IFAPP WORLD
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International Federation of Associations of Pharmaceutical Physicians
I·2008·APRIL

CONTENT

Working hard at the IFAPP Executive Committee face-to-face meeting in Barcelona, Spain

President's Letter

Dear Colleagues

Dr Luis F. Collia, IFAPP President

This is the 6th IFAPP World issue after its re-launch in 2006, providing valuable information well prepared again. In particular, I would like to point at the interview with Dr Kihito Takahashi, President of the Japanese Association of Pharmaceutical Medicine (JAPhMed). He provides a deep insight into the chances and challenges of Pharmaceutical Medicine in Japan and the Asian-Pacific region. He also reflects the eminent role IFAPP plays in promoting Pharmaceutical Medicine in general and in supporting JAPhMed in particular.

Well, during the last IFAPP Executive Committee face-to-face meeting in Barcelona in March, IFAPP delegates from 13 countries and two co-opted members were discussing the financial status of IFAPP, created a plan to improve the financial results and fixed the targets for the next few years. Afterwards the results of IFAPP day-to-day activities and functioning were presented. Among that, we got an update of the ▶ page 2

IFAPP's Calendar

How can we get an efficient and accurate update of all the latest scientific developments in the fast moving field of Pharmaceutical Medicine?

Do we still need a blockbuster mindset?

Where can we learn from each other the latest trends in clinical development or the new scientific drivers behind our new pharmaceuticals?

Where can we share with each other our best practices in fields such as risk assessment or pharmaceutical crisis management?

How can we meet our international medical business colleagues in a non-competitive atmosphere?

ICPM 2008 in Amsterdam

Developing Pharmaceutical Care – Medicines After the Blockbuster Area

ICPM 2008

Make up your mind and register today!

The International Conference on Pharmaceutical Medicine 2008 – ICPM 2008 – in Amsterdam, the Netherlands, 7-10 September 2008 will provide answers! Make up your mind and register today at www.icpm2008.org where you also find the most up-to-date ▶ page 2

Questions & Answers

Pharmaceutical Medicine in Japan and its Particularities

JAPhMed Celebrates its 40th Anniversary

In 2008 the Japanese Association of Pharmaceutical Medicine (JAPhMed) celebrates its 40th anniversary. However, "The term 'Pharmaceutical Medicine' is still not familiar in Japan, and its Japanese translation of 'seiyaku igaku' is not widely accepted here yet," as JAPhMed admits on its website. What is the matter, Dr Kihito Takahashi, President of JAPhMed? He answered this question in a conversation with Eckhard Boettcher-Buehler from IFAPP World.

Dr Kihito Takahashi: "It is a very new concept in Japan to interpret the whole process of drug development from research to approval and postmarketing surveillance as a sole medical discipline."

IFAPP World • Dr Takahashi, why is 'Pharmaceutical Medicine' respectively 'seiyaku igaku' still an unusual term in Japan and what are the consequences?

Dr Kihito Takahashi • In Japan, non-physicians, most of them pharmacists, have historically driven both pharmaceutical development and regulatory review. There are specialists for each process in drug development including biostatistics and pharmacokinetics, and each process is established as a pharmaceutical science. However, only clinical pharmacology has been recognized as a specific medical discipline and some clinical pharmacologists use the term 'clinical pharmacology' in a wider sense to refer to clinical trials. With this ▶ page 2

President's Letter

◀ page 1 IFAPP Council for Education in Pharmaceutical Medicine (CEPM) and also refreshed all aspects related to the International Conference of Pharmaceutical Medicine in September 2008 in Amsterdam – ICPM 2008.

Most important perhaps – we reconsidered our vision and operational targets and discussed our strategy and tactics in order to improve our image, profile and publicity, and to gain ever more influence on decisions in the world of Pharmaceutical Medicine as a distinguished stakeholder. Worth mentioning is the fact that we invested more than one day of the meeting to discuss it all in detail. For instance, we analyzed the role of the Executive Committee and created new Working Groups to strengthen our activities with regard to the main duties: to increase the high profile of IFAPP, to win new sponsors for financial support, to develop, plan and implement the participation of IFAPP in appropriate congresses, to review our strategy in our relationship with the US Food and Drug Administration (FDA), the European Medicines Agency (EMEA) and with other authorities, to organize new conferences in cooperation with the EMEA and the FDA, and, last but not least, to encourage national member associations to take a more active role and part in IFAPP and its activities and operations.

To get all this work completed in one and a half days, we formed several groups which worked on specific subjects and presented their results to all the others for final discussion in search of an agreement. The results of these efforts provide a sound basis for the future of IFAPP and we are all confident that we are on the right track.

The organization of ICPM 2008 is in continuous progress – take the opportunity to review all ICPM news at www.icpm2008.org where you can register for the event, send abstracts and book hotel accommodation and tours. Last month we distributed the First Announcement with the designated chairpersons and speakers – please distribute it to all members of your association and place it on your homepage to ensure a widespread circulation of our ICPM 2008 event. Hard copies of the First Announcement for distribution at your national meetings can be obtained from the IFAPP secretariat (ifapp@planet.nl).

Regarding ICPM 2010, the IFAPP Executive Committee has accepted the Association of Pharmaceutical Physicians, Singapore as the host of the event. We will provide further information at ICPM 2008 in Amsterdam.

Last but not least, it's my pleasure to congratulate all newly elected presidents of the IFAPP member associations, who took over these positions shortly ago: Dr Manuel Ruiz Caballero from the Mexican Society, Dr Ilja Fiser from the Austrian Society, Dr Maarit Hillila from the Society in Finland, Dr Jean-Michel Joubert from the French Society, Dr Greg Koski from the Society in the US, Dr Gábor Szepesi from the Hungarian Society, Dr Lars Thomander from the Swedish Society, and Dr Raza Zaidi from the Pakistani Society – in alphabetical order. Last but not least, I would like to thank all of you for participating in the IFAPP operations.

Dr Luis Francisco Collia, IFAPP President, Medical Manager Merck Serono Argentina, Buenos Aires, Argentina ■

IFAPP's Calendar

◀ page 1 scientific program, all call for abstract details and accommodation information as well as social activities during the conference.

We have selected a faculty of more than 40 industrial and academic executives for discussing the real highlights on all the key topics of their and our daily work. You will get expert-to-expert briefings on the critical issues of our pharmaceutical business. The venue will bring the right atmosphere to meet your colleague delegates and speakers.

In addition to the state-of-the-art scientific program we will have the opportunity to follow different executive classes on medical statistics about non-interventional studies and risk-benefit analyses, and there will be a short course covering all you want to know about media interactions.

Spend two and a half days at ICPM 2008 to boost your knowledge on Pharmaceutical Medicine to the proper professional level. Don't miss this opportunity and register today! We are looking forward to welcoming you to Amsterdam!

Dr Rudolf van Olden, Member of IFAPP's Executive Committee, Chairperson ICPM 2008 on behalf of the local organizing and scientific committee ■

Join ICPM 2008 in Amsterdam!

Questions & Answers

◀ page 1 historical background, it is a very new concept in Japan to interpret the whole process of drug development from research to approval and postmarketing surveillance as a sole medical discipline.

Well, JAPhMed has reinforced its initiatives in 2003 and proactively promoted Pharmaceutical Medicine. Since then, new postgraduate courses for Pharmaceutical Medicine have been established in the industry and the academia. JAPhMed has supported these courses by providing the expertise. Moreover, JAPhMed is just about to establish a certification for Pharmaceutical Medicine specialists. Actually, I am confident that Pharmaceutical Medicine will become a common concept in Japan in the near future.

IFAPP World • When JAPhMed was constituted 40 years ago, did the founders expect that it would take so long to establish Pharmaceutical Medicine?

Dr Kihito Takahashi • JAPhMed started as a small group of physicians who were employed by pharmaceutical companies in Japan in the 1960's. In those days physicians joining the industry were rather the exception. Most of these physicians studied or practiced medicine either in the US or in a European country where they considered the roles physicians played in drug development and drug safety to be important. When they came back to Japan, they were confronted with rather a different situation.

These Japanese pioneer physicians, who all experienced similar situations, felt the need to constitute a group in order to improve Japanese drug development from a medical point of view. This was the beginning of JAPhMed.

Since then, the number of physicians working in the pharmaceutical industry has gradually increased and today JAPhMed counts more than 200 members, all of them being physicians. Many of them fill major positions in their companies allowing them to have an influence on the environment of drug development in Japan and spur on changes of the way drug development is conducted.

IFAPP World • What are they actually doing?

Dr Kihito Takahashi • Currently JAPhMed is particularly engaged with two sub-teams: The JAPhMed education sub-team holds lectures in Pharmaceutical Medicine based on the curriculum of IFAPP's Council for Education in Pharmaceutical Medicine (CEPM). They also organize courses in Pharmaceutical Medicine and we will initiate a special certification for the successors of these courses and work hard on the approval by IFAPP's CEPM. JAPhMed's safety sub-team holds meetings at ▶ page 3

Questions & Answers

◀ page 2 regular intervals sharing information and experience and discussing issues in pharmacovigilance. They propose new ideas for improving drug safety management in Japan.

The teams are enthusiastic to improve the Japanese environment of Pharmaceutical Medicine as we call it now. Many JAPhMed members express their wishes to collaborate in the teams. However, all JAPhMed members are quite busy playing their respective important roles in their companies. Therefore, the resource to expand our activities is always limited, which, I believe, is similar in all the other IFAPP member associations.

IFAPP World • What do you consider as particular challenges for Pharmaceutical Medicine in Japan?

Dr Kihito Takahashi • Currently, various courses and programs are available to develop expertise needed for effective drug development in Japan. However, these programs and courses are rather isolated and the efforts are therefore segmented. In addition, no clear criteria exist regarding the level of knowledge, skills and experience required for individuals to be accepted as experts in drug development and regulatory review. The lack of clear criteria often results in inconsistencies in the quality of clinical trials conducted and the evaluation of respective trial results. Several authoritative experts have criticized this as a significant issue in Japan.

JAPhMed is committed to put its full strength on promoting excellence in Pharmaceutical Medicine in Japan. Therefore, it is absolutely necessary to consolidate training and education from isolated and segmented forms to a highly organized, continuous, and comprehensive activity. In fact, JAPhMed educates and trains experts in drug development for the industry, for academia and for regulatory agencies in Japan – experts who are capable of promoting and leading high-quality drug development at global standards.

We also cooperate with the Japanese Center of Pharmaceutical Medicine, a non-profit organization, whose mission is to promote Pharmaceutical Medicine broadly to investigators in academic clinical research, again aiming at reaching consensus on the standards of Pharmaceutical Medicine in Japan.

IFAPP World • Considering the new emerging markets in Asia: Is this 'neighborhood' an opportunity or a challenge for JAPhMed, for the Japanese Pharmaceutical Medicine, and the Japanese pharmaceutical industry altogether? Actually, is it a 'neighborhood' at all or just geographical proximity?

Dr Kihito Takahashi • All over Asia, various English-speaking, highly-motivated work forces are poised and well suited to meet the needs of global drug development sponsors. To support this, most of the region's leading specialists have received postgraduate medical training in the US or the United Kingdom. Since per-subject trial costs are significantly lower in some of the Asian countries than they are in Japan, overall cost savings by including non-Japanese Asian countries in global clinical trials promise to be substantial. For example, according to a recently published report the average per-subject trial cost in Japan was more than $US 20,000 whereas the equivalent cost in Korea or Taiwan was less than $US 10,000.

Dr Kihito Takahashi: "Asian countries have made concerted efforts to support global clinical trials and have surpassed Japan's clinical trial performance."

At the same time, positive changes in the regulatory climates combined with continuous and fast improvements of the clinical trial environment under strong government leadership occurred in non-Japanese Asian countries. All this allows a smoother and earlier market access for new drugs in these countries compared to Japan. With these trends, other Asian countries have made concerted efforts to support global clinical trials and have surpassed Japan's clinical trial performance.

A provincial and rather inflexible clinical trial infrastructure combined with unique local regulatory requirements and variations in the interpretation and implementation of ICH guidelines has served to set Japan apart from other regions. This situation obviously constitutes a major challenge for the Japanese pharmaceutical industry but, at the same time, it is also a chance for Pharmaceutical Medicine in Japan.

IFAPP World • This is severe criticism. What would you consider in order to overcome all the obstacles?

Dr Kihito Takahashi • This is self-criticism too. But there is optimism. Several significant initiatives to transform and globalize the Japanese pharmaceutical industry have been put forward with a serious sense of urgency in Japan. And a lot of improvements have been observed these days. Currently, an increasing number of Asian clinical trials involving Japan and other Asian countries such as Korea, Taiwan and China are ongoing, and many JAPhMed members are playing important roles in driving these clinical trials.

Furthermore, JAPhMed considers this challenging situation as a big opportunity to advance Pharmaceutical Medicine in Japan and to spur a global approach for the Japanese drug development. I am confident that Japan and other Asian countries will improve their collaboration and Japan – a leading country in science – will play an important role in expanding opportunities in the Asian-Pacific region to contribute to global public health.

IFAPP World • Focussing on new emerging markets again with regards to the International Conference on Harmonisation (ICH): Does it seem appropriate or even essential to you or to JAPhMed to expand this initiative and invite other countries to cooperate?

Dr Kihito Takahashi • Many Asian countries have already adopted ICH standards in their clinical trials, as I already mentioned. This has been a big driver for many Asian countries to develop and establish a global clinical trial infrastructure. I believe ICH is a global standard now and contributes to promote global drug development in all relevant regions.

However, continuous efforts to further extend ICH standards is an essential component for the improvement of drug development, and I think it is necessary and useful to invite Asian key countries to cooperate in the ICH initiatives.

IFAPP World • Another cue is 'First-in-Human': What is the Japanese initiative regarding an improvement of the safety of 'First-in-Human' clinical trials with potentially high-risk medicinal products?

Dr Kihito Takahashi • Japan has a relatively risk-sensitive culture and the TeGenero TGN1412 incident in the United Kingdom in 2006 has induced a great deal of discussion here, but there have been no changes in the guidances or regulations that apply to first-in-man studies in Japan. However, when the first phase I trial is performed in Japanese subjects, the compound has often passed first tests in the US or European ▶ page 4

Questions & Answers

◀ page 3 volunteers already. Nonetheless, the regulatory agency in Japan will very carefully review previous non-clinical as well as clinical data before any trial is allowed in Japan.

IFAPP World • Last but not least: What does JAPhMed expect from IFAPP as a representative of Pharmaceutical Medicine worldwide? Have you got any recommendations?

Dr Kihito Takahashi • We – the JAPhMed members – are looking forward to expanding the concept of Pharmaceutical Medicine in Japan more broadly. IFAPP plays an eminent role in supporting us. IFAPP could help to direct the concept of Pharmaceutical Medicine to Japanese authorities for health and education and to the academia, which need to know that Pharmaceutical Medicine is a well-established medical specialty or even a distinct medical discipline in most developed countries except Japan.

For instance, it would be helpful if IFAPP could send delegates to Japan when a meeting is held with the authorities and academia. These delegates could expose the situation in the US, in Europe and in other parts of the globe. This is how the urgent need to establish Pharmaceutical Medicine in Japan can be better met.

IFAPP could also promote Pharmaceutical Medicine worldwide beyond the assembly of the International Conference of Pharmaceutical Medicine (ICPM), as most ICPM attendees come from IFAPP's member associations, predominantly from those close to the ICPM venue. An idea is to collaborate with the World Medical Association to emphasize Pharmaceutical Medicine as a medical specialty. In addition, a position of IFAPP at the Pharmaceutical Research and Manufacturers of America (PhRMA) and some committees sponsored by the Food and Drug Administration (FDA) also might be helpful to make Pharmaceutical Medicine an integral part of medicine.

IFAPP World: Thank you very much. And all the best for making your initiative a success! ■

IFAPP Secretariat – New Address

Please take notice of the IFAPP secretariat's new address:

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Reports & Concepts

9th IFAPP European Conference

Europe: Steep Learning Curve in Pediatric Trials

By Philip Ward

Over the past decade, pediatric drug development has been one of the most talked about topics in European clinical research. Almost everybody accepts that high quality, ethical research into medicines for children is a good thing, but they have disagreed about how to achieve this goal.

New legislation finally became a reality during 2007. EU regulation 1901/2006 on medicinal products for pediatric use, amended by regulation 1902/2006, introduces sweeping changes in the regulatory environment for pediatric medicines, according to Catherine Drai, scientific administrator at the European Medicines Agency's (EMEA's) pediatrics & orphan drugs sector.

At the 9th IFAPP European Conference, held in London on 19 October 2007, she explained that the regulation brings in many new tasks and responsibilities for the EMEA, including the creation and operation of a pediatric committee to provide free, objective scientific opinions on any development plan for medicines for use in children. A system of rewards, incentives, and obligations now exists for sponsor companies.

From 26 July 2008, sponsors must submit the results of studies conducted according to a pediatric investigation plan (PIP) in order to have a valid application for marketing authorization throughout the EU. This obligation will be waived for medicines that are unlikely to benefit children, and studies may be deferred until after the medicine has been authorized for use in adults, she noted (figure 1 and 2). The reward for complying with a PIP is a six-month extension of the supplementary protection certificate, provided the results are included in the product information and authorization is obtained in all EU countries.

"The obligations for orphan-designated medicinal products are the same as for unauthorized medicinal products. The reward is two years of market exclusivity in addition to the existing 10-year exclusivity awarded under the EU Orphan Regulation," said Drai.

From 26 January 2009, sponsors must submit the results of studies conducted according to a PIP when seeking a variation or extension of the marketing authorization for a new indication, new route of administration, or new pharmaceutical form. Waivers or deferrals may also be granted, and the reward is a six-month extension of the supplementary protection certificate (SPC). Off-patent medicines developed specifically for pediatric use can benefit from a new marketing authorization, which gives 10 years of data protection.

The new pediatric committee consists of five members of the EMEA's Committee for Medicinal Products for Human Use, representing five EU member states, and one expert representing each of the 22 other countries. Additional experts are ▶ page 6

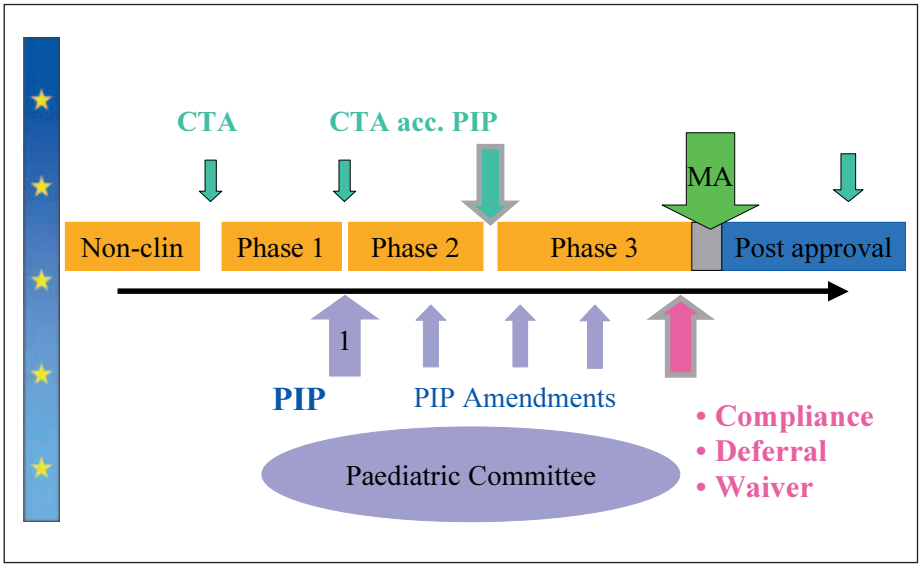

Figure 1: Timing consultation of pediatric committee – PIP: pediatric investigation plan, CTA: clinical trial authorization, MA: marketing authorization. (Source: Catherine Drai, EMEA)

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THE FLAG

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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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◀ page 4 representing Iceland, Liechtenstein, and Norway. Six patient/family representatives and healthcare professionals also sit on the committee. Its inaugural two-day meeting was held in July 2007. Between January and October 2007, there were 41 pediatric applications, and 71% of products were authorized, Drai said. Additionally, the EMEA and FDA are working to establish principles for interaction and exchange of information on pediatric matters, with a view to global development of medicines for children.

"So far implementation is on track, but still lots of work needs to be done," Drai explained. "We are still in a learning phase, and we need to ensure flexible, pragmatic, and collaborative implementation to facilitate its success."

A balance must be found between fulfilling the objectives of the regulation and avoiding unnecessary trials in children, delaying adult drug development, and maintaining competitiveness. Collaboration with stakeholders is essential, and giving feedback is important, she concluded.

During the same session, Dr Klaus Rose, head of pediatrics at Roche Pharma Development, also stressed the need for continuing dialog between the various partners (figure 3). Although legislation does not change the general scope of drug development, it does link the adult market to children and facilitate the pediatric use of drugs. The EU regulation does not exclude biologics, and it will have a big impact, he noted. Progress on several open-ended questions is being made, and a shift of political exposure from countries to a pan-EU scenario is taking place. Most imminent challenges are in the field of oncology, but other areas are coming, and pressure for innovation is on industry, academia, and the regulators, concluded Rose. ■

(Reprinted with kind permission of Applied Clinical Trials)

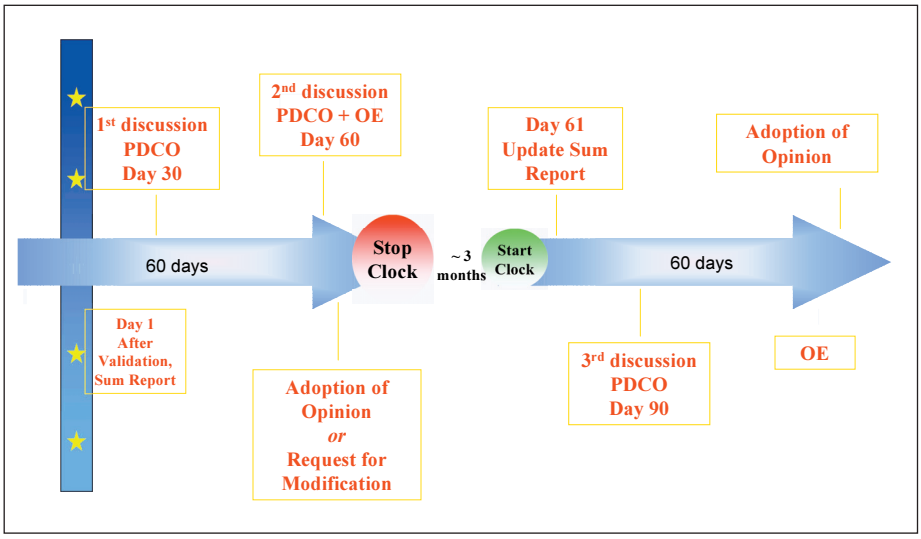

Figure 2: Overview of the pediatric investigation plan procedure – PDCO = pediatric committee, OE = oral explanation / meeting with applicant. (Source: Catherine Drai, EMEA)

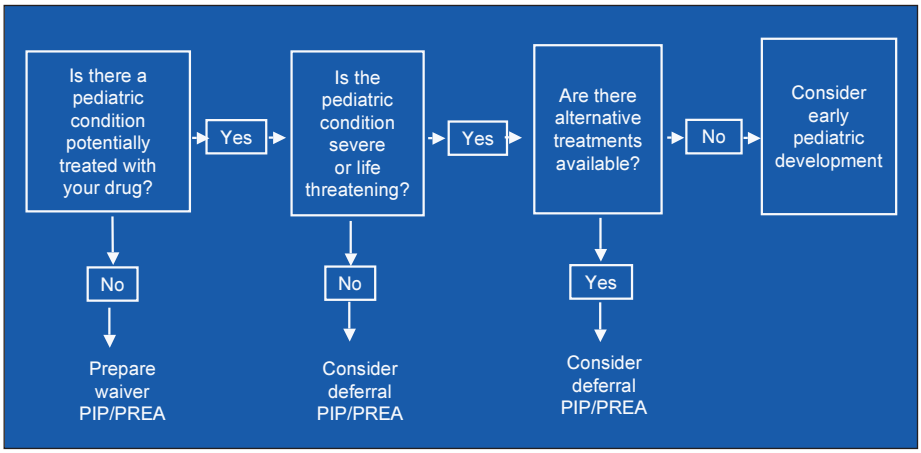

Figure 3: Clinical algorithm for pediatric drug development – PIP: pediatric investigation plan, PREA: pediatric research equity act. (Source: Klaus Rose, Roche)

Reports & Concepts

4th Latin American Congress of Clinical Research • São Paulo, Brazil, in September 2007 • Second and Final Part

Global Initiatives of Clinical Research in Latin America

Dr Paulo Aligieri, São Paulo, Brazil • The first part of the report was published in IFAPP World III-2007

Brazil • The Clinical Research Support Center (NAPesq – Núcleo de Apoio à Pesquisa Clínica – www.napesq.hcnet.usp.br) of the Medical School at the University of São Paulo, Brazil (HCFMUSP – Hospital das Clínicas, Faculdade de Medicina da Universidade de São Paulo) presented 5 posters at the 4th Latin American Congress of Clinical Research which took place in September 2007, jointly organized by the Sociedade Brasileira de Medicina Farmacêutica (SBMF – www.sbmf.org.br) and the Drug Information Association (DIA – www.diahome.org) in São Paulo, Brazil. The posters related to NAPesq's activities in the clinical research setting in Brazil.

Brazilian Network of Clinical Research

The experience of HCFMUSP in the Brazilian Network of Clinical Research two years after its implementation was a topic addressed by Sonia M. Dainesi, manager of NAPesq and member of the Board of Directors of SBMF.

In view of increased participation of national research sites in international multicenter clinical trials, the development of personnel expertise in research has become a need as well as an opportunity. In this context, the development of networks as a strategy to increase research capacity has been implemented in some countries such as the United Kingdom, Australia and the US. Brazil, too, has established its Clinical Research Network in 2005, funded by the Brazilian Ministry of Science and Technology, the Ministry of Health, and the Brazilian Agency for Research and Project Financing, also called Brazilian Agency of Innovation (FINEP – Financiadora de Estudos e Projectos – www.finep.gov.br).

Centers, which became part of the Brazilian Clinical Research Network, were selected by their strategic capacity defined as appropriate infrastructure and equipment, professional training and sustainability. At first, 14 centers were chosen and additional 5 centers were included later on. The goal of the network is to harmonize activities related to clinical research and to strengthen the public clinical research activity. To this effect the centers were offered state-of-the-art resources, e.g., suitable technical-scientific and Good Clinical Practices (GCP) training programs and appropriate infrastructure allowing to efficiently monitor national and international research protocols. According to the main priorities of public health policies in Brazil, the development of local research protocols is another fundamental goal of this network.

Maria Auxiliadora Ferraz and colleagues presented a second poster – a reflection of the introduction of GCP concepts in academic clinical research and investigator-initiated trials. The poster described the support offered by NAPesq for a randomized, double-blind, local clinical trial within HCFMUSP. This approach included, among others, GCP training of a nurse as a study coordinator and of all research team members, as well as discussions of protocol-specific issues and informed consent, file maintenance and adverse event reporting, screening and recruitment strategies, design of a case report form (CRF) and monitoring visits.

Creating a model for a clinical trial agreement (CTA) was an issue addressed by Nanci Valeis and colleagues. The poster summarized the HCFMUSP experience in developing a standard CTA, as done by other universities and networks around the world. The model is not mandatory but strongly recommended, simply because it can accelerate the approval procedure and harmonize the concepts in such a complex institution.

Rodrigo Morita and colleagues presented a poster addressing the importance of electronic data capture. A new database has been created, which better meets the demands with the huge number of projects amounting to more than 1,200 per year. It also accelerates the process keeping and improving the process as a whole. Policies ruling the safety of circulating confidential information were closely considered, too. The process is still ongoing, always seeking for improvements in order to do the best for the investigators, for the institution and, certainly, for the patients who will be included in a trial.

The last poster submitted by the NAPesq team raised the discussion regarding the clinical trial budget and all the difficulties involved. Denise Nunes and colleagues summarized some of the main issues, such as the proper assessment of costs, the definition of all direct and indirect costs, and the overheads sometimes applied by the institutions. The questions of how to measure the risk of non-planned tests and procedures, how to include screening payment failures and how to work with fixed costs but variable income were also addressed.

▶ page 8

Gerfried Nell, Austria, Christopher Allen, USA, Luis Collia, Argentina, and Sonia M. Dainesi, Brazil (left to right)

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The Profile of Clinical Trials in Brazil

A study was conducted to evaluate professional qualification, regulatory knowledge and GCP training of clinical trial group members in Brazil. Helena S. Paschoale and colleagues from the Department of Gastroenterology at the University of São Paulo School of Medicine presented a poster with preliminary results of this study.

The study was designed as a transversal study including investigators of clinical trials as study subjects. Study subjects were recruited from a public data base. For an appropriate selection the authors of this study relied on specific keywords for their data base research, e.g., 'clinical trial', 'pesquisa clínica', 'ensaio clínico', which would discriminate only persons who in fact have clinical trial experience.

Altogether, 64 investigators met the inclusion criteria and were interviewed; 69% of them were male. A graduate degree was noted among 91% of the sample subjects and 91% of them had a GCP knowledge although only 69% had undergone a formal GCP training. Concerning the experience in trials, 43% and 58% of the investigators had experience in phase II and III, respectively. 41% of them dedicated 10 hours per week to their work on clinical trials and 80% of them also have academic activities. In 2006, 29% of the investigators had published one or two scientific articles in any international journal.

With regards to the trial centers, 64% were academic public institutions; 21%, 41% and 28% of the clinical trials were in phase II, III and IV, respectively. An analysis of the teams revealed that 71% of the teams employed coordinating nurses and 51% pharmacist; 86% of the staff had GCP knowledge, virtually all of them had undergone formal GCP training. ■

Gustavo Kesselring, Helena S. Paschoale, both Brazil

Reports & Concepts

DIA's 43rd Annual Meeting • Second part: Latin America and Europe • Conclusion

Bioethics – a Global Challenge

Professor Dr Gerfried Nell, Vienna, Austria, IFAPP President Elect

Atlanta, Georgia, USA

The first part of this report was published in IFAPP World III in December 2007. In addition to an introduction, it focused on US bioethics, with the heading "USA: Selective Approaches, no Consistent Standards." In this issue, the role of bioethics in Latin American and Europe is considered.

A colorful picture in Latin America

In Latin America there is a colorful picture concerning activities, measures and programs currently in place for the continued education and professional training of Ethics Committee (EC) and Institutional Review Board (IRB) members. According to Dr Daniel Mazzolenis, Kendle Servicios, S.A. de C.V., Mexico, a series of local and national approaches are utilized. Larger programs are offered in Argentina, Brazil and Mexico.

In Brazil an optional one-week training course is available with an emphasis on ethics in medical research within the context of policy, social conditions and human rights; the course also trains participants in national and international regulatory requirements.

In Argentina training for IRB members is provided by various organizations. FLACSO Argentina (Facultad Latinoamericana de Ciencias Sociales) offers an annual course in cooperation with the US American Fogarty International Center – part of the National Institutes of Health (NIH). The tenor covers ethics in clinical research, duties and responsibilities of IRB members, as well as planning of research projects. Bio & Sur (Bioethics and Human Rights Association), another provider of professional training, arranges postgraduate courses in bioethics and human rights in Latin America, with a diploma upon successful completion. FEFyM (Foundation of Pharmacology and Drug Studies) also provides training courses for IRB members.

In Mexico the federal government runs recurring one-week training courses for IRB members. The Peruvian government plans a similar course.

The common regional objective is to set-up adequate programs for education and training regarding ethical conduct in clinical research throughout Latin America. There are plans to harmonize these programs with diplomas issued after completion.

Europe: Variety of Initiatives

In Europe the common opinion prevails that continued education and professional training in ethics should be a standard requirement for EC members. A variety of such initiatives are on-going.

In 2005 at the "Research Ethics Committees in Europe – Facing the Future" conference in Brussels, Belgium, the European Commission proposed a two-step system with a basic training and then additional courses to address specific issues. Basic training focuses on duties and responsibilities of ECs, on general criteria for ethical evaluations, on statutory and regulatory requirements, clinical research basics and benefit-risks assessments. Specific issues for addition courses are e.g., the pros and cons of placebo control, protection of particular persons or patient groups.

The EU Commission did not adopt a regulation to legislate education and training for EC members, but favors a "grass-roots" approach based on the variety of initiatives available in Europe. To merge such initiatives, the European Network of Research Ethics Committees (EUREC) has been established by the EU Commission. EUREC aims to, e.g., exchange information, experience and teaching material among the hosts of courses for EC members in Europe. EUREC also functions as a point of contact for the EU Commission and its inquiries concerning ECs.

In the United Kingdom, the Netherlands, and Switzerland statutory provisions are already in place for the training of EC members. In several European countries many universities offer appropriate courses.

Conclusion

Overall the picture in the three regions USA, Europe and Latin America is as follows:

1) The need for continued education and professional training of EC and IRB members is commonly accepted.

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2) In fact there are recommendations by the appropriate authorities available in all reviewed countries regarding the qualifications of EC and IRB members. However, there are only few countries, which have established legal stipulations. As a consequence, all of the different existing initiatives generate a motley scene.

3) The ultimate goal is global harmonization of continued education and professional training as a premise for certification and accreditation of Ethics Committees and Institutional Review Boards. ■

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."

IFAPP's Regional Update

IFAPP's Member Associations: New Presidents

Mexico • In February 2007 Dr Manuel Ruiz-Caballero was elected as Vice President and President Elect of the Asociación de Médicos Especialistas en la Industria Farmacéutica, A.C. (AMEIFAC), the Mexican Pharmaceutical Physicians Association. At the last election in February 2008 Dr Ruiz-Caballero was inaugurated as President and now heads the AMEIFAC Executive Consultative Committee. Dr Manuel Ruiz Caballero is also delegate to IFAPP.

Austria • The Austrian Society of Pharmaceutical Medicine (GPMed – Gesellschaft für Pharmazeutische Medizin) has elected Dr Ilja Fiser as new President. He is the successor of Dr Helmut Schuh. Professor Dr Gerfried Nell, IFAPP's President Elect, is GPMed's delegate to IFAPP.

Finland • The Finnish Association of Pharmaceutical Physicians (SuLL/FIAPP) has elected Dr Maarit Hillila as new President. SuLL/FIAPP's delegate to IFAPP is Dr Marjo Hahka-Kemppinen.

France • The French Association of Physicians for Health Products (AMIPS) has elected Dr Jean-Michel Joubert as new President. AMIPS' delegate to IFAPP is Dr Bertrand Baumelou.

United States of America • The US Academy of Pharmaceutical Physicians and Investigators (APPI) has elected Dr Greg Koski as new President. APPI's delegate to IFAPP is Dr Christopher Allen.

Hungary • The Clinical Trial Management Society Hungary (CTMS) has elected Dr Gábor Szepesi, Budapest, as new President.

Sweden • In January 2008 Dr Lars Thomander has been elected as new President of the Swedish Society of Pharmaceutical Medicine (SSPM – Svenska Sällskapet för Pharmaceutical Medicine). Dr John Lee is SSPM's delegate to IFAPP.

Pakistan • The Pakistan Association of Pharmaceutical Physicians has elected Dr Raza Zaidi as the new President. ■

Dates & Deadlines

3-7 May 2008 • Toronto, Ontario, Canada
ISPOR 13th Annual International Meeting
International Society for Pharmacoeconomics and Outcome Research (ISPOR) • www.ispor.org

11-13 May 2008 • Shanghai, China
ISSX's 2nd Asian Pacific Meeting
International Society for the Study of Xenobiotics (ISSX) – Studying the Metabolism and Disposition of Chemicals in Biological Systems • www.issx.org

18-21 May 2008 • Vienna, Austria
ISSX's 10th European Meeting
International Society for the Study of Xenobiotics (ISSX) – Studying the Metabolism and Disposition of Chemicals in Biological Systems • www.issx.org

22-26 June 2008 • Boston, MA, USA
DIA's 44th Annual Meeting
Drug Information Association (DIA) • www.diahome.org

27 July – 1 August 2008 • Québec, Canada
IXth World Conference on Clinical Pharmacology and Therapeutics
International Union of Basic and Clinical Pharmacology (IUPHAR) • www.cpt2008.org

17-20 August 2008 • Copenhagen, Denmark
24th International Conference on Pharmacoepidemiology & Therapeutic Risk Management
International Society for Pharmacoepidemiology (ISPE) • www.pharmacoepi.org

7-10 September 2008 • Amsterdam, the Netherlands
ICPM 2008 – 15th International Conference on Pharmaceutical Medicine
Please note the article "ICPM 2008 in Amsterdam" on page 1 • www.icpm2008.org

14-15 September 2008 • Philadelphia, PA, USA
ACCP's 37th Annual Meeting
American College of Clinical Pharmacology (ACCP) • www.accp1.org

5-8 October 2008 • Buenos Aires, Argentina
ISOP's 8th Annual Meeting
International Society of Pharmacovigilance (ISOP) • www.isop2008.org

12-16 October 2008 • San Diego, CA, USA
ISSX's 15th North American Meeting
International Society for the Study of Xenobiotics (ISSX) – Studying the Metabolism and Disposition of Chemicals in Biological Systems • www.issx.org

28-30 October 2008 • Ottawa, Canada
DIA's 5th Canadian Annual Meeting
Drug Information Association (DIA) • www.diahome.org

17-23 July 2010 • Copenhagen, Denmark
16th World Congress on Basic and Clinical Pharmacology 2010
International Union of Basic and Clinical Pharmacology (IUPHAR), Danish Society of Pharmacology and Toxicology, Danish Society of Clinical Pharmacology • www.worldpharma2010.org

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ICPM 2008, Amsterdam

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