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Worldwide Executive Director
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PUBLISHING INFORMATION

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Innovations in DIA Publications and Regulatory Science

The New Year has brought with it a change in DIA publications, which affect the Global Forum and other communication sources. Those members that read the electronic version of Global Forum will not notice and will not be surprised by the disappearance of our paper edition. The change to a paperless version has been announced on the title page of the last several issues of 2012. This move will be accompanied by a better access to the forum content via other electronic media, e.g. a tablet, android, etc. With this change we have reached the end of an era during which many of us kept copies of issues of GF on the shelf for future reference on many topics, which this publication has covered in the Special Topic section over the last 4 years. From now on the ‘shelf’ will be on the DIA website or in a form of personal electronic storage.

The other previously announced change, the members would have already seen when they received the paper copy of Therapeutic Innovation & Regulatory Science (TIRS), a replacement of the Drug Information Journal that has been with us for over 40 years. It is a continuation of DIA scientific publishing, but it is also a reflection of a change in focus and adjustment to the current and future needs of membership. It is a welcome modification of the DIA publication focus, which creates a solid foundation for the provision of information and communication to the outside world in years to come.

This issue’s Special Topic in the INFORM section has been put together, just as in the previous issues, by Jean Soul-Lawton (Big ‘Thank you’ to Jean from the Editorial Board, myself and the readers). It provides a second part of the update on ‘Emerging Markets.’ The majority of articles cover the conduct of clinical trials in several ‘emerging’ countries. Those readers that remember the implementation of GCP, and where and how CTs were conducted
some 25 years ago, and since then, can only admire how big a change ‘emerging’ countries have gone through during these past few decades. This section also includes an article on Health Technology Assessment (HTA), which presents an interesting tool that allows for comparison between the markets.

The pharmaceutical sector has achieved substantial progress in all its activities. The change also applies widely to the regulatory environment where it is driven partly by legal aspects, but predominantly by the development of science. No surprise therefore that the co-chairperson of our Euromeeting, to be held next month in Amsterdam, Beatriz Vincen Banzo, in her profile interview, clearly states that “those involved in regulatory affairs require continuous training in regulations but also in associated science” and therefore a ‘must’ for this kind of job is a “continuous update in the understanding of scientific/technological innovations.” From this perspective the DIA scientific journal TIRS, new by design and broadened scope, is very well positioned to publish scientific information, which will allow readers to follow the progress in the important areas of innovation looked at and seen from the perspective of regulatory science.

Many of us remember the Oxford debate on the European regulatory environment and achievements (“DIA Oxford Debate and Future of Medicines,” GF June 2011), which clearly expressed the audience’s views on outcomes of regulatory decisions. With a much clearer understanding of fast evolving science and regulatory science, we may see a much more positive and constant change in the field of drug innovations supported by the regulatory science. This development, and applicability of this science is very high on the agenda of regulatory authorities, which has been very clearly indicated in the two profiles of Dr. Gerald Dal Pan and Dr. Tatsuya Kondo published in the Global Forum issues last year.

Welcoming the New Year, we look with optimism on a positive future of drug development led by a close collaboration of scientists from academia, regulatory and industry, and supported by patients, members from all these representations brainstorming and discussing ideas on the independent platform provided by the DIA in meetings and developing publications.

Happy New Year to all.

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ANNOUNCEMENT
Statement from DIA Worldwide Executive Director

It is with mixed emotions that I announce my departure as DIA Worldwide Executive Director, effective March 3, 2013. It has been a privilege and honor to serve DIA, and I am committed to working with the DIA Board of Directors and Global Management Team to facilitate the organization’s seamless transition to new executive leadership.

The last three years as DIA’s executive director have been among the most rewarding of my professional career. DIA is an outstanding organization, led by dedicated volunteers and supported by a committed and competent professional staff. During our time together, we have ushered in a new era of organizational stability, expanded our offerings around the globe, developed new content areas, and enhanced stakeholder relations, particularly among patients, students, and global health organizations.

As a result of our strategic plan and the hard work of many individuals, DIA is continuing its successful transformation into a world-class, knowledge-driven organization. Much remains to be done, but DIA is in an excellent position and in very good hands. By following the course of action embodied in our strategic plan, I am confident that DIA will continue to prosper and grow.

DIA was founded nearly 50 years ago with a singular purpose: to create a neutral forum to discuss scientific issues in the development, regulation, and use of medical products. In this purpose, there is a clear passion for the health of patients and the improvement of their lives. It is a passion that is evident every day in the work of our volunteers and staff, and I am proud to count you as colleagues.

I did not take my decision to resign lightly. In March, I will assume a position as the first CEO for the American Society of Anesthesiologists, a rapidly growing, influential, and member-driven organization. This position at ASA represents an exciting opportunity to advance the educational, scientific, and policy goals of the organization. It is not a position that I sought, but it is one I found I could not decline.

During this transition period, please feel free to contact me. Thank you for the opportunity to be part of DIA. I look forward to staying in touch and offer my best wishes for your future success.

Sincerely,

Paul Pomerantz
Worldwide Executive Director, DIA
ANNOUNCEMENT
Statement from Ling Su, PhD
President, DIA Board of Directors

Dear Colleagues,

As you know, DIA has announced that Worldwide Executive Director Paul Pomerantz will leave his position with DIA effective March 3, 2013. Paul has accepted a position as CEO for the American Society of Anesthesiologists based in Chicago and Washington, D.C. This is an exciting opportunity to lead an association of health care professionals that he felt he could not decline.

Paul's leadership during his three years with DIA has laid the groundwork for our current and future success. Under his direction, we have achieved rapid global expansion and significantly increased our stakeholder relationships. DIA is becoming a world-class, knowledge-driven organization. We thank Paul for his service and wish him the best of success in his new position.

While Paul will be missed, we are confident in the ability of our Board of Directors, Global Management Team, and staff to manage a smooth transition and continue building on our 50-year history. We will soon start a search for the new executive director. I can assure you that the board and staff are committed to continuing our direction and programs in the service of our members and stakeholders. In the meantime, please let me know if you have any concerns.

I thank you for your support and look forward to continuing to work with you.

Sincerely yours,

Ling Su, PhD
President, DIA Board of Directors
PRESIDENT’S MESSAGE

Emerging Regions and New Challenges

This issue of your Global Forum continues the discussions of drug development in emerging regions that began in our previous issue (Volume 4, Issue 6, December 2012), which focused on the Asia-Pacific region. I invite you to read the second part of this two-part series, which explores national and regional aspects of drug development in Russia, India, Korea and elsewhere.

This focus on every region of the world continues to sharpen DIA’s focus on stakeholders – members, volunteers, staff and supporters – in every region, and on developing pertinent education and training opportunities to them no matter where they are located. As a result of their efforts, I can invite you to such in-person opportunities as our 4th Pharmacovigilance Conference or 6th Regulatory Conference in India, our 25th EuroMeeting: Amsterdam 2013, and programs in the US that will advance medical and scientific communications, and marketing pharmaceuticals. Or join us through your internet connection for training in benefit/risk assessment and communication, how to prepare for a safety inspection and other online programs.

I also invite you to join me and extend best wishes to Paul Pomerantz as he moves into a new chapter of his professional life as Chief Executive Officer of the American Society of Anesthesiologists. Along with the rest of the Board of Directors, and our worldwide staff, I have greatly enjoyed working with Paul during my time as President-elect and now Board President.

While I turn this page into a new chapter for DIA with personal sadness, I also turn it with confidence because I know that we have worked with Paul to ensure that DIA as an organization maintains a strong foundation. We have a refined strategic direction for the near-and long-term future, which we finalized in the strategic planning exercise at our recent Board of Directors meeting in Beijing.

We have a strong management team at worldwide headquarters as well as within each DIA region. I am personally fortunate to have a unique place in DIA’s leadership continuum and continue to rely upon, and be extremely grateful for, the good and practical advice that comes from consulting with Immediate Past President Dr. Yves Juillet and President-elect Minnie Baylor-Henry. We expect this continuity to drive our activities and value to our membership.

Let’s expect to face changes and challenges, but let’s also expect to find opportunities in them.

LING SU
President, DIA
Board of Directors
WORLDWIDE EXECUTIVE DIRECTOR’S MESSAGE

By now you are aware that I will soon transition from my position as DIA Worldwide Executive Director to become Chief Executive Officer for the American Society of Anesthesiologists effective March 3, 2013. This change returns me to the arenas in which I have spent most of my career: Health care delivery, policy, and medical continuing education and research. While I am very enthusiastic about my new position, I will miss DIA, my volunteer and staff colleagues, and most of all, our important work. It has been a tremendous honor to serve DIA for the last three years. In this final column, I would like to reflect on our years together.

I feel privileged to have helped shape DIA at a critical point in its 50 year history. This is a unique and outstanding organization that has strived to make, and has made, a difference in the quality of health care and the lives of patients. No other organization brings together so many diverse interests to solve the scientific and regulatory challenges in the development and use of medical products. DIA has been and will remain a vibrant and essential part of the health care industry and those this industry serves. Over the years, DIA has had many Presidents and many Executive Directors. Despite changes in people, DIA has remained faithful to the values of its founders: Neutrality, multi-stakeholder engagement, global views and scientific integrity.

However, DIA is at an inflection point. We are a reflection of the community we serve and are likewise challenged by the same economic, organizational and societal pressures including health care reform, industry consolidation and restructuring, globalization, and the impact of new technology. For DIA to achieve our purpose in this new landscape, a very different structure and strategy will be required. DIA’s Board of Directors and staff leadership have been working towards this end and you will see ongoing reports on DIA’s strategy in your Global Forum.
A professional transition always provides an opportunity for reflection. While much remains to be accomplished, I do believe that our work over the last three years has achieved much to build the foundation for DIA’s transformation. Four critical areas involve people, expanded stakeholder engagement, globalization and transformation to a knowledge-driven scientific organization.

Management Team: According to Jim Collins, author of Good to Great, the most important imperative of any organization is “getting the right people on the bus, the wrong people off the bus, and the right people in the right seats.” I feel that we have built an “all-star” management team. Each one has excelled in their career prior to DIA. The mix of skills, cultures and attributes is creating a talent cocktail of sorts, and unbeatable synergy. Our new additions, Director for DIA Europe (Dr. Jytte Lyngvig) and new CFO (Bayard Gardineer III) complement our regional executives in China, India, Japan, Latin America and North America and global executives in headquarters for Human Resources, Information Technology and Operations (see sidebar). This team has inspired and challenged me, and I believe they have inspired our members, volunteers, other stakeholders and staff, too.

Globalization: When I started at DIA, DIA was a North American organization with international outreach. Today, I believe DIA has become a truly global organization reflected by our representative board and global rotation of presidents, global management team, and regional offices. More than this, our global outlook and strategy has engaged DIA with other like-minded organizations such as the WHO, ICH, World Bank and Gates Foundation, all of whom view DIA as a partner in identifying and solving global health care issues, and as a partner in training and capacity building.

Stakeholder Engagement: DIA has traditionally been viewed as an organization of industry and regulatory professionals. In recent years, DIA has engaged the voice of the patient as an equal stakeholder in innovation, product development, and regulatory policy. The patient is now engaged in DIA in many ways, through our DIA Europe and North America fellowship programs; as volunteers in our communities and as speakers, panelists, editorial board members and authors; and, increasingly, on our advisory councils and soon on our board. The patient voice is essential to decision-making and policy on medical products and regulation. Patient engagement has significantly strengthened DIA’s relevance in today’s environment.

For this I claim no credit – DIA’s patient initiatives began with Dr. Yves Juillet’s vision for patient fellowships to our EuroMeeting years ago – but I am glad to have helped build the value of the patient and patient engagement with DIA in North America and globally.

Transformation from an Events-based to Knowledge-driven Organization: Today’s challenges are clear. People have less time and funds available than in years past, and their need for timely, relevant information to support decision-making is continuous and urgent. To truly meet the needs of our modern stakeholders, DIA must implement new means to engage our stakeholders and to make relevant information available in “real time.” We must determine how DIA can help address key issues through a knowledge agenda and identify ways that we can leverage and deliver this content across our multiple platforms. This transition requires a reshaping of how DIA works. It impacts our website, our programs and our publications; but more profoundly, this will change DIA’s role in the world of science. DIA has started to engage this transformation in several ways:

First, the Drug Information Journal has been re-launched as Therapeutic Innovation & Regulatory Science, and has just announced its new Editor-in-Chief, Dr. Stephen Spielberg, to help strengthen our journal as a primary source for applied science surrounding medical products.

Second, our ongoing digital strategy has resulted in improvements to DIA’s website and community networking (such as DIA ConneX). Starting with this issue, your Global Forum will be
“digital only.” Emphasis will be placed on the development of DIA’s regional web capability and mobile sites. Long term, DIA is exploring the means to become a first-in-class web-based knowledge center.

Third, DIA has begun to engage stakeholders in defining our needs and knowledge in emerging areas. I’d like to briefly mention two specific new areas: We have elevated awareness that regulatory approval is no longer the finish line, but that pricing and reimbursement and post-marketing safety must be critical considerations in modern medical product development. We have also helped to elevate and illuminate the interface between drugs and devices, and have made clear that DIA plans to be a key voice as we learn how drugs, devices, and even IT and other types of technology, can work together for the patients’ good. These are still in their early stages but will certainly form part of our future.

Many challenges remain. We all want DIA to become well-known and well-understood. How do we establish DIA as a “brand” as well-known as the WHO and other global organizations? When we review membership data, it is clear that people engage with DIA through certain seasons of their career. But how do we get them to view DIA as their professional career partner? For DIA, these will be keys to a successful future.

Now, a few closing personal reflections:

First, I greatly enjoyed this experience and the thing I enjoyed the most was meeting members at our events. The conversations we had in receptions and hallways, about your experience from serving on a committee, or an article you read or session you just attended, was really the best part. That’s really what I enjoyed the most. And although we have a long way to go, I’m very proud of the chapter that we’ve written together during my tenure at DIA.

Anesthesiologists work extensively with pharmaceuticals and devices, and they’re very concerned about product safety and quality, and the integrity of the supply chain. I will stay involved with DIA in my next position with ASA because that does something I’ve always wanted to do – build stronger connections between healthcare providers and DIA. This next step is one more chapter in working with DIA: I’ll become a DIA member.

DIA Worldwide Management Team

Carlos E. Fulcher, MBA
Worldwide Deputy Executive Director
Bayard Gardineer III, CPA
Worldwide Director
Finance/CFO
Elizabeth Lincoln, MA
Worldwide Director
Human Resources
Jane Y. Cai, PhD
Director, DIA China
Jytte Lyngvig, PhD
Director, DIA Europe
Kaushik Desai, MPharm
Director, DIA India
Ko Sekiguchi, MBA
Director, DIA Japan
Susan Cantrell, RPh
Director, DIA North America
INFORM now houses the Special Sections: Devised to educate and update you on advances in a specific area of research, drugs, diagnostics or devices.
In the previous edition of the Global Forum we introduced this topic (Part 1), reviewing some aspects of the practicalities of clinical drug development in Emerging Markets. The Asia Pacific region was a focus, and included in the section was a review of venues for collaboration of regulatory agencies and other bodies such as the World Health Organisation (WHO), co-location of regulatory agencies and science parks, practical experiences in the regulatory review process for clinical trial applications, and the establishment of investigator sites.

In Part 2 of this special topic, we look at the practicalities of running studies in different phases and countries, the preparation of marketing applications for regulatory review, the complexities of health technology assessments, and efforts to bring together pharmaceutical development professionals within and across regions. Specifically included are reviews of running phase 1 trials in India and Korea, and we gain an insight into running studies in Eastern European countries including the Ukraine. We also hear about the differing requirements for clinical regulatory submissions in ‘ICH Outlier’ countries, and the efforts to identify common features of health technology assessment agencies and their processes. Also included are the activities of the Sino-American Pharmaceutical Professionals Association (SAPA) and its efforts to bridge the gap between the industries in China and the USA. Related to this special section on Emerging Markets, you can also read in this issue of the Global Forum, in the Latin America section of REACH, about the plans for the 5th Latin American Regulatory Conference (LARC) to be held in May in Bogota, Colombia, with a theme of ‘Pharma-Co-Vergence.’
In the last 15 years, India has emerged as a major destination for clinical trials. According to the Clinical Trial Registry India (CTRI), the total number of phase I studies registered as of 14th June 2012 was 127; the total number of ongoing studies was 42. Out of the total number of phase I trials, 89% were compounds developed in India.

As described in the Indian regulations, first-in-human clinical studies for compounds developed outside India are not allowed; however, it would be possible to do a first-in-human study in India if the compound is of medical relevance to the Indian population or if it addresses an unmet need. The regulations allow for the conduct of repeat Phase I studies for compounds which have already undergone Phase I studies outside India. Phase IIa studies could be done concurrently in India as part of a global trial.

India brings potential opportunities for carrying out clinical trials, in terms of good recruitment speed, reduced costs and increases in health and allied infrastructure. Along with these advantages, there are some unique opportunities which India brings of relevance to early phase trials like access to a largely treatment-naïve population with a high rate of advanced disease, patient populations of orphan diseases and a diverse genomic pool. As well as opportunities for development of niche...
busters (orphan drugs), there are opportunities for re-purposing of the existing drug molecules, for exploratory biomarker studies and for pharmacogenomic studies.

The regulatory scenarios for early drug development in force today are depicted in the table below and need to be more facilitative:

<table>
<thead>
<tr>
<th>POSSIBLE SCENARIOS</th>
<th>PERMISSION FOR CONDUCT OF CLINICAL TRIAL IN INDIA</th>
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<tbody>
<tr>
<td>Phase I for the compounds developed in India</td>
<td>Yes</td>
</tr>
<tr>
<td>Phase I for the compounds which have already undergone Phase I Trials outside India</td>
<td>Yes</td>
</tr>
<tr>
<td>Phase I for the compounds which would simultaneously undergo Phase I trial in COO* &amp; India</td>
<td>Possible but Agency comfort level is less</td>
</tr>
<tr>
<td>First-in-human studies for compounds developed outside India</td>
<td>No</td>
</tr>
<tr>
<td>First-in-human studies for compounds developed outside India but also addresses an unmet medical need in India</td>
<td>Possible</td>
</tr>
<tr>
<td>Phase IIa for any compound</td>
<td>Yes</td>
</tr>
<tr>
<td>Microdosing for any compound</td>
<td>No</td>
</tr>
</tbody>
</table>

There are certain regulatory, operational and ethical challenges related to conduct of early phase clinical trials in India. Indian regulatory authorities are in the process of building up the infrastructure required to monitor the clinical trials as strictly as is desirable. The regulatory authorities have come up with various regulations in the last five years. Still there is a need for laws on compensation, punishment for defaulters and declaration of “conflicts of interest” by investigators and members of ethics committees. With the increasing number of partnerships and co-development there is a need to have a uniform understanding and interpretation of how to handle Indian versus foreign compounds.

The regulatory infrastructure is still evolving and therefore sometimes clinical trial approvals can be delayed. There have been announcements by the Indian government that there will be a strengthening in the regulatory capacity soon. In general, the regulatory requirements for early phase research are more restrictive than facilitative when compared with other global regulatory bodies.

There are few specific confined research units in India which have access to patients and are located in hospitals, and few experienced physicians and clinical research professionals in early phase trials.

In the inspections conducted by the Central Drugs Standard Control Organization (CDSCO) in India in 2011, Indian regulatory authorities reported irregularities related to subject recruitment and informed consent processes as well as the independence of the ethics committee involved and its review and decision-making procedures.

There have been challenges in the participant recruitment and consenting processes due to social, economic and cultural diversity in India. The commitment level and time devoted by the clinicians in the conduct of clinical trials have been a concern, though this appears to have been improving with reinforcement of good clinical practice (GCP) training and growing regulations.

In conclusion, in view of all the challenges, some of the recommendations to the sponsors planning to conduct early phase trials for their molecules in India are:

- Be rigorous in the site identification, qualification and selection process
- Preferably engage with accredited sites
- Ensure that the institutional ethics committee for the project has the expertise in reviewing early phase clinical studies
- Ensure that there is audiovisual recording of the informed consent process and a questionnaire to check participants’ comprehension and understanding regarding study information
- Plan a few co-monitoring visits
- Discuss all the clinical studies with the regulatory authorities prior to study start
- Raise public awareness of the research

References/citations from this article are available upon request.
Over the past 10 years, the trend towards globalization of clinical drug development has received a great amount of attention as well as scrutiny; nevertheless, it has become a widely accepted phenomenon in the global community. Starting with successes in late phase development, Asian countries have emerged as an attractive region for global development, evidenced by a rapid growth in the number of trials placed there. Among the Asian countries that have shown a capability in drug development, Korea has been one of the ‘late comers.’ Korea first appeared in the global arena in the early 2000s and within a decade has pushed its way up to its current status as a leading country in Asia. Part of the reason for this is that Korea has been involved in a public-private partnership (PPP) model. Launched in December 2007, the Korea National Enterprise for Clinical Trials (KoNECT), a not-for-profit organization supported by the Ministry of Health and Welfare, led the initiative. As a part of the infrastructure-building project, KoNECT selected, through competition, and supported the establishment of 15 regional clinical trials Centers of Excellence that continuously underwent improvement through annual evaluations to meet the global industry standards. The Clinical Trials Training Academy at MIN SOO PARK

Recent Development of Activities in Phase 1 Clinical Studies in Korea
KoNECT has operated nationwide training programs to meet specific professional needs since 2008. There are programs targeted for clinical investigators, clinical research coordinators (CRCs), trial pharmacists, clinical pharmacologists, pharmaceutical medicine specialists, biostatisticians, and pharmacoepidemiology and data management specialists. Currently KoNECT runs certification systems for physician investigators, CRCs and CRAs. Research grants were made available for development of new trial technologies. To protect and ensure the safety of research participants and quality of data, regulatory agencies as well as ethics committees at individual sites strengthened the regulations as well as tightening the surveillance on the ethical conduct of trials. Investigative sites, mostly university hospitals, reshaped their internal oversight and governance systems. With respect to the quality of studies, the official reports of the USFDA inspections have shown that there was almost no difference between sites in North America and sites in Asia. This all-out effort resulted in high-quality data, ethical conduct, and reliable performance in global clinical trials.

In terms of early phase clinical development, most global pharmaceutical companies have heavily, if not almost exclusively, depended on the core countries, mainly the US and EU, until recently. The critical value of the data obtained from early phase trials, especially phase 1 studies, along with the difficulty, complexity, and intensity of these studies have traditionally made pharmaceutical companies look for suitable sites only within advanced countries. Proof-of-concept and early phase clinical pharmacology studies, previously regarded as milestones that can only be achieved by sites in core countries, have recently started to find their place in certain sites outside core countries. There is a slow but definite change in the pattern of different phases of studies placed in the Asian region, and notably in Korea (Figure 1). The PPP model in Korea has helped domestic pharmaceutical companies develop new drugs by providing Centers of Excellence fit for early phase trials in Korea without the need to go the core countries. Most of the clinical trials centers out of the 15 regional CTCs have set up outstanding phase 1 units that deserve global recognition in terms of operating systems, facilities, personnel, and clinical pharmacology and technical support. Many global pharmaceutical companies that have successfully run late phase clinical trials in Korea have started to bring early phase studies to certain sites in Korea. With a booming growth in research and development activities of domestic pharmaceutical companies, many of the phase 1 units in Korea have acquired a substantial amount of experience and expertise in a rather short period. Analysis of phase 1 studies approved by Korea FDA in 2011 shows over 60% involved pharmacokinetic or drug interaction components. There were 20 first-in-human studies, 23 phase 1 studies in cancer patients, and 8 pharmacokinetic studies in non-cancer patient populations. Unlike most studies from global pharmaceutical companies, many studies from domestic companies require services from the phase 1 units ranging from study design and protocol development to pharmacokinetic analysis and clinical study report writing. In addition, in most of these units there are full time clinical pharmacologists and clinical investigators as well as teams of research nurses dedicated to early phase studies. To this end, it is important to recognize the
active roles that the members of the Korean Society for Clinical Pharmacology and Therapeutics have played in drug development in Korea. Their strong academic and research activities along with active participation as key opinion leaders in the policy-making and project planning by the government have had a great influence in the PPP model. Most of these units have already acquired internationally acceptable quality standards for human research protection programs or institutional review board (IRB) activities as shown by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) accreditation or the Forum for Ethical Review Committees in the Asian and Western Pacific Region (FERCAP) recognition. These units have had the opportunity to conduct a wide variety of early phase studies including first-in-human studies that involve healthy volunteers as well as patient populations with various diseases. They are confident and ready to prove their competency, competitiveness and excellence in the global community. Another important aspect to be highlighted is the high quality medical care systems in many major university hospitals in Korea. There are a few university hospitals that have been accredited by the Joint Commission for International Health Care Quality Standards for Patient Care and Organization Management. Most clinical trials centers in Korea have dedicated phase 1 facilities and are within the university hospital setting with easy access to most of the hospital medical care facilities and services. Many university hospitals have huge medical care facilities with mostly greater than 2,000 beds and daily outpatient populations of up to 10,000. They also have a strong IT environment including electronic medical record systems that facilitate database-driven feasibility assessment and promote development of next-generation electronic data capture systems.

In summary, despite a relatively short history of clinical development, Korea has proved itself capable in late phase development and has established an environment suitable for early phase trials. With its well-built infrastructure, training systems, experienced personnel, growing expertise, awareness for patient safety and efficient operating systems supported by IT technologies, Korea looks forward to contributing further to the crucial, early phases of global drug development.

MIN SOO PARK, MD, PHD
graduated from Yonsei University College of Medicine in Seoul, Korea, and was trained in Pediatrics and Neonatology at Severance Hospital, Yonsei University. He received his Master of Science degree in Clinical Pharmacology at University of Aberdeen, UK, and PhD in Medicine at Ajou University, Korea. He is currently Associate Professor in Pediatrics and Clinical Pharmacology at Yonsei University College of Medicine and holds a dual position as Professor at Yonsei University School of Pharmacy. As the Director of Clinical Trials Center of Severance Hospital, Yonsei University College of Medicine, he is in charge of the governance and support of clinical research activities. He is currently Vice President of the Korean Society of Pharmaceutical Medicine and a co-director of Joint Graduate Program of Pharmaceutical Medicine and Regulatory Sciences at Yonsei University School of Pharmacy and College of Medicine.
SUMMARY

Clinical research processes are becoming more complex, resulting in an increase in the regulatory burden, recruitment challenges and an increase in costs. Today, the USA is still the region where the majority of clinical trials are designed and executed; however, many other geographical areas are becoming involved in drug development, bringing more and more data to the “general clinical trials dataset.” The peculiarities of clinical trials in one of these emerging regions, namely the Commonwealth of Independent States (CIS), with a focus on Ukraine (that is an unofficial CIS member state), are discussed in this article.

The health care services in Ukraine and Russia were built with the aim of providing a service, free of charge, for the population. Taking into account the low gross domestic product (GDP) per capita (Table 1) in these countries, expensive medications and costly health care services cannot always be covered by the state budget. Thus, participation in clinical trials has been desired by patients with severe and chronic diseases, and in oncology diseases, for example, approximately 165,000 people are diagnosed every year in Ukraine alone, making the country attractive for clinical trials that require centres for recruitment in this disease area.
Another similar statistic for CIS countries is health expenditure. This parameter is broadly defined as activities, the primary purpose of which is to promote, restore, or maintain health. Total health expenditure as a percentage of GDP for 2009 in Russia, Ukraine and Belarus was 5.4%, 7% and 5.8% respectively, in comparison with 16.2% in USA.

Thus, health care systems in all the CIS countries have similarities; this is especially the case in Russia, Ukraine and Belarus due to the fact that the systems derived from the Union of Soviet Socialist Republics (USSR). The most prominent characteristics of the system are centralization, state coverage of medical insurance, established networks of health care settings for particular pathologies and their respective databases (e.g. in oncology, skin and venereal diseases, psycho-neurology diseases).

However, there are differences in the size of the population, infrastructure and resources among Russia, Ukraine and Belarus, which contribute to the difference in clinical trial records in each of the countries. Table 1 shows GDP per capita in US Dollars for these countries.

Russia, Ukraine and Belarus can broadly be described as countries that have a high recruitment potential. This is because they have large populations that are concentrated in big cities that would enable fast patient recruitment. They also have centralized medical services and broad networks of large specialized clinics with patient registers and referral schemes.

When considering Ukraine as a model of a CIS country for running clinical trials, the following factors will facilitate the achievement of the best results at each step of the process.

1. Feasibility stage. Local Clinical Research professionals are very efficient in contacting sites, and sites are very responsive due to the ease of communication between medical doctors from clinical research organizations (CROs) and sites who speak “the same language.” Even more benefits are achieved when personnel from ongoing or recent trials are involved, to give an indication of feasibility.

2. Study start. Preparation of the documents for submission to Competent Authorities (for the clinical trial approval) should include a preliminary careful cross-check of the content of all the documents and their translations to achieve an almost 90% success for timely study approval and therefore, study start. The regulatory process is well described for the respective documents and can be tracked. In contrast to many other countries, contracting with

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<tr>
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<th>Russian Federation</th>
<th>Ukraine</th>
<th>Belarus</th>
<th>United States</th>
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<tbody>
<tr>
<td>GDP per Capita, $</td>
<td>10,351</td>
<td>3,035</td>
<td>5,702</td>
<td>46,546</td>
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</tbody>
</table>

Table 1. GDP Per Capita in US Dollars (2012)
study sites may be done after submission.

It is important to mention that clinical trial agreements (CTAs) for clinical trials in Ukraine are completed for institutes and investigators separately. Often CTAs for study team members (e.g. sub-investigator or study coordinator) are required. In each particular case, the distribution of roles and responsibilities and their inclusion in the CTAs for each site are made by the Principal Investigators in agreement with the management of the institute/clinic.

Preparation of documents has some peculiarities, such as the requirement for an Apostille for Delegation of Authority. An Apostille is required for Competent Authorities (CAs) to confirm that the applicant of the clinical trial has rights to act on behalf of the Sponsor, and the Apostille is a “version” of a legal confirmation that is performed for official documents circulated between different countries. Legal confirmation is required for documents circulated between countries if at least one of them is not in the list of “Convention of 5 October 1961 Abolishing the Requirement of Legalization for Foreign Public Documents.” An additional time saving at this stage is achieved by learning which documents can be in the Russian language. This minimizes the amount of translation needed, and maintains consistency with clinical trial applications in other CIS countries. Special attention must be paid to insurance of study subjects. Insurance for subjects participating in clinical trials must be done by an insurance company that is resident in the country (in other words, only Ukrainian insurance companies can be used for insurance of the trial subjects’ health and life in Ukraine).

An example of improvements in regulatory process in Ukraine is that recently implemented changes in clinical trials legislation (order of the Ministry of Health of Ukraine #523 dd. 12 Jul 2012) aim to shorten the Clinical Trial application time. A further factor that helps in the regulatory process is that dates of the forthcoming meetings at CAs are often predictable, and therefore submissions 35 - 40 days prior to the targeted meeting at the CA leads to the most time-efficient results if no additional requests from the CA are made.

Following receipt of the clinical trial approval by the CA, an application for an import license must be made immediately. It is important to mention that Russia and Belarus are members of a customs union that ease logistics in clinical trials. Ukraine requires separate logistics including customs clearance. Customs procedures are different in the amount of time required and the taxation charged for different types of imported goods, but roughly 4 – 6 weeks must be allowed for getting permissions and importation of study materials including Investigational Medicinal Products (IMP).

3. Study conclusion. While coming to the end of the study, it is advisable to prepare an archiving plan and allocating some time to its implementation with site staff. It is important that IMP (used and unused) is returned to the Sponsor/CRO or destroyed. Destruction cannot be carried out by sites, as this type of activity requires licensing and is usually done by specialized vendors. Typically, destruction of study materials including IMP in the country carrying out the clinical trial is cheaper than returning the materials to the Sponsor for destruction.

Historically, the main reasons for considering new regions for clinical trials were the availability of trial subjects, time and costs. Competition for subjects, along with escalating research and development (R&D) costs, has forced many major pharmaceutical companies to look towards emerging markets to conduct their clinical studies. These markets offered an opportunity to reduce R&D time and costs if managed appropriately, and permitted access to large, treatment naïve populations. The major emerging regions are still Eastern Europe, Asia and Latin America. The Commonwealth of Independent States (CIS), formed in 1991, is located in two of these emerging regions (Asia and Eastern Europe) and includes Russia, Belarus, Armenia, Azerbaijan, Uzbekistan, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan. Ukraine and Turkmenistan are unofficial member states of CIS. In addition, Russia, Belarus and Kazakhstan entered into a Customs Union which plays an important role in the importation of goods, especially for clinical trials.

Utilizing its medical and demographic potential in the mid-nineties, Russia was the first of the ex-USSR countries to become a viable location for international multicenter clinical
trials. Around that time the first clinical trial investigators started to work under Investigational New Drug (IND) regulations. By the end of the century, the number of investigators working under an IND in Russia increased more than 30-fold reaching a total number of 170 investigators. Nowadays, Russia has 63 higher medical schools (universities, institutes) and postgraduate education institutions (institutes and academies) (http://www.spruce.ru) and is ranked 8th place in the world by the number of foreign students in the country (http://www.russia.edu.ru/edu/instr/why/). Medicine is the most in-demand subject for foreign students in Russia (19.2% of all foreign students in Russia study medicine) (http://www.russia.edu.ru/news/1358). With 715,800 physicians, Russia also has great coverage of the population in terms of medical care, and has one of the world’s highest rates of this parameter (5.1 per 1000 inhabitants) (Russian Federal Statistics State Service, http://www.gks.ru, end of 2010).

Ukraine has approximately 48 million inhabitants and is the second most populated Central Eastern European (CEE) country after Russia. It is interesting that even though it is one of the three CIS-forming countries, Ukraine did not ratify the CIS Charter, and officially is not a member of CIS, but nevertheless is participating in CIS activities. Medical resources in Ukraine include 19 higher medical schools and postgraduate education institutions, 225,000 physicians (4.9 per 1000 inhabitants which is one of the highest in the world) and 2800 hospitals (431,000 hospital beds, 9.4 per 1000), and provides an excellent background for the country to enter the clinical trial arena and take one of the leading positions in the region.

As of the 1991 dissolution of the Soviet Union, Belarus was one of the world’s most industrially developed states by percentage of gross domestic product (GDP) as well as being the richest CIS state. With 46,965 physicians (4.87 per 1000 inhabitants, one of the highest in the world) (http://belstat.gov.by/homep/ru/indicators/pressrel/demogr.php), Belarus is attractive for Sponsors to place clinical trials there; however, the number of international trials are lower than in Ukraine and Russia.

The total population in all three CEE countries is close to 200 million inhabitants; this provides a large pool of potential clinical trial subjects, but not all of these subjects are equally accessible. Table 2 shows some factors that influence a subject’s accessibility.

CONCLUSIONS

The CIS is the biggest community of countries in the CEE region and is emerging in terms of the number and complexity of the clinical trials performed within its borders. Common historical roots, similar healthcare processes and procedures, cultural peculiarities and language simplify the coordination of clinical trials in the region. Providing detailed study start-up plans has assured up to 90% success in gaining approval to carry out international clinical trials in CIS. In addition, a reliable partnership with companies having deep local knowledge is the best approach for CROs and sponsors interested in achieving the best performance in running clinical trials in the CIS countries.

Table 2. Geography in CIS countries

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<thead>
<tr>
<th></th>
<th>Russian Federation</th>
<th>Ukraine</th>
<th>Belarus</th>
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<tbody>
<tr>
<td>Area, sq km</td>
<td>17,098,240</td>
<td>603,700</td>
<td>207,600</td>
</tr>
<tr>
<td>Population density per sq km</td>
<td>8.2</td>
<td>76.2</td>
<td>46.6</td>
</tr>
<tr>
<td>Roadways, km</td>
<td>982,000</td>
<td>169,495</td>
<td>94,797</td>
</tr>
</tbody>
</table>


References/citations from this article are available upon request.
ANDREI KRAVCHENKO, MD, PHD
Head of Representative office in Ukraine of HCR (Harrison Clinical Research) Deutschland GmbH

Dr. Andrei Kravchenko began in the pharmaceutical industry as a CRA in 2002, and became a clinical trial manager in 2003. He has served as head of the Ukrainian office of HCR since 2007. He holds his PhD in dermatology.

MAXIME STEVENS
Head of International Business Development HCR (Harrison Clinical Research) Group GmbH

Max has extensive experience in the surgical, medical device and more recently in the CRO environs. She spent many years in the surgical training field, focusing on both innovative laparoscopic procedures, and later neurological and vagal therapies for paediatric epilepsy. For two decades, she has built and trained global business development teams across Europe, MENA and South Africa. She also worked closely with the WHO for many years and sat on the FDA Medical Devices Board.

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Over the last decade, there has been a shift in the pharmaceutical industry that is bringing drug discovery and development in China to the forefront. As the industry evolves to be more global in scope, emerging markets play an increasingly important role in pharmaceutical development. Companies in China and other emerging markets, with fewer overheads, deep talent pools, and strong government support, have an opportunity to gain ground by growing the industry outside of the United States.

In order to bridge the gap between industry professionals in the US and China, the Sino-American Pharmaceutical Professionals Association (SAPA) was founded in 1993. SAPA’s mission is to promote the advancement of pharmaceutical science and biotechnology, to make contributions benefiting public health education, to promote scientific exchange and business cooperation between US and China, and to foster the career growth of pharmaceutical professionals.

The need for such a bridge is evident given SAPA’s rapid growth into a membership of nearly 4000, including individuals from drug discovery, preclinical sciences, drug product development, clinical research and development (R&D), Contract Research Organizations (CRO)/ Contract Manufacture Organizations (CMO), academia, and other professionals across the US, China, Hong Kong, Taiwan, Japan and other Asian Pacific areas. Originally founded in New...
Jersey of the United States, SAPA has spawned several regional organizations including one in New England (SAPA-NE), one in Greater Philadelphia (SAPA-GP), and one in Shanghai, China.

SAPA is committed to promoting pharmaceutical science and technology and its essential role in fostering member’s career development. In service to science, SAPA facilitates communication among scientists, policy makers, government officers, educators, and journalists from both the United States and China through its interdisciplinary conferences, symposia, seminars, webinars, workshops and diverse publications. SAPA Programs draw upon the foremost experts and the most current information about advances in drug discovery and development to inform analysis and discussion of public health issues, and to promote scientific exchanges and networking opportunities.

Jingsong Wang, MD, Head of China R&D and Head of Translational Medicine, Asia Pacific at Sanofi, speaks highly of SAPA and the importance of its mission. “What I like the most [about SAPA] is the quality of its scientific programs, the desire for continued improvement, the caring it has for its members, and the broad professional networks across both the US and China,” said Wang, who previously served as President of SAPA-GP.

SAPA’s various programs aim not only to benefit its members, but also the community at large. An example is SAPA’s work to organize educational seminars on severe acute respiratory syndrome (SARS) in conjunction with local communities, as well as contributing to the China Red Cross for the fight against SARS. Additionally, SAPA-GP has held a number of investment forums for biopharmaceutical companies and New Technology/Scientific Districts, such as those for ZhangJiang, Shanghai Pu Dong, Suzhou, Wuxi, Benxi, Chongqing, and ShanDong, to name a few. There are many opportunities for Chinese-American professionals to impact innovation, restructuring and globalization within the pharmaceutical industry. SAPA’s membership works to create a stronger impact by hosting scientific meetings, symposiums, member conferences, and workshops to promote scientific exchange and business cooperation between the US and China. In particular, the organizations host an Annual Conferences for pharmaceutical professionals and executives, as well as representatives from the regulatory authorities - the State Food and Drug Administration (SFDA) of China and the US Food and Drug Administration (FDA). This allows for the exchange of ideas and for the education of attendees on new approaches to increase innovation and productivity in pharmaceutical development. It also provides a forum for discussing current trends in emerging markets. As bridging platforms, SAPA organizations provide venues for the Chinese national biopharmaceutical industry entrepreneurs, government officials and academic professionals to meet their overseas counterparts in the US. It also helps to explore new opportunities and job openings in emerging markets, and foresee the globalization of the biomedical industry, including what unprecedented challenges we may encounter and how we can prepare for new paradigms that may emerge in the future.

LAURA HONG, MD, PhD is the immediate past president of SAPA-GP. Dr. Hong is an Associate Principal Scientist at Merck Research Laboratories specialized in vaccine and biologic drug development.

SEAN ZHANG, MD, FCP is the current President of SAPA-GP. Dr. Zhang is a Medical Director and Liaison to Bristol-Myers Squibb (BMS) China R&D at the Department of Discovery Medicine and Clinical Pharmacology (DMCP) of BMS.

WEIGUO DAI, PhD is the Scientific Director and an Inaugural Janssen Fellow in drug product development at Johnson and Johnson. Dr. Dai is currently the President-Elect of SAPA-GP, and also serves as 2012-2013 Vice Chair of Physical Pharmacy and Biopharmaceutics (PPB) Section in AAPS.

BIN SHI, PhD is the General Secretary and Chair of Media Communication of SAPA-GP. Dr. Shi is a Research Fellow at Merck Research Laboratories and leads multiple projects in RNAi therapeutics, In vivo Pharmacology and Oncology franchises.
A NEED FOR CLARITY

It has been established that the most important aspects of the regulatory review of medicines are predictability, transparency, timeliness, and quality. It has also been recognized that the health technology assessment (HTA) of these medicines can benefit from these same characteristics.

HTA agencies all have a common goal: the efficient allocation of scarce resources in the face of increasing health care demands, new medical technologies and ageing populations. However, this goal is accomplished through many different approaches, and unlike regulatory submission and review processes for which regional and international standards have been developed, procedures for HTA and coverage bodies remain fragmented, with often heterogeneous requirements. For example, although there is only one regulatory agency whose decisions apply across Europe, there are over 30 HTA agencies at national and regional levels with different processes and requirements and more than 30 coverage bodies with differing abilities to pay and to allocate resources. This diversity adds to the complexity of medicines' development and clouds the transparency and predictability of the HTA and coverage body review process, ultimately resulting in unequal access to medicines for the 501 million patients in Europe.

In fact, in a recent review and reimbursement survey conducted by the Centre for Innovation in Regulatory Science (CIRS), industry respondents indicated that a high level of transparency (94%) existed for regulatory requirements while an extremely low level of transparency (13%) surrounded the requirements for HTA.

Furthermore, a lack of timeliness in HTA can contribute to significant delays in patient access to new medicines. This is particularly true in countries with emerging pharmaceutical markets where adding the time required for HTA assessment to that country’s Lag Time (the delay in submission to an emerging market country from the time of approval in the first market) and the subsequent regulatory review time in that market, can result in years of unequal access to important new therapies.
If regulatory reviews can be aligned on a regional or jurisdictional basis by focusing on the elements of common science, can HTA decision-making frameworks be similarly aligned, based on scientific principles and the use of common data? Several national and international initiatives are now underway to examine this issue, but these have not yet examined the subject in detail in the Emerging Markets. This gap is largely due to the nascent state of the HTA development in these economies, where currently only a handful of countries, – Indonesia, South Korea, Taiwan and Malaysia – have formal HTA agencies that undertake single technology assessment. While the other countries with emerging pharmaceutical markets also necessarily conduct value assessments of new medicines, formal procedures have often not yet been codified. As these countries begin to assess other established HTA processes upon which to model their emerging systems, a clear understanding of the specific HTA processes undertaken by other countries and their relevance to the Emerging Markets would be of great benefit.

Due to the diversity of HTA requirements and decision-making processes, it is recognised that it is critical to develop a clear map of the processes in each jurisdiction. This has been undertaken by the International Society of Pharmacoeconomic and Outcomes Research (ISPOR) to provide a general overview of key aspects of HTA activities in selected countries. In turn, this process mapping can help establish appropriate benchmarks to inform efficient and timely HTA activity. Ultimately, this would enable the identification of best practices across HTAs from which emerging agencies could chose, allowing them to build their own high-quality, efficient, science-based, bespoke systems.

ADVANCES IN PROCESS MAPPING

Since 2010, CIRS has undertaken a project to systematically map the processes in jurisdictions that have formal HTA activities to elucidate the organization of different health care systems and to allow the systems to be compared with one another. It was envisioned that these maps could be used as a straightforward instrument to visually convey the structure and differences of various HTA and coverage systems to all stakeholders with an interest in healthcare. The CIRS HTA Process Maps are developed in a stepwise fashion.

• In the first step, agencies involved in the HTA process are identified and their status as government or independent bodies is specified. External connections between the sponsor of a new medicine and the regulatory, HTA and coverage bodies and internal connections among the agencies are numbered to indicate the typical order in which these contacts occur.

• In step two, seven functions that represent significant measurable key components of the system are defined: Regulator, Market Authorisation, HTA, Price Authority, Recommender, Decision Maker and Provider. These functions are then mapped onto the agencies that conduct those functions in order to show where in the system such activities occur and how they relate to one another.

• In step three, a “task bar” of key activities is developed for the HTA function in order to characterise a selection of defining elements of the HTA process. These activities are Scientific Advice, Therapeutic Value, Economic Value, Reimbursement Rate, Public Consultation, and Coverage with Evidence Development. Each activity is given an identifying icon that is shown in the HTA task bar if that activity is a normal part of that agency’s actions.

Using this process, CIRS has begun to identify key similarities and differences among HTA agencies. Variability in the connection between the assessment of a medicine’s therapeutic and economic value, the government’s role in the evaluation process, the structural setting of decision makers and how evidence flows to support decision making were among the differences identified by the construction of the Process Maps. General similarities across jurisdictions could also be observed in HTA processes and procedures.

The maps permit simple visual comparisons and are extremely useful for agency and industry training and educational purposes, providing a consistent terminology for cross-stakeholder discussion (Figure 1). For industry, the potential impact of HTA mapping on product life cycle management is significant: it identifies science-
based HTA requirements applicable to all jurisdictions while characterizing regional variations in requirements and processes. Process changes over time can be assessed using a consistent mapping approach. For agencies, the granular mapping of HTA activities permits benchmarking and identification of best practices and has the potential to streamline and enhance both HTA and regulatory review processes. Additionally, the mapping system offers the rapidly evolving emerging market counties a way to assess how best to organise their agencies and how to apply their limited resources to the goal of providing efficient and transparent science-based HTA recommendations.

**SUMMARY AND THE WAY FORWARD**

Despite the fact that HTA and coverage decision making processes and practices are heterogeneous across jurisdictions, these systems share many common elements that can form the basis for activity benchmarking and best-practice identification, enhancing the quality, timeliness, transparency and predictability of decision-making processes. Multistakeholder initiatives are underway that are looking to align HTA requirements during the development and review of new medicines.

Enabling stakeholder understanding of the processes surrounding the movement of scientific evidence from development through the registration and reimbursement represents a significant step in achieving expedited and equal international patient access to innovative medicines.

References/citations from this article are available upon request.

**LAWRENCE E. LIBERTI,** MSc, RPh, RAC, has worked for the past 34 years in and with the pharmaceutical industry, in the fields of regulatory affairs and clinical R&D. Since 2009 he has served as the Executive Director of CIRS (the Centre for Innovation in Regulatory Science, Ltd; formerly the CMR International Institute for Regulatory Science), an independent division of the IP and Science business of Thomson Reuters.

Mr. Liberti is a pharmacist with a master’s degree in pharmacognosy (both from the Philadelphia College of Pharmacy and Science). He is a Fellow of the American Medical Writers Association and is a recipient of their Golden Apple award for excellence in teaching.

Figure 1. Process Maps as a comparative tool
Over the past several years, Health Authorities, particularly in emerging markets, have required clinical documents beyond International Conference on Harmonization (ICH) Common Technical Document (CTD) in order to support successful New Drug Applications. This includes Health Authorities in markets with potentially high patient access needs such as Brazil, China and Mexico (Figure 1). Regulatory success in these increasingly important markets is dependent on the Sponsor’s ability to meet these additional clinical document and information requirements. As an introduction to the topic, this article explores those clinical documents required as part of marketing applications to China, Taiwan, Korea and the Association of South East Asian Nations (ASEAN) markets.

Regional/National requirements including subset analyses:

The Health Authorities from these local markets are not signatories to ICH. Thus, it is not surprising that local/regional clinical data requirements to support marketing approval vary significantly across these Health Authorities. Previously, conduct of local registration studies may have been required; more recently greater flexibility has been seen. For example, a national subgroup from within a single multi-national pivotal/non-pivotal phase III trial in the relevant patient population may be sufficient to achieve registration.
Regardless, what is becoming apparent is that expert clinical and regulatory input is required to build the optimal package to demonstrate the relevance of mainly foreign clinical data to these markets as is described below.

CHINA

The China Import Drug License (IDL) is the marketing application and incorporates a variety of clinical programme and study-level documents (Figure 2); note that the format of the China CTP (Clinical Trial Permission) and the IDL is the same. One can view the CTP as analogous to the EU Clinical Trial Application (CTA). The clinical/regulatory documentation differences between the IDL and ICH CTD are magnified within Module 1 and especially Module 2.

Provided in Part I of the IDL application, China Items 3 (Rationale for Drug Development) and 4 (Summary and Evaluation of Major Research Results) are cross-functional documents (Chemistry, Manufacturing and Controls (CMC)/Nonclinical and Clinical) that should incorporate certain specific elements from the ICH CTD Clinical Overview and Summary. China Item 28 (Clinical Study Summary provided in Part IV of the IDL application), is a clinical document meeting the China specific format that may be substantially based on the Clinical Overview and Summary.

CHINA SUPPLEMENTARY CLINICAL STUDY REPORT

One caveat to the China IDL is the requirement for the provision of a standalone supplementary report for patients at China recruitment centres. This report is submitted in addition to the ICH Clinical Study Report (CSR) from the same study. A key requirement is to include an analysis of Chinese patient data on key safety and efficacy endpoints. The statistical methods and presentation should broadly follow that of the ICH CSR. This supplementary report needs to be a “standalone” document as in essence it is standing in the place of a local registration study CSR. Some sections of the China CSR will essentially be duplicates of the parent global CSR.

TAIWAN

In order to obtain regulatory approval for a new chemical entity (NCE) in Taiwan, a Bridging Study Exemption (BSE) is usually sought that involves submission of a ‘Bridging Study Checklist’ perhaps prior to the NDA application. The ‘Checklist’ requires provision of the necessary supporting data and includes an assessment against ICH E5 Appendix D (A Medicine’s Sensitivity to Ethnic Factors) criteria. In addition, a provision of subgroup data is required on Asian patients (e.g., Taiwanese/Japanese/Chinese/Korean/Hong Kong) as part of the BSE application.

The Taiwan Guidelines on Drug Review and Registration, Article 22-1 clarify that “When applying for bridging study assessment, manufacturers should fill out the checklist for bridging study assessment and provide a complete clinical data package, preferably with data on ethnic groups in Asia.”

There is no formal requirement for pooling of Asian patient data but this may be requested by Taiwan Food and Drug Administration (TFDA). Most multinational companies will proactively provide a pooled analysis of the Asian data, especially when few Taiwanese subjects are enrolled in the programme.

SOUTH KOREA

In order to obtain regulatory approval in South Korea for NCEs, it is necessary to provide in a Bridging Position Paper (BPP) either:
• Data from a Korean clinical study to bridge to ‘foreign’ data;
• Clinical data from Korea (and other Asian) patients to gain a bridging study waiver; or
• Justification for a bridging data waiver (strict criteria apply)

**The BPP will typically incorporate:**

• An assessment in relation to ICH E5;
• Western/Japanese and/or Chinese pharmacokinetic data;
• Primary/secondary objectives and safety in Korean patients;
• Subgroup analyses data guided by input from the Korea Food and Drug Administration (KFDA): Total vs. Korean, Non-Korean vs. Korean, Asian vs. Korean, Total vs. Asian; and
• Product overview and summary of the clinical development program.

Data on a sufficient number of Korean patients (no clear KFDA definition) are required to support the claim that no additional local studies in Korean patients are required. Waivers are available for certain categories of applications (e.g. orphan drugs), but strict criteria are applied. In general it may be perceived that there is a low probability of success in obtaining a “Bridging Data Waiver” category for NDAs covering solid oral dosage forms, even if an ICH E5 conforming evaluation shows a low likelihood of ethnic sensitivity. Finally, equivalent data from Asian Countries are considered supportive only and are unlikely to be directly usable for registration in lieu of Korean data even with clinical evidence of lack of ethnic sensitivity.

**ASEAN COUNTRIES**

Comprised of 10 countries, the Association of Southeast Asia Nations (ASEAN) was established in August 1967 to foster their overall health and economic development. In order to facilitate trade and investment in the region, the ASEAN committee on standards and quality has endeavored to harmonize national standards with international standards. The ASEAN CTD (ACTD) is part of the marketing authorization application dossier that is common for all ASEAN members.

The content of the ASEAN CTD Part IV (Clinical) is the same as the ICH CTD – no ASEAN specific documents are required to be authored. The Clinical Summary and Overview are included along with Clinical Study Reports in ASEAN Part IV. As shown in Figure 3, the ACTD differs in format from the ICH CTD.

While the format differs between the ICH CTD (5 modules) and ACTD (4 modules), the clinical content remains the same for most marketing applications - no new ASEAN documents are required. One exception is Vietnam where in some circumstances local Vietnamese clinical data may need to be provided in a supplementary CSR.

**CONCLUSION**

Emerging markets are striving for improved health standards; therefore it is vital that the Sponsor demonstrates that their drug is safe and effective in the relevant population. While the pharmaceutical industry places an emphasis on ‘emerging markets,’ a discrete number of non-ICH clinical deliverables are required to support regulatory submissions. Bear in mind that:

![Figure 3. ASEAN CTD vs. ICH CTD](image-url)
• Requirements vary between countries
• Support from Clinical and Regulatory functions is essential
• Most documents can be provided post NDA/MAA (although subgroup analyses may be identified prospectively prior to unblinding of data)
• Science is not the only driver behind non-ICH clinical requirements
  – Regulations and the local environment also need to be considered in order to demonstrate the relevance of “foreign” clinical data

Expect future change! Plan ahead; consult with your regulatory affairs representatives to understand what additional documents and new subgroup analyses will be needed beyond an ICH CTD.

Finally, an encouraging look to what could be ahead: A “Tripartite Agreement” has been forged between Japan’s Ministry of Health, Labour and Welfare, the China SFDA and the Korean FDA to examine the effect of ethnic differences. In the long term, this collaboration *may* lead to mutual acceptance of foreign data generated in these three markets, though no definitive outputs are anticipated just yet.

References/citations from this article are available upon request.

FRANK HUBBARD, PhD, is currently a Group Manager within Scientific Communications at AstraZeneca (AZ) where he manages a staff of Medical Communications Scientists, who lead cross-functional clinical and regulatory authoring teams to develop market applications for ICH and non-ICH accepting countries. A trained cancer geneticist, Frank possesses an earned doctorate in the life sciences from New York University with over 15+ years in clinical research experience in oncology, cardiovascular disease, CNS, respiratory, GI, and functional genomics. He is a recognized expert in both ICH Common Technical Documents (CTD) and non-ICH marketing applications.

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ADVISE includes the “how to” articles you have become accustomed to reading in the former Best Practices section: Time management, skill development, technology, software topics and more are examined for day-to-day implementation in your own jobs and offices.
For more than two decades, life sciences organizations have purchased, configured and deployed a series of ever-expanding and complex content management systems. At first, these systems had to be heavily customized for the unique needs of life sciences companies. Over time, industry-specific applications that better support life sciences-specific processes have evolved.

These content management tools continue to tack on new capabilities, but they have failed to fundamentally change to meet the new business challenges facing the life sciences market: greater collaboration, fast-paced globalization, increasing compliance and stronger focus on cost reduction.

Despite these radical shifts in the business environment, life sciences content management systems have remained largely unchanged. They are built on the same basic platforms and technologies, and they are often only affordable to larger organizations with significant time and resources to invest in systems development projects and customization.

Consequently, many life sciences organizations have grown frustrated with the cost and complexity of implementing, maintaining and updating inadequate content management systems — a process that can
often cost hundreds of thousands of dollars every year. Even worse, smaller companies are left with few, if any, good options for the implementation of IT systems supporting their regulated content management processes.

The life sciences industry requires an entirely new solution, a content management technology that truly fits the new needs of all life sciences companies regardless of their size. One technology has emerged that may support this kind of change: cloud computing. (See sidebar.)

**COLLABORATE CLOSELY**

Over the last five years, the number of external partners (co-development partners, clinical research organizations, co-marketing partners, ad agencies and more) that life sciences companies employ has increased by as much as 50% or more. The use of these partners has reduced costs and increased speed to market. However, this new model has also created significant content management challenges, specifically surrounding collaboration.

While traditional on-premise content management systems often support working collaboratively within an organization, they are not designed for external collaboration. It takes too long, is too complicated and too expensive to give secure access to all external collaborators. Rather than deal with these obstacles, companies tend to simply pull content out of their controlled repositories and distribute it via e-mail or secure FTP. These methods, however, are inherently risky because they skirt the compliance checks and audit trails maintained by the core content management system.

In contrast, cloud-based content management systems allow life sciences companies to meet the needs of the current business climate to collaborate closely, connect globally, comply swiftly and manage costs effectively.
on-premise or hosted systems are difficult and costly to change. Even simple changes, such as adding new fields, tracking document distribution and changing security structures require elaborate system validation, development, installation and deployment. This can require thousands of dollars and as long as four to six months to implement. That’s too long for teams that need to focus on creating, assembling and delivering content, rather than implementing and validating system changes.

In contrast, cloud systems can reduce the time to deploy and validate such changes by more than 50%. This is because cloud content management systems automatically receive updates as part of the underlying application structure, are easily tailored to meet changing regulatory requirements through simple configuration, and significantly reduce the time and effort of validation by sharing that burden across organizations. The result is less time spent on IT systems and more time spent on core business functions.

Administrators simply provide a secure log-in. Content is visible by all authorized team members immediately and without significant IT intervention. Additionally, the documents stay in a controlled environment throughout the collaboration process, providing a more compliant system and reducing risk.

**CONNECT GLOBALLY**

Annual global spending on pharmaceuticals is expected to grow to nearly $1.2 trillion by 2016, according to a report from the IMS Institute for Healthcare Informatics. In addition, the IMS reported that annual global spending growth will increase from $30 billion in 2012 to $70 billion in 2016. This is driven, overall, by volume growth in emerging pharmaceutical markets and higher spending by developed nations.

Given this explosive growth, both small and large life sciences companies will be challenged with managing their content globally. Affiliates around the world, including geographies where affiliate offices have only a few people, will need the same system access, speed and performance that central offices have typically enjoyed.

Because the cloud is ubiquitous, cloud content management systems provide — for the first time — a truly global view of how content is created and used. Systems in the cloud are accessible from wherever users have an internet connection. Additionally, cloud solutions are cost-effective enough to deploy to even the smallest local affiliates. This enables content access to participants around the globe, thereby eliminating the common, less secure approach where central offices email or FTP documents out to local affiliates to make their changes and then back again.

This approach resulted in a lack of visibility (for example, local content changes were not accessible to the central offices and vice versa), a proliferation of uncontrolled content copies and a sense of version confusion as people were unsure which document version was the most current. In contrast, by providing equal and immediate access for all, cloud content management systems avoid these issues, resulting in greater transparency and better communication.

**COMPLY SWIFTLY**

From product development to manufacturing, from drug safety to marketing, the rate and scope of regulatory change and reinterpretation are increasing exponentially. Across the globe, regulatory authorities are fundamentally changing the way in which life sciences organizations conduct business.

Because much of a life sciences organization’s information is contained in the form of content such as safety reports, promotional materials and health authority submissions, the increasing rate of regulatory change presents a special challenge for today’s content management systems. These

**MANAGE COSTS EFFECTIVELY**

Technology is notoriously expensive, and life sciences content management systems are no exception. But with an increasingly challenging global
economic environment, greater competition, expiring patents and a shift from the blockbuster drug models of yesterday, companies must find ways of maximizing technology effectiveness while reducing overall costs.

Cloud computing makes content management affordable to even the smallest organizations or business units by reducing both up-front costs, as well as costs associated with ongoing system updates and maintenance. As a result, companies typically save anywhere from 30% to 50% over on-premise or hosted systems.

How? By completely avoiding the capital costs of servers, software and maintenance and, instead, adopting a highly predictable pay-as-you-go-model. Additionally, costly administrative tasks common with on-premise systems (upgrades and back-ups, for example) are eliminated with cloud technology since there is no hardware or software to manage on site. All upgrades and back-ups are handled by the solution provider.

2013: THE YEAR FOR FUNDAMENTAL CHANGE IN CONTENT MANAGEMENT

Collaborate closely. Connect globally. Comply swiftly. Manage costs effectively. These simple requirements are having a profound effect on how life sciences organizations need to manage their content today and in the future. It is no longer enough to patch, update and upgrade existing, on-premise systems.

Fundamental business change requires fundamental technology change. New cloud applications provide that leap forward – and, according to analysts, are the fastest growing technology. For the first time, companies of all sizes can meet the challenges of today and tomorrow, without the complexity, cost and uncertainty of traditional, enterprise on-premise or hosted content management implementations.

References/citations from this article are available upon request.
 whilst life sciences organizations are known for being risk-averse, clinging protectively to their data, this strategy will hold them back going forward. With markets showing no immediate sign of recovery and competitive pressures fiercer than ever, pharma organizations must now rethink their business models in order to stay lean and agile.

Yet at the same time intensifying regulatory demands are creating new complexity around content management. In the face of these two conflicting scenarios, companies are realizing they have no choice but to entrust aspects of their operations to specialist service providers - those offering superior economies of scale in handling non-core activities.
AstraZeneca SHOWS THE WAY

AstraZeneca’s chief technology officer Angela Yochem has been pretty open about the company’s need to relax its internal controls, and to reach out to a wide range of external sources. Her view is that shifting the responsibility for certain aspects of IT delivery to third parties frees the company to focus on opportunities that improve the business’s bottom line. Yochem is not alone either: to improve their abilities to collaborate and expand mobility other large pharma organizations too are making significant changes to the ways they function, having recognized that such capabilities as content management are commodity components of their business, not competitive differentiators.

Harnessing external services adds up too. Buying or building vast, costly internal solutions that cater to peak workloads is wasteful. Owning systems and running them carry cost burdens too, in terms of license fees, maintenance and upgrades. Also, systems’ fitness for purpose could be short-lived as the needs of the business evolve and change.

Whilst outsourcing services have not always had good reputations, virtualization technology and cloud-based delivery models have proven transformational - enabling rapid access to new technologies, facilitating easy scalability and leading to substantial cost savings. The ability to scale IT infrastructures both up and down in terms of capacity is a huge pull for companies — especially when companies will most likely only need to pay for the resources they actually use — because the services are being provisioned as a service.

As well as introducing additional cost efficiencies — because staff are freed from repetitive administrative burdens — the prospect of holding content somewhere external and central offers other benefits. In the life sciences industry, information is continually being created, updated, used and read by multiple people in different departments and locations. The more global markets have become, the more widely content needs to be shared. Whatever companies feel about entrusting valued assets to third parties, there is now a competitive imperative that scientists and thought leaders have seamless access to information that has the potential to advance discovery.

FACILITATING ADVANCED COLLABORATION

Collaboration is a driver too. This is increasing between academia, biotech companies and even competitors. With such a diverse group of people involved in the drug development and marketing process today, the ways content is gathered and managed must evolve. Whilst intellectual property needs to be safeguarded, it has become clear that strategically organizations now need greater visibility than traditional bespoke electronic content management solutions have allowed.

Pharma organizations can take reassurance from the fact that content as a service, or cloud-based information delivery, has evolved considerably — to offer secure transmission and the ability to partition one company’s data from that of others. This means that data that needs to be secured can be, whilst information vital to a collaborative effort can be made available to authorized parties via a common but secure Internet-based framework — removing a layer of complexity and permitting the participants in a project to access the same common core of data directly.

PLANNING IS KEY

Any shift from internal control to content as a service requires a willingness on the parts of IT and business leaders to surrender a certain amount of control over the location of their data, of course. But rather than needing control over where data is held, what companies really need is assurance that their data will be managed securely and a dedicated managed service provider with a purpose-built data centre will be much better equipped to ensure this than an internal IT department ever could be.

Where there is resistance to the proposed changes — in defense of people’s jobs, legacy investments and the interwoven business processes linked to
those bespoke solutions — cloud-based solutions can provide a way forward here too, offering organizations a migration path.

So long as they plan well.

Success in adopting content as a service demands a best-practice approach that starts with the appointment of a high-level internal sponsor — such as the head of research and development, chief scientific officer or even CEO — to drive and support the initiative through all of its phases. Next, the project will need an IT leader — perhaps an external partner, or the chief information officer or chief technology officer.

A clear IT strategy is crucial: business processes must be well thought out and technology solutions considered in terms of both short-term and long-term implications and benefits.

**FUELING COMPETITIVE ADVANTAGE**

Any concerns about system performance have been largely addressed, as cloud-based services have matured and the success of software-as-a-service-based applications has been proven.

Sure, electronic content management is a more complex proposition. But increasingly IT leaders — and, close behind, business leaders — are beginning to accept that content-as-a-service will lift a costly and onerous burden from the industry.

Those quick to embrace the opportunity will gain most because of the extra agility cloud-based solutions offer them. As organizations begin to map out new growth strategies, innovative thinking and a dynamic, service-based approach to content management will go a long way in setting them up to reach out and exploit new markets.

References/citations from this article are available upon request.

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NEW: DIA Online Career Center

Whether you are job hunting, want to expand your professional skills and knowledge, or are looking to connect with others in your field, you can find what you need at DIA’s online Career Center.

DIA’s newly launched Career Center is designed to meet the professional development needs of our stakeholders around the world. The new Career Center, found at [http://www.diahome.org/en-US/Career-Center.aspx](http://www.diahome.org/en-US/Career-Center.aspx), provides comprehensive resources for every stage of your career.

The new Career Center features:

- **Job listings and Information**: Job seekers can search health care positions, or post their resume for employers to view. Employers can post positions and find employer strategies.

- **Career Resources**: Career Corner, a daily online newspaper featuring articles, blog posts, videos, and photos from hundreds of media outlets, is your partner in the job search process and provides many helpful resources to assist you along the way.

- **Meetings and Training**: This section is designed to help you find solutions to critical issues and challenges. Links to DIA conferences, live and online training courses, webinars, and eLearning modules provide timely and authoritative information to advance the overall medical product industry and individual professional development.

- **Membership**: Take advantage of all the benefits of membership to network, learn, and lead. This section will point you to free webinars, members-only publications, and other benefits of membership that can help your career.

- **Networking and Communities**: DIA has many opportunities to interact with a global network of professionals who share your interest in a particular topic. This section will help you navigate our Communities (formerly SIACs), ConneX, and Student and Patient Initiatives.
REACH: Reflects the global nature of DIA and exposes readers to what we are doing around the globe and how advances in each region can have a worldwide impact. This is where Upcoming Events now resides, in an easy-to-read sidebar box for each region outlining their educational offerings.
After a great success in October 2012, the fifth edition of the Latin American Regulatory Conference (LARC) is to be held on May 15th-16th, 2013 in Bogota, Colombia. This year meeting’s focus is pharma-co-vergence and brings in exciting new features resulting from specific regional needs, feedback from the DIA attendees at the past 4th LARC, and DIA’s global knowledge on current global trends.

The recent expansion and increasing operation of the industry in Latin America has brought a real need for regional cooperation, hence the focus of the 5th LARC on pharma-co-vergence. The term — coined in 2012 by DIA’s LARC Scientific Committee Co-Chair, Justina Molzon, MS Pharm, JD, CAPT. USPHS, Associate Director for International Programs, CDER, FDA — refers to drug regulatory authorities working in a collaborative way to best utilize
resources for promoting improved public health globally; and stems from the English words a) Pharma: pertaining to pharmaceuticals; b) co: together, joint, jointly, mutually, and c) verging: being on the edge or margin of something—the limit or point beyond which something begins or occurs.

Fostering “pharma-co-vergence” among the Latin American Regulatory agencies and, of course, the industry, is a real need regionally, especially with the positive sales increase and forecasts for the industry in Latin America. Collaboration is certainly most needed for it to maximize gains and to evolve in an optimal way.

The LARC Program in 2013 includes exciting new plenary and concurrent sessions, tailored to the needs of the industry regionally and stemming from discussions with the Latin American community itself, the past LARC Attendees and DIA’s Advisory Council for Latin America. Likewise, the presence of Latin American Regulatory agencies and inclusion of current global topics were taken into account to bring about the most complete LARC program ever.

Colombia was selected by DIA’s 5th LARC Scientific Committee as the best location this year since its market is precisely an excellent example of the expansion of the pharmaceutical industry in the region in recent years. It became the 4th largest market in Latin America, valued at US $4.1 billion at 2011 retail prices. Additionally, the Pan-American Health Organization (PAHO) certified in 2011 the Colombian Regulator, INVIMA, as the National Regulatory Authority for Drugs in Latin America. “This is the highest PAHO qualification, thereby positioning INVIMA as a National Regulatory Authority within the international sanitary environment.”

This year’s conference constitutes the 3rd activity in the Andean country since last year and is a testament to DIA’s commitment to foster collaboration and cooperation regionally, as DIA expands operations in Latin America to serve as the only global and impartial forum for all stakeholders in the region.●

References/citations from this article are available upon request.

**UPCOMING EVENTS**

**LATIN AMERICA CONFERENCE**

Latin American Regulatory Conference (LARC) 2013: “Pharma-Co-Vergence”
May 15-16, 2013
Bogota, Colombia

10th Latin American Conference on Clinical Research: The Role of Clinical Research in the Future of Medicine
October 20-22, 2013
Maksoud Plaza Hotel
São Paulo, Brazil

For more information contact Alejandro Bermudez-Del-Villar at Alejandro.Bermudez@dialatinamerica.org.

**SAVE THE DATE!**

Latin American Regulatory Conference (LARC) 2013
May 15-16, 2013
Bogota, Colombia
Modern computer and other scientific technologies have made it possible for drug researchers and developers to generate and analyze more data than ever before. In response to louder calls for patient safety, and the multiple review jurisdictions called into multinational or global clinical trials, such data are also subject to more (and more intense) scrutiny during regulatory review and approval than ever before. As a result, for the past several years, regulatory departments have been asked to do more than ever before, too.

The DIA Regulatory Affairs Special Interest Area Community and an expert program committee have teamed to build upon DIA’s inaugural conference, presented in April 2012, and will present *Regulatory Information Management 2013*, April 3-4, at the Baltimore (MD) Marriott Inner Harbor at Camden Yards. All four committee members have returned from last year’s program: Sarah Powell, RAC (Liquent, Inc.); Linda F. Bowen, MS, RAC (Sanofi); Dominique E. Lagrave, PharmD, MSc (Dendreon Corporation); and Andrew P. Marr, PhD (Marr Consultancy, Ltd., UK).

This committee has worked with the RA SIAC to develop a program that will address topics of
essential importance to regulatory information management (RIM) professionals in an environment of mergers and acquisitions, multinational corporations, and the Food & Drug Administration Safety & Innovation Act (FDASIA), presented along two tracks, Business Considerations and Tools & Technology. In addition, vendors will present the latest information management products and services on tabletop exhibits.

“We received some terrific feedback on the evaluation forms from the conference last year. We took this feedback into consideration in planning this year’s conference,” Sarah explains. “For example, speakers will be asked to ensure that their presentations are globally focused and there will be opportunities for attendees to spend more time looking at tools that assist with RIM.”

“Separating the conference into two tracks allows for the opportunity to provide more information to the participants than a single track would allow,” she continues. “The format allows attendees to attend the sessions that are most relevant to their jobs thus ensuring maximum value from attendance at the conference.”

Exhibits, business sessions, tools and technology sessions, and plenary sessions are planned to combine into a valuable educational experience for every professional who works with regulatory information and its management. “Regulatory information management continues to receive acknowledgement for the importance it plays in strategic decision making and regulatory compliance within organizations,” Sarah concludes. “Just a few years ago, this topic was rarely discussed in this focused of a forum. Attendees have an opportunity to learn from their peers regarding what is (or is not) working with regard to RIM and, perhaps more importantly, network with each other and exchange contact information to keep the discussions going after the conference.”

For more information about Regulatory Information Management 2013, please visit http://www.diahome.org/RIM2013.

Medical & Scientific Communications 2013

The Medical & Scientific Communications 2013 Annual Forum, scheduled for March 19-21 at the Sheraton Wild Horse Pass Resort & Spa in Chandler, AZ, truly reflects the multidisciplinary and collaborative nature of modern drug development, review and approval, as it has been jointly developed by three DIA Special Interest Area Communities (SIACs): Medical Communications, Medical Writing and Medical Science Liaisons, a new SIAC formed just last year (see related article in this issue under “SIAC Corner”).

This meeting has been integrated to provide content that meets the needs of professionals who work in pharmaceutical-based medical and scientific communications through a single unified offering presented along three tracks: medical communications, medical writing – regulatory and publication, and medical science liaisons.
“A separate MSL track is extremely important from the sense that we’re now recognized as a significant entity within the DIA organization,” explains Dr. David L. Cram (Corcept Therapeutics), a member of the MSL SIAC Core Committee. “For this year’s Medical & Scientific Communications Forum, program co-chairpersons Rebecca Vermuelen and Ramineh Zoka are both big powerhouses who engender a lot of respect within the MSL world. It’s important to have that representation be part of and drive this program. In the past, most of the attendees at these meetings have probably been drug information people with a relatively minor group of MSLs. MSLs have gone to other meetings presented by other companies because those meetings catered to them. Now, topics that you might have seen in those forums are coming into the MSL track for DIA. This has now become our forum.”

What message does David, as part of the MSL SIAC leadership, hope attendees bring back to their workplaces after attending our Medical & Scientific Communications Forum 2013?

“I am hoping that they return and say that this was something that I got a lot out of. Very inexperienced MSLs, who are either just entering industry or have only been there for a short time, don’t know what they don’t know. Hopefully, they will come and be simply dazzled,” David explains. “But I am also hoping that the experienced MSLs – the ones who have been around for a long time, who have ‘seen everything’ and are at that point where they believe that they have nothing more to learn – those are the ones who I hope say, ‘Wow, there’s something different going on here. I might just abandon all my other meetings. This is the meeting that I want to go to!’ We’re hoping we provide something for the very experienced as well as for the inexperienced MSL professional.”

Prior to this forum, four preconference tutorials will provide more detailed instruction on quality in promotional materials; medical communication compliance obligations; the art and science of managing a contact center; and preparing a Clinical Overview for pharmaceutical products in accordance with ICH guidelines on Module 2.5 of a Common Technical Document (CTD). The annual Core Curriculum, which delivers comprehensive and foundational instruction on building medical communication skill sets and how they provide value to internal and external customers, will also be presented this year.

For more information about our Medical & Scientific Communications 2013 Annual Forum, please visit http://www.diahome.org /Flagship-Meetings/ MedComm2013.aspx.

Marketing Pharmaceuticals 2013

In an era of shrinking health care dollars and a highly competitive market, marketing and promoting pharmaceuticals, biologics, over-the-counter drugs and medical devices – and complying with various regulatory and legal requirements for marketing and promotion – is more important than ever. The ongoing implementation of the Affordable Care Act (ACA), the FDA Safety & Innovation Act (FDASIA) and PDUFA V make this marketing environment even more complicated and challenging.
Since 1989, DIA has annually developed and presented a marketing conference to advance the state of the marketing art (and science) and provide professionals with practical advice on these and myriad ancillary issues. This year, DIA will present Marketing Pharmaceuticals 2013: Workshop for Regulatory/Legal/Communications Professionals & Promotional Review Teams, February 20-21 at the Grand Hyatt Washington in Washington, DC.

The program committee includes Thomas W. Abrams, MBA, RPh, Director, Office of Prescription Drug Promotion, CDER, FDA. Mr. Abrams is scheduled to present the CDER update during the “FDA Update: Recent Enforcement Actions” session that will open this workshop, and participate in the FDA Q&A session that will conclude it.

The committee has developed a workshop that will provide first-hand updates from senior FDA regulators on the level of evidence FDA requires for making promotional claims, the status of social media guidelines, recent guidance documents and new policies being considered, and other aspects of the current regulatory and legal environment for marketing drugs and devices.

Health economics are becoming increasingly important in the drug development landscape, a point this conference will address through sessions titled “Fundamental Issues in the Regulatory Evaluation of Health Economic Information.” What are some of these “fundamental issues”?

“One of the main issues surrounding the regulatory evaluation of health economic information is clarity concerning the standard of evidence required for the proactive dissemination of health economic information for payers/plans, etc., called ‘competent and reliable scientific evidence,’ and the fact that this standard is quite different than the ‘substantial evidence standard’ required to support other forms of company product promotion and label claims,” explains Philomena McArthur (Johnson & Johnson Pharmaceutical Research & Development L.L.), who will chair one of these sessions.

“Contributing to this issue are the lack of clarity regarding what constitutes appropriate data, a lack of transparent regulatory policy in this area, and other initiatives underway that intersect with these principles, such as the proliferation of comparative effectiveness research and the need for such ‘real world’ data by many different stakeholders. In order to push forward, it is important to identify and understand these underlying scientific and analytical issues and what companies can do in meeting the many different stakeholder needs despite the complex challenges and lack of clarity in this area.”

If you are new or relatively new to advertising or promotional compliance, the pre-conference tutorial OPDP/APLB & Compliance 101: A Primer, taught by Lucy Rose, MBA (Lucy Rose & Associates, LLC), a longstanding member of DIA’s instructional faculty, will provide a strong introductory foundation to FDA advertising and promotional requirements from the Office of Prescription Drug Promotion and the Advertising & Promotional Labeling Branch, plus the current regulatory compliance environment.

As preparations continue for our DIA 2013 49th Annual Meeting: Advancing Therapeutic Innovation & Regulatory Science, Keynote Speaker Dr. Daniel Kraft took time from preparing his address to share his thoughts about the meeting theme with the Global Forum. A Stanford- and Harvard-trained physician-scientist, entrepreneur and innovator, Dr. Kraft has more than two decades of experience in clinical practice, biomedical research and healthcare innovation. He chairs the Medicine track for Singularity University and also serves as Executive Director for FutureMed, a program which explores convergent, exponentially developing technologies and their potential for biomedicine and health care.

What does the term “innovation” mean to Dr. Kraft, and how has he observed and applied this meaning in the course of his career?

“To me, innovation means understanding and approaching a problem, unmet need, inefficiency or other challenge, and coming up with effective, novel approaches to address them,” Dr. Kraft said. “Increasingly, in health care and biomedicine, this involves leveraging and pulling together different capabilities, technologies and approaches in new ways, particularly at points where technologies and other inventions converge – for example in mobile, big data, artificial intelligence, 3D printing, all the way social networks and user interface design.”

“From my mix of clinical experience, biomedical research and involvement with both traditional biotechnology and the startup world, I’ve seen the most exciting and effective innovations happen when the ‘problem’ is well understood from the clinical, regulatory, reimbursement, patient and other perspectives, and the innovations utilize multi- and cross-disciplinary lessons and insights from other fields and experiences which often come from outside of traditional biomedicine.”

“Effective Regulatory Science is critical to advancement of
Therapeutic Innovation” because regulatory frameworks and the understanding and perceptions of them shape how clinicians, scientists, engineers, biologists and others see the ‘box’ and how they may need to constrain their innovations and ideas to fit within them,” Dr. Kraft continued. “The challenge, that regulation can sometimes lag technology and the rapid pace of innovation, remains.”

“Regulatory science can, hopefully, help large systems adapt to foster new therapeutics and approaches while still maintaining safety, efficacy and quality.”

What message is Dr. Kraft hoping to share through his Keynote Address?

“I hope that in my keynote I can inspire attendees to see and approach the world of biomedical and healthcare innovation bit differently, by appreciating how various technologies – which in many cases are moving exponentially faster, smaller, cheaper and smarter – can be applied to ‘re-invent’ and ‘disrupt’ healthcare and biomedical innovation in new, powerful and effective ways. How can we work together and leverage the explosion of faster computing, artificial intelligence, and mobile and wearable technologies, with the growth of new fields such as low-cost ‘omics,’ big data and analytics, synthetic biology, 3D printing, the utilization of stem cells and regenerative medicine, to catalyze innovation?”

DIA2013 49th Annual Meeting: Advancing Therapeutic Innovation & Regulatory Science will be presented June 23-27 at the Boston (MA) Convention & Exhibition Center.

To learn more about this “Exhibitor Invites” program for our DIA 2013 49th Annual Meeting, please visit http://expo.jspargo.com/exhibitor/dia2013marketingsupportopps.pdf or contact Craig.Baker@jspargo.com (Companies A-L) or Michele.LaFrance@jspargo.com (Companies M-Z).

DIA’s Annual Meeting is a true collective effort that comes together through the dedication of a cadre of program committee members; other DIA members and volunteers; and DIA staff. Work on each year’s program actually begins before the previous year’s meeting has finished and continues throughout the year.

Keith Wenzel (Senior Director at Perceptive Informatics) has served on the DIA Annual Meeting program committee since July 2010, when work began for the 2011 Annual Meeting in Chicago. He is serving as co-chair of the Processes & Technologies for Clinical Research Track for our upcoming DIA 2013: 49th Annual Meeting: Advancing Therapeutic Innovation & Regulatory Science, June 23-27 in Boston, MA, and will wrap up his three years of committee service upon its conclusion.

“Hello, But I Must Be Going Now”
A frequent speaker for DIA educational offerings in North America and in Europe, Keith also served on the program committee for Measuring Study Endpoints in Multinational Clinical Trials presented by the Study Endpoints Special Interest Area Community (SIAC) in 2009. He continues to Chair the Study Endpoints SIAC Core Committee and is also a member of the eClinical SIAC.

What was the most surprising thing that Keith has learned while serving on the Annual Meeting program committee?

“How difficult it is to utilize and maximize inclusion of the diverse content of the abstract submissions while designing a cohesive track,” he begins. “From the outside looking in, it is difficult to understand that, each year, there are many abstracts that we are unable to use, not because of abstract quality but because of the meeting’s focus and developing industry trends. I have also been very impressed with the intelligence and breadth and depth of industry knowledge of, not only of the program committee, but also the DIA staff. The DIA staff does an excellent job of supporting and coordinating the Program Committee through the lengthy, complex process of designing the final program.”

What changes have had the most impact on clinical research processes and technologies during Keith’s service on this Committee and how will this Track at DIA 2013 reflect these changes?

“Out of the need to consolidate several individual tracks to reflect the numerous ways in which multiple disciplines are converging and collaborating in clinical processes – and because of increasing topic overlap between IT, eClinical, validation, study endpoints, clinical data management and document management – all of these tracks needed to come under one umbrella,” Keith suggests. “In the same way that eClinical Technology is blurring the lines between individual applications and processes, the Clinical Research Processes and Technologies Track needed to converge to complement, enhance and reinforce these sub-tracks. Over the last few years, we’ve placed major emphases on: updating the industry on tried and true processes and technologies that have been improved or completely been re-invented; increasing the number of sessions that have real-world case studies; and, yet, still embracing visionaries and their cutting-edge, even if not yet proven, solutions.”

Looking back upon his three years of service, Keith says, “It has been a juggling act of competing priorities on the professional side, but that is true of this industry in general. The positives far outweigh the negatives. I have been fortunate to make new acquaintances and to learn from the expertise of my fellow track and program chairs. DIA staff does an excellent job of making efficient use of the program committee’s time and setting expectations. The effect on my personal life has been minimal, but it seems that I always end up reviewing abstracts on a plane on my way to or back from vacation!”
Dear Colleague,

In 1995, I presented a student poster to our 31st DIA Annual Meeting, while I was studying for my PhD at the University of North Carolina. My advisor at that time, Dr. Harry Guess, was heavily involved with DIA and served as DIA Board President in 1992. I think the topic of my student poster was product registration in China, but I clearly remember my first reaction to the DIA Annual Meeting. It truly opened my eyes to a new world, of new information and new people, and was a very good starting experience for a student taking my professional first steps.

Information and technology in today’s environment may be totally different compared to when I was a student years ago. But DIA still offers students a unique and very valuable platform. When I presented my own poster, for example, knowledge about product registration in China was quite limited in the US. The DIA student poster program presents an opportunity to showcase your own expertise to the scientific, academic, regulatory and industry leadership which attends our Annual Meeting from literally all around the world.

I later learned that DIA was interested in presenting an educational program in China. Although I was based in the US, I worked remotely with the regulatory agency in China, and so I stepped up to help organize the first DIA meeting in China (in Beijing, in 1997). I clearly remember the topic was clinical trials and statistics because this was the very first time that biostatistics in drug development was introduced to the pharmaceutical world in China. Working alongside other DIA members on these and other DIA activities enriched my own skills and experiences, helped me evolve and grow, and prepared me to assume more leadership roles throughout my career.

I graduated in 1996 and have attended every DIA Annual Meeting since 1997. Our Annual Meeting student poster sessions can help you even more than they helped me when I was a student many years ago. Please take advantage of this tremendous opportunity by accepting this invitation, which I extend on behalf of our entire global multidisciplinary network of DIA members and volunteers, to submit a student poster abstract for our upcoming DIA 2013 49th Annual Meeting: Advancing Therapeutic Innovation & Regulatory Science, June 23-27 at the Boston Convention & Exhibition Center.

Thank you for your time and consideration.

Sincerely Yours,

Dr. Ling Su
President, DIA Board of Directors
Strategic Advisor, Life Sciences, Sidley Austin LLP

The Call for Student Poster Abstracts will remain open until Monday March 11, 2013. To learn more about this process or submit your abstract, please contact Joanne. Wallace@diahome.org or visit http://www.diahome.org/Flagship-Meetings/DIA2013/Mt-Program/Posters.aspx.
UPCOMING EVENTS

NORTH AMERICA

Online Training Course: Development of a Clinical Study Report
February 5, 7 & 12
12:00-2:00PM ET

Online Training Course: Clinical Statistics for the Nonstatistician
February 13-15 & 20-21
Time Varies

Solution Provider Webinar: Oncology Clinical Trial Endpoints - Keys to Maximizing Success in Your Development Programs
February 14
11:00AM-12:30PM ET
Register Online for FREE!

Marketing Pharmaceuticals 2013
February 19-21
Washington, DC

Premarketing Clinical Safety and Pharmacovigilance
February 25-26
Horsham, PA
Register by February 4 to Save

February 27 | 11:00AM-12:30PM ET
Register for Two or More in This Series and Save 15%

The Leadership Experience
March 5-7
Horsham, PA

Regulatory Affairs for Biologics
March 11-12
Horsham, PA
Register by February 18 to Save

Regulatory Affairs: The IND, NDA, and Postmarketing
March 17-20
Irvine, CA
Register by February 24 to Save

Risk Management and Safety Communications Strategies
March 18-19
Horsham, PA
Register by February 25 to Save

Medical and Scientific Communications 2013 Annual Forum
March 18-21
Chandler, AZ
Register by February 25 to Save

March 20
11:00AM-12:30PM ET
Register for Two or More in This Series and Save 15%

Advanced Clinical Vendor Oversight: Vendor Lifecycle Management
March 26-27
Horsham, PA
Register by March 5 to Save

Online Training Course: How to Prepare for a Safety Inspection
March 26-28
11:00AM-1:00PM ET

Regulatory Information Management 2013
April 3-4
Baltimore, MD

Online Training Course: Fundamentals of Project Management
April 9, 11, 16 & 18
11:30AM-1:30PM ET

Introduction to Signal Detection and Data Mining
April 15
Horsham, PA
Register by March 25 to Save

Overview of Drug Development
April 15
Horsham, PA
Register by March 25 to Save

CMC Workshop 2013
April 15-17
Washington, DC
Register by March 25 to Save

Global Considerations for Regulatory Strategy Development
April 16-17
Horsham, PA
Register by March 26 to Save

April 24
11:00AM-12:30PM ET
Register for Two or More in This Series and Save 15%

DIA/FDA Statistics Forum 2013
April 28-May 1
North Bethesda, MD

DIA 2013 49th Annual Meeting: Advancing Therapeutic Innovation and Regulatory Science
June 23-27 | Boston, MA
This new course, held in Vienna, Austria at the end of September 2012 provided a comprehensive description of the strategies for developing a product according to the ICH guidelines ICH Q8, Q9, Q10, and also the brand-new released ICH Q11 guideline ‘Development and Manufacture of Drug Substances (chemical entities and biotechnological/biological entities).’

In this interactive course, the key elements of Quality by Design for small molecules and biotech products were discussed. Participants learned with practical work on case studies (solid dosage form of a small molecule...
and manufacturing process for a biotech product), how to use Quality Risk Management (QRM), Process Characterisation, Design of Experiments (DoE), and Development of a Design Space and Control Strategy. The case study demonstrated that a systematic approach to pharmaceutical development is faster, needs fewer resources and leads to robust processes.

The trainers — Dr. Siegfried Adam, QA Manager, Hermes Pharma, Austria; Dr. Fritz Erni, a Switzerland-based industry expert with long experience in research, development, QA/QC and manufacturing; Dr. Erich Hochuli, ICB Consulting, Switzerland, an expert in biotech manufacturing; Prof. Dr. Johannes Khinast, Head of the Institute for Process and Particle Engineering, University of Technology and Scientific Director of the Research Centre for Pharmaceutical Engineering in Austria; together with Dr. Christa Wirthumer-Hoche, head of the unit for Marketing Authorisation and Life cycle Management of human medicinal products at AGES PharmMed (Austrian Medicines and Medical Device Agency), led the case studies for a small molecule tablet formulation and a monoclonal antibody drug substance.

Dr. Fritz Erni stressed that, “A systematic approach to pharmaceutical development with science based tools and adequate use of Quality Risk management can make the big difference for competitive manufacturing of drug substance and drug products, for new drugs and for generics, for small molecules and for biotech products. There was a lot of very positive feedback from the participants. They are very enthusiastic about using the newly learned QbD approach in their daily lives.”

Buoyed by the success of this QbD training, DIA Europe will be holding the next training course on QbD, with the same trainers, in November 2013 in Dubai.
Amsterdam On-Location

For those attending *DIA’s 25th Annual EuroMeeting*, March is the perfect time to visit Amsterdam. Popular with visitors from around the world, the city is well-known for its laid-back atmosphere, famous canals, rich history, theatres and museums.

Visitors can also enjoy cozy outdoor terraces, fabulous shops, and beautiful parks, where there’s always so much to see and do.

No other city has so many sights per square kilometre. But Amsterdam is also a thriving urban centre — a pulsing metropolis in a compact cityscape. You’ll find that sights in the city centre are all within walking distance, and most are less than 30 minutes by tram or metro from the conference location at RAI.

Amsterdam is most famous throughout the world for its canals. The reflection of the historic facades, bridges and boats in the water creates a unique atmosphere. But the city’s web of waterways also offers plenty of surprises even for city residents, such as a number...
of canal houses that are open to visitors, featuring beautiful interiors dating from the 17th, 18th or 19th centuries. Perhaps the gardens hidden behind these houses offer the biggest surprise of all - with only the sound of chirping birds, these gardens offer an oasis of tranquility, shutting out the hustle and bustle of the city around them.

Amsterdam is one of the most bicycle-friendly cities in the world. **Amsterdammers** are born on bikes and you’ll see them whizzing by at breakneck speeds. Thanks to the many bike paths in the city, pedal power is all you need to uncover the city’s gems on your own, or as part of a guided bike tour.

While the Netherlands enjoys moderate temperatures year-round, you can (and should!) count on the weather to change quickly, so plan to dress in layers. We recommend you pack an umbrella, a sweater and perhaps even a scarf to be prepared for the March weather. It’s also a good idea to bring some comfortable walking shoes that can handle several hours of sightseeing.

In early March, visitors can see the flower fields beginning to bloom and trees are turning green. You can expect a wide range of temperatures – perhaps all in one day. Rain is quite common, but it’s mixed with gorgeous days when everyone heads outside to soak up the sun.

**GETTING AROUND THE CITY**

Travelling within Amsterdam is straight-forward and convenient. The city centre is fairly compact, with most tourist sites in walking distance from each other. There is also an extensive transport network connecting city districts, and commuters can choose a variety of methods to reach their destination as efficiently as possible. This includes the train, tram, metro, bus and ferry. The **Iamsterdam City Card** gives you unlimited use of the GVB public transport system for 24, 48 or 72 hours.

**MUST-SEE SIGHTS**

Which sights shouldn’t you miss? Although Amsterdammers believe that the only thing anyone “should” be doing is “as they please,” there are a few gems highlights include the cosy 17th century Jordaan district, the lively Pijp with its terrace cafés and Albert Cuyp Market, the Plantage district, where nature, culture, history and science go hand in hand, the Eastern Docklands boasting modern architecture and design, and the up-scale museum Mecca that is the Oud-Zuid area. Then why not head to Westerpark area and discover Cultuurpark Westergasfabriek or

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**Traveling Between RAI Conference Centre (Euro-Meeting Venue) and the City Centre**

From Amsterdam Central Station (CS), take the Amstelveen express tram 51 (travel time: 12 minutes, exit at the Amsterdam RAI station) or tram 4 (travel time: 30 minutes, exit at the RAI Europaplein).

From the Amstel station, take the Amstelveen express tram 51 (travelling time: 5 minutes) or the bus (route 15, 69 or 169), which will bring you to the RAI within 10 minutes. In this case you should get off at RAI Europaplein.

From Amsterdam Sloterdijk station, the best way to reach the RAI is with **express tram 50**.
surprises in store including historic riding academy Hollandse Manege, the seven buildings of United Europe and a giant bookcase that’s part of a housing estate.

And speaking about must-see sights - don’t miss taking a boat tour through the canals, exploring the city by bike, and enjoying sunny terrace breaks in between. No matter what your interests, there is plenty to discover.

**MUSEUMS**

Museums are the main tourist attraction in Amsterdam. Most famous are the Rijksmuseum, Van Gogh Museum and Stedelijk Museum, but there are many more. In fact, Amsterdam has over fifty museums which attract millions of visitors every year. The following sites and monuments should also be of interest and are an essential part of the Amsterdam experience.

Anne Frank is one of Amsterdam’s best-known historical figures. Anne and her family lived in hiding from the Nazis for more than two years in a house on the Prinsengracht. Eventually she was deported to the Bergen-Belsen concentration camp in 1945, where she later died at the young age of 15. Today, Anne’s spirit lives on through her diary and the million visitors who come to Amsterdam every year to learn more about her short life. Anne’s original diary and other notebooks are on display in the **Anne Frank Huis**.

The **Hermitage Amsterdam** is the Dutch branch of the world-famous Hermitage in Saint Petersburg, Russia. Located on the banks of the Amstel River, the Hermitage Amsterdam is an exhibition space and cultural education centre with a focus on Russian history and culture. Hermitage Amsterdam displays rotating selections of pieces from the Hermitage collection in Russia. These include paintings, graphic works, sculptures, applied art and archaeological discoveries. During the time of the **EuroMeeting** in March, the Hermitage will also have 75 paintings by Vincent Van Gogh on display.

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**Museums under Renovation in 2013**

Two of Amsterdam’s most famous museums will be under renovation in early March during the **EuroMeeting**.

Amsterdam’s Rijksmuseum is the largest museum in the Netherlands. Its collection features some of the country’s most famous works, including ‘The Night Watch’ by Rembrandt and pieces by Vermeer and Frans Hals. The collection also includes Delftware, sculptures, Asian art, prints and many other culturally significant objects.

The Rijksmuseum will be under renovation until April 2013, however a selection of the best-loved Golden Age masterpieces will be on display in the Philips Wing or on the 1st floor of the museum. A number of pieces will also be displayed at the Rijksmuseum branch in Schiphol Airport.

If you go: Rijksmuseum is located at: P Cornelisz Hooftstr 1, 1071 CH AMSTERDAM, 020-6747000. It is open daily from 9 a.m. to 6 p.m. Admission is € 14.

The Van Gogh Museum, which features not only the largest collection of Vincent Van Gogh’s works, but also chronicles his life, will unfortunately be closed to the public in early March. However, approximately 75 paintings by Van Gogh and other works on paper will be on display in the Hermitage Amsterdam.

If you go: The Anne Frank Huis is situated in the centre of Amsterdam at Prinsengracht 263-267. It is open daily from 9 a.m. to 7 p.m. and admission is 9 Euros. Trams 13, 14 and 17 and buses 170, 172 and 174 stop nearby, at the ‘Westermarkt’ stop.
For a true sense of the city, stroll through Amsterdam’s charming Canal District and discover the city’s hidden gems in the canal house museums. The city’s elegant canal-side mansions house some of the most fascinating museums with collections ranging from stately to quirky and including everything from ancient artefacts to cutting-edge art. A great place to start exploring Amsterdam’s hidden museums is Het Grachtenhuis (Museum of the Canals). This recent addition is a tribute to the Canal District, with multimedia exhibitions showing how the now grand district is really an engineering marvel built on swamp land. From here, visitors can easily explore other museums housed in canal mansions and the museum is even equipped to help them plan their itineraries.

**If you go:** Het Grachtenhuis is located at Herengracht 386. Admission is €12, or free with an Iamsterdam card. By tram, take line 1, 2 or 5 to Koningsplein.

For something a little different, visit the former Heineken Brewery, a national monument and listed in the European Route of Industrial Heritage. Millions of hectolitres of Heineken beer were brewed here until 1988, when the Heineken brewery in Zoeterwoude took over production from the Amsterdam brewer. Attractions at the Heineken Experience include a mini brewery, a tasting bar, as well as the ‘Stable Walk,’ where visitors can access the stables to view Heineken’s iconic Shire horses which still deliver beer throughout the city. A visit to the Heineken Experience attraction takes about 90 minutes, and two drinks are included in the admission price.

**If you go:** Located at Stadhouderskade 78, the Heineken Experience can be reached by tram 4, 7, 10, 16, 24, or 25. Admission is €17.

**PLACES TO SOAK UP THE ATMOSPHERE:**

The Canal Ring treads a tight rope between being a tourist attraction that requires drinking and eating facilities and a major residential area that needs quiet. The Canal Ring includes the city’s two main nightlife and culture squares. Leidseplein features such legendary concert halls as Paradiso and Melkweg along with the more highbrow city theatre Stadsschouwburg and multimedia centre De Balie and Melkweg. Rembrandtplein has several bars which cater to tourists (both international and from the rest of Holland), two large nightclubs (Escape and Air), and ‘old world’ evocative treasures such as De Kroon and Café Schiller. But meanwhile the whole area is dotted with neighbourhood-bound ‘brown cafes’.

The Jordaan is probably the most famous neighbourhood in the Netherlands. Akin to the reputation enjoyed by London’s Cockneys, this once working-class bastion was renowned for tight community bonds, radical politics and a love for drink.
and over-the-top sing-a-long. Gentrification of decades past worked to attract more galleries, restaurants, specialty shops and upwardly-mobile residents to its higgledy-piggledy scenic streets. Its maze-like streets offer hidden courtyards, cafés (both traditional and trendy), art galleries and pleasantly nosy neighbours. One also has access to some of the more scenic outdoor markets in the country.

SHOPPING:

Amsterdam offers an array of shopping opportunities for everyone from the exclusive boutique shopper to the bargain hunter.

Located in the heart of the city’s historic canal district, the area of nine narrow streets called the Negen Straatjes (Nine Streets) intersect the main canals between the Leidsestraat and the Jordaan district. The area is dotted with great restaurants, cafés, art galleries, jewellers, boutiques and antique shops. With an exceptional array of styles, trends and prices, this area is truly a shopper’s paradise.

The two main shopping streets in Amsterdam’s city centre are the Kalverstraat and the Leidsestraat. Of the two, the Leidsestraat has the more exclusive shops like Filippa K, Karen Millen, Paul Warmer and Shoebaloo. The Kalverstraat is home to all the shops you would expect to find in a large European city like H&M, Mexx, Zara and Esprit.

To truly experience Amsterdam, check out the open-air neighbourhood markets, which feature a variety of sights, snacks, and shopping. The Albert Cuypmarkt is arguably the best-known and busiest outdoor market in Europe. It attracts thousands of visitors every day, and it is especially popular on Saturdays. More than 250 stalls sell everything from cheese, bike chains and fresh produce to fried snacks, shaving cream and shoes. The Albert Cuyp Market is a true feast for the senses and it’s Amsterdam’s busiest daily market. The market is located in the Pijp district, surrounded by many pleasant cafes and small shops.

If you go: Albert Cuypmarkt is open Mon-Saturday, 9 a.m. to 5 p.m. Take tram lines 4, 16, 24 or 25 to get there.

AMSTERDAM FAST FACTS:

- Dating back to the 13th century, Amsterdam began as a fishing village and trading centre on the Amstel river
- There are more bikes in Amsterdam than permanent residents
- Amsterdam’s maze of canals is its most distinguishing feature: Amsterdam actually has more canals than Venice, Italy!
- There are 51 museums to visit in the city
- Amsterdam’s coat of arms, which can be seen all over the city, features the XXX symbol, which symbolises St Andrew’s crosses.
- About six million souvenir clogs are produced in the Netherlands each year

AMSTERDAM FOR YOUR TASTE BUDS

One of the best things about travelling is getting to taste the local cuisine and discover new specialties. The Netherlands also has its share of culinary delights. Be sure to try at least one of the many Dutch specialties on offer in Amsterdam!

Food to try: So what is Dutch food exactly? Generally speaking, it’s simple, hearty, meat and potatoes fare. Favourites include erwtensoep (pea soup with ham and smoked sausage), stamppot (mashed potatoes mixed with vegetables, served with meat and gravy) and suddervlees (slowly braised meat). Thanks to its proximity to the sea, fish and seafood also feature heavily on Dutch menus, especially plaice, mackerel, eel, mussels and shrimp. The Dutch are also crazy for their friet (chips/fries)! Even upscale restaurants often serve their meals with a side of friet and mayonnaise.

The Dutch have a passion for cheese, so be sure to sample some, whether served in plain cubes with mustard (kaasblokjes), or deep-fried with a crispy coating...
Kaassoufflés and kaasstengels. For something a little fancier, try geitenkaaskroketten (a croquette filled with goat cheese).

Coffee houses: For a taste of authentic Amsterdam flavour and Dutch culture, don’t miss a visit to an authentic Dutch pub known as a ‘brown café’ (bruin café). These local watering-holes are a quintessential part of Amsterdam’s culture – and are the favoured haunts of some colourful local personalities. In general, brown cafés are laid-back and the fare is pretty simple. In addition to local and regional beers, soft drinks and coffee or tea, you can also sip jenever – a Dutch spirit similar to gin. Light meals and snacks (hapjes) are also usually on offer. A typical Dutch pub snack is bitterballen (breaded and deep-fried balls with a ragout filling), often served with mustard.

Restaurants: Moeders (Mothers), located at Rozengracht 251, offers traditional Dutch foods (you can even order a sampling plate of typical dishes) with a fun, informal atmosphere.
Restaurant Greetje, at Peperstraat 23, is another great choice for “home-cooked” Dutch flavours in a friendly atmosphere. Tucked in a side street between two canals, ‘t Zwaantje (Berenstraat 12) is a cosy brown café serving no-nonsense local favourites. For a more elegant meal, try Restaurant d’Vijff Vlieghen, which occupies five adjoining 17th century houses at Spuistraat 294-302.

OTHER THINGS TO SEE:

Beatrixpark: If you find yourself with just a short break from the meeting, check out Beatrixpark. One of the nicest parks in Amsterdam, Beatrixpark was originally designed as a romantic park, but after World War II it has been redesigned into the more modern style of functionalism. The oldest part of the park is the nicest, as it kept its original romantic character influenced by English parks – with a small lake and open landscape. How to get there: Walking — from the RAI congress centre, facing the main entry to the right and turn left direction the Amstelhal of the RAI. Pass in front of this building and behind the canal you will see the park — it is located at the rear all exhibit halls.

Artis ZOO: If the weather is nice, visit the oldest zoo in Holland, right in the centre of Amsterdam. It consists of four main areas: Zoo, Planetarium, Botanical Gardens and Geological and Zoological museum. In the zoo itself you will find animals from all over the world. In addition, a unique canal aquarium shows you which animals roam the canals of Amsterdam. You can also tour the peaceful gardens. Located at Plantage Kerklaan 38-40, admission is € 18,95.

Red Light District: The majority of people have heard about The Wallen — also known as the roosse buurt to Amsterdammers and the Red Light District to visitors — well before their visit. The oldest part of Amsterdam, the neighbourhood is chock-full of interesting shops, pubs, fantastic restaurants, leaning gabled houses and the city’s most charming canals, in addition to the stereotypical red-lit windows and peep shows. Don’t miss the vibrant Nieuwmarkt square, the gothic Oude Kerk or a walk along the centre of Amsterdam’s Chinatown, the Zeedijk (also home to an impressive Buddhist temple). Although it is generally considered to be a very safe area, care should still be taken when walking through the quieter streets of the area. There is a strict “no photography” policy.

Helpful Websites:
For full tourist info: www.iamsterdam.com
For detailed EuroMeeting information: www.diahome.org/EM2013 For maps and information on public transportation: www.gvb.nl
To plan a specific route on public transportation: www.9292.nl
The themes at DIA Europe’s 25th Annual EuroMeeting in Amsterdam in March will examine the issues of the day, provide a forum for creating solutions and focus on the hot topics that most exercise the medicines development community. For many, the most critical challenge facing the drug development community in the current restrictive environment throughout Europe is the return on investment. For small and medium-sized enterprises this challenge is even more difficult to overcome. In a rapidly evolving legislative environment, the EuroMeeting covers most areas of interest for any pharmaceutical industry professional, providing a prime opportunity to get a fresh update on most advances in drug R&D, regulatory, and quality of human medicinal products as well as medical devices.

With a focus on better public health protection, greater transparency of the processes, improving the public perception of the pharmaceutical industry and the way it is portrayed in the media as well as the rational use of medicinal products, the proposed areas for discussion for the EuroMeeting 2013 are classified into general disciplines including pharmacovigilance and regulatory affairs for medicinal products and medical devices, R&D and clinical trials.

The scope of presentations will cover the experience gathered after the implementation of the new Pharmacovigilance legislative framework, as well as from the patients’ and Health Technology Assessment (HTA) perspective – What did happen to the ‘Information to Patients’ initiative from the EU Commission? Experts
and authorities in the fields will be presenting their considerations for debate.

The theme **Health Technology Assessment (HTA)/Sustainability of Health Systems in Europe** is led by Luca De Nigro, Coordinator, Drugs Monitoring Registers Unit, Italian Medicines Agency, Italy; and Lidia Retkowska-Mika, Director Legal Department, Offices of Medicinal Products, Medical Devices and Biocides, Poland. Recent EU pharmacovigilance legislation has added new instruments which may be helpful to bring closer regulatory activities and HTA and this theme will be devoted to discussion on new developments in this area.

Gesine Bejeuhr, Regulatory Affairs/Quality, vfa Research-Based Pharm Companies, Germany; and Markus Pasterk, COO and VP of Science, International Prevention Research Institute, France will steer **Development of Medicinal Products for Paediatric, Elderly and Other Special Populations**. Special populations such as children, the elderly or ethnic minorities require particular attention during drug development. The Paediatric Regulation started slowly to deliver more, better data for medicines used in children. The European Commission’s conclusions after five years of experience are eagerly awaited and will be discussed. Practical solutions for questions that often occur during paediatric clinical trials will also be presented.

Our changing demography, with a dramatic increase in the elderly population, means reconsideration of other aspects. Multiple conditions, specific settings and other difficulties in performing clinical trials in the elderly will be discussed in terms of design, modelling and recruitment. And practical experience will be given. The European Commission launched the “healthy ageing” initiative and has funded several new research projects whose initial results will be presented and analysed. These cohort studies and developments in the biobanking domain form innovative new tools for drug development and testing.

**Legal/Transparency-Risk Assessment** is led by Burkhard Sträter, a Partner at the Kanzlei Sträter law firm in Germany. Approval procedures for pharmaceuticals, biosimilars and clinical trials as well as for paediatric investigation plans are based on European public administrative law. This sets the legal framework for scientific assessment and for protection of intellectual property rights of innovators. The European Commission’s sector investigation establishes a new cartel-law-based framework for generic applications and Regulatory Data Protection. The aim of this theme is to provide scientists and regulators with guidance on European approval procedures for clinical research and marketing authorisations.

Vicki Edwards, Senior Director, European Pharmacovigilance, Abbott, UK; and Jan Petracek, CEO, Director of Pharmacovigilance Services, Pharminvest, Czech Republic lead the **Pharmacovigilance** theme. Some say that the new pharmacovigilance legislation represents the biggest change in pharmaceutical legislation since 1995 — some say even longer. The Pharmacovigilance (PV) theme will look at the impact of these changes and explore how both regulators and the industry are rising to the challenges of implementation. The sessions will look at some of the more practical aspects of implementation such as the Pharmacovigilance System Master File (PSMF) but also explore the impact of some of the less tangible elements such as transparency and communication issues. Additionally, the theme will look at other advances in PV such as the IMI PROTECT initiative relating to benefit/risk methodology and the use of new technologies.

**Clinical Research and Development** is led by Nermeen Varawalla, Founder and CEO, ECCRO, UK; together with Andrei Kravchenko, Head of Office, Harrison Clinical Research, Ukraine. The potential to adopt game changing technologies and innovative methodologies, the demand for “real world” outcome data and the continued drive for efficiency make clinical research today more challenging and exciting than perhaps ever before. These drivers of change notwithstanding, the relevance of more traditional approaches to deliver data quality and operational effectiveness remains. The sessions in the Clinical Research theme present the latest thinking and best practices in the context of the current environment, addressing both newer trends and reviewing established approaches.

Susanne Keitel, Director, European Directorate for the Quality of Medicines and Healthcare
of the new “scrutiny procedure” including the potential impact Regulations will be assessed, EU’s medical device and IVD proposed changes to the impact of the most significant and companion diagnostics. The combinations, borderline products and IVDs on the drug/device regulation of medical devices on the impact of the European This theme will especially focus and Scientific Communication, Switzerland; and Sinisa Tomiæ, Counselor for European Affairs, Agency for Medicinal Products and Medical Devices, Croatia. This theme will especially focus on the impact of the European Commission’s proposals for the regulation of medical devices and IVDs on the drug/device combinations, borderline products and companion diagnostics. The impact of the most significant proposed changes to the EU’s medical device and IVD Regulations will be assessed, including the potential impact of the new “scrutiny procedure” and the new requirements for combinations regulated as drugs. The theme will consider the likely reactions of the European Parliament and Council as well as the latest work towards global convergence by the International Medical Device Regulators Forum. Participants from the industry will learn how to adapt their regulatory strategies to avoid any risk of regulatory bottlenecks. As well as providing the regulatory context, practical guidance on developing combination products will be given. In addition, the development and approval of e-Health/tele-health solutions designed to improve patient adherence to their medication will be addressed. The future regulation of companion diagnostics, including the new role for notified bodies and the involvement of drug authorities in the premarket phase are also on the agenda. Case studies will provide advice on how to develop companion diagnostics in compliance with the regulatory requirements in the EU and US.

In eTools and Data Management, experts will elaborate on how data (content) can be seen, processed and interpreted in the context of various purposes. For example, the Common Submission European Platform, already available at the HMA website, allows a simple and secure means of exchange of submission information between applicants and regulatory agencies, reducing the burden for both industry and regulators. Led by Hans van Bruggen, Director, eCTDConsultancy, Netherlands; and Rob Middel, Head of R&D Business Development, Pharmaceutical R&D Quality & Compliance, Senior Director Janssen Biologics, Netherlands, participants will hear that data about products is exchanged between industry and agencies in the context of a dossier. However, product data or study data is also captured in databases not necessarily in context of a specific dossier. Data is often copied, but it would be easier to reuse or refer to the authoritative data sources for various purposes. The theme will also examine how the use of standards, standardised processes and tools improves consistency and reliability of information. This applies to data managed in conventional ways and also using methods such as social media. The challenge is that improved transparency raises doubts about the security of confidential data. Gonzalo Calvo Rojas, President of the European Association for Clinical Pharmacology and Therapeutics (EACPT), Spain; and Judith Creba, Head EU Liaison & Policy, Novartis Pharma, Switzerland, together lead, Involvement of Experts in the Drug Approval Process. There is a growing perception that involvement of all stakeholders during the regulatory review process of drug marketing authorisation applications is a valuable tool for widening the perspective under which the assessment is conducted, increasing the quality of the outcome. Experts and patients are in a privileged position to provide a reliable and practice-based view on how the demonstrated and expected benefits and risks of any new therapeutic options are perceived. As with any other contribution, transparency in the process of involvement of
patients and experts, and in the management of potential conflict of interest, is paramount. The European Regulatory System has made significant steps forward in this respect during the last years. Discussions will focus on identifying the added value of patient and expert contributions. They will also address the daily problems that academic and patient bodies and regulators need to face in order to secure quality and transparency during the whole process.

In the regulatory affairs business, most activities and the majority of resources are focused on or around known active substances. During Known Active Substances, seven sessions shed light on the different aspects of known active substances covering regulatory product life-cycle and the rules for assessment as well as specific aspects for fixed combination medicinal products. Specifically, an approach on known active substances in the self-care sector is discussed, as well as a more thorough understanding of a known active substance in terms of biosimilars. Also, in pharmacovigilance legislation, known active substances play a key role and are among the base data elements for the new European database on authorised products (EVMPD).

One session will focus on the efforts spent to build up this database. The view of industry and authority will be presented for all aspects with respect to efficiently fulfilling agencies’ and legal demands, safe resources, and keep products on the market. The theme is jointly led by Maren von Fritschen, Managing Partner, Director Regulatory Affairs, PharmaLex, Germany; and Marta Marcelino, Member CMDh, Medicines Evaluation Department, National Authority of Medicines and Health Products (INFARMED), Portugal.

Isabelle Stöckert, Head Global Regulatory Affairs Europe/Canada, Bayer Healthcare Pharmaceuticals, Germany; and Melek Bostanci Önol, Head of Regulatory Affairs & Quality Assurance, Boehringer Ingelheim, Turkey, co-lead a fascinating theme titled, Effectiveness and Efficiency of the EU Regulatory System — Does new legislation enable innovation and facilitate co-operation? This theme provides high-level discussion on the efficiency of the current legislation and various new legislative proposals in Europe. It will deal with issues such as: How will they shape the regulatory system? How can quality be built into a new legislation? Is it effectively implemented? Has it reached its primary objective? Does it improve public health? Does it increase efficiency and decrease bureaucracy? Does it increase competitiveness?

Globalisation is one of the drivers that can bring a new drug to the global market faster, especially the emerging and developing market. To further speed up the drug development, the industry, regulators, and academics are working together trying to harmonise regulations; to standardise quality; to overcome cultural differences; to better understand various markets; to drive cross-national communication and collaboration. Christer Backman, Member CMDh, EU Coordinator and Senior Expert, Medical Products Agency, Sweden; and Ning Xu, Vice President, Head of Clinical Development Service, Covance, China, will lead presentations and discussions on the multiple challenges of globalisation and ways to understand and manage those challenges, turning them into opportunities for more successful drug development. The aim being to spare limited resources, promote common global harmonisation and enhance healthcare for the benefit of patients.

Regulatory Science contributes to the scientific basis of regulation and decision making. The urge of society for transparency and understanding has caused FDA, EMA and its member states to put regulatory science high on their agenda. The spin-off of such interest is highlighted in this theme led by Christine Gispen-De Wied, Clinical Coordinator; Member of SAWP, Medicines Evaluation Board (MEB), Netherlands; and Hubert Leufkens, Co-Opted member, CHMP, Chairman, Medicines Evaluation Board (MEB), Netherlands. The first session starts out by setting the scene: What can we learn from regulatory science? What is the scope? What can be gained? In the subsequent session, this is illustrated through regulatory procedures, modelling of the decision making process, and communication with consumers. The new concept of adaptive licensing is one potential solution considered as a means of providing faster access to medicines, for example in meeting unmet needs, without compromising safety and efficacy.

Growing Demand for Quantitative Approaches in Drug Development is co-chaired
The last decade has witnessed a rapid growth in both the amount and the accessibility of data – matched by the expectation to optimally exploit it. This theme will touch on areas where sound statistical approaches play an integral role in ensuring informed decision making. There will be a thorough discussion of new approaches as well as a critical appraisal of current recommendations and guidelines. The theme aims to provide a forum for discussion between industry, academic and regulatory thought leaders. Relevant experience will be shared and discussed, reflecting on lessons learned. Recommendations for best practice will also be developed.

Jan Willem Van der Laan, Senior Pharmacological Toxicological Assessor, Medicines Evaluation Board (MEB), Netherlands will steer Developments in Non-Clinical. New therapeutic areas as well as new technical methodologies are challenging the classical way of thinking in the non-clinical area. Furthermore, the public and political pressure to reduce the use of animals is a factor that cannot be ignored. These trends come together in new areas such as the in-vitro assessment of toxicology, but also in new products areas. Even an old issue, such as carcinogenicity testing, can learn from this.

There are five IMI Education and Training Projects. Three of them are dedicated to developing,
testing and establishing research master programmes on medicines safety. Hans Lindén, Leader European Projects , European Federation for Pharmaceutical Sciences (EUF EPS), Sweden, is the Chair for IMI Public-Private Partnership in Medicines Research Education and Training. This theme will provide a bird’s eye view of key IMI projects in these pre-competitive areas: Predicting safety, predicting efficacy, knowledge management, and education and training. These projects include SafeSciMET, integrated medicines development (PharmaTrain), and on pharmacovigilance and pharmacoepidemiology in medicines usage (Eu2P). There is also (EMTRAIN); how to establish a European education and training network; and the European Patients’ Academy on Therapeutic Innovation (EUPATI).

There is also a compelling Antibiotics/Anti-infective Treatments theme. This is headed up by Richard Bergström, Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium; together with Marco Cavalieri, Head of Anti-Infectives and Vaccines, Safety & Efficacy Sector, European Medicines Agency, EU. This theme is currently under development.

For more information please go the EuroMeeting website at www.diahome.org/em2013. Contact DIA Europe Customer Services on +41 61 225 5151, or email us at euromeeting@diaeurope.org.
Aiming at providing better insight over pharmacovigilance and risk management to professionals in China’s pharmaceutical sector, DIA China held the ICH Pharmacovigilance Training on October 22-24, 2012 in Beijing with the assistance from Information Center of the State Food and Drug Administration. This training was a success as it not only furnished the professionals with latest pharmacovigilance knowledge, principles and implementation of relevant processes, but also promoted international communication and cooperation.

This training course, which was the first cooperation between ICH and DIA China, was specially designed for Chinese professionals at which Dr. Jan Petracek, an invited European experienced pharmacovigilance expert made an impressive presentation on ICH E2 series of guidelines, implementation details and practical case studies in ICH countries. The Chinese experts from the Training Program Committee (see page 73) also shared their accumulative rich experience in pharmacovigilance with participants on how to apply the international rules and standards for the best practices in their work. There was attendance of newly 100 people to
the training, mainly coming from health regulators of China, Hong Kong, Taiwan and Singapore and multinational pharmaceutical companies, with their relevance in the field of pharmacovigilance, risk management and clinical work. All the participants were issued with ICH Pharmacovigilance Training Certificates at the end of the Training.

According to the definition by the World Health Organization (WHO), pharmacovigilance is a kind of scientific research activity which relates to exploration, evaluation, understanding and prevention of adverse drug reactions or any other possible drug-related problems. In 1974, France first proposed the concept of “pharmacovigilance” (PV) which has given to a new meaning and been generally understood as surveillance, guard, ready to cope with possible harm from drugs. Currently, under the coordination of the international drug monitoring program of the World Health Organization, more than 80 member countries around the world have enrolled into the formation system.

China officially joined the WHO International Drug Monitoring Cooperation Center in March 1998 and became the 68th member. Since the 1990s, China has been experiencing the stages of first setting up adverse drug reaction monitoring system; then, the pilot and later the development which have formulated a series of laws and regulations for drug safety supervision, such as “Adverse Drug Reaction Monitoring Management (tentative)” in 1999, “Drug Administration Law of the People’s Republic of China” in 2001, “Adverse Drug Reaction Reporting & Monitoring Management Approach” in 2004 and “Drug Recall” in 2007 as well as the newly revised “The Provision for Adverse Drug Reaction Reporting and Monitoring” in 2011. The “National Adverse Drug Reaction Monitoring Center” was established in 1999 on the basis of merger of the Original Drugs Adverse Reactions Monitoring Center of Ministry of Health and Drug Evaluation Center of the State Food and Drug Administration, and is responsible for supervision of national post-marketing drug safety monitoring and technical evaluation. The construction of the system for drug adverse reaction monitoring has really shown that China development of drug supervision entered into a new era after the State Food and Drug Administration was establish in 1998.

During the training, participants gained comprehensive knowledge of ICH guidelines, including international pharmacovigilance standards, rules and process of their implementation as well as pre- and post- marketing safety management and safety update report. They also learned about the origin of ICH establishment, the purpose, forms of organization, terms of reference and workflow for implementation of pharmacovigilance which can be as a reference for making further laws and regulations for China pharmacovigilance and construction of adverse drug reaction monitoring system. This training was a good opportunity for professionals to expand their horizons, enrich their knowledge and learn from each other’s experiences.
This article was prepared by staff reporter Donglei Mao of the Medicine Economic News and is based on an interview with Dr. David Ho, who is a Professor at The Rockefeller University and CEO of the Aaron Diamond AIDS Research Center, NY, NY, and is on a journey to discover a vaccine against AIDS following his renowned breakthrough of combination therapy.

Dr. Ho was one of the honored guest speakers at DIA’s 4th China Annual Conference in Shanghai and this interview was conducted during this meeting.

In preparation for this interview, I reviewed two decades of coverage in Chinese and foreign media, including RTHK’s TV series “Success Stories,” Time magazine 1996 Man of the Year cover story, CCTV celebrity interview, as well as Phoenix Satellite TV Century Forum, among others.

Dr. Ho was portrayed by the media as a real hero for reversing the hopeless situation in the fight against HIV/AIDS through his discovery of the cocktail therapy treatment. Dr. Ho, who is nearly 60 years old, is relentless in his pursuit of an AIDS vaccine and still works more than 10 hours a day.

Cocktail therapy was successfully developed and tested 16 years ago. Dr. Ho is one of the first scientists in the world who recognized that AIDS is caused by a virus, and the AIDS diversity
is caused by the replication of the AIDS virus. Based on this knowledge and understanding, Dr. Ho and his colleagues worked on developing and testing effective combination antiretroviral therapy, which became known as cocktail therapy. Dr. Ho has been at the forefront of AIDS research for the past 26 years. The AIDS mortality rate has decreased by 60% in developed countries since the introduction of cocktail therapy, and the international community has taken measures to provide this therapy for millions of AIDS patients in developing countries.

Dr. Ho was selected as “Person of the Year” in 1996 by *Time* magazine, and received countless honors for his achievements. These honors placed Dr. Ho at the center of attention in the fight against AIDS. A lot of people think that AIDS was defeated by the invention of cocktail therapy, “but in fact, we just won one battle,” Dr. Ho said.

Analyzing his past achievements and all the attention they attracted, Dr. Ho said: “Some reports were true, some were from reasonable guesses. This is the media, they exaggerate, try to play things down, or somewhere in between, isn’t it?” he asked me in his reply.

“Although my work had been well-known in the scientific field, praises from *Time*, *The Wall Street Journal* and other mainstream media pushed me into the public eye, which allowed the general public to learn more about AIDS prevention and treatment. I am grateful for this recognition,” says Dr. Ho.

**AIDS VACCINE RESEARCH SHOWS PROMISE**

Several years after his famous breakthrough, Dr. Ho and his Aaron Diamond AIDS Research Center faced a series of setbacks, searching for a new research direction. These challenges made some people concerned about the future of the Aaron Diamond AIDS Research Center. Some questioned whether the Center and its famous leader would ever see another breakthrough, or remain stagnant in the fight against HIV/AIDS.

An effective vaccine against HIV is the only hope to completely defeat AIDS. Vaccine development has been the focus of Dr. Ho’s work during this period. He believes, “The development of an AIDS vaccine gave us the greatest challenge we have ever met. We have to wait for a scientific breakthrough, which may happen tomorrow, or many years in the future.”

Dr. Ho’s research team has developed two deoxyribonucleic acid (DNA) vaccines for the prevention of HIV recently. Phase I clinical trials in humans of the two vaccines were started in the United States. However, it will take at least five years before the vaccines can be introduced into the market. Dr. Ho said that his research center has been cooperating with Chinese research institutions, such as Chinese Academy of Medical Sciences and human trials of new HIV vaccines may be carried out in China in the future.

Dr. Ho has traveled between China and the United States frequently in the last 20 years. As a scientist, Dr. Ho’s work is not only limited to the laboratories, but he has also expanded his AIDS research, prevention and treatment efforts all over the world, especially in China.

Dr. Ho said that many other scientists have brought cocktail therapy to regions in the world with serious AIDS epidemics, such as Africa and Thailand. “My background naturally leads me to China,” he said. David Ho was born in November 1952, Taichung City, Taiwan Province, and immigrated to the United States with his family when he was 12 years old. In his view, to leave and then return to China, is a very meaningful cycle.

When talking about vaccines, Dr. Ho is enthusiastic. I was excited to hear that Dr. Ho would discuss his team’s latest progress in AIDS vaccine research at the recent DIA China conference.

“In 20 years, you will be 80 years old. Will you still be working in this area?” I asked. “I should be, I am optimistic by nature, otherwise I could not work in the field of HIV research,” Dr. Ho said.

**BELOW IS THE INTERVIEW BETWEEN DR. HO AND STAFF REPORTER, DONGLEI MAO, OF THE MEDICINE ECONOMIC NEWS**

What is the status of the research and development in your AIDS vaccine project?

We have a new HIV prevention project, which is a passive immunization method by using antibodies to block HIV infection. A lot of research will be developed, including one study to promote a proof-of-concept test, aiming to show that this antibody
will have better pharmacokinetic effect in its anti-HIV activity.

We have conducted Phase I and will conduct Phase IIa clinical trials in the U.S. We plan to conduct a pivotal study, a Phase IIb clinical trial, in China in the next two years. There are many reasons to carry out these studies in China. For example, China has a large high-risk population; many scientists and research institutions are interested to participate in the studies; Ministry of Science and Technology and Ministry of Health are eager to participate in innovative research now. Because it is a very new path, the process is not easy, and will probably take at least two years.

**Which procedures should be modified after Phase IIb clinical trials enroll Chinese subjects?**

I hope that China will be included in the study of the next Phase IIb clinical trial. However, it will be very difficult to carry out if there are many operation standards for the study.

I do not think that Western standards are golden standards. However, we should coordinate with each other and establish a system, which is suitable not only for the Western scientists and Western pharmaceutical companies. If the Chinese scientists want to participate in competition with the rest of the world, we should recognize what is the path as a whole.

It is a time-consuming marathon to carry out Phase IIb trial in China, and it requires long-term effort. We will discuss with many relevant officials in China, including the Ministry of Science and Technology, AIDS Fund, and the Ministry of Health. Both the Ministry of Science and Technology and the Ministry of Health have agreed to give us support. In addition, we need to contact with the SFDA, which is the last step in the process.

**Do you have a shortage in research funds?**

Yes, very often. Sometimes I feel like I am running on a treadmill nonstop. The current economic situation in the United States has made the government cut a large amount of research funds, whereas the situation is better in China. As a foreign scientist, however, I can’t make a direct application for funding from the Ministry of Science and Technology or the Ministry of Health in China. However, the establishment of a research institute in the School of Medicine, Tsinghua University could be a base for funding application. As this study is a multinational trial, we will make full use of the international funding system to carry out this cooperative research.

**Nearly one-third of the researchers at the Aaron Diamond AIDS Research Center are from Asia, especially from China,. However, more and more Chinese scholars have returned to China to do research. How do you evaluate the overall domestic academic environment?**

The scientists who have come out of our research center have brought the latest developments in HIV/AIDS prevention and treatment to the rest of the world, including China. I am very pleased to see that the leading scientists in AIDS research organizations such as the Chinese Center for Disease Control and Prevention, Tsinghua University, the University of Hong Kong, and other institutes, are my former students.

There are a lot of very talented scientists in China. If you visit the laboratories in the Western countries, you will find a lot of Chinese people working there. Many Chinese professionals take new techniques and thinking back to China, so the gap between Western scientists and Chinese scientists is narrowing constantly.

The Chinese government’s investment is growing, which really attracts scientists to come back to China to work, or for the establishment of cooperative research. Chinese government leadership is also very far-sighted, and they hope that China will become a powerful country in research and development, so that more investments will be made. Certainly, it will take time to change the deep-rooted culture in China.

**As a team leader, how do you see the failures and successes of scientific research?**

If you never fail, you will never be successful; if you do not want to fail, you can only be mediocre. Failing requires making a correction and changing course. This is prominent in the United States value system, which is different from the oriental culture. The scientific progress is a self-correcting process to a great extent.
From January 28-30, the Health Sciences Authority (HSA) in Singapore hosted Asia Regulatory Conference 2013, the first time the HSA has hosted this event. Developed on the theme “Regulatory Convergence and Cooperation to Improve Access and Quality,” this conference brought together experts from health authorities, pharmaceutical companies and academia across almost 30 countries in the Americas, Asia and Europe to identify specific areas that will enhance patient access to new and improved medicines. It was co-organized by the HSA, DIA and the International Federation of Pharmaceutical Manufacturers Association (IFPMA).

“This three-day conference offers a unique opportunity for key stakeholders from health authorities, local and multinational pharmaceutical companies, and clinical research to meet and exchange views, discuss topics of interest and identify focus areas for ongoing efforts to increase patient access to new and improved medicines,” said Dr. Ling Su, DIA Board President, in his welcoming remarks. “We are honored to have Dr. Amy Khor, Minister of State for Health and Manpower in Singapore, speaking at the event as well as speakers from top-level regulatory authorities in several Asian countries and leading experts in the International Conference of Harmonization process.”

During this conference, the HSA signed a Memorandum of Understanding (MOU) with the Medicines Evaluation Board (MEB) of the Netherlands to further collaboration between the two agencies on pharmacovigilance and risk management strategies, improved benefit/risk assessment of medicinal products, joint education and training of regulators and postgraduate students, and other initiatives. This MOU was signed by Associate Professor John Lim, Chief Executive Officer of HSA and by Professor Hubert Leufkens, Chairman of MEB, and witnessed by Dr. Khor.

In 2011, DIA co-presented the first Asia Regulatory Conference with the IFPMA and Asia-Pacific Economic Cooperation (APEC) Harmonization Center (AHC) in Seoul, Korea.

Look for more detailed coverage from the Asia Regulatory Conference 2013 in your April Global Forum.
The 9th DIA Japan Annual Meeting was held at the Toshi Center Hotel (Tokyo, Japan) over three days from November 19-21, 2012. The focus of this meeting was “Importance of Development Strategies for Lifecycle Management of Safe and Effective Medical Products—What can we do from the start of development to benefit patients?” Including speakers and exhibitors, the annual meeting was attended by around 800 participants from home and abroad, which was almost 300 more than last year. Among others, Dr. Peter Bachman (BfArM) attended as a keynote speaker and panelist, and Dr. Gerald J. Dal Pan (FDA) attended as a speaker and panelist. We were also extremely pleased and grateful to have over 75 participants from PMDA in attendance.

In this article, I would like to reflect upon the new improvements implemented at the 9th Japan Annual Meeting.

THE STATE OF NEW DRUG DEVELOPMENT IN JAPAN AND THE JAPAN ANNUAL MEETING

The strategies for new drug development in Japan are diversified, with three main approaches: domestic full...
development, bridging strategy, and simultaneous global development including global clinical trials. Furthermore, simultaneous global development also includes Asian development strategy. Such strategies should be adopted in accordance with what is optimal for the therapeutic area and background of each project. A current trend is to develop in collaboration with PMDA from the early development phase, and move forward on development together. On the other hand, in terms of the review stage, in the country's effort to eliminate drug lag, a development program and review period are steadily shortened. These developments are a great leap forward in terms of delivering new drugs to Japanese patients more quickly. However, it seems that something of great importance has been forgotten as a result of being overly focused on development speed and shortening review. The concept of "patient benefits" is once again being upheld by people in various positions which transcend industry, government, and academia, and it is important to exchange opinions and to disseminate information regarding the identification of issues and solutions, as well as future expectations. It is also important to inquire directly with medical staff and especially patients about their opinions on new drug development and to have the opportunity to fully process that information. Furthermore, as mentioned above, this is the time for simultaneous global development, and as development and review take place simultaneously throughout the world it is no longer the time for addressing pharmaceutical regulations exclusively, but it is essential for us to comprehend the regulations and trends in East Asia and the West as well.

The meeting theme and content was decided taking into consideration the current situation in Japan.

NEW ENDEAVORS AT THE JAPAN ANNUAL MEETING

This was the 9th Japan Annual Meeting, but a survey of participants at the 8th Japan Annual Meeting (2011) revealed several comments that sessions were primarily focused on strategies and policies and there were few operational matters at the practical level. While some maintain that explicit discussions of practicalities are not of importance at a meeting of representatives from industries, government and academia, there is also the opinion that precisely because it is a meeting of such representatives, current issues in each field should be shared and as lessons are brought forth, there should be discussions on problem resolution. As DIA is unaffiliated, it is a place of equality where opinions can be expressed and debates can be held, so it was decided that opinions from experts in each field would be included in the agenda for the 9th Japan Annual Meeting.

1. Involved Contents Committee members and their Contribution

At DIA Japan there is a committee representing perspectives from expert or operational staff that proposes and coordinates innovative ideas about content of annual meeting, workshops and training courses in Japan. This Contents Committee was launched in 2012. Please see the June 2012 Global Forum for an introduction to the Contents Committee's organizational structure, roles and responsibilities. Composed of members who work on the forefront of new drug development and new drug review, the Contents Committee members have firsthand knowledge of areas that are going well and of problematic/improvement points. Furthermore, they possess solutions and prospects for the future. These members do not only have ideas on session content but also ideas for candidates for chairpersons and speakers in each professional area. Therefore, the Contents Committee concurrently worked as Program Committee members for the 9th Japan Annual Meeting. A majority of the Contents Committee members are relatively young, so while Program Committee members had a great responsibility, they were highly motivated to manage such a big event from the planning stage to carrying out operations on the day of the meeting. The Contents Committee can claim a major role in the 9th Japan Annual Meeting.

2. Changes to Meeting Scale and Location

Opinion at DIA Japan was unified about expanding the Japan Annual Meeting to include experts from specialties that were not formerly involved. Therefore, although sessions in the past were mainly focused on regulatory affairs, clinical development, and statisticians, at the 9th Japan Annual Meeting we decided to hold sessions on post-market safety, project management,
CMC, patient groups, HTA (Health Technology Assessment), and other important topics relevant to Japan. As session numbers increased, the previous two-day, three-track program did not provide enough time slots. Thus, a three-day, six-track program was decided upon. Furthermore, over the past few years the meeting was held at a location which was somewhat distant from the center of Tokyo, but for this meeting an improvement was made which took convenience for participants into consideration and the conference was held at a hotel in the heart of Tokyo with convenient access to public transportation.

3. Introduction of Tutorials, Student Sessions, and the PMDA Town Hall

Although tutorials, student sessions and the PMDA Town Hall have been established in programs at the DIA EuroMeeting and the DIA Annual Meeting, they were not previously held in Japan. However, in addition to increasing the scale of the meeting, it was decided that these programs would be introduced at this meeting. While cooperation was necessary from PMDA officials for the PMDA Town Hall, academic professors for the student sessions, and lecturers for the tutorials, everyone graciously undertook the task for us, furthering the impression that DIA is an organization which helps realize cooperation between industry, government and academia. Also, in addition to these sessions, we held a workshop entitled “Diversity Forum” on the second night to exchange opinions on career paths and women working in Japan in pharmaceutical industries. We feel that having DIA incorporate not only science but also work-life balance into the Japan Annual Meeting helps to increase the value of DIA.

REFLECTIONS ON THE JAPAN ANNUAL MEETING

We would like to take this opportunity to express our gratitude towards the many who participated and all of the parties who cooperated with us. As the planners of the meeting, we were extremely pleased with the great turn-out at the newly incorporated student sessions, tutorials, and sessions on project management, CMC, and patient groups. What kind of development strategy should be the best scenario to deliver safe drugs to patients quickly and effectively, and what to pay attention to in order to encourage manufacturing and supply of drugs and safe use even in the post-market phase were realized through each session. In general we feel that the goal of this conference was achieved.

There were many first-time participants at the DIA Japan Annual Meeting. This is attributable to the fact that our new programs, which targeted people in the field, differed from the past and the fact that the lecturers and panelists offered a balance of industry, government, and academia. It was clear that expectations are ripe for the Japan Annual Meeting to offer programs in the future which serve the interests of many and take into consideration a balance between policy and practice. Furthermore, in terms of the future, it is important and meaningful for students to develop an interest in and have a hand in DIA Japan through the student sessions.

We intend to continue with concepts of 9th Annual Meeting at the 10th Annual Meeting as well. There are many improvement points in 9th Japan Annual Meeting, we think. We look forward to making the next Japan Annual Meeting even better based on opinions received from participants. Furthermore, we hope that the DIA Japan Annual Meeting becomes the key conference in Japan on new drug development and that it will continue to be notable as a place where industry, government, and academia unite to have heated discussions for medicine and patients in Japan.

UPCOMING EVENTS

JAPAN

16th Annual Workshop in Japan for Clinical Data Management
Feb. 7-8

3rd Labeling Workshop in Japan
March 16

7th Annual Conference in Japan for Asian New Drug Development
April 15-16

2nd CMC Forum in Japan
June 10

2nd FDA IND/NDA Training in Japan
June 12-13

4th Cardiac Safety Workshop in Japan
July 11-12
Over last 2 decades, gene based therapy has evolved from bench to bedside. As of June 2012, over 1800 trials were registered in Journal of Gene Medicine Database.¹ In 1982, the US President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research concluded that the therapeutic applications of gene based therapy were analogous to other forms of therapy. Hence, general ethical standards and procedures were considered adequate to assess the usefulness of gene based therapy.² However, death of Jesse Gelsinger in an early phase trial of gene therapy raised several challenging ethical issues. In India, the field of gene therapy is still in infancy. But Indian researchers are developing gene therapy for conditions such as thalassemia and hemophilia, which affect Indians in large numbers.³ Therefore an understanding of ethical issues in clinical trials of gene therapy is vital for Indian regulators, ethics committees, investigators, and sponsors.

**GENE THERAPY**

Gene therapy, more precisely called gene transfer, is a form of experimental treatment that involves transferring genetic material into the cells of a
patient with a disease caused by a missing or mutated gene. The goal is to cure the disease by modifying the genetic information of the patient’s cells, thereby inducing normal protein expression to replace the mutated or lost gene.

Gene transfer research includes somatic (non-reproductive) cell gene therapy and the germ (reproductive) line therapy. The somatic gene transfer only affects the treated individual. In contrast, in germ cell transfer the modified gene is incorporated in the genome of the individual and can be transmitted to subsequent generations. As of now, germ line transfer therapy is considered ethically unacceptable due to its unknown risks. Hence, research on this therapy is prohibited.

The complexities in the biology of gene transfer make the therapy a scientifically and ethically challenging procedure.

**GELSINGER CASE : A MILESTONE IN ETHICAL EVOLUTION**

The death of Jesse Gelsinger, an 18-year-old patient, in a Phase I study involving ornithine transcarbamylase (OTC) deficiency, has become a major milestone in the debate on ethical issues surrounding gene therapy. This event raised several ethical questions, which include:

- **Selection of subjects** – Gelsinger had mild OTC deficiency, controlled with medication and diet. Although the adenoviral-based intervention was designed to treat infants suffering from severe OTC deficiency, selection of patients such as Gelsinger with mild OTC might have placed them at unnecessary risk.

  - Informed consent – Researchers failed to inform the subjects about the risks involved in the study e.g. rhesus monkey deaths in preclinical studies, the primitive nature of gene therapy research.

  - Conflict of interest – The clinical trial was conducted at University of Pennsylvania School of Medicine, which had financial links with Genovo, the company holding licensing rights to the study intervention, and the lead investigator James Wilson. The US Food and Drug Administration inspections revealed many protocol violations, fudging of eligibility criteria, and failure to report the up-to-date safety information, and failure to report the findings from preclinical studies that suggested a significant risk for human subjects, and failure to update informed consent document with reports of significant adverse reactions – grade III liver enzyme elevations.

The Gelsinger case has become a watershed event in the evolution of ethical policies for gene transfer research.

**GLOBAL ETHICAL CONCERNS**

The ethical challenges of gene transfer therapy could be discussed in relation to general ethical principles and benchmarks, applicable to all research:

- **Social value of intervention**
  - The main justification for gene transfer therapy is that it offers a true cure or a useful remedy for patients who are suffering from a serious illness, and for whom there are very few therapeutic options available.

- **Scientific validity**
  - Most of the gene transfer studies in early stage are conducted to assess feasibility and safety of the therapy. Hence, most such studies are uncontrolled in nature. Also the available preclinical information is still primitive. So one of the most difficult questions is: when to begin human studies. Information from early clinical studies often leads to new animal studies, which in turn suggests the need for additional human studies.

  - As gene transfer has potential for exposing the trial participants to the possibility of serious, unforeseeable, and latent harms, the objective of trials should be to generate information that can be applied to the development of gene transfer rather than to support commercialization.

  - As some of the serious adverse events (AE) may be latent or delayed, a long term and robust surveillance of safety issues is a must during clinical trials. The uncertainty of risks mandates a high scientific standard for all gene therapy trials.

- **Fair selection of study population**
  - One major dilemma has been whether to select adults with mild disease, who can give
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consent or patients with serious life threatening conditions, who may benefit from the gene transfer, but who are vulnerable.

- As the risks of gene therapy are latent and uncertain, the selection of healthy volunteers is not usually favored. For similar reasons, the hazards of conducting gene transfer trials are enhanced in children who have non-life threatening diseases.

**Favorable Risk-benefit Ratio**

- Death of two subjects in early phase studies - Gelsinger and a child with X linked severe combined immunodeficiency (X-SCID) succumbing to leukemia, highlight the challenges and uncertainties of assessing the risk. In X-SCID study, three more children had developed leukemia. Such serious AEs have been difficult to anticipate, because the animal models and toxicity assays used in preclinical safety assessment were primitive. The levels of uncertainty are likely to be greater in the context of gene transfer, compared to other novel medicinal entities.

**Independent review**

- The ECs have to face formidable challenges in the evaluation of the risk: benefit ratio of the gene therapy and oversight of disclosure of risk in consent documents and process.

- The scientific complexity and ethical concerns require that the independent review should be done by an ethics committee which has members who are competent for review of human protocols. Indian Council Of Medical Research (ICMR) Ethical guidelines recommend that the ethics committee (EC) reviewing research proposals related to research on human genetics should have necessary expertise, which includes knowledge of latest developments in the field of human genetics.

- The inherent uncertainties of risks require central ethical review of all trial protocols. In most countries use of two ethics committees (EC) - a central EC and an institutional EC is mandatory. The responsibility of central EC is to review genetic research from a national perspective, enhance the capacity of local EC, and organize conferences to discuss/debate on safety or study design to evolve consensus.

- The uncertainty of risk profile, potential for future serious AEs e.g. malignancy, availability of limited preclinical data and high expectations of potential benefit amongst desperately ill subjects, makes the consent process demanding. Such severely ill subjects are liable to therapeutic misconception and could misunderstand the clinical trial as a “therapy” rather than a scientific experiment.

- The investigators should spend enough time and effort in discussing the possibility of unforeseen consequences and should provide full disclosure of serious AE which have occurred in previous human gene transfer trials.

**Respect for recruited participants**

- The issues of privacy and confidentiality are paramount in genetic research. The high risk and potential for late development of serious AE brings into focus the problems of compensation for medical injury and death.

- A major issue concerns cost and access of therapy. Gene therapy involves high development cost. Most of the gene therapy targets are orphan diseases, with an expensive treatment cost. As gene therapy would be usually a onetime intervention, the cost of therapy has to be borne upfront. These factors are likely to limit the potential of global access to gene therapy.

**INdIAN SITUATION**

In India, there is a growing interest in genomic research. Hence, Department of Biotechnology (DBT) has issued ethical policies for genetic research and services. The policies emphasize basic principles – autonomy, privacy, justice and integrity and provide general guidance to researchers, ECs, institutions and organizations for conduct and design of research and services. Similarly ICMR ethical guidelines cover issues related to genetic research and gene therapy. However, both DBT and ICMR guidelines do not discuss issues of gene therapy in detail. Hence, one has to apply global principles to local research on human gene therapy.

Some genetic disorders – thalassemia, hemophilia, sickle cell diseases – prevalent in Indian
population have serious medical consequences. For thalassemia, the treatment is lifelong and expensive. For such a condition, gene therapy may provide a good medical option. It would be worth discussing ethical challenges of gene therapy, using thalassemia as a model. Beta thalassemia is one of the most common single-gene defect condition, which poses a severe health and economic burden to patients and families. Every year approximately 10,000 children with Thalassemia Major are born in India. India has 65,000-67,000 Beta thalassemia patients, with around 9,000-10,000 cases being added every year. The treatment, which is lifelong, includes regular cell transfusions, and chelation therapy for iron overload. The iron overload, associated chronic blood transfusions, is the most important cause of death. Gene therapy offers the promise of cure by transferring the normal B-globin or y-globin gene into hematopoietic stem cells to permanently produce normal red blood cells. However, gene therapy for thalassemia in India, is fraught with several ethical dilemmas, such as:

- For a genetic condition such as thalassemia, prevalent in certain communities e.g. Sindhis and Punjabis from Northern India, and Bhanushalis, Kutchis, Lohanas from Gujarat, the issue of selection of subjects becomes quite complex. The selection of subjects for clinical trial would pose a challenge of enrolling an individual subject vs. enrolling several children from one family or from a close nit community. As the gene therapy in a trial setting would be experimental, with uncertain risk profile, the investigator would like to include a few patients in the trial. However, the potential for cure in a condition, which has serious health impact, would make the family / community demand that all patients be included in the trial.

- The independent review by EC suffers because of deficiencies in EC functioning. A recent survey of approval letters of Indian ECs revealed deficiencies in composition, quorum, and review of insurance, and clinical trial agreement. Hence, as recommended by ICMR, the EC reviewing gene therapy proposals should have necessary expertise, which includes knowledge of latest developments in the field of human genetics. Also, we need to have a National EC to provide a robust review and guide institutional ECs.

- The population of patients – mostly children – and the cost/complications of therapy, is vulnerable and requires adequate safe guards to protect their rights, safety and wellbeing.

- The consent process would need a thorough disclosure of all risks and transparency to protect the vulnerable subjects from therapeutic misconception.

- Indian framework for surveillance of adverse reactions during trials and in postmarketing setting is not well developed enough to pick up early signals for important adverse drug reactions. As the nature of risk of gene therapy is uncertain and latent, there has to be a special focus on long term surveillance of adverse events beyond the trial period.

- The cost is a major issue for thalassemia treatment. The treatment costs for thalassemic child of 4 years is around Rs. 90,000-100,000 annually in a private set-up. Hence, not more than 5-10% of thalassemic children receive optimal treatment. Stem cell transplantation, which is a curative treatment, costs between Rs 600,000 – 1,600,000. Gene therapy has a high cost in development. Hence, the access to this promising therapy would be restricted to the most affluent Indian patients.

CONCLUSIONS

The potential benefits of gene therapy bring hope to a patient suffering from a serious genetic condition. However, the uncertainty of risk profile, the vulnerability of subjects, and the commercial potential of gene therapy pose significant ethical challenges, which the investigator and ethics committees have to deal with proactively.

ARUN D. BHATT

MD, FICA, FICR, is President of Clininvent Research Pvt Ltd. He has extensive experience over 3 decades in the pharmaceutical industry, including serving as CEO of CMI (India) Pvt Ltd and as Medical Director of Novartis India Limited, and as a consultant in Pharmaceutical Medicine & Clinical Pharmacology. He is a former president of the Indian Society for Clinical Research (ISCR) and the recipient of DIA’s Outstanding Service Award 2012.

References/citations from this article are available upon request.
Upcoming DIA India Meetings 2013

- e-CTD Hands on Training Workshop
  FEBRUARY 4-5 | MUMBAI

- Pharmacovigilance
  MARCH 8-9 | BANGALORE

- Technological Advancements to Meet Regulatory Challenges
  APRIL 25 | MUMBAI

- 6th Regulatory Conference
  APRIL 5-6 | AHMEDABAD

- Generics/APIs
  JULY | HYDERABAD

- 8th Annual Conference
  OCTOBER 24-26 | MUMBAI

To know more on the upcoming DIA India meetings write to DIAIndia@diaindia.org

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April 15-16, 2013
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Beijing, China
EDUCATE does just that: Keeps you abreast of the association, membership, regulatory, and legislative news while including features such as career advice, book reviews, patient perspectives and more.
In your current position as Head of Regulatory Affairs and Technical Department, what are your main responsibilities?

My responsibilities include those related to the company interactions with Central and Regional Spanish Health Authorities with regard to Regulatory Affairs, Quality Assurance, Pricing, Market Access and Government Affairs. Making sure that innovative medicines are available to patients with the best possible quality as soon as possible is one of my main priorities. The current crisis environment in European countries like Spain makes the market access policies of particular importance, making my daily work a continuous challenge. We should also try and get experience in different ways of public and private partnerships that allow the public health systems to overcome the current critical scenarios and also permit the industry to continue investments to get better medicines for the global population.

Beatriz Vicén Banzo, who will serve as Co-Chair of our 25th EuroMeeting: Amsterdam 2013, March 4-6 at RAI in Amsterdam, is a Pharmacist by training with specialization in Biochemistry by the University of Barcelona. She also holds a Master in Business Administration of the Pharmaceutical Industry from the University of Barcelona (1992), a Master in European Regulatory Procedures from the Autonomous University of Barcelona (1999), and a Master in Business Administration from the Business School ESADE (2005) Barcelona – Spain.

With a regulatory background of more than 20 years, she currently holds the position of Head of Public Affairs and Technical Department at Bayer in Spain. Prior to joining Bayer as Head of Regulatory Affairs and Quality Assurance in June 2008, she held the position of Head of Regulatory Affairs in Novartis Pharma, Spain.
What was your first career step in this pharmaceutical development and regulation arena and what advice would you give to people who want to begin a career in this industry?

When I started in Regulatory Affairs, only one year after I concluded my University degree in Pharmacy, and after some months of working in a pharmacy (also a great experience, I must say) the daily work in this field was mostly bureaucratic and not very appealing for young people, at least in an affiliate. In contrast, Marketing was at that time much more interesting for most of the recently graduated people. Regulatory Affairs departments were seen as like a post office without possibilities to influence on the development of the products. Nowadays, it involves a continuous update in the understanding of scientific/technological innovations and knowledge of regulations; from this starting point, the regulatory strategy has to be thoroughly prepared in order to overcome the barriers in the currently restrictive economic environment. The regulatory input is nowadays of crucial importance to better develop the product in the way that companies fulfill the requirements to avoid hurdles and accelerate as much as possible the approvals that will eventually permit an earlier access to the market.

My advice to those who want to begin a career in Regulatory Affairs, having all these important items in mind, would be to keep studying and, if possible, try starting by applying for an internship in the Regulatory Affairs department of a pharmaceutical company in your country. Getting experience through work and knowledge will undoubtedly make you a valuable professional in the field.

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

The most amazing change I have experienced was when I was able to participate in the first Mutual Recognition and Centralized procedures at Novartis, and see that there was a common agreement among the participating countries, fulfilling the pre-established procedural timelines and achieving the market access within a reasonable timeframe in countries otherwise considered ‘slow.’ In Spain, this has meant at least one year of earlier approval when compared to the old national procedures. Nowadays, however, it is not a matter of just filing submissions and getting approvals; those involved in Regulatory Affairs require continuous training not only on the new regulations but also on the associated technicalities, which translates into a deep involvement in an ever-challenging arena.

On the other hand, the new Information Technologies have also been notably important in the development of this area and have contributed to improvement in the daily management of any regulatory procedure. In this context, some European Agencies – and, I am proud to say, among them the Spanish Agency – have been pioneers in the implementation of these new systems, namely the electronic submissions. This has also influenced the training of people who want to work today in a Regulatory Affairs department, where the knowledge as a pharmacist is best combined with a variety of other different disciplines in this field.

You have found time in your professional life to contribute in a major way to DIA. Why?

I have attended most DIA EuroMeetings since I started in the regulatory arena. DIA forums always provide productive discussions on a number of current regulatory and scientific topics that most have on our office desks every day. I am delighted with this opportunity to devote a part of my time to contribute to the forthcoming DIA EuroMeeting. It has been, and is still, a challenge and an excellent opportunity to network with colleagues from different pharmaceutical disciplines.

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

Although I am totally satisfied with my career, I often think that studying law in addition to my current studies would be really interesting, as I feel very attracted to law and it is very much linked to my current profession. ●
What are some of your constituents' biggest fears about participating in a clinical trial and did you see or hear anything at DIA 2012 that could help alleviate or overcome those fears?

Most people don’t find it difficult to walk across a gravel driveway, transition from walking on a sidewalk to grass, or get out of bed in the middle of the night without stumbling. However, with impaired balance such activities can be extremely fatiguing and sometimes dangerous. Symptoms of a vestibular disorder that accompany unsteadiness include dizziness, vertigo, hearing and vision problems, and difficulty with concentration or memory.

People with vestibular (inner ear balance) disorders suffer from a chronic, invisible illness. They may not look sick, but their capacity to function normally is severely impaired, often to the extent that they can no longer work, drive, or participate in social activities. Vestibular disorders are misdiagnosed and under-treated, resulting in extended periods of discomfort and frustration on the part of the vestibular patient, and often a resulting distrust of the medical community.
Surprisingly, in a recent website poll, 72% of respondents said that they would be willing to participate in research to help develop better treatments for vestibular disorders. This represents the desperation that many vestibular patients feel in the lack of current understanding about these conditions, and the limited treatment options available. The good news is that it signals an open door for the medical community to engage the so-called ‘dizzy patient’ in research designed to reduce diagnosis times and improve treatment outcomes for people with vestibular disorders.

Ten percent of survey respondents said that they were concerned about unknown side effects the treatment they received during a clinical trial could cause. Considering the sensitivity of vestibular patients to motion, sound, and visual stimuli, in addition to dietary restrictions, their concern is understandable. However, to them I would quote the first goal of any clinical trial, which is to do no harm. Safety first was a consistent theme throughout the workshops I attended during DIA 2012, reinforced by the FDA's diligent oversight policies. The stringent screening process for clinical trial participants assures that only appropriate subjects will be selected, and patient monitoring is built into study protocol.

Another theme repeated during DIA 2012 was that patients who live with a disease have a direct stake in the drug review process and are in a unique position to provide input. Validating the patient perspective empowers patients to take a more active role in their own medical care, which in turn strengthens patient confidence in the medical system. Establishing relationships with patients through transparent two-way communication is essential to building trust and increasing patient participation in the clinical trial process.

Finally, nine percent of survey respondents indicated that they don’t know enough about the clinical trial process or how to find out about an appropriate clinical trial in their area. So how do vestibular patients become informed about research and get connected with clinical trials that are actively recruiting participants? VEDA is a resource hub for people suffering from vestibular disorders. We provide information on symptoms, treatments, and coping strategies, and serve as a conduit for researchers to recruit study participants through our website. We also provide information about why research studies are important, and explain the benefits/consequences a research participant can reasonably expect. By partnering with patient advocacy organizations like VEDA, the medical community can reach out to targeted patient groups while educating them about the research process.

Multiple DIA 2012 sessions discussed pharma’s increasing use of social media to manage and inform relationships and build patient engagement. There is a recognition that patients are going online to look for information about their medical concerns, and that patients need support tools to facilitate their participation in the research process, and enable them to make informed decisions.

Many vestibular patients find the strain of travel difficult, and/or may be negatively impacted by the bright lights and busy atmosphere of the typical hospital or research setting. Seven percent of our survey respondents indicated that they would participate in a clinical trial if they could do so remotely. During DIA 2012, I learned about a growing movement to enable patients to enter data electronically, thereby removing a potential barrier to participation in research.

**May we ask you to please explain and describe your work with VEDA, and how can organizations such as DIA collaborate to help?**

VEDA’s mission is to serve people with vestibular disorders by providing access to information, offering a support network, and elevating awareness of the challenges associated with these disorders. We provide patients with information and tools to educate themselves about what it means to live with a vestibular disorder, how and where to get help, and what they can do to give back to the vestibular community.

VEDA welcomes partnerships with organizations like DIA that promote patient-centered issues and increase awareness about the value of patient participation in the diagnostic and treatment process. We consider it a service to our members – patients and professionals – to provide relevant news and information on current research therapies, clinical trials recruiting patients, and other topics that affect patient care, and invite individuals and organizations to submit such articles for publication in our newsletter and/or on our website.
VEDA’s website receives hundreds of thousands of visitors annually. Our Facebook page has an active following. Our audience can be your audience. We invite researchers to post clinical trials on our website, submit research findings for publication in our newsletter, and distribute other information to help vestibular patients learn about how new treatments are developed and decrease the stigma often associated with being a research ‘guinea pig.’

Similarly, VEDA needs accurate and scientifically validated data to continue and strengthen our advocacy efforts. Such data is a valuable tool when approaching medical schools to encourage better training for primary care physicians in vestibular dysfunction, or lobbying insurance companies for better coverage of vestibular conditions.

As many as 35% of adults aged 40 years or older in the United States – approximately 69 million Americans – have experienced some form of vestibular dysfunction. As VEDA continues to reach out to people affected by inner ear balance disorders, we look forward to developing relationships within the medical community that help us achieve our goal to reduce diagnosis times and improve treatment effectiveness for vestibular patients.

To learn more about the Vestibular Disorders Association, please visit www.vestibular.org.

Karen Ball, Sturge-Weber Foundation (SWF)

Karen L. Ball serves as President and CEO of the Sturge-Weber Foundation. She also served as a Patient Advocate Fellow for our DIA 2012 Annual Meeting. While DIA continues to prepare for our DIA 2013 49th Annual Meeting: Advancing Therapeutic Innovation & Regulatory Science, Karen shared these thoughts about her DIA 2012 experience and how that experience can benefit the patients this organization represents.

Approximately 10,000 individuals in the US live with Sturge-Weber syndrome (SWS) and its hallmark features of a port wine birthmark on the face, glaucoma, and seizures with varying degrees of cognitive and physical impairment. Over one million people have a port wine birthmark on one particular body part. Because the vascular malformation involves

Q: What are some of your constituents' biggest fears about participating in a clinical trial and did you see or hear anything at DIA 2012 that could help alleviate or overcome those fears?
so many parts of the body, these individuals (depending on the degree of involvement) must juggle medical appointments with neurologists, dermatologists, ophthalmologists and therapists. So far, there are less than a handful of SWS clinical trials for our members. The SWF’s goal is to increase the number of these clinical trials through our ten Centers of Excellence across the country. The SWF helped facilitate an Office of Rare Disease Research (ORDR), National Center for Advancing Translational Sciences (NCATS), Brain Vascular Malformation Consortium (BVMC) grant to study three diseases, one of which included SWS and the genetics of SWS, and our members have been very responsive to participating at these Centers.

One of the first questions members typically ask about clinical trials is, ‘How much more time out of my schedule will it take?’ They know the SWF has been at the forefront of engaging researchers and funding small research seed grants to obtain baseline data necessary for larger investigations. The SWF and our members have been in dialogue through printed publications and online endeavors to become better versed on clinical trial terms, the value of clinical trials and the need for participants which will increase the pace of discovery. They understand the SWF has done our due diligence on the trials before we notify them for participation. Our members are ready for more clinical trials because there have been so few on the syndrome.

Another question that inevitably comes up is, ‘What are the risks involved?’ The SWF always includes this information on the risks as well as potential benefits of involvement but this question comes up often. *DIA 2012* was beneficial in helping me understand even more about the clinical trials process and the benefits of telemedicine, and getting to meet vendors in this area. Another bonus of *DIA 2012* was the information shared amongst all the patient advocate fellows. Since many of us don’t have dedicated staffers for public policy or clinical trials, these exchanges solidified what we are doing well and identified other channels of distribution that we could employ across sectors to maintain communication and participation.

SWF’s participation in umbrella and industry events such as *DIA 2012* provides global access to key opinion leaders, industry leaders and scientists. The plethora of *DIA 2012* sessions allowed me to choose tracks that benefit our learning curve for trials today and will guide us to lay the proper groundwork for a program to utilize compounds that might benefit the members in the future. Our members are excited to know we are engaging individuals in dialogue and awareness opportunities at every turn.

**May we ask you to please explain and describe your work with the SWF, and how can organizations such as DIA collaborate to help?**

The Sturge-Weber Foundation (SWF) is an international 501c3 organization with a mission to improve the quality of life and care for people with Sturge-Weber syndrome and associated Port Wine Birthmark conditions through collaborative education, advocacy, research and friendly support.”

I founded the SWF 25 years ago when my daughter was diagnosed at birth with Sturge-Weber syndrome. Following three eye surgeries in the first three months of her life, I began a crash course on the lifelong medical and other implications she would face with this rare disease. It was a short course: A handful of medical articles on the syndrome, demeaning photos associated with the articles, and less than a handful of ‘experts’ on the syndrome, most of them neurologists who dispensed palliative care but with none focused on finding a cure.

The SWF started out as a clearinghouse of information on the syndrome. In those days, support was dispensed by phone or with the postmaster’s help. Slowly, word reached the medical community that there was a central point to refer patients to for support and awareness. Former First Lady Betty Ford and Anne Landers helped boost the organization’s profile and we were off and running! The SWF was an all volunteer organization for the first four years. When we added staff positions, our outreach and fundraising efforts to support the mission and infrastructure across the country grew. A research fund was established with a Betty Ford Award stipend and the National Organization for Rare Disorders (NORD) provided an opportunity to share and learn with other emerging not-for-profit organizational leaders.

It’s been a very humbling and exciting 25 years. The SWF has
been responsible for increasing the number of health care providers who know more about the natural history of the syndrome and now care for our more than 4,300 members. Increased internet communication allows the SWF to assist families and care providers in over 96 countries. NIH co-sponsored workshops and member participation in studies through the informal Natural History database have confirmed the involvement of angiogenesis, immune suppression, growth hormone abnormalities and more. As the SWF launches this database online, I am eager to engage a new generation of clinicians and investigators as we work together to improve the quality of life and care for the members with more tailored treatment options.

When I was invited by a physician to speak at the DIA 39th Annual Meeting in San Antonio (2003), I was looked upon as an anomaly and people kept asking me why I was there. I found it odd then – and I still do now – that individuals who represent the patient would not be seen as a valued resource and an equal partner at the table. We can learn so much more from each other when we come together! Thankfully, DIA has been at the vanguard of advocacy inclusion and launched the Patient Advocates Fellows program. The SWF has become a richer and even more exciting community through our DIA partnership and our patients will ultimately benefit sooner rather than later. I look forward to highlighting our blossoming partnership with DIA during the Sturge-Weber Foundation’s annual Month of Awareness events in May. We welcome volunteers and supporters for a reason, a season or a lifetime!

To learn more about the Sturge-Weber Foundation, please visit www.sturge-weber.org.

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DIA’s mission to provide educational and networking forums that anticipate and meet the needs of our professional constituencies requires the constant reevaluation and assessment of these forums in the context of continual and dynamic scientific, industry, regulatory and market change. As progress marches forward, some forums are no longer necessary and may be left behind while new forums are created as other emerging needs are identified.

DIA is proud to announce the formation of a new Medical Science Liaison (MSL) Special Interest Area Community (SIAC). The goals of creating this new community is to raise awareness of the MSL profession; to encourage dialogue about that profession among regulators, academic institutions, industry personnel and others; and to promote the professional development of MSL SIAC members.

Rebecca Vermeulen, RPh (Genentech) serves as MSL SIAC Chair. Dr. David L. Cram (Corcept Therapeutics) serves on MSL SIAC Core Committee and shared his thoughts on the concerns of the MSL professional community, and how this SIAC hopes to address them through programming and networking, in the following Q&A. “I have to commend the leadership of DIA. DIA has done worlds of good for the MSL community,” David says.
When was the MSL SIAC formed and what needs within the healthcare community was it formed to address?

This SIAC has been in development for a long time and a very positive environment at DIA over the past five years or so has made this possible. Prior to that, the MSL world was basically relegated to a subgroup of the Drug Information SIAC. As the number of MSL teams grew over the years, we felt it was important to have our own SIAC. At this point in time, there are probably more MSLs in the pharmaceutical world than drug information professionals.

Some history: Back in the late 1980s/early 1990s, there were probably three or four MSL teams. That number just exploded throughout the ‘90s. By the year 2000, almost every company had an MSL team, and now every startup company has an MSL team, of some sort – even small companies such as my own where we have one half-time drug information person and nine MSLs. There’s this huge group now, and we felt like we needed more representation than what we’d been getting. Not that the Drug Information SIAC was not paying attention to us or not giving us what we needed – they did a really good job of that – but we were getting to that point where our needs started overwhelming their needs. So we officially established the MSL SIAC core team in May 2012.

We started looking around at global MSL leadership and established a core group and communication group of international as well as national experts in this field. Our core committee is led globally by Rebecca Vermeulen and in the US by Ramineh Zoka. I serve as a co-chair for our regional development. Geoff Brockway serves as co-chair for Canada. Amy Gomez serves as European lead. J. Lynn Bass is our communications coordinator and Ken Massey is our strategic development co-chair.

Do MSL professionals across the pharmaceutical, medical device, and biotechnology industries have essentially the same needs, or are they different?

MSL organizations have become a lot more uniform over the years but there is clearly still a difference if you work for the device industry versus the pharmaceutical industry. The pharmaceutical industry has a lot more restrictions than the device industry in general, but that’s tightening up really fast. The device world has always had a lot more flexibility, but I think that’s tightened up quite a bit. So we are becoming a lot more uniform in the things we worry about. That’s the best way to put it: We worry about the same things.

What are some of these concerns?

Where are the limits of ‘clinical exchange’? That’s the number one concern right now: Where does ‘clinical exchange’ end and become ‘off label promotion’? Or, where does ‘clinical exchange’ end and you’re no longer able to provide a balanced argument against somebody who’s mislabeling your drug? For example, if managed care says something that mislabels your product, we are in no position to proactively counter that without some level of risk.

Another is the environment around compliance. We want to do the right thing but the rules can be very hazy. You only know that you break them when they call you.

I started in this industry in 1991 and I can tell you that there were things the industry considered acceptable in 1991 that would put us all in striped jumpsuits today. Although the FDA really hasn’t changed many rules, they enforce them more heavily now than they did. Nasty letters from the FDA have evolved into fines. We ask government regulators to fill in the rules for us, a double-edged sword because they become even more conservative. Right now, the general rules are: You do not promote off-label indications in your drug. You can address questions associated with that. You can review things with people when they ask you. But you cannot proactively go out there and promote. That’s as simple as it gets.

Other issues would include: How do you evaluate MSL performance? What are the career tracks that MSLs might have? How is this environment changing, and if this environment is changing, how do we change along with it? What is the measured value of an MSL team? The main thing for this DIA group is that we create a forum for networking to talk about these issues.

Please visit “Networking & Communities” on our www.diahome.org website to learn more about the MSL SIAC and other DIA Special Interest Area Communities.
SIAC Corner

Don’t Be Caught off Guard: Meeting Tips for DIA’s Annual Meeting

LISA PALLADINO KIM

just completed a masters degree in Clinical Sciences from University of Medicine and Dentistry of New Jersey. In addition, she has 13 years of experience in the pharmaceutical industry across both Clinical Sciences and Clinical Operations. She is currently employed at PharmaNet/I3, dedicated to Merck & Co., as a Global Trial Optimization Specialist. Most recently, Lisa developed a process for engaging worldwide investigators in early program and protocol design with the expectation of improving operational execution.

LISA PALLADINO KIM

The DIA 2013 49th Annual Meeting: Advancing Therapeutic Innovation & Regulatory Science is “the largest multidisciplinary event that brings together a community of professionals from all levels and across all disciplines in the discovery, development, and life cycle management of medical products.” As in years past, DIA 2013 will feature 280 sessions with comprehensive coverage of today’s hottest medical topics. If this is your first DIA Annual Meeting with over 200 speakers and 450 plus exhibitors, you may feel overwhelmed initially, but relax, take a deep breath, and invest some time into planning. This is key for an excellent experience and pre-conference planning is best. To enhance this experience, here are some tips to consider:

1. Set objectives and narrow your focus before attending. The DIA Annual Meeting offers over 19 different interest tracks, across three levels of experience. You will feel like a child in a candy store, so approach your choices systematically.

   a. Select one or two tracks you are currently working on or learning about, a track you would like to work on in the future, or a track of personal interest.

   b. Determine your level of knowledge per track and choose accordingly.

Also remember, sessions you do not attend in person are offered online after the conference.
2. What to wear: Business casual with comfortable shoes and layers. You may be tempted to wear a pretty new pair of high-heeled shoes, but keep in mind the conference space is vast; envision football field size in length with sessions at both ends. You will do A LOT of walking, and do it all over again the next day, so save the stylish shoes for another event. In addition, wear layers, because it is impossible to make the temperature comfortable for everyone who attends.

3. There are many, many exhibitors; therefore, be strategic with your choices before navigating the exhibit hall. Prior to the meeting, plan your visit to this area, and create a targeted list of top exhibitors. If you are looking for employment, visit the booths dedicated to “job hunter.” If you are looking for new ways to recruit patients for your clinical study, focus on the recruitment vendors, etc.

4. Leave space in your suitcase for conference and exhibitor items! On top of receiving conference materials, business brochures and fact sheets, exhibitors may offer reminder gifts, which can be really fun for you and others in your office. They often request a business card or will scan your badge.

5. Bring tons of business cards, and then bring more. Exchange business cards with attendees and exhibitors. With XX amount of attendees, your collection of these can be overwhelming. Therefore, when you receive one, record a few distinguishing notes about the person or conversation on the back: location (exhibit hall near DIA booth), appearance (bright pink suit), or topic (2 yr old son, school for pharmacy degree, etc.). Save time spent sorting these: Pick one pocket for “follow-up” and one pocket for the “future reference” business cards.

6. Network! Network! Network! There are countless opportunities to meet diverse and potential colleagues!
   a. If you’re reserved, you may be uncomfortable meeting new people. Take a risk and introduce yourself, you’ll have a high chance of meeting somebody who will change your life. If you want to practice, be sure to stop by the DIA Advocate Patient Fellow booth for a very interesting and diverse group!
   b. Scope out lunch tables and use this as a networking opportunity to meet new people with different background or expertise. Everyone has something to share.
   c. Keep an ear out for non-DIA sponsored informal get-togethers after the meeting. These provide another great opportunity to network and can be tons of fun!
   d. Take a picture of yourself next to the key person you want to follow-up with at a later date. Prior to sending the follow-up e-mail, attach the photo of the two of you. This provides a unique opportunity to remind the person who you are and when you met them.

7. Ensure your badge has the bar code facing out to make it easier for scanning. DIA tracks attendees at each session; they will scan your badge prior to entering a meeting session.

8. Volunteer! DIA is always looking for people to help with the annual conference. Contact the volunteer group, offer to take photos, or perform informal surveys.

9. Give your opinion. DIA improves each annual meeting based on feedback from attendees.

10. Trim your conference carry items, bring only what is necessary, and of course don’t leave your personal items unattended. What feels light at 7 am will feel heavy by 5 pm. Utilize the DIA app or pull out the schedule-at-a-glance sheet from the DIA program. Plan the best time to pick up exhibitor information so you are not carrying around extra weight for 8 hours.

Enjoy DIA’s 2013 49th Annual Meeting! In addition to this amazing learning opportunity, it provides an excellent opportunity to meet people from around the globe, share your views and knowledge, and establish new relationships!
DIA is a global member association that provides knowledge resources across the full spectrum of medical product development. In the last few years the organization has expanded that global reach and will continue to grow to meet the needs for health care knowledge exchange around the world. As DIA’s reach expands globally, our volunteers have suggested that the term SIAC does not resonate globally in its explanation of what the special interest groups represent.

The CLC (Community Leadership Council) has discussed this topic and asked for feedback from the SIACs. The consensus is that changing the name “SIAC” to “Community” will enhance the visibility and purpose of these groups. The CLC has also agreed that if a region wishes to use a local language term other than Community that will be more acceptable to their membership, they are free to use that regional term.

<table>
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<tr>
<th>SIAC Name Change</th>
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<tr>
<td><strong>BELOW IS A LISTING OF ALL THE ACTIVE SIACS AND THEIR CHAIRPERSONS</strong></td>
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<td><strong>SIACS AND CHAIRPERSONS</strong></td>
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<td>Chairperson Barbara Leishman F. Hoffmann-La Roche Ltd. Switzerland</td>
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<td><strong>Biotechnology and Innovative Preclinical Sciences</strong></td>
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<td>Chairperson Joy Cavagnaro Access BIO United States</td>
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<td>Chairperson Kristin Neff TARIS Biomedical, Inc. United States</td>
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<td><strong>Chemistry Manufacturing and Controls and Quality Systems</strong></td>
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<td>Chairperson Georges France Novartis Consumer Health S.A. Switzerland</td>
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<td><strong>Clinical Pharmacology</strong></td>
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Clinical Research
Chairperson
Susan Nunchuck
Actelion Clinical Research
United States

Clinical Safety and Pharmacovigilance
Chairperson
Michael Bui
Bayer Healthcare Pharmaceuticals Inc.
United States

Clinical Trial Disclosure
Chairperson
Robert Paarlberg
Paarlberg & Associates LLC
United States

Devices & Diagnostics
Chairperson
Shayesteh Fuerst-Ladani
SFL Regulatory Affairs and Scientific Communication
Switzerland

Documents and Records Management
Chairperson
Lisa Mulcahy
Mulcahy Consulting, LLC
United States

eClinical
Chairperson
Munish Mehra
Global Alliance of Indian Biomedical Professionals
United States

Emerging Professionals
Chairperson
Yasmin de Faria Krim
Janssen Pharmaceutical Companies of Johnson & Johnson
Belgium

Good Clinical Practices and Quality Assurance
Chairperson
Leslie Sam
Eli Lilly and Company
United States

Investigator and Investigative Sites
Chairperson
Ana Marquez
Marquez Clinical Site Partners, LLC
United States

Information Technology
Chairperson
Pamela Campbell
EMC Corporation
United States

Medical Communications
Chairperson
Stacey Fung
Genentech, Inc.
United States

Medical Science Liaison
Chairperson
Rebecca Vermeulen
Genentech, Inc.
United States

Medical Writing
Chairperson
David Clemow
Eli Lilly and Company
United States

Natural Health Products
Chairperson
Pradip Paul
Strategic Pharmacovigilance and Risk Management Consultant
United States

Pediatric
Chairperson
Gesine Bejeuhr
vfa Research-based Pharmaceutical Companies
Germany

Professional Education, Training and Development
Chairperson
Daniel Mudgett
Medidata Solutions Worldwide
United States

Project Management
Chairperson
John Sun
Novartis Pharmaceuticals Corporation
United States

Quality Risk Management
Chairperson
Peter Schiemann
Widler & Schiemann Ltd
Switzerland

Regulatory Affairs
Chairperson
Sarah Powell
Liquent, Inc.
United States

Statistics
Chairperson
Joan Buenconsejo
FDA
United States

Study Endpoints
Chairperson
Keith Wenzel
Perceptive Informatics
United States

Translational Medicine
Chairperson
Aamir Shahzad
European Society For Translational Medicine (EUSTM)
Austria

Validation
Chairperson
Richard Chamberlain
Executive Consultant Services
United States
ASSOCIATION NEWS compiles the latest updates from DIA plus news from and about our global network of members and volunteers in one comprehensive section.
DIA is pleased to announce
Stephen P. Spielberg, MD, PhD,
former FDA Deputy Commissioner
for Medical Products & Tobacco,
as *TIRS* Editor-in-Chief effective March 1

Dr. Spielberg, a pediatrician who is the former dean of Dartmouth Medical School, has deep ties to the pharmaceutical industry. Until he was selected by Margaret Hamburg to serve in the Office of the FDA Commissioner, he was Director of Personalized Medicine at Children’s Mercy Hospital in Kansas City. He also served for six years as Johnson & Johnson's Vice President for Pediatric Drug Development, after tenure in senior positions at Merck & Co's Research Laboratories. He is also a former member of PhRMA's pediatric task force.

“[I]’m incredibly excited to have joined the DIA at this time,” said Dr. Spielberg. “Medical science is advancing at an ever-increasing rate, and the journal is part of DIA’s efforts to ensure the flow of information to all our members – more than 17,000 around the world – and to interpret that information, to ensure that the public has access to safe, effective and high quality medical products. We see an opportunity here, with the rapidity of change in science, the rapid accrual of new understanding of the mechanisms of human disease, and converting that understanding of mechanisms into new products that I could not have even imagined when I began medical school more than 35 years ago.”

“With that rate of accrual of new knowledge, we have a challenge of how to inform each other about science – everything from basic science and genomics, rapidly understanding how the human genome impacts health and disease – and how that converts into the discovery, the
development, the regulation, and the use of new medical products. All of us who are involved, from basic scientists in academia through industry, through regulatory science, have a major stake in ensuring that the new information is in fact used on behalf of all patients in need of improved diagnostics and interventions for serious illness. So I’m extremely excited about the idea of bringing new generations of scientists, of drug developers, of industry, of discoverers of new medicines, together with the regulatory community, together with the academic community; as well as thinking more broadly about the implications of the consequences of international drug development, everything from international supply chains, of medicines and constituents of medicines; through how we need to think about the economics of the availability of complex new medicines."

“All of these are huge challenges: To convert human brilliance and discovery into real products. And DIA is unusually well-situated to be able to use all of our resources – our journal, our educational activities throughout the world – in an integrated way to bring together all of those who have a stake in the future of human health,” Dr. Spielberg said.

“The title of the journal synthesizes our thinking about the future. It certainly is about innovation, and innovation in all respects, everything from understanding molecular biology through new manufacturing through new distribution processes, through more rational and effective use of medicines in clinical practice.”

To see and hear Dr. Spielberg share his thoughts on DIA and our new journal, please visit Therapeutic Innovation & Regulatory Science under “Publications & Research” on our www.diahome.org website. You’ll find them in the “Newsroom” under our “News & Publications.”
FDLI Honors DIA Board Member
Minnie Baylor-Henry

DIA President-elect Minnie Baylor-Henry, JD, RPh (Johnson & Johnson Medical Devices & Diagnostics) received the Food & Drug Law Institute (FDLI) Distinguished Service & Leadership Award at FDLI’s annual Holiday & Leadership Award Reception held at the Westin Georgetown in Washington (DC) this past December 12. The FDLI Distinguished Service & Leadership Award, established in 1993, annually recognizes up to four individuals who have a record of sustained service, leadership and contribution to the food and drug law community and/or FDLI; or provided an exceptional contribution to FDLI and/or the food and drug law community, for example, through outstanding writing or scholarship, by developing new legal theories and precedents or engaging in significant activities on behalf of the public interest.

“Minnie’s service to the food and drug law community – as a regulator with FDA, consultant with Deloitte and executive with Johnson and Johnson – has been extraordinary,” stated Susan C. Winckler, FDLI President and CEO. “Her contributions to the FDLI Board of Directors as Chair further demonstrate her commitment and leadership.”

FDLI, founded in 1949, is a non-profit organization that provides a marketplace for discussing food and drug law issues through conferences, publications and member interaction. The scope of FDLI includes food, drugs, animal drugs, biologics, cosmetics, diagnostics, dietary supplements, medical devices and tobacco.

Upon receipt of her award, Minnie commented, “I have worked for 20+ years as a regulatory professional in pharmaceuticals, consumer products and medical devices. To be recognized with such an honor by FDLI is one of the greatest moments of my career.”

Alan Bennett (Ropes & Grey, DC Office), Thomas O. Henteleff (Kleinfeld, Kaplan and Becker) and John M. Taylor III (Counselor to the Commissioner, Office of the Commissioner, FDA) also received this award.
In January 2013, DIA worldwide headquarters in Horsham (PA) welcomed Bayard Gardineer as Director of Finance/Chief Financial Officer for DIA. Bayard previously served as Chief Financial Officer (CFO) of one of the nation’s largest regional American Red Cross chapters, where he developed strategies for financial stability and provided financial oversight for Upper Division 6 (Delaware, Pennsylvania, Maryland, the National Capital Area and West Virginia), responsible for more than $50 million in annual revenue and $50 million in assets, and oversaw fundraising operations that generated well over $50 million of humanitarian relief, from the Philadelphia area alone, in response to the Indian Ocean tsunami, Haiti earthquake and Hurricane Katrina.

Bayard has also contributed executive financial leadership to Vocaltec Communications (as General Manager/Vice President of Finance), Heraeus Instruments (Corporate Controller/Director of Operations) and Sony Corporation of America (Interim Internal Audit Director/Senior Financial Auditor). He earned his undergraduate and master’s degrees in accounting from the State University of New York at Albany and is a CPA (Certified Public Accountant) as well as a member of the American Institute of Certified Public Accountants. In 2009, Bayard was recognized by the Philadelphia Business Journal and Drexel University’s LeBow College of Business as Nonprofit CFO of the Year.

“With a career spanning high-profile worldwide corporations, Bayard brings exceptional experience to our association,” said DIA Worldwide Executive Director, Paul Pomerantz. “His wealth of financial knowledge will allow DIA to continue to support the development and regulation of safe and effective medical products and improvements in patient care.”

Bayard will oversee DIA’s global finance operations and information technology efforts and shared these thoughts with the Global Forum.

What most attracted you to DIA as an organization through which you could continue to serve the world’s health care communities?

I have an extensive history with many of the markets that DIA works with as well as with various other groups, from biomedical to medical devices, but I have always been interested in health care. Interestingly enough, the reason I live in New Jersey is because of health care. In 1979, my father was the lead mechanical engineer for Johnson and Johnson’s ‘Special...”
Research Group’ that helped to make ultrasound an everyday diagnostic tool. He was an MIT graduate who loved the field, and so do I. In fact, I worked several summers with the Special Research Group. It was new and really exciting. In addition, I feel comfortable in the non-profit as well as in the for-profit environment. That said, non-profits typically require action that is very often above and beyond the call of duty. It’s not unusual – it’s expected. Many who work in this type of environment are extremely caring and dedicated to excellence. It’s something I personally strive for each and every day. To sum up, it’s a logical next step in my professional career.

What previous professional experiences will most benefit your service with DIA, and how?

Most certainly, my recent experience serving eight years with the American Red Cross, an organization with a strong and extensive volunteer network, highlights the fact that when you’re working with others you can really accomplish a lot with very little. You also learn that it’s not all about you, but about the mission. My ‘value add’ was stewarding each dollar donated to the organization. I think it highlighted the fact that every dollar is precious, and that it’s very important to challenge everyone involved with being effective and financially cost efficient. It’s important to note that, despite moving on professionally, I remain a dedicated Red Cross donor and volunteer.

What opportunities with DIA are you looking forward to the most?

Working in and around health care. Currently, we have offices in China, India, Japan and Switzerland, and I love that international component. Now the mission for me isn’t just regional – it’s global. I worked for various types of international companies earlier in my career, so I feel comfortable in this environment. It’s even better when you’re looking at many of those regions or locations as potential growth opportunities: It allows me to get in on the ground floor as part of that growth as well as to help manage the cost associated with it. It’s a chance to really make a difference.

As you join a new company in an environment undergoing such profound and extensive change, what’s your primary focus?

Stewardship of the non-profit dollar and providing the necessary back-office support which inevitably allows others to be more proactive as well as effective. We are a team and we must all work together to provide our members with support and services. It’s critical to provide the organization with efficient and cost-effective back-office financial support to help it not only provide the necessary services but the flexibility to grow, despite a challenging environment. When the non-profit dollar is tough to come by, the reality is that you’ve got to provide enhanced services with greater quality. With the worldwide web, the instantaneous transmission of real time information, and competition being what it is, it’s extremely important to make sure that diligence prevails.

What do you enjoy when you’re away from the office?

I am the proud father of three. My children are in various colleges: My oldest son is a graduate of Princeton currently working toward his PhD at Stanford; my daughter is at Syracuse, looking to pursue her graduate degree in psychology; and my youngest son is going to Centenary College, looking to be a business major. The simple fact that they’re attending college leaves my wife Mary and I a lot of extra time, at least on weekends, that we have never had before. We love to do cultural things. We love Philadelphia and New York. We love cultural events and we also love theatre. One of my other passions is reading US history, especially American history with a particular love for our Founding Fathers and the Civil War. According to family lore, I am a descendant of President John Adams, of Vice President Aaron Burr, and of Nathan Hale. Last but certainly not least, I love baseball and my team is the New York Yankees.

What message would you like to share with DIA’s global network of members and volunteers?

I’m thrilled to manage DIA’s financial operations as the association continues to expand globally and bring high-quality programs and services to our members and stakeholders around the world. I have already seen our members, our volunteers, our Board and our staff all go above and beyond the call of duty whenever possible. One thing is for sure: I’ve already seen at DIA a tremendous energy and a true willingness on everyone’s part to deliver the best to our members.
DIA Welcomes New Director, DIA Europe

On January 10, 2013, Dr. Jytte Lyngvig began service as Director, DIA Europe. Dr. Lyngvig brings considerable breadth and depth of experience to DIA, especially in Europe, and most recently served as the Chief Executive Officer of the Danish Medicines Agency. In her new position, she will be responsible for oversight of DIA programs and operations in Europe, the Middle East and Africa.

In addition to serving as CEO of the Danish Medicines Agency, Jytte participated as a member of the European Medicines Agency Management Board as Vice-chair and Heads of Medicines Agencies as Chair of the Management Group. She additionally participates as a Senior Adviser on individual assignments at the Copenhagen Business School. Prior to this, Jytte served in Director or Consultant positions with Greater Copenhagen Transportation, Mercuri Urval a/s, City of Copenhagen, Ministry of Environment and the Technical University of Denmark.

Jytte is a Chemical Engineer with a PhD in Socioeconomic Planning from the Institute of Mathematical Statistics and Operations Research at the Technical University of Denmark.

She will work in close collaboration with the Advisory Council of Europe, supported by our staff in Basel, Switzerland, and will also serve on DIA's global management team, which consists of DIA's global executives and six regional staff leaders. As she prepared for this new position, she spoke about its promises and challenges.
What most attracted you to DIA as an organization through which you could serve the health care communities in Europe?

What first attracted me was DIA’s obvious role in the development of health. At the moment, the health agenda is changing all over the world, including Europe. And to be part of that, with the platform of DIA as a non-profit, neutral global organization, is a gift.

What opportunities to serve in this new position are you looking forward to the most?

The challenge in Europe, as in nearly the rest of the world, is the financial challenges of the society. You have citizens who are used to a well-functioning health system and democracy also puts on challenges. We will have to, all together, find our way through, because if we just go on like we are now, in five or ten years we will go bankrupt. Nobody wants that.

On the other hand, you have the challenge of innovation. You have more empowered patients and citizens, and much more large demand for quality of life. I’m in a generation where we had everything, always, and we will always be demanding. And, of course, its European background, a very social health system. There needs some sort of radical change. Again, the possibility to be part of that is a privilege.

Why is the concept of “the empowered patient” so important?

‘The empowered patient’ is a very strange expression. If I could express that in another way, just to challenge that, I think it’s ‘the empowered citizens’ because we’re all ‘patients to be.’ I have always preferred to talk about citizens and not patients.

In some ways, this concept is contradictory. In general, or on average, we have more access to knowledge. We have the internet, but we also have much crap in the internet. And so, this empowerment is nearly two-faced: There is much more knowledge out there, but there is much more non-validated knowledge out there.

In some way, people have to be taken seriously. We are the citizens. It is our lives, and we need to have influence in that way. Demands and understanding are a part of the society that we are living in nowadays. There’s no way back. Instead of being frustrated – because I know many are frustrated, that patients complicate things and they don’t know things and so on – I think that we should see how it can add to the decision.

Benefit/risk is a key discussion in this area: Benefit/risk seen from a regulatory point of view is one thing; benefit/risk seen from a scientific point of view is something else; benefit/risk seen from a patient point of view is something third; benefit/risk from a future patient is something else again. In some way, if we continue this example, benefit/risk should be balanced out and the decision should level out the state of the art and the understanding of society. Could we tolerate that? Today we will not tolerate risks in some areas that we would have tolerated fifteen years ago. It’s a moving target because what is moving is society. And society is citizens. And therefore we need to be involved. It’s really complex.

Q: What unique challenges and benefits does the European Union (EU) legislative framework present to the science of therapeutic innovation and regulatory approval?

I have been part of that system, through my service with the Danish Medicines Agency, and I can see all the advantage of it. Normally, it is seen as a disadvantage. The US with the FDA, for example, and everybody in Europe says, ‘Oh, if we just had an FDA and then everybody could be settled in one minute.’ That’s a part of it.

But the strength of the European system – and I prefer to talk about its strengths instead of its weaknesses – is that we have managed to create a European medicines network. We have the European Medicines Agency, which has their roles to play. We have the European Commission. And we also have national agencies, and you cannot understand Europe without understanding that these are working together. And this has
been very hard, to have all these differences going in the same way. But the base of regulators is not only the people sitting (at the EMA) in London, it is all the staff at all the agencies working together in a scientific network.

What does that add, at least to Europe? It adds the possibility to take into account the very different historical and cultural approaches to health. The easiest example is the use of antibiotics: Southern Europe is completely different than Northern Europe. And if you just say ‘One size fits all,’ it would never work. We sometimes forget that this complex system also has advantages in coping with historical differences. Because harmonizing health or healthcare is harmonizing history.

In what specific professional disciplines or areas can DIA help the most professionals from industry, regulatory, and academia in Europe?

This question is very relevant. The new health care agenda or whatever you call it is a science. It’s much more than pharmaceutical or medical science. You can mention computer science, you can mention statistics, and also some of the more advanced biological sciences and so on. Development in innovation in health care will rely not on medical science or pharmaceutical science ‘adding some statistics’ but that they are fully integrated from the start. This will require the education of all scientific participants to see the synergy of really working together.

If you could change one thing about the clinical research enterprise in Europe, what would you focus on first?

It would be to arrive at true multidisciplinarity and efficiency in research. I would focus on the efficiency of clinical research. I don’t have the answers of how to make it more efficient but let’s dare to ask for efficiency in research.

Another would be to include other scientific areas. I can give you an example from my world. Operations research, as you might know, was so to say ‘invented’ during the Second World War. There was put together, either in the US or the UK or perhaps it was combined, a multidisciplinary group which piloted the efficient use of biostatistics, of mathematics and so on, within military technology, and they improved to create much more war technology, which of course creates things that are not so pleasant. But how would you ever have the invasion in Northern France during the Second World War if you had put that into ‘traditional development’?

If you say we have a burning platform for innovation, then you have to think out of the box. If you do it the traditional way, it takes too long. The goal is of course to improve the time and efficiency. Efficiency is also to be able to spot the potential ‘goes’ and get rid of the others, the ‘non-goes,’ more quickly. Focus on efficiency in research and a truly multidisciplinary approach that meets all stakeholder needs.

One of these opportunities is information technology, to see it truly as a tool to support and serve the business and the people. There are many opportunities but sometimes it’s so complex and so complicated that we simply give up, so you have this division between the people who can survive in that world and others who are strangers in that world. Of course, there are lots of opportunities not only for efficiency but also for communication – for getting together in a globalized world.

The other is the emerging discussion, if you could put it that way, which will challenge our understanding of, ‘What is a disease?’ If you go from a symptom-based disease understanding to a molecular-based understanding, then you will also have a shift of these paradigms. That will also mean very much to innovation.
But I don’t think any of these are quick and they will be very difficult because you will challenge the traditional system and therefore will also challenge the people who are the spokespersons for this system, and that’s always a little difficult.

What message would you like to share with DIA’s network of members and volunteers in Europe?

I would first say hello! I am very happy and challenged to work with you, and I really appreciate the contributions from our volunteers, members, individuals from industry, regulators, and so on. Because, at the end of the day, this area is so complex but also so important. If we don’t go this way together, we will not be able to achieve what we all want at the end of the day: Not eternal life, but better quality of life.

What message would you like to share about DIA’s upcoming 25th Annual EuroMeeting: Amsterdam 2013?

It’s a very important meeting. It is a great opportunity to strengthen your network and listen and contribute to the very important discussions in the sessions. We have a great program. What topics can you get? You can get everything! It’s a very easy way to be in one spot and be completely up to date in very attractive surroundings in Amsterdam, meeting all your good friends and making new friends.

New Director on New Pharmacovigilance Legislation in Europe

In an exclusive November 2012 interview with Scrip Regulatory Affairs, Jytte also commented on the new pharmacovigilance legislation in Europe, which will bring tremendous change to the drug regulation system in the EU.

It establishes a new EMA pharmacovigilance committee (PRAC) to contribute specific assessments or reports that will be in the public domain and must be taken into account by the Committee for Medicinal Products for Human Use (CHMP), the EMA’s key scientific committee. The legislation also allows the PRAC to hold public hearings. “I think it’s very important that we firstly find out what should they be used for, where will they give added value to the process,” she explained.

This new legislation has to work regardless of its challenges, she said. There will be problems – “but it’s our duty to overcome.”

To read the complete interview, visit www.scripregulatoryaffairs.com.
2012-2013 was a landmark year for the DIA Philanthropy Grant Program. A record-breaking 62 eligible applications were received. The Philanthropy Committee had a very difficult task of selecting winners to receive the limited funding.

It was not an easy choice, as each and every application showed compassion for patients and a determination to improve quality of life. On behalf of Chairman Tatsuo Kurokawa and the DIA Philanthropy Committee, we are proud to announce the awardees of the 2012-2013 Philanthropy Grant Program:

RARE GENOMICS INSTITUTE
Derwood, Maryland, USA

ARTHRITIS FOUNDATION, NORTHEAST REGION, INC.
New York, New York, USA

FUNDACION HUESPED
Buenos Aires, Argentina

Congratulations to these three fine organizations!
We also announce at this time that, upon the awarding of this year’s funding, the DIA Philanthropy Grant Program will sunset in its current form and will be transformed to provide direct support to DIA’s Patient Advocate Fellowship program. The DIA Philanthropy Committee will be dissolved.

The DIA Philanthropy Program began about 15 years ago with an annual budget of $150,000. It helped to promote individual and group activities which met the mission and vision of DIA. However, while DIA is still rooted in supporting causes that benefit the public, some important changes have taken place over recent years. As patients and their organizations play a role of increasing importance in research, regulatory and policy matters, the DIA Board of Directors (BOD) agreed in 2012 that the philanthropic resources should be directed to support DIA’s growing portfolio of patient programs – including fellowships and education – beginning in January 2013. “The DIA patient initiative includes programs in five events, including the EuroMeeting, European Rare Disease Conference, North America Annual Meeting, North America Rare Disease Conference, and EuroMeeting Clinical Forum. The bottom line here is that patients will continue to be at the center of the funding,” stated DIA Worldwide Executive Director Paul Pomerantz. Dr. Tatsuo Kurokawa added, “At the same time that DIA was promoting grant funding for others, we have been developing several initiatives that also serve a philanthropic purpose. For seven years, DIA has had various Patient Fellowship programs in Europe and North America, and there is interest in expanding this globally.” For additional information about DIA’s patient initiatives, please contact Donna Mayer at donna.mayer@diahome.org.

We extend heartfelt thanks to the DIA Philanthropy Committee for their time and dedication:
- Dr. Tatsuo Kurokawa, Chair
  Keio University School of Pharmacy
- Karen Arts
  Ontario Institute for Cancer Research
- Kelley Hill
  Shire Human Genetic Therapies, Inc.
- Truus Janse-de Hoog
  Medicines Evaluation Board
- Larisa Nagra Singh
  Quintiles
- Per Spindler
  BioPeople; University of Copenhagen

DIA 2013 Board of Directors Election Just Around the Corner

It’s never too early to start thinking of the upcoming DIA Board of Directors election. Even though the election is still a month away, please plan ahead and ensure that your member profile includes your current email address. In mid-March, look for an email that provides your personal link to the 2013 Election Ballot and secure electronic voting. Don’t miss your chance to vote in the annual DIA Board of Directors election!

With the disbanding of the Philanthropy Committee and the merging of two other committees, Bylaws revisions will be necessary. Your next issue of the Global Forum will provide more detailed information on these Bylaws revisions for 2013.
Members on the Move

DIA is committed to improving the professional practice 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.

DR. HUBERT C. CHEN was appointed Vice President of Clinical Development, Endocrine & Metabolic Disease, for Aileron Therapeutics, Inc. Dr. Chen previously served as Vice President of Translational Medicine for Regulus Therapeutics, and as Senior Director of Clinical Research and Corporate Development for Amynin Pharmaceuticals. Dr. Chen received his residency training at Massachusetts General Hospital, his MD from Columbia University, and a BAS in political sciences and biological sciences from Stanford University. He is board certified in internal medicine and endocrinology.

DR. SUSAN DALLABRIDA was appointed Senior Scientific Advisor for PHT Consulting Services. Dr. Dallabrida previously served as consultant and strategic advisor for Biogen Idec, Rubin Anders Scientific, Zafgen, Dana Farber Cancer Institute, Brigham & Women’s Hospital, and Children’s Hospital of Boston. Dr. Dallabrida earned her BS in biology and BA in chemistry from Bloomsburg (PA) University, and her PhD in biochemistry and molecular biology from Pennsylvania State University. She conducted her post-doctoral training at Harvard Medical School.

PROFESSOR EARL W. HULIHAN received the East Stroudsburg University Alumni Association’s Distinguished Alumni Award. Prof. Hulihan serves as Principal, EW Hulihan & Associates, Inc. He also serves as Professor at the Chinese State Food and Drug Administration Institute of Executive Development, as Associate Professor at University of Medicine and Dentistry of New Jersey and Visiting Professor at Shanghai University of Traditional Chinese Medicine. He has also served as Chair of the DIA Validation SIAC, a member of the DIA Annual Meeting Steering Committee, and as a member and Vice-chair of the DIA Advisory Council of North America. Professor Hulihan is also a past recipient of the DIA Founders Service Award.

ALISON LAWTON was appointed Chief Operating Officer of OvaScience. Alison previously served as Senior Vice President and General Manager of Sanofi Biosurgery (formerly Genzyme Biosurgery). In addition, Alison was appointed to the Verastem, Inc., Board of Directors. She also serves as a Director of Cubist Pharmaceuticals and MassMEDIC, and is a past President and Chair of the Board of the Regulatory Affairs Professional Society. Alison earned her BSc with Honors in pharmacology from King’s College London, University of London (UK).

CINDY PERETTIE has been named President, SCRI Services, for the Sarah Cannon Research Institute. Cindy previously served as Vice President, Global Regulatory Operations & Clinical Safety/Documentation, for Roche/Genentech. She also serves as Chair of the BIO (Biotechnology Industry Organization) Pharmacovigilance Group. Cindy earned her BS in biochemistry from the State University of New York and her MBA from St. Mary’s College (CA).

DR. DEBORAH A. THOMAS, was appointed Vice President, Regulatory Affairs, for Sunesis Pharmaceuticals, Inc. Dr. Thomas previously served as Executive Director, Regulatory Affairs; prior to Sunesis, she served as Vice President, Regulatory Affairs, for BiPar Sciences. Dr. Thomas earned her BS in microbiology and PhD in toxicology from the University of Kentucky.

DIANE WONG was appointed Director of Quality Assurance for ProTrials Research, Inc. Diane previously served as Associate Director of Clinical Quality Assurance for Janssen Alzheimer Immunotherapy Research & Development. Diane earned her BA in molecular cell biology from the University of California, Berkeley.

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. All submissions are subject to DIA editorial review and approval. Please remember to keep your DIA member profile current by logging into “MyDIA” and updating your contact information to reflect your new job title, employer or email address, too.
DIA EUROPE
TRAINING PROGRAMME
2013

Chemistry, Manufacturing and Controls (CMC) / Quality
- Global CTD Dossier – Regulatory aspects and focus on quality documentation
  including concepts of Quality by Design
  1-3 December 2013 | Dubai, United Arab Emirates | ID 13562
- Quality by Design for Chemical and Biotech Products – A hands-on course for the pharmaceutical industry and regulators
  11-13 September 2013 | Vienna, Austria | ID 13559

Clinical Research
- Advanced GCP Study Monitoring
  5-6 June 2013 | Basel, Switzerland | ID 13549
- Clinical Aspects of Quality Risk Management and Quality by Design
  19-20 September 2013 | Basel, Switzerland | ID 13560
- Clinical Project Management – Part I
  18-20 September 2013 | Basel, Switzerland
- Clinical Project Management – Part II
  Dates and location to be confirmed
- Clinical Statistics for Non-Statisticians
  24-25 October 2013 | London, United Kingdom | ID 13551
- Essentials of Clinical Study Management
  17-19 April 2013 | Vienna, Austria | ID 13527
  20-22 November 2013 | Paris, France | ID 13554
- Practical GCP Compliance Auditing of Trials and Systems
  23-25 October 2013 | London, United Kingdom | ID 13548

Non-Clinical Safety Sciences
- Non-Clinical Safety Sciences and Their Regulatory Aspects
  November 2013 | Lisbon, Portugal

Regulatory Affairs
- Authorisation of Biopharmaceuticals, Biosimilars and Advanced Therapies in Europe
  18-20 September 2013 | Basel, Switzerland | ID 13546
- European Regulatory Affairs: In-depth review of current registration procedures in the European Union
  21-22 February 2013 | Berlin, Germany | ID 13525
  6-7 June 2013 | Basel, Switzerland | ID 13550
  21-22 November 2013 | Paris, France | ID 13553
- Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics: Legal and practical aspects of devices
  10-12 June 2013 | Amsterdam, the Netherlands | ID 13547
- Health Authority Interactions – Preparation, consultation and implementation
  15-16 October 2013 | Location to be confirmed
- Health Technology Assessment (HTA)
  26-27 November 2013 | Zurich, Switzerland | ID 13561
- Paediatric Investigation Plans (PIP)
  15-16 April 2013 | Amsterdam, the Netherlands | ID 13503
- The Impact of Regulatory Affairs on Chemistry, Manufacturing & Controls (CMC)
  2-4 October 2013 | Basel, Switzerland | ID 13532
- US Regulatory Affairs: A comprehensive review of regulatory procedures for INDs and NDAs in the US
  6-8 November 2013 | Paris, France | ID 13552

Safety and Pharmacovigilance
- Benefit/Risk Management
  13-14 May 2013 | Zurich, Switzerland | ID 13523
  26-27 September 2013 | Prague, Czech Republic | ID 13524
- Diagnosis and Management of Drug-Induced Liver Injury (DILI)
  19-20 September 2013 | Paris, France | ID 13563
- How to Prepare for Pharmacovigilance Audits and Inspections
  11-12 June 2013 | Nice, France | ID 13555
  7-8 November 2013 | Paris, France | ID 13556
- Pre-Marketing Clinical Safety
  18-19 April 2013 | Vienna, Austria | ID 13556
- Signal Management in Pharmacovigilance
  10-11 June 2013 | Nice, France | ID 13557
  6-7 November 2013 | Paris, France | ID 13558

European Medicines Agency Information Days and Courses
- EudraVigilance Information Day
  17 May 2013 | London, United Kingdom | ID 13529
  22 October 2013 | London, United Kingdom | ID 13530
- Excellence in Pharmacovigilance: Clinical trials and post-marketing
  18-22 November 2013 | London, United Kingdom | ID 13522
- IDMP International Standards ICH M5/M2 and the Implementation of eSubmission of MPIs in the EU, Article 57(2) Information Day
  20 November 2013 | London, United Kingdom | ID 13531
- EudraVigilance courses:
  EudraVigilance – Electronic reporting of ICSR
  eXtended EudraVigilance Medicinal Product Dictionary
  Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of EudraVigilance at the European Medicines Agency

Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.
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