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International Federation of Associations of Pharmaceutical Physicians
I·2010·AUGUST

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President's Letter

Professor Dr Gerfried Nell, IFAPP President

Dear Colleagues

The Asia Pacific region is becoming a Pharmaceutical Medicine powerhouse. I envision a New Era in Pharmaceutical Medicine, which in fact is the theme of the upcoming 16th International Conference on Pharmaceutical Medicine – ICPM 2010. It will be held in Beijing, China, 23-26 October 2010 in conjunction with the 3rd Chinese Conference on Pharmaceutical Medicine and jointly organized by IFAPP and the Chinese Pharmaceutical Medicine Forum.

It is my personal pleasure to work with our Chinese colleagues preparing for ICPM 2010. Their engagement in organizing this conference reflects the same enthusiasm that is driving research progress and development in China. For further details on ICPM 2010 please note the interview below.

It reflects the consensus of the ICPM 2010 organizing committee. ▶▶ page 3

Reports & Concepts

ACRES: Alliance for Clinical Research Excellence and Safety

A Global Network for Clinical Research Modeled after the International Air Transport System

Greg Koski, PhD, MD, CPI (Hon), Harvard Medical School, Boston, Massachusetts, USA
Andrew Olmsted, MBA, IRBNet, Cambridge, Massachusetts, USA
Beat Widler, PhD, Hoffmann-La Roche Ltd., Basel, Switzerland

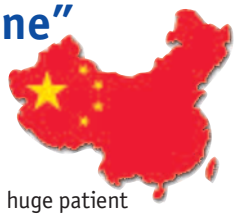
Clinical Research: Soaring Like an Eagle?

It was unusually cold in Monte Carlo last March when delegates from across the continent and around the world convened for the 22nd Annual EuroMeeting of the Drug Information Association. Many in attendance noted somewhat cynically that the current climate for clinical research around the world was not much better. Indeed, the meeting opened with a standing room only plenary session debate of the proposition that "the current approach to clinical trials is inefficient and ineffective." It wasn't much of a debate – in fact, neither side could hide its acceptance of the proposition. The synchronized nodding of agreeing heads in the audience was nearly enough to set off a tidal wave across the usually placid Cote d'Azure. In truth, a tidal wave of concern about the inefficiencies and ▶▶ page 3

Questions & Answers

"A New Era of Pharmaceutical Medicine"

The 16th International Conference on Pharmaceutical Medicine – ICPM 2010 – 23-26 October 2010 in Beijing, China – Interview with Professor Dr Gerfried Nell, IFAPP President



IFAPP World • Professor Nell, this 16th International Conference on Pharmaceutical Medicine is the second ICPM held in the Asia Pacific region and the second within the past four years. Is China and the Asia Pacific region as a whole a new hot spot for pharmaceutical medicine?

Professor Dr Gerfried Nell • The Asia Pacific region is becoming a powerhouse of Pharmaceutical Medicine due to its huge patient population, high quality of data, low cost and skilled manpower. Several forces are driving this progress.

Firstly during the past decade, pharmaceutical research and development activities have increased tremendously in the Asia Pacific region. Most globally operating pharmaceutical and healthcare companies have ▶ page 2

Questions & Answers

◀ page 1 already set up their R&D centers or are just about to do so; making huge monetary investments in the region, especially in the Greater China, India, Korea and Singapore markets, to name just a few.

Secondly, the number of professionals practicing Pharmaceutical Medicine has dramatically increased during the last ten years. Physicians and other healthcare professionals are either joining pharmaceutical companies or collaborating with them to conduct basic and clinical research.

Thirdly, governments' regulations adopted by countries in the Asia Pacific region controlling the conduct of clinical trials, drug approval and surveillance are becoming more and more flexible and harmonized with the regulations of the United States, the European Union and Japan. The clinical trial data collected in the region have become acceptable for the regulatory authorities of these industrialized countries.

Although Pharmaceutical Medicine has not been recognized as a medical specialty in most of the countries of the Asia Pacific region, it has been accepted as a post-graduate continuing education and development platform to the pharmaceutical physicians and clinical research professionals in the region.

IFAPP World • The theme of ICPM 2010 is "A New Era of Pharmaceutical Medicine" – is this relevant purely from a Chinese and Asia Pacific point of view or do you believe this is true for the global pharmaceutical business?

Professor Dr Gerfried Nell • Presently, due to the globalization of business operations, Pharmaceutical Medicine is undergoing huge changes and is entering a new and challenging era.

Firstly, the healthcare environment is evolving. The burden of chronic disease is soaring, patients are becoming more informed, regulatory authorities increasingly are demanding the highest quality and safety, while prevention also will gain a higher healthcare profile.

Secondly, pharmaceutical R&D has to improve its productivity and efficiency to satisfy all the unmet medical needs. R&D is becoming more virtualized and the research base is shifting to Asia. Demand for outcome data is increasing and a wider, more multidisciplinary talent base is in need.

Thirdly, public-private partnership is booming. By working together to build on advances in drug discovery and development, partnerships between public and private organizations are paving the way for a new generation of medicines to help improve and save more people's lives. Public-private partnership will play an important role in getting new medicines from bench to bedside by speeding up the translation of basic research into real applications to help patients.

It will be the vital role of Pharmaceutical Medicine to manage all these challenges in the next ten years.

IFAPP World • In addition to China, India and Korea also are very dynamic countries in the Asia Pacific region with regards to Pharmaceutical Medicine. Isn't that challenging for China? Or is there cooperation rather than competition?

Professor Dr Gerfried Nell • The pharmaceutical market in China is one of the fastest growing pharmaceutical markets in the world. It is estimated it will be the 5th largest by 2010 and the 3rd largest by 2020. China offers many opportunities for Pharmaceutical Medicine, e.g., a huge patient population, relatively low costs for preclinical and clinical research, and well-educated R&D professionals. The Chinese government is committed to promote and protect pharmaceutical R&D as a key business or a "pillar of industry".

India also is considered as an important and well-respected country with regards to pharmaceutical R&D in the Asia Pacific region. The huge population of patients who are easy to recruit, the diverse disease profile within the patient population, the well-equipped institutions, and the highly skilled professionals are the major forces to establish a new era of Pharmaceutical Medicine in India. The drug laws in India are also being amended to allow same phase clinical trials as in the country of origin. In addition, India has regulations that provide fiscal incentives for R&D activities, and India also boasts about a robust IT industry offering IT solutions to stimulate pharmaceutical R&D.

Korea also is doing very well in Asia by conducting high-quality clinical research. Korea is one of the first-round countries in Asia to set up their Society of Pharmaceutical Medicine. The 14th International Conference on Pharmaceutical Medicine ICPM 2006 held in Seoul with the theme "Beyond the Horizon" was a very successful event in the history of IFAPP.

The collaboration and partnership of our colleagues in China, India, Korea and other countries is vital for the development of Pharmaceutical Medicine in the Asia Pacific region. We are looking forward to join their efforts to further more promote Pharmaceutical Medicine globally.

Professor Dr Gerfried Nell, IFAPP President: "Pharmaceutical Medicine is undergoing huge changes and is entering a new and challenging era."

IFAPP World • What are the key aspects of the scientific programs of ICPM 2010?

Professor Dr Gerfried Nell • ICPM 2010 is a 3-day event. Key topics on the scientific program include: Global R&D Strategy, Harmonized Regulations and ICH, Academic and Industry Collaborations on Clinical Development, Bridging Strategy in Drug Development for Different Ethnics Populations, Conducting Proof-of-Concept Studies in China, China Regulations as Compared to ICH Regions, Medical Governance – The Role of Chief Medical Officer in the Pharmaceutical Industry, Experiences Sharing on Clinical Developments in Asia, Central and Eastern Europe and Latin America, Simultaneous Global Development, India Highlights, Latin America Updates, Outcome Research & Pharmacoeconomics, the Role of Large Population Studies, Defining the Value of a New Drug, "Pay for Results" – is it the Right Approach? The speakers are key opinion leaders coming from 15 different countries worldwide.

IFAPP World • Last but not least: What should ICPM 2010 attendees expect in Beijing, the capital of China?

Professor Dr Gerfried Nell • We should be aware, that the capital city of the People's Republic of China, Beijing, also called Peking, is a fast growing, dynamic metropolis with a rich cultural heritage and a modern life, high-rising buildings, shopping malls and a vast number of international hotels.

In August 2008, Beijing hosted the Olympic Games and the well-known National Stadium, better known as the "bird nest", is not far away from the National Convention Center, the site where ICPM 2010 will be held.

And as the organizers say, autumn is a particularly pleasant time to visit Beijing as the days are warm and the leaves of the many trees in the city turn glorious shades of red and gold.

We look forward to meeting all of you in China's capital Beijing soon.

IFAPP World • Thank you and wishing you and your colleagues well for ICPM 2010.

Professor Dr Gerfried Nell was interviewed by Eckhard Boettcher-Buehler, IFAPP World Editor in Chief. ■

President's Letter

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I look forward to this exciting conference and kindly invite you to attend. I hope to meet many colleagues from all over the world on this occasion. The ICPM 2010 Scientific Program at a Glance is attached at page 10.

A substantial contribution for this IFAPP World issue is the presentation of the Alliance for Clinical Research Excellence and Safety – ACRES. It is a global network for clinical research modeled on the international air transport system – an independent, non-for-profit, non-governmental membership organization dedicated to promoting safety, professionalism, excellence and opportunity in clinical research globally for the benefit of all. As the creative head of this alliance, Dr Greg Koski from the Harvard Medical School in Boston, USA, explains, it will positively align ethics, scientific integrity and good business practices, provide appropriate opportunities and incentives to further the mission of drug and device development in a safer, scientifically sound, socially responsible manner that rewards all participants and stakeholders.In fact, clinical research excellence and safety increasingly is a salient topic as outlined in the article "ACRES: Alliance for Clinical Research Excellence and Safety" starting on the front page. IFAPP was the first to join this alliance.

I kindly invite you to get involved and share your thoughts about it and to cooperate with us in developing Pharmaceutical Medicine worldwide.

With kind regards
Professor Dr Gerfried Nell,
IFAPP President, Austria ■

Reports & Concepts

◀◀ page 1 • ACRES: Alliance for Clinical Research Excellence and Safety

ineffectiveness of the processes upon which international pharmaceutical and device manufacturers depend for testing the safety and efficacy of promising new products has grown steadily as costs soar, enrollment in trials languishes, pipelines run dry, blockbuster patents expire, regulatory agencies run amuck in their well intended efforts to streamline the process, and public outrage over exploitation of "treatment naïve" patients (an euphemism for patients with no access to healthcare), particularly in developing countries, leaves a black mark on the entire industry.

Earlier this year, Pfizer supported and Harvard University hosted a Multi-Regional Clinical Trials Summit, and the same message could be heard loudly and clearly – the way we are going about clinical trials today is simply not sustainable and is not an acceptable model for the future. And yet, as delegates from the several working groups offered their observations and recommendations, many attendees, including myself, seemed unwilling to believe, even in the face of enormous hope and good will, that the kinds of changes needed are likely to be realized without adoption of a new paradigm.

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Reports & Concepts

◀ page 3 To achieve real progress, the clinical research endeavor must adopt a paradigm in which highly competitive companies, fiercely independent regulatory agencies and operationally challenged ethics committees actually work together toward goals that serve their common interests, namely, to get new drugs and devices safely and efficiently tested and ultimately, marketed. All of this, of course, must be done in an ethical and professional manner that enhances safety, improves quality, dramatically cuts costs, slashes regulatory red-tape and concurrently builds sustainable capacity in developing countries.

"Have you ever heard of the Chance brothers?" one of my colleagues used to ask when confronted with the unlikely or the impossible – "Fat Chance, Slim Chance and No Chance", he would retort. I suppose many in the clinical trials endeavor today would react similarly if asked whether it would be possible to achieve even a modest fraction of the goals alluded to above. But if one were to ask the same question of individuals working today in the international air transport industry, the response would be simply, "Why not?"

The notion that the airline industry may have something very important to teach the pharmaceutical industry first occurred to me on our final approach to San Diego International Airport about seven years ago. As we came in for our landing, I realized that flights were also arriving in San Diego from Asia, South America, and other countries, and yet all were speaking the same language and using the same policies and procedures for approach and clearance to land, and communicating with the same traffic controllers, would use the same runways and baggage handlers, even though the several airlines were fierce competitors.

Somewhere along the line, the airlines realized that everyone in their safety-conscious, tightly regulated, highly competitive industry would benefit from building a shared infrastructure, adopting uniform standards for safety, training, policies and practices, and ensuring that these standards are met in all participating countries through independent third-party validation, namely accreditation of facilities and certification of processes and professional personnel, from the pilots to the luggage handlers.

It didn't take much searching to find out that in 1945, the major international airlines came together to create the International Air Transport Association (IATA) with precisely these goals in mind (www.IATA.org). From its start with a dozen carriers, IATA has since grown to include over 230 airlines operating internationally, with thousands of airports, all operating within a common international framework, carrying over 95% of all international passengers and goods. The organization has worked with regulatory agencies from around the world to negotiate uniform policies and procedures that have resulted in one of the safest, most efficient, and yet still fiercely competitive industries in existence – not just an international system for air travel, but a truly global system (Table 1).

While such a system sounds complex, the concept is exquisitely simple, as depicted in Figure 1. It consists of a global network of accredited airports and specifically trained and certified air-traffic controllers that are completely interactive, allowing flights to originate and land safely and efficiently anywhere in the world.

In many respects, the pharmaceutical industry today finds itself in a position not unlike that confronting the air transport industry in 1945. Amidst growing competition and skyrocketing costs for clinical trials, the industry has increasingly turned to the international arena in search of ways to get clinical trials done more expeditiously by taking advantage of the less restrictive regulatory environment in some developing countries and the readily available populations of patients who appear more eager to be trial subjects than their counterparts in Europe and North America, the traditional base for most clinical trials. The rate of growth of trial numbers and enrollment of subjects in countries like India, China and Brazil, as well as in Eastern Europe continues to accelerate, as do concerns about quality, ethics and effectiveness of regulatory oversight. The list of countries to which industry now looks for investigators and research sites grows annually.

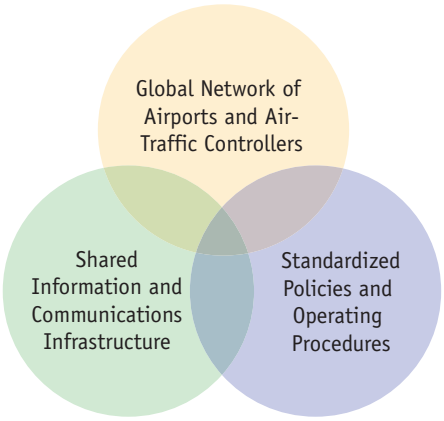


Figure 1 • A Global Air Transportation System

Clinical research and drug development are clearly international endeavors today, but the expansion of international venues poses extraordinary challenges, particularly when trials are placed in countries lacking a strong tradition participation in such work, which may also lack a well-established infrastructure to support it. With safety, quality and efficiency being the principles drivers of responsible clinical trials and drug development, the pharmaceutical industry shares common ground with the airline industry, where safety, service and efficiency are paramount, not to mention the necessity to control costs in a highly competitive and costly business.

At the recent Multi-Regional Clinical Trials Summit mentioned above, a senior manager from a major pharmaceutical company noted that for a single large scale Phase III international trial, the company may screen as many as 8000 potential sites, from which as many as 6000 may be chosen to ensure sufficient and timely enrollment, at a fixed start-up cost of around 15,000 Euros. Of these many sites, two-thirds are likely to enroll no more than one or two subjects, and yet they must be monitored regularly, and still too many will fail to operate in compliance with good clinical practice standards and regulatory requirements, ▶ page 5

Table 1 • International Air Transport Association

- ***Safety & Security*** to promote safe, reliable and secure air services.
- ***Industry Recognition*** to achieve recognition of the importance of air transport woldwide social and economic development.
- ***Financial Viability*** to assist the industry to achieve adequate levels of profitability, by optimizing revenues while minimizing costs (fuel, charges and taxation)
- ***Products & Services*** to provide high-quality, value for money, industry required products and services that assist the airlines in meeting the needs of the consumer
- ***Standards & Procedures*** to develop cost-effective, environmentally-friendly standards to facilitate the operations of international air transport
- ***Industry & Support*** to identify and articulate common industry positions and support the resolutions of key industry issues (congestion, infrastructure).

Reports & Concepts

◀ page 4 potentially jeopardizing the entire trial. One need not rely upon "new math" to appreciate that much of the company's investment is squandered at these non-performing sites and that focused investment in the preferred sites could ensure quality, safety and improved performance at greatly reduced cost. And as a positive spin-off benefit, investment in building high quality sites in developing countries can create a sustainable, valuable local enterprise that supports local economies – a true win-win option.

If the pharmaceutical and medical device companies of the world were to look to the international air transport system for insight into how the clinical trials process could benefit from a comparable approach, a true global network for clinical research, what might such a system look like? As depicted in Figure 2, the similarities are strikingly obvious. This is not at all surprising, given the similarity of the challenges and the nature of the proposed solutions, along with the tools available and the drivers and incentives, as discussed above.

Imagine a network of 40,000 sustainable research sites, all independently accredited according to internationally accepted uniform global standards, all staffed by trained and certified professional personnel, supported by a shared, web-based information system and data-warehouse that would permit tracking of trial progress in real time, including continuous pharmacovigilance surveillance, monitoring and auditing data as well as related quality improvement measures, all operating according to uniform standard operating policies and procedures adopted as part of an industry-wide effort to streamline operations and improve quality and safety.

Impossible? No more so than the prospect of the international airlines working together to realize their shared goals in a global marketplace must have seemed in 1944, the year before they agreed to establish IATA. The results speak for themselves.

Figure 2 • A Global Clinical Research System

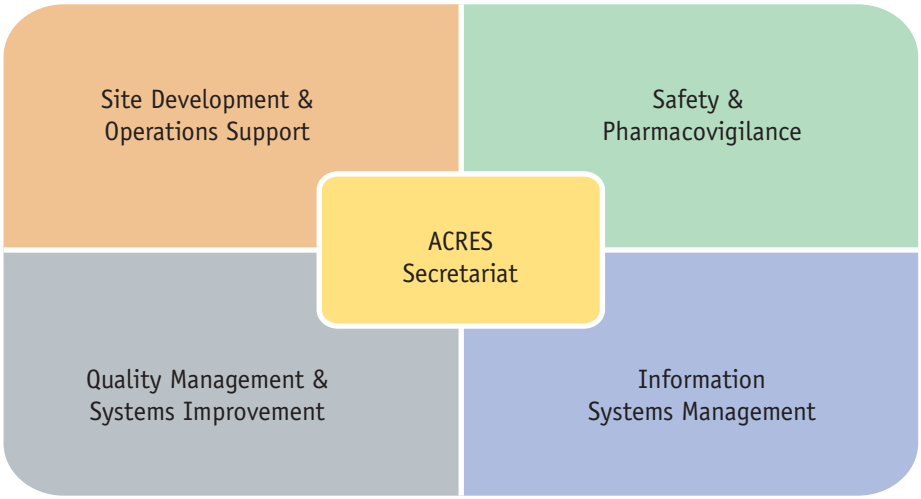


Figure 3 • ACRES Network Architecture – The Core

So, what can and should the pharmaceutical industry do? With the model of IATA in mind, consider what could happen if even a dozen of the world's leading drug and device companies were to join forces as the highly competitive airlines did in 1945 to build a global network infrastructure to support and streamline their global operations and enhance safety by establishing a non-profit, non-governmental organization to spearhead the required initiatives, set the relevant standards and build the technological infrastructure for a truly global system, one in which all of the components work seamlessly and interactively to achieve shared goals. Overnight, such a system could revolutionize the field of clinical research. Once established, a global clinical trial could be approved, up and running at professionally accredited quality sites in just a few weeks compared with the many months currently required, with dramatically reduced costs and enhanced productivity, quality and safety.

Toward this end, and after years of discussions among like-minded individuals and organizations that are committed to safe, high-quality efficient clinical trials, the Alliance for Clinical Research Excellence and Safety, ACRES, is being created in the likeness of IATA. Still in its nascent stage, ACRES charter and by-laws are being written and the new organization will soon be constructing a web site at www.acresglobal.net. The heart of the new organization will be its secretariat and 4 proposed operating divisions as depicted in Figure 3. Supported by a robust shared information platform, ACRES will work to establish a network of accredited clinical trials sites around the world, taking full advantage of existing networks and organizations to jumpstart the process. ▶ page 6

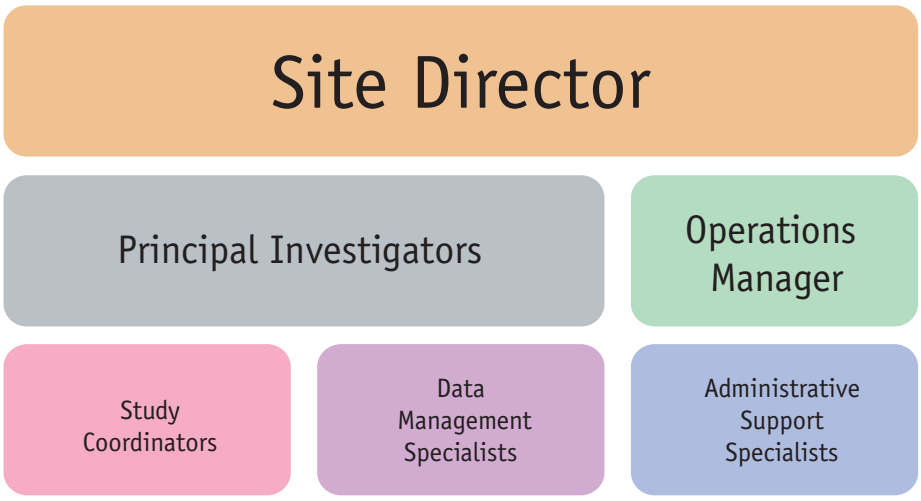
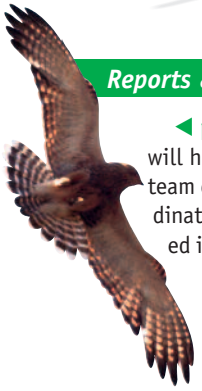


Figure 4 • ACRES Network Architecture – The Sites



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◀ page 5 Each participating site will have a certified clinical research team consisting of investigators, coordinators and data managers as depicted in Figure 4.

ACRES, like IATA has done for the airline industry, will work to identify best-practice policies and procedures that can be adopted and implemented uniformly across the network, using the information technology platform to facilitate and streamline workflow and enhance both quality and regulatory compliance. Real-time data capture from process events such as enrollment, adverse event reporting, protocol deviations, audit outcomes (including key risk and performance indicators) and other activities can be used to populate a data warehouse to support continuous quality and safety improvement (Table 2).

Table 2 • ACRES Network Infrastructure – The Neural Net

- Web-based integrated information system with central data warehouse and knowledge engines
- System support/facilitation of all operations
  - Point-of-entry EDC, including AE reporting
  - SOP driven continuous compliance / quality control
  - Shared database for trial initiation and support
  - Centralized quality assurance and safety monitoring

ACRES is currently seeking as charter members like-minded organizations committed to excellence and safety in clinical research, organizations that can share their expertise to support ACRES mission – the International Federation of Associations of Pharmaceutical Physicians, IFAPP, was the first to join, and it is likely that soon others will follow. As envisioned, ACRES would be supported by a trust fund established by initial contributions from industry partners and sustained by user fees.

Much remains to be done and many details must be ironed out before ACRES can become a viable organization, but the seeds have been planted and they are growing. Looking ahead, the field of clinical research may be more fertile than ever.

For further information about ACRES or to become involved, please e-mail: gkoski@acresglobal.net. ■

IFAPP's CEPM Update

South Korea: Yonsei University Pharmaceutical Medicine Course Accredited by CEPM

The Yonsei University Graduate School of Public Health in Seoul, South Korea, has become the first institution in Asia to receive a Council for Education in Pharmaceutical Medicine (CEPM) accreditation for a Pharmaceutical Medicine course. The course, initially established in 2007 with the collaboration of the Korean Society of Pharmaceutical Medicine (KSPM), is directed by Associate Professor Dr Hye-Young Kang of the Graduate School of Public Health along with Co-Director Professor Dr Min-Soo Park (see the picture below) of the College of Medicine. Both a Diploma program and a longer Master's course in Pharmaceutical Medicine and Industry are offered.

For the Record · The **Council for Education in Pharmaceutical Medicine (CEPM)** was created in 2001 under the auspices of IFAPP; its main objective was to undertake the task to harmonize the programs of the existing postgraduate courses in Pharmaceutical Medicine.

Strong in Pharmacoeconomics

While both the Diploma and Master's programs cover the CEPM syllabus in Pharmaceutical Medicine, the program is especially strong in pharmacoeconomics and aspects of clinical pharmacology including pediatric and maternal-fetal clinical pharmacology. Professor Kang commented on the importance of pharmacoeconomics in the Korean healthcare system and said, "Korea has introduced the positive drug listing system since 2007. This new system requires drug companies to submit cost-effectiveness evidence for new drugs to be included in the reimbursement list by the National Health Insurance."

The course is also remarkable for the number and variety of instructors from academia, industry and the Korean Food & Drug Administration. Commenting on the reasons behind utilizing a broad faculty for the course Professor Kang noted, "We tried to ensure that our program provides students practical knowledge as well as theory. So, experience shared by various experts from the real field is a crucial resource of our program."

An Example for Other Universities

While the Yonsei University Pharmaceutical Medicine course is the first to achieve CEPM accreditation in Asia, it is expected that programs in China, India and Japan will also work toward CEPM accreditation. Professor Dr Jean-Paul Deslypere, member of the IFAPP Executive Committee and Chair of IFAPP's CEPM, commented on the prospects for Pharmaceutical Medicine education in Asia: "More and more biomedical research is being done in Asia and for this it is important to have well trained personnel so that the quality of the work done is guaranteed. Since Pharmaceutical Medicine is not recognized as a medical specialty in Asia yet, it is even more important to establish robust training programs in order to give all persons involved in Pharmaceutical Medicine a strong base to start their professional work. Let us hope that the pioneer course at Yonsei University will be an example for many universities in the region."

Dr Stewart Geary, Japan, member of the IFAPP Executive Committee and of the Japanese Association of Pharmaceutical Medicine (JAPhMed) ■

IFAPP's CEPM evaluation procedure at the Yonsei University Graduate School of Public Health in Seoul, South Korea: (from left to right) Dr Yil-Seob Lee (KSPM and GSK; Seoul, South Korea), Dr Stewart Geary (IFAPP Board Member, evaluating the course, Tokyo, Japan), Professor Dr Min-Soo Park (College of Medicine, Seoul, South Korea) and Professor Dr Hye-Young Kang (Graduate School of Public Health, Seoul, South Korea)

IFAPP News & Views

IFAPP News Alerts

10-12 November: 7th Latin American Congress of Clinical Research: Harmonization and the Future of Drug Development in Latin America, São Paulo, Brazil

23-26 October: 16th International Conference on Pharmaceutical Medicine – ICPM 2010, Beijing, China

24 June: In autumn IMI PharmaTrain launches New High Quality Training Programmes on Integrated Drug Development Sciences / Pharmaceutical Medicine with Europe-wide Scope and Impact.

5 April: In 2010, "Shaping IFAPP's Future" is a puzzle worth exploring – an article in Pharmaceutical Medicine [Pharm Med 2010; 24(1):7-10]

1 February: New President for the Sociedade Brasileira de Medicina Farmacêutica (SBMF), Brazil.

29 January: GlaxoSmithKline provides IFAPP Platinum Sponsorship

4 January: New IFAPP EC member from the Korean Society of Pharmaceutical Medicine (KSPM), South Korea

4 January: New President for the Academy of Pharmaceutical Physicians and Investigators (APPI), USA

4 January: New President for and IFAPP representative from the Asociación de Medicina de la Industria Farmaceutica Española (AMIFE), Spain

4 January: New IFAPP EC member from the Belgian Association of Pharmaceutical Physicians (BeAPP), Belgium.

Detailed information available at: www.ifapp.org/home/news/latest-news/archive or via subscriptions (see below). ■

IFAPP News & Views

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IFAPP's Regional Update

Latin America: GCP Inspections and Education in Pharmaceutical Medicine

Dr Paulo Aligieri, Executive Secretary of the Brazilian Society of Pharmaceutical Medicine, São Paulo, Brazil, reports from the 35th Brazilian Congress of Pharmaceutical Medicine

Pharmaceutical Medicine's self-conception is to provide medical doctors, clinical investigators and clinical research personnel, members of Research Ethics Committees (RECs) respectively Institutional Review Boards (IRBs) and regulatory authority officers with a practical, in-depth understanding of the issues involved in clinical research and development, in clinical trial quality assurance, in health economics, pharmacosurveillance and in ethical medicine promotion. This was highlighted at the 35th Brazilian Congress of Pharmaceutical Medicine (PM) in São Paulo, Brazil, in November 2009 by Dr Gustavo Kesselring, at that time President of the Brazilian Society of Pharmaceutical Medicine (Sociedade Brasileira de Medicina Farmacêutica – SBMF) and Member of IFAPP's Executive Committee.

Initial Remarks

Congress attendance included more than 300 attendees from several Latin American countries. The lectures and slides were all in English, but simultaneous translation was available in all sessions.

Speakers came from national and international academic health centers, national regulatory agencies, governmental funding agencies, national medical associations and sponsors of clinical research. Dr Dirceu Raposo de Mello, President-Director of the Agência Nacional de Vigilância Sanitária (ANVISA), the Brazilian regulatory agency, gave a well-regarded lecture, while he was honored with the metal plate awarded by the SBMF board (see photo).

Brazil has installed a double level clinical research ethics judgment protocol. If the sponsor of the trial is an international company, decisions of a local REC respectively IRB have to be reinforced by a centrally held national committee called Comissão Nacional de Ética em Pesquisa (CONEP). Representatives of both levels had lectures at the 35th Congress.

At the general SBMF congress assembly, a new board of directors was elected with Dr Marcelo Lima, Medical Director, Latin America GE Healthcare, as the new SBMF President for 2010 and 2011 and Dr Gustavo Kesselring, former SBMF President, as the Vice-President for 2010 and 2011; Dr Kesselring will remain the delegate to the IFAPP Executive Committee.

FDA Good Clinical Practice inspections in Latin America

Dr David Lepay, Senior Advisor for Clinical Science of the U.S. Food and Drug Administration (FDA) and Director of the Good Clinical Practice (GCP) Program, well known and much respected by Brazilian professionals involved in clinical trials, spoke about „FDA GCP Inspections in Latin America – Findings and Where We Must Improve".

GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting research that involves human subjects. GCP embraces trial objectives, trial design, study oversight, data collection and quality assurance, study analysis, as well as human subject protection in clinical trials.

▶ page 8

Dr Gustavo Kesselring, at that time SBMF President, honors Dr Dirceu Raposo de Mello, President-Director of the Agência Nacional de Vigilância Sanitária (ANVISA), the Brazilian regulatory agency, and presents him the SBMF Metal Plate.

IFAPP's Regional Update

◀ page 7 With regard to inspections of GCP practices, Dr Lepay stated that the FDA must have subject-matter jurisdiction over the data of any trial and any site in order to conduct inspections. FDA jurisdiction includes U.S. and non-U.S. trial sites, which are conducting a trial for any U.S. investigational new drug (IND) application.

Commonly an inspection is pre-announced and performed by one or two inspectors, accompanied by a medical scientific expert. An inspection lasts four or five days on average. Inspectors follow the Compliance Program Guidance Manual (CPGM), publicly available for each inspection type.

After the inspection, the FDA inspector will draw up an Establishment Inspection Report (EIR), which will be submitted to the inspected site and the FDA headquarters for review. The responsible persons from the inspected site are encouraged to respond to the report within 15 days; these responses will be considered for the headquarters' review. After the FDA headquarters completed its review, a final inspection category will be assigned:

- NAI: No Action Indicated (GCP compliant)
- VAI: Voluntary Action Indicated
- OAI: Official Action Indicated (compromise to the goals of GCP).

The first FDA inspection in Brazil was completed in 1996 Dr Lepay noted. Since then 20 have been finalized up to March 2009. Eight were classified as NAI and twelve as VAI. Most common GCP violations were related to …

- failures to follow protocol (n=8)
- record keeping (n=4)
- failures to report adverse drug reactions (n=4)
- inadequate drug accountability (n=1)
- failures to inform RECs respectively IRBs about protocol changes or provide progress reports (n=1).

GCP inspections in Brazil: ANVISA's perspective

Dr Ricardo Eccard da Silva is a health professional and ANVISA inspector in charge of clinical research regulatory control in Brazil. He spoke on GCP inspections by the Brazilian authorities.

Since its establishment in 1999, ANVISA has developed progressive regulations regarding therapeutic or diagnostic interventions utilizing drugs or medical devices in clinical research phases I, II and III. Dr da Silva works at the Coordination of Researches, Clinical Trials and New Drugs (COPEM), which is a section of the General Office of Drugs (GGMED) at ANVISA.

In addition to inspection of clinical research sites, this ANVISA section also assesses …

- clinical trial projects
- control of imported products for human related research
- expanded drug access and compassionate use.

Dr da Silva's presentation clarified that inspections will be directed to research and clinical trials while ANVISA's inspectors are not concerned with site certifications.

The site will be notified 15 days prior to a routine inspection. In the case of a complaint or suspected irregularities, the inspection may start without prior notification.

During the initial phase, the agency has focused on particular aspects, e.g., …

- trials or sites that have not been inspected by other agencies
- trials that have a high number of subjects
- trials with high numbers of serious adverse events
- high trial complexity.

Three inspections were concluded by ANVIA in 2009 with these findings:

- The trial site did not provide rooms for trial subjects to make an informed consent privately.
- The trial subjects did not receive a copy of the informed consent form.
- There was no documentation available concerning certification, calibration, validation and quality, guides or Standard Operating Procedures (SOPs) did not exist.
- The investigational products were not stored properly.
- The archive of trial documents was not adequately organized.
- A monitoring schedule was not available.

Education in Pharmaceutical Medicine: Status in Latin America

During the past 10 years, pharmaceutical companies have increased their research in Latin-American countries. Considering the increasing clinical research demands, the medical associations of the respective countries have established courses to educate and train professionals who work within the pharmaceutical industry or at research sites and doing clinical research.

Dr Luis Collia, IFAPP Past President and Medical Manager of Merck Serono in Argentina, has described the education and training initiatives of three Latin American countries.

Mexico

In Mexico City a postgraduate course in Pharmaceutical Medicine called Especializacion en Medicina Farmaceutica (Specialization in Pharmaceutical Medicine) has been established in January 2000 at the Escuela Superior de Medicina (Superior School of Medicine) at the Instituto Politécnico National. The course is offering the degree Pharmaceutical Medicine Specialist which is ▶ page 9

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IFAPP's Regional Update

Chair persons and speakers at the session Globalization of Clinical Trials: Challenges in the Ethical Regulatory Environment (from left to right): Dr Ricardo Eccard da Silva (Brazil), Dr Gustavo Kesselring (Brazil), Dr Fabio Thiers (USA) and Dr Octávio Ferraz (England).

For the Record · **Innovative Medicines Initiative (IMI)** is a coordinated public and private partnership between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA). It will boost Europe's biomedical R&D base, help correct the relative under-funding of biomedical R&D in Europe compared to other regions of the world and create biomedical R&D leadership for Europe to benefit patients and society. Importantly, IMI will help to maintain and augment the European science base in order to make Europe more competitive and an attractive place for biopharmaceutical research investment.

◀ page 10 recognized by the Superior School of Medicine. This course has been accredited by IFAPP's Council for Education in Pharmaceutical Medicine (CEPM – see text box on page 6). Thus far 112 experts have been conferred with the degree. In Mexico Pharmaceutical Medicine has been recognized as a medical specialty in February 2007.

Brazil

The Curso de Especialização en Medicina Farmacêutica (Course of Specialization in Pharmaceutical Medicine) in Brazil was created in 1999 at the Universidade Federal de São Paulo (Federal University of São Paulo) and was accredited by IFAPP's CEPM in September 2007. The course offers the degree Pharmaceutical Medicine Specialist which is recognized by the Federal University and the Brazilian Ministry of Education.

Thus far 110 professionals have graduated; 46 professionals attended the course in 2009.

In addition to this course, there are many events spurring scientific and professional progress. Since 2001, a Forum of RECs respectively IRBs of the Estado de São Paulo has been organized each year by four faculties of medicine of São Paulo, supported by the SBMF. A partnership with the Pharmaceutical Producers Union in São Paulo prompted several events related to Pharmaceutical Medicine, namely clinical research development, old and new laws ruling clinical trials, health economics, career in the pharmaceutical industry, pharmacosurveillance and ethical support to pharmaceutical marketing, etc.

Argentina

Many steps forward in Pharmaceutical Medicine have been enabled by the devoted work of the Sociedad Argentina de Medicina Farmacéutica (SAMEFA – Argentinean Society of Pharmaceutical Medicine). As in Mexico, Pharmaceutical Medicine is a formally recognized medical specialty in Argentina. However, Dr Collia reaches further and said, "With regards to Pharmaceutical Medicine in Latin America we need to develop a program similar to the Innovative Medicines Initiative (IMI – see text box above right) of the European Union. In this way, the first step is to integrate Chile, Colombia, Ecuador, Peru, Venezuela and other Latin American countries in a multinational program for continued medical education (CME) and continued professional development (CPD) in Pharmaceutical Medicine". As a first step he highlighted the need to establish a Latin American working group with the aim of creating a network of postgraduate courses on Pharmaceutical Medicine across Latin America with two final objectives:

- To establish courses in each country adapted to current needs, harmonized and subject to a process of accreditation, certification and quality control on an international level.
- To obtain recognition of Pharmaceutical Medicine as a medical specialty and the title Physician Specialist in Pharmaceutical Medicine in all Latin American countries.

Details regarding CEPM accredited courses in Pharmaceutical Medicine please find at www.ifapp.org/home/education/courses/ifapp-accredited ■

IFAPP's Vision Statement

"By 2011, IFAPP is recognized and accepted as an authoritative voice on the medical aspects of the pharmaceutical industry and education and standards within Pharmaceutical Medicine by governmental and regulatory authorities, pharmaceutical industry bodies, the public, healthcare providers, healthcare professionals, academic bodies and the media."

THE FLAG

IFAPP World is a publication of the

International Federation of Associations of Pharmaceutical Physicians (IFAPP)

IFAPP, founded in 1975, is a non-profit organization with 28 national member associations worldwide. IFAPP acts as an international forum for all pharmaceutical physicians' organizations worldwide by dealing with matters brought to its attention through national member associations.

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Design & Layout:
Novum Verlag & Werbung GmbH, D-90542 Eckental, Germany

16th International Conference on Pharmaceutical Medicine – ICPM 201023-26 October 2010 in Beijing, China

Scientific Program at a Glance

Oct.23, 2010 Saturday

Pre-conference Workshop:

(1) Career development in pharmaceutical R&D
(2) Data and Safety Monitoring Board – roles & functions

Oct.24, 2010 Sunday

Theme: Where are we? Current status in developing new medicines

Opening Ceremony

Plenary session – Keynote Speeches

Global R&D Strategy
Harmonized Regulations and ICH
Academic and Industry Collaborations on Clinical Development

Coffee Break

Innovations in Clinical Development

Bridging strategy in drug development for different ethnics populations
Conducting Proof-of-Concept studies in China
Phase 0 studies in oncology: a new strategy?
Developing vaccines for chronic diseases

Lunch

Track I	Track II
Regulations to Market Place (1)	**Regulations to Market Place (2)**
* Are regulations facilitatory or prohibitory?	* Roles of Medical Marketing in today's market place
* EU clinical trials directive; 10 years of experience	* Medical marketing activities in Asia
* FDA regulations for studies in children: an analysis MHW role in Japanese environment	* Marketing a global drug in Latin America
* China regulations as compared to ICH regions	

Coffee Break

Plenary Session: Medical Governance

The role of Chief Medical Officer in the pharmaceutical industry
(Panel discussion with CMOs) China + Japan + Korea + US+EU

Oct.25, 2010 Monday

Theme: Issues and Challenges in Drug Development

Plenary session – Keynote Speeches

Role of Emerging Markets in Delivering New Medicines
Experiences sharing on clinical developments in Asia, CEE, and Latin America
Simultaneous global development – What does it mean for China?
India Highlights
LatAm Updates

Coffee Break

Managing Risks

Risk management plans in drug development
Regulators plans to minimize risks
Pharmacovigilance in the market place
Recent drug withdrawals: have we learnt some lessons?

Lunch

Track I	Track II
* Outcome research & Pharmacoeconomics	* Lessons learnt from Oncology Drug Development
* The role of large population studies	* Accelerating oncology clinical development in Asia
* Defining the value of a new drug	* Opportunities and Challenges of Oncology clinical development in China
* "Pay for results": is it the right approach?	

Coffee Break

* Quality and Ethics Consideration	* Clinical Operations strategies under financial constraints
* How to improve the study quality – from clinical quality assurance viewpoints	* Optimal patient enrollment strategies
* Chinese patients on study informed consent process	* Development of SMO in China
* ACRES program	* Operational Excellence to improve efficiency in clinical development
* The fight against counterfeiting medicines	

Oct.26, 2010 Tuesday

Theme: Future drivers

Plenary Session

* New Advances in Pharmaceutical Medicine
* Regenerative Medicine
* Translational Science
* Personalized Medicine
* Education in Pharmaceutical Medicine

Closing Ceremony