathy struggled to continue with "life as normal" but soon had to quit her job as a fashion buyer. She endured debilitating headaches, aching joints, temporary vision loss, constant mouth ulcers and numerous other symptoms. It took all her strength to care for her young son: the simple task of making breakfast exhausted her. Still, she was determined to fight back. She started raising money for the American Behçet's Disease Association, volunteering from home.

Looking for Answers

Cathy's rheumatologist treated her with oral steroids; Solu-Medrol, a powerful IV steroid; and Cytoxan, a chemotherapy to suppress her overactive immunity, which was causing symptoms in her eyes and brain. But Cathy still struggled with her pain, and the powerful steroids were causing problems of their own: Cathy's bones were becoming weak, and she'd developed steroid-induced diabetes.

After two years, hobbling along on the regimen, she learned about Dr. Yusuf Yazici, a rheumatologist and associate director of the Seligman Center for Advanced Therapeutics at New York University Hospital for Joint Diseases.

"Dr. Yazici introduced me to clinical trials," she says. "I guess I looked at the clinical trials as hope. A lot of the medication I take is for rheumatoid arthritis or for lupus. I got excited because the trials were looking for something that was geared toward my symptoms."

Cathy admits she was nervous. To participate in the trial Cathy would have to stop taking the Solu-Medrol, Cytoxan, and any other immune suppressants. "With this disease if you let it flare up, the consequences can be irreversible, so going off my medicines was scary," she says. "I kept wondering: What if it doesn't work? What if it made me worse? When you take a medicine that has been around for 10 years you know it has helped some people. You don't get that sense of comfort in a clinical trial."

Cathy asked Dr. Yazici lots of questions and consulted every member of her medical team. She was terrified that if she went off her medications she might suffer another bout of pericarditis.

"I have a big team of doctors that includes a heart doctor, urologist,

eye doctor, rheumatologist, gastroenterologist, and endocrinologist," she explains. "I talked with every one of them before I went off my meds and joined the trial."

Cathy solicited input and support from her family as well. She knew that if she decided to participate, she'd need their help getting in and out of Brooklyn, where the trial was taking place. Her family was worried that neither she nor the researchers knew enough about the new medication, a tumor necrosis factor (TNF) inhibitor, but agreed to support her in her decision.

In the end, Cathy decided she had no choice but to participate. Standard therapy wasn't giving her the relief she craved and was causing too many problems. What's more, she felt like she needed to take action against her disease.

"One of the reasons I started volunteering with the ABDA was it was my way to fight back against the disease. I guess I felt the same way about clinical trials. I felt like it was my responsibility to myself and to others to do my part and fight back. I looked at it almost like a job."

To participate in the trial Cathy had to make biweekly trips into Brooklyn, a 75-minute drive from her home in Rockland County. Parking in the city was nearly impossible, so she'd often have a family member drive with her and stay in the car – circling the block or double parking when possible – while she went in for her appointments. The research staff was accommodating and friendly, but the hassle factor of getting in and out of the city, particularly on days when she felt her worst, was high. Cathy

admits that, had she not begun to experience positive results after only a few weeks, she might have been tempted to drop out of the six-month study.

"I can't imagine what it would have been like to stick with it if I wasn't getting relief," she says. "That's was what kept me going. I knew it was helping me."

Every two weeks Cathy visited the clinic, where she would be given an injection in her abdomen. Staff would draw blood and Cathy would fill out a questionnaire about how she was feeling. Although the shot hurt, Cathy says she didn't suffer any side effects.

Within six weeks of joining the trial, Cathy started feeling better.

"Because of my joint pain it's very hard for me to walk down the block or up stairs," she says. "But I suddenly noticed that it wasn't so painful. My hands weren't hurting as much either, and I had more strength. About two days after a shot I'd feel better but by day 12 I'd start hurting again, so I could tell the drug was working."

The trial drug Cathy took was approved by the FDA in December 2002 for rheumatoid arthritis and is now marketed by Abbott Laboratories under the name Humira. Although Humira gave Cathy relief from her Behçet's symptoms, her current insurance prescription coverage doesn't cover injectable drugs so she is once again dependent on Cytoxan and Solu-Medrol, as well as pain medication, which she takes twice a day.

Cathy still struggles with her disease. Every few months she'll have a bout of pericarditis, and she's lost nearly all her vision in one eye on several occasions. She'd love to participate in another trial, she says, but there aren't many trials for Behçet's and she hasn't been able to find one near her home.

"Participating in a clinical trial was scary and a pain in the neck," she says, "But it worked. In the end for me it was a blessing."

While she encourages others to get involved in clinical trials, she always underscores the need for commitment: participating can be burdensome, but it is empowering.

"Everybody can sit around and complain," she says. "But if we all do a little bit, there is power in numbers. If we all do our part, we can get so much further and we may have an answer in the end." ■

This story is from a series of articles created by CISCRP as part of their educational awareness campaign to increase public understanding that those who volunteer to participate in clinical trials are genuine "Medical Heroes."

Regulatory Updates: DEVICES & COMBINATION PRODUCTS

To update members about regulatory activity around the world, DIA provides a weekly **Global Regulatory Activity Digest** for members who opt in to receive it. DIA has licensed this content from Thomson Reuters, parent of the IDRAC regulatory database; to access the actual documents summarized therein, you must become a subscribing IDRAC member on their website.

Recent regulatory updates on the topic of medical devices, the special focus of this issue, plus updates on drug/device combination products, include:

Australia – Therapeutic Goods (Medical Devices) Amendment Regulations 2011 (No. 1), 10-Mar-2011
These Regulations amend the Therapeutic Goods (Medical Devices) Regulations 2002 (47726) to clarify that systems or procedure packs (which are regulated as medical devices under the Act) may include one or more biologicals, and to make other consequential changes. These Regulations commence on the commencement of Schedule 1 to the Therapeutic Goods Amendment (2009 Measures No. 3) Act 2010 (109919), which will be on 31 May 2011.

Canada – Guidance Document: How to Complete the Application for a New Medical Device License, 01-Mar-2011
The guidance document describes how to complete an application for a new medical device licence for Class II, III and IV medical devices, including payment of applicable licence fees. Location and Reason for Change: - Section 5 c): This section was updated to reflect that fees must be submitted either with the licence application or upon receipt of an invoice as outlined in the Fees in Respect of Drugs and Medical Devices Regulations (121845) - Class II Applications, Items 15 to 22, Class III Applications, Items 16 to 24, Class IV Applications, Items 17 to 25: These sections were updated to reflect the new name of the cost recovery guidance document Fees for the Review of Medical Device Licence Applications (121845). CONTENT: 1. Purpose 2. Background 3. Definitions 4. Who needs to apply for a medical device licence 5. How to apply for a medical device licence 6. When is a new medical device licence required 7. The medical device licence application forms -Device Classification - Class II Applications - Class III and IV Applications 8. REFERENCES.

European Union – How to Market Drug / Device Combination Products
This document is intended to provide help to better identify the demarcation between medical devices and medicinal products. It deals in particular with the borderline and the consultation process for: - devices having incorporating a medicinal substance having ancillary action and - medicinal products with device related features.

European Union – How to Market Medical Devices
This IDRAC Explanatory Document relates to medical devices. It provides definitions of medical devices and explains their legal position vis a vis medicinal products. It outlines the legal framework in the EU, explains the rules for classifying devices and provides practical help on how to obtain the CE marking. This document also provides details about fees, clinical research, labeling, post-marketing requirements, pricing and reimbursement, advertising and the international aspects. This document also provides details about the regulation of human tissue engeneered products.

France – AFSSAPS: Explanatory Note Regarding Pilot Phase on the Reporting of Serious Adverse Events Occurred in Biomedical Research Involving a Medical Device, Apr-2011 (French & English Versions)
Pending the transposition into French legislation of Directive 2007/47/EC, the AFSSAPS carries out a pilot phase to enable the implementation of European measures and provides a table in English (strictly identical in all European countries). A French version is also available for tests

taking place only in France. The sponsor may choose to report to the AFSSAPS and CPP (Committee for the Protection of Persons) serious adverse events/reactions by using the table available in the AFSSAPS website.

International – GHTF/SG1/ N063:2011: Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety & Performance of In Vitro Diagnostic Medical Devices, 17-Mar-2011
This document provides guidance on the content of summary technical documentation (STED) for In Vitro Diagnostic (IVD) medical devices to be assembled and submitted to a Regulatory Authority or Conformity Assessment Body for premarket review, and for post-market purposes to assess continuing conformity to the Essential Principles of safety and performance of IVD medical devices.

United Kingdom – MHRA Device Bulletin 2011(01): Reporting Adverse Incidents and Disseminating Medical Device Alerts, Mar-2011
This Device Bulletin provides guidance on the MHRA's adverse incident reporting system for medical devices. It encourages users to report incidents to us and provides information on the dissemination of Medical Device Alerts. This guidance is updated annually. It defines the role of the medical device liaison officer (MDLO) in disseminating Medical Device Alerts. The online reporting system and printable adverse incident report forms are available on the MHRA website along with further, regularly updated, supporting information.

USA – GAO Testimony: Medical Devices: FDA's Premarket Review & Postmarket Safety Efforts, (GAO-11-556T), 13-Apr-2011
This testimony was provided by Marcia Crosse, Director, Health Care, Government Accountability Office for a hearing held by the U.S. Senate Special Committee on Aging, on April 13, 2011 and entitled " A Delicate Balance: FDA and the Reform of the Medical Device Approval Process " This statement provides an update on FDA's actions in response to a recommendation made in GAO's report, Medical Devices: FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process (GAO-09-190, January 15, 2009). It also contains preliminary information on FDA's oversight of medical device recalls.

USA – Federal Register: Guidance for Industry and Food & Drug Administration Staff; 30-Day Notices, 135-Day Premarket Approval Supplements & 75-Day Humanitarian Device Exemption Supplements for Manufacturing Method or Process Changes; Availability (Notice), 13-Apr-2011
The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes." (122653) This document provides guidance on the type of changes to an approved application that FDA believes may qualify for submission as 30-day notices, the type of information to submit in a 30-day notice, and the user fees associated with these submissions. The guidance document is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices (GGP).

USA – Federal Register: Draft Guidance for Industry and FDA Staff: Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods & Labeling; Availability (Notice), 02-May-2011
The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled "Draft Guidance for Industry and FDA Staff: Processing/ Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." (123249) The recommendations in this guidance are intended to improve the safety and effectiveness of devices with processing or reprocessing labeling. This draft guidance is not final; nor is it in effect at this time.

USA – Press Release: FDA Issues Final Guidance for Liquid OTC Drug Products with Dispensing Devices, 04-May-2011
On May 04, 2011, the FDA informed about the release of a guidance for industry (123340) intended to suggest ways manufacturers can improve their labeling in order to minimize the risk of accidental overdose with OTC products packaged with a delivery device to measure and dispense the doses of medication. The guidance for industry is aimed at improving the clarity of the markings on dosing devices and the consistency between product labeling and dosing devices.

To learn more about IDRAC, please visit http://thomsonreuters.com/products_services/science/science_products/a-z/idrac/ ■

Ted Gawlicki

One-on-One
Life Science Translation Expert

Ted Gawlicki, Senior Vice President, Corporate Translations, Inc. answers our questions about the intricacies of selecting the right translation provider for the life science industry.

As a leading provider of translation services to the life science industry, what are the key criteria a pharmaceutical company should consider when selecting a language service provider (LSP)?

It's most important that the LSP has experience in the life science industry. Corporate Translations has over 21 years of experience and has completed over 70,000 translation and linguistic validation projects exclusively for the life science industry. In addition, the most important factor when selecting an LSP is that they have an ISO 9001-certified quality management system (QMS) that is monitored and utilized to enforce quality and drive continual improvement. The QMS must include a well documented translator selection and qualification process, multiple quality inspections, and a dynamic corrective and preventative action system. Another requirement is that the LSP understands the importance of the life science industry's deadlines regardless of how stringent they may be. Corporate Translations' ISO 9001:2008 QMS has resulted in superior quality translations and a 99% on-time delivery rate. We achieved an overall customer satisfaction score of 9.17 out of 10 with 94% of clients responding that our performance consistently exceeded their expectations.

You first mentioned that an LSP must specialize in the life science industry. Could you elaborate on how LSPs demonstrate this specialty?

Identifying a company's primary area of expertise can be done by assessing what percentage of its business is in life sciences. For example, 100% of Corporate Translations' business comprises pharmaceutical, biotech, and medical device companies, including their IRBs and CROs. The LSP's translators should also have documented advanced degrees in the sciences (chemistry, biology, pharmacology).

Corporate Translations works with the most elite group of translators. Each translator is qualified through our rigorous Translator Qualification System™ to prove their proficiency in their language pair and in translating clinical trial documentation such as PIs, Protocols, and ICFs. When an LSP focuses on one industry, it becomes an expert in that field and can develop specialized services that address the needs of its clients. Some of the services we have perfected and offer include the linguistic validation of PRO instruments, PRO administrative services, searchable document libraries, multilingual desktop publishing, and translation memory management.

It seems as though the linguistic validation of patient-reported outcomes instruments is a niche area of expertise. Can you explain your role in translating this document type?

Corporate Translations has been a leading and trusted authority on the linguistic validation of PRO instruments to the world's leading life science companies for the last 15 years. In order to deliver a scientifically sound translation every time, we have developed a state-of-the-art linguistic validation process and effective global relationships with our translators, interviewers, instrument developers, survey research experts, clinicians, in-country reviewers, and clients. Additionally, we have developed an array of PRO administrative services such as instrument research, licensing or copyright permissions, ePRO consultation, manuscript and poster presentation design and document libraries for controlling previously validated instruments. Corporate Translations validated over 2,500 PRO instruments in 2010 and is the preferred supplier for PRO translation at several major life science companies.

Is there anything in particular you'd like to leave us with?

Life science companies spend millions of dollars on translations each year. It is imperative that they receive clinical quality translations to ensure the reliability of their trial results, eliminate risks inherent to their document types, and yield the maximum ROI.

If you'd like to meet a translations expert from Corporate Translations, stop by booth #1005 at DIA 2011 in Chicago, June 19-23. ■

DIA Members on the Move

DIA is committed to improving the professional performance of our members and volunteers through our educational and networking forums. Please join us in congratulating the following DIA members for their recent professional accomplishments:

James Dixon was appointed Senior Vice President, Quality & Compliance, for Cetero Research.

James previously served as Vice President of GxP Quality Compliance for MedImmune, LLC. James is also a member of the Society of Quality Assurance (SQA) and serves on the Board of Directors for the Frederick (MD) Memorial Healthcare System. He earned his BS in Biology from Campbell University (NC)

Tony Frankland was appointed Global Head of Sales & Marketing for Cenduit, a joint venture between Thermo Fisher Scientific and Quintiles. Tony previously served as

Sales Director for Fisher Clinical Services in the UK. Tony earned his Chemistry Degree from The University of Newcastle Upon Tyne.

Dr. Gustavo Kesselring received the 2011 Honorary Lifetime Membership Award from the Academy of Pharmaceutical Physicians and Investigators. This honor is granted

each year to an individual recognized for having made an outstanding contribution to research and/or pharmaceutical medicine. Dr. Kesselring serves as Executive Director, VIS Research Institute, in Sao Paulo, Brazil. He has also served as President of the Brazilian Society of Pharmaceutical Medicine.

Michael McKelvey, PhD, was appointed Executive Vice President & Chief Operating Officer of Aptiv Solutions. Dr. McKelvey most

recently served as President and CEO of eResearch Technology, Inc. Dr. NcKelvey earned his PhD and MA from the Wharton School, University of Pennsylvania, and his AB from Williams College (MA).

Ellen Morgan was appointed Chairman of the Board of Directors of Synteract, Inc. Ms. Morgan co-

founded and has served as President and CEO of Synteract, a CRO focused on meeting the needs of emerging biopharmaceutical companies, since its inception. Prior to founding Synteract, Ellen held positions at Gensia, Inc., Pfizer, and Sterling Drug. Ellen earned her Bachelor's degree in Chemistry from Siena College (NY) and her Master's in Management Engineering/Statistics from Rensselaer Polytechnic Institute (NY).

Laura A. Navalta was appointed Vice President of Clinical Operations for C3 Jian, Inc. She previously served as

Chief Operating Officer for Novalar Pharmaceuticals. Laura earned her BA in Psychology from the University of Southern California. She has earned training in multiple therapeutic areas such as oncology & wound management, and has certified training in areas of Study Management, Regulations & Guidelines, and Drug & Study Development, by the Association of Clinical Research Professionals (ACRP).

ON THE MOVE? LET US KNOW

If you're an active DIA member and would like to share your professional or career news with other members in our *Global Forum*, please send your announcement (and high resolution digital photograph, if you have one) to Chris.Slawecki@diahome.org. Please remember to keep your DIA member profile current by logging into "My DIA" and updating your contact information to reflect your new job title, employer, or email address, too.

MARKETPLACE

LOOK WHO'S SPEAKING @DIA 2011

DIA 2011: Convergence of Science, Medicine & Health will feature presentations and other insights shared by many of our industry's leading professionals. A small sampling of the 900 speakers featured at DIA 2011 includes:

Vincent I. Ahonkhai, MD, FAAP, serves in the Senior Regulatory Office, Global Health Delivery, for the Bill & Melinda Gates Foundation. He will serve as panelist in the *Vaccines for Low- & Middle-Income Countries: Navigating the Regulatory Challenges* session scheduled for 10:30am on June 20.

Marc M. Boutin, JD, serves as Executive Vice President and Chief Operating Officer of the (US) National Health Council. He will serve as panelist in the *Postmarketing Commitments: Is It Time for Industry and FDA to Seek Therapy?* session scheduled for 10:00am on June 22.

Dr. Freda Lewis Hall serves as Chief Medical Officer and Senior Vice President for Pfizer, Inc. She also serves on the Board of Governors for the Patient-Centered Outcomes Research Institute. Dr. Lewis Hall will serve as panelist in the *Comparative Effectiveness Research and Health Technology Assessment: How National Agencies Are Addressing the Challenge* session scheduled for 3:30pm on June 20.

Hans-Georg Eichler, MD, MSc, serves as Senior Medical Officer for the European Medicines Agency (EMA), EU, UK. On June 20, Dr. Eichler will serve as panelist in the EMA Town Hall forum and as chair for Benefit-risk Methodology: An Interactive Workshop. He will also present the EMA perspective in the forum What is an Endpoint? A Disease-Specific Discussion of Study Endpoints on June 21, and in The Challenges of Improving the Science of Regulatory Decision Making forum on June 22.

Justina Molzon, JD, MPharm, serves as Associate Director for International Programs, Office of the Center Director (OCD), CDER, FDA (US). Justina will serve as chair for the Asia-Pacific Economic Cooperation (APEC) Town Hall forum on June 22. She will serve as presenter for the Global Harmonization Beyond ICH forum on June 20, and as panelist for the two-part CDER Town Hall forum on June 23.

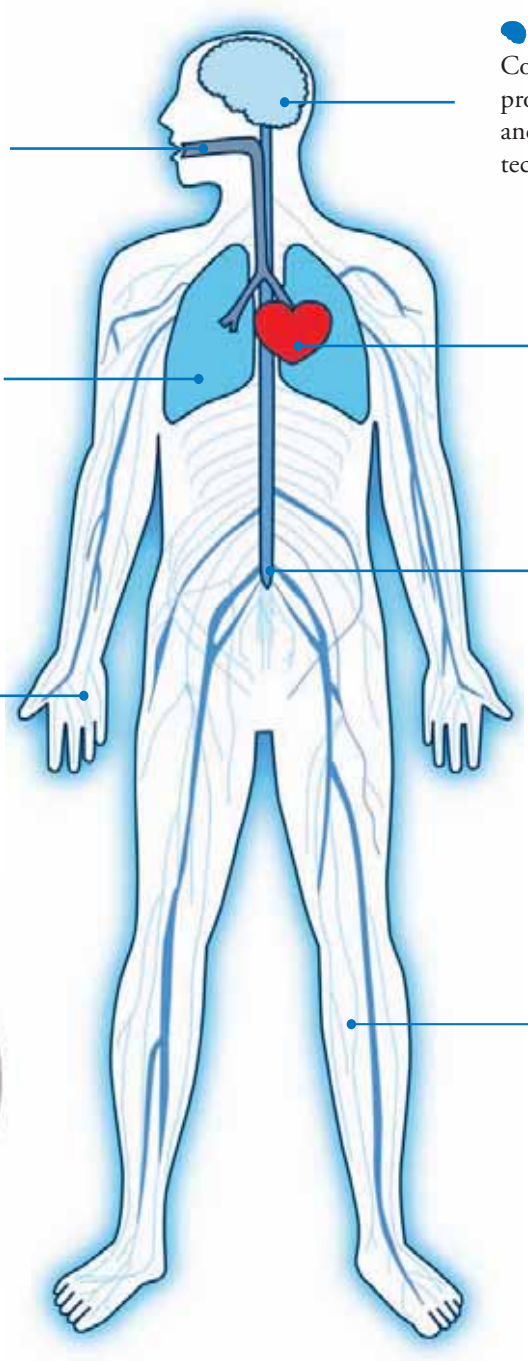
Steven Pearson, MD, MSc, FRCP, serves as President of the Institute for Clinical and Economic Review. He will serve as panelist in the *Establishing a Framework for CER Assessment: How Do Managed Care Decision-Makers Consider the Evidence?* session scheduled for 10:00am on June 22.

Central Resource For All Your Vital Translation Needs

MOUTH:
Communication vehicle used to ensure zero-defect quality by effectively transmitting information among members of the translation team

LUNGS:
The organs that convert over 20 years of experience into an array of highly specialized translation and linguistic validation services

HANDS:
The appendages used to perfect the fine details of each translation



BRAIN:
Control center essential for processing translation requests and delivering cost-effective technical solutions

HEART:
Core element responsible for circulating ISO 9001 quality standards throughout the translation process

SPINAL CORD:
A vital conduit that transmits a rapid response to any translation request

LEGS:
Steady and stable foundation necessary to support the Life Science Industry

CORPORATE TRANSLATIONS

Driven by Definition™

77 Hartland St. | East Hartford, CT 06108 | Tel: 1-855-727-6003 | Fax: 860-727-6001 | www.corptransinc.com