2013 JANUARY

IFAPPWORLD

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS & PHARMACEUTICAL MEDICINE

PRESIDENT'S LETTER

Dear Colleagues

First of all, I would like to express my sincere thanks to all national member associations and their delegates for your support to IFAPP. It's my great honor to be President of IFAPP, especially as I am the first IFAPP President from Asia. I also would like to thank Dr Rudolf van Olden for his devoted contribution and strong leadership for ...

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FOCUS ON SOUTH KOREA

A Short History of Trial Conduct in South Korea

There is a joint effort behind South Korea's significant achievements and remarkable successes in clinical research (see the bullets in the box) with people involved from academia, industry and administration. In 2002 South Korea adopted ICH-GCP and separated the approval of trial protocols regarding investigational new drugs (IND) and new drug applications (NDA). At the same time, the Korean Association of Institutional Review Boards (KAIRB) was ...

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THE INTERNATIONAL PERSPECTIVE

KoNECT – South Korean Clinical Trial Enterprise

South Korea entered the international clinical research scene as a serious international partner around the turn of the millennium 2000. Due to its joint efforts, the country was very successful in trial participation, and the number of trials conducted constantly increased, which challenged the infrastructure available in the country ever more.

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Dr Yil-Seob Lee, IFAPP President

IFAPP will undergo structural changes and will become more open and more transparent for getting closer to the national member associations.

President's Letter

Dear Colleagues

First of all, I would like to express my sincere thanks to all national member associations and their delegates for your support to IFAPP. It's my great honor to be President of IFAPP, especially as I am the first IFAPP President from Asia.

I also would like to thank Dr Rudolf van Olden for his devoted contribution and strong leadership for the last two years as the president of IFAPP. He has initiated a changing of IFAPP, which will be continued the next few years, and IFAPP and its national member associations will benefit from these changes. And I also would like to thank our Spanish member association AMIFE, the Asociación de Medicina de la Industria Farmacéutica Española, for the perfect organization of the International Conference on Pharmaceutical Medicine – ICPM 2012 – as a successful meeting.

The Pharmaceutical Market in Transition

Since the foundation of IFAPP in 1975 IFAPP representatives have been working hard to promote Pharmaceutical Medicine by enhancing knowledge, expertise and skills of pharmaceutical physicians and Pharmaceutical Medicine experts in order to ensure the availability and the appropriate use of medicines for the benefit of patients and societies. The pharmaceutical environment today is very challenging due to low R&D productivity, patent loss of major blockbusters, low market accessibility of new medicines, and a low growth rate in developed markets. The pharmaceutical market, however, is expected to undergo a number of transitions which would impact our activities. The transitions include a shift of growth from the developed to the emerging markets, an increasing focus on biopharmaceuticals, an increasing volume of generics and so on. It is true that the environment

Photo © BöBü

changes but our expertise and our leadership as Pharmaceutical Medicine experts will still be demanded. Therefore, we have to develop our expertise further on and we have to keep doing our leadership roles.

The Pharmaceutical Environment is Challenging

Looking inside of IFAPP we also face several challenges resulting from the changes of the pharmaceutical environment. Both our federation and ourselves will have to undergo several changes to ensure we can better cope with this. First, IFAPP will undergo structural changes and will become more open and more transparent for getting closer to the national member associations and to better embrace them.

Each national member association's expectations from IFAPP will vary according to the location of the respective country. For example, the expectations of a developed market in Europe are likely to be different from the expectations ▶

Dr Yil-Seob Lee, IFAPP President

of an emerging market in Asia, Latin America or Africa. Therefore, we will try to develop values of IFAPP, which can meet their expectations. And IFAPP will reach out to all countries, which do need Pharmaceutical Medicine, to help them set up training courses in Pharmaceutical Medicine, and to become our member. The IFAPP Council for Education in Pharmaceutical Medicine (CEPM) and PharmaTrain, the European platform for postgraduate training in Pharmaceutical Medicine, will actively contribute to reach this objective.

Better Shape IFAPP's Structure Accordingly

I personally believe, IFAPP should set up strong regional structures in order to take a more active stand both in developed markets of the USA, Europe and Japan, and in emerging markets of Asia, Latin America and Africa. And we will.

We also need to develop a model showing how to successfully organize IFAPP meetings such as the International Conference on Pharmaceutical Medicine (ICPM) and Science-to-Business (S2B) conferences. To go for all these goals we may need to establish stable links with big pharmaceutical companies, contract research organizations (CROs) and academia. These bodies will cooperate for a next S2B conference in Seoul, South Korea, in September 2013 and for ICPM 2014 in Berlin, Germany in March 2014.

Overall, our IFAPP mission and objectives remain the same. To keep on implementing them successfully, we need to better shape IFAPP's structure. However, IFAPP's success cannot be achieved by myself alone or by IFAPP's Board members only. The success of IFAPP can only be achieved together with strong contributions by all of you and by each national member association.

Thank you again for your support.

With kind regards
Dr Yil-Seob Lee, IFAPP President

Personal Snapshot

IFAPP President in Person: Dr Yil-Seob Lee

Dr Yil-Seob Lee currently works for GlaxoSmithKline (GSK) South Korea as Director in charge of medical and regulatory, and is also an Affiliate Professor in an advanced course for Pharmaceutical Medicine at the Seoul National University Hospital in Seoul, South Korea.

He graduated at Yonsei University Medical School and completed residence training in pediatrics at Yonsei University Hospital. He finished research-fellowship training in clinical pharmacology at Cornell University Medical College in New York, USA. He also got awarded his PhD of Korea University majoring in pharmacology, and his MBA of Yonsei University Business School.

In 1990, he started his career in the pharmaceutical industry as a Medical Director of Handok Pharmaceuticals Co., a joint venture of Hoechst AG. He was a founding member of the Korean Society of Pharmaceutical Medicine (KSPM – www.kspm.org) in 1995, and he served as its President from 2005 to 2008. During his KSPM presidency, he was host and chair of the organizing committee of the successful 14th International Conference on Pharmaceutical Medicine – ICPM 2006 – in Seoul, South Korea. He has also been Director of the Korean Society for Clinical Pharmacology & Therapeutics and chair of the R&D Committee in the Korea Research based Pharmaceutical Industry Association (KRPIA).

Dr Yil-Seob Lee, who serves as an elder in a Seo-Hyun Presbyterian Church in Seoul and also is a member of the church's choir, is married – his wife is a scientist in neuroscience. Their daughter is also attached to life sciences – she is a graduate student in organic chemistry.

BöBü

Dr Yil-Seob Lee, IFAPP President

"IFAPP should set up strong regional structures in order to take a more active stand both in developed and in emerging markets. And we will."

Questions & Answers

IFAPP Revisited

IFAPP's new President Dr Yil-Seob Lee outlines IFAPP's plans and perspectives

The pharmaceutical market is in transition and the pharmaceutical environment is challenging. To better cope with all this, IFAPP has to change and may develop different plans for different regions. What is behind that, is explained by IFAPP's new President Dr Yil-Seob Lee from Seoul in South Korea in an interview with the IFAPP WORLD Editor in Chief, Eckhard Böttcher-Bühler, Germany.

"Before implementing any changes, IFAPP will request their national member associations for their input, their comments, and their consent regarding the new structure." Dr Yil-Seob Lee

IFAPP WORLD: Despite ongoing globalization – the globe in general and global Pharmaceutical Medicine (PM) in particular might appear different from a North or Latin American, a European or an Asian Pacific or African point of view. Dr Yil-Seob Lee, as a South Korean expert in Pharmaceutical Medicine – how is your perception of that with respect to PM?

Dr Yil-Seob Lee: Pharmaceutical Medicine in Asia is different from PM in Western Europe. Pharmaceutical Medicine in Asia and in Latin America has a much shorter history, has fewer people involved, and – not at least – has fewer opportunities for PM training. The pharmaceutical market in Western Europe is stagnating while in the future it is expanding in emerging markets in Asia and in Latin America.

Consequently, IFAPP should make plans and develop strategies for how to keep up with Pharmaceutical Medicine according to the needs in the respective region and country. In order to achieve this goal, IFAPP first has to review the current status of Pharmaceutical Medicine in all countries of their member associations and then has to reconsider how to support PM in these countries if necessary. Therefore, IFAPP may develop different plans for different regions to foster continuing education and training in Pharmaceutical Medicine. This means it might be valuable or even necessary to establish regional strategies and programs under the IFAPP umbrella.

Dr Yil-Seob Lee, IFAPP President

"IFAPP may develop different plans and strategies for different geographic regions to foster education in Pharmaceutical Medicine worldwide."

IFAPP WORLD: The recently held IFAPP-AMIFE International Conference on Pharmaceutical Medicine – ICPM 2012* – in Barcelona, Spain, has revealed numerous initiatives for creating networks and alliances in the field of clinical research, e.g., the Alliance for Clinical Research Excellence and Safety (ACRES), the ViS Research Institute platform, and – in your country – the Korea National Enterprise for Clinical Trials (KoNECT). Initiatives like that support globalization in clinical research and Pharmaceutical Medicine. What is the role of IFAPP in this context; where does IFAPP fit in?

Dr Yil-Seob Lee: As clinical research is one of the major scopes of pharmaceutical physicians or even the major scope, IFAPP should be involved in all activities regarding clinical research, and in fact IFAPP is in close collaboration with those groups and has to support national member associations to work close at national levels.

For example, the Korean Society of Pharmaceutical Medicine (KSPM), an IFAPP member association, is collaborating with the Korea National Enterprise for Clinical Trials (KoNECT) and is involving in many activities of KoNECT as major player; both initiatives are working together to improve the environment for clinical research in South Korea.

I am convinced that both IFAPP and our national member associations can easily collaborate with these groups you have mentioned and others at national and international levels. It is to the benefit of Pharmaceutical Medicine all over the globe. And I hope we have more organizations in countries to foster clinical research.

IFAPP WORLD: As IFAPP President – what are your plans with regards to IFAPP and IFAPP's next steps?

** 16th International Conference on Pharmaceutical Medicine – ICPM 2012 – 14th-16th November 2012, Barcelona, Spain. Jointly organized by the International Federation of Pharmaceutical Physicians (IFAPP) and the Spanish Association of Medicine in Pharmaceutical Industry (AMIFE).*

Dr Yil-Seob Lee: First of all, to achieve our mission, IFAPP should strive for getting more members, which fit to the name of IFAPP. This means, we all together as IFAPP representatives should contact and invite all national organizations dealing with Pharmaceutical Medicine in any way and in any country.

This is the reason why we are currently changing IFAPP's structure. With the structural changes, it will become easier for IFAPP to get in closer contact to national member associations and to get them involved in our federation more easily. However, before implementing any changes, IFAPP will request their national member associations for their input, their comments, and their consent regarding the new structure.

Secondly, as I already said, IFAPP may develop different plans and strategies for different geographic regions to foster education in Pharmaceutical Medicine worldwide. Well, IFAPP with its Council for Education in Pharmaceutical Medicine (CEPM) closely collaborates with PharmaTrain, the European platform for postgraduate training in Pharmaceutical Medicine. This is an excellent concept, a story of success and a good experience, which could be adapted to other regions all over the world. IFAPP will definitely go this way and IFAPP's CEPM will take an important role in this process.

With all these kinds of steps I do hope IFAPP will manage to achieve its mission and objectives smoothly.

IFAPP WORLD: You mentioned the need for structural changes within IFAPP and the process of revisiting and renewing. How will you go on with that?

Dr Yil-Seob Lee: As I explained in my message in the President's Letter above, IFAPP will go through structural changes, which are already on the way. This process of

change will be shared with all delegates in regular meetings and with all of our member associations through IFAPP WORLD; they all will see the proposed changes. And IFAPP will listen to their voices and their comments on these proposals.

IFAPP wants to get closer to its national member associations, and IFAPP WORLD will assist IFAPP in its efforts to this effect.

Overall, IFAPP will communicate to national member associations more frequently and more closely. And IFAPP will also encourage national member associations to communicate vice versa to IFAPP or just to other national member associations in bi- or tri-directional communications. IFAPP welcomes all news to be shared with other member associations.

IFAPP WORLD: Dr Yil-Seob Lee, thank you very much for your detailed answers. ■

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IFAPP News

IFAPP Treasurer

Dr Rudolf van Olden (left), here in one of his last official acts as IFAPP President, has thanked Dr Norbert Clemens for the commitment, the reliability and the accuracy he revealed in his function as IFAPP Treasurer.

Dr Gerfried Nell from Austria was elected IFAPP Treasurer and took up his office from January 2013 on. He is very familiar with the IFAPP business since he has served the federation since 2001. He was IFAPP President from 2008 to 2011 and joined the group of initiators who initially launched the IMI PharmaTrain project (see IFAPP WORLD 1-2009 and 2-2011).

http://ifapp.org/Publications/IFAPP-World

He succeeds Dr Norbert Clemens, who resigns from his IFAPP Treasurer duties at his own request. Dr Norbert Clemens has been in office since January 2009 and will pass it over early in 2013. ■

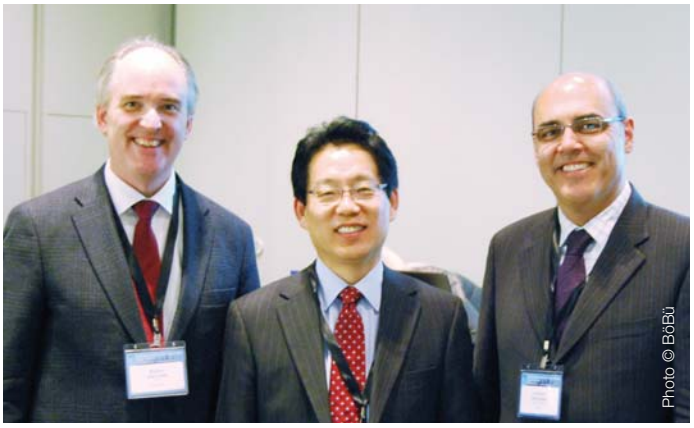
IFAPP News from the Executive Committee and House of Delegates Meeting and the General Assembly at ICPM 2012 in Barcelona, Spain, 14th – 16th November 2012.

IFAPP News

New President

New IFAPP President is Dr Yil-Seob Lee from Seoul, South Korea. He has served as a member of the IFAPP Executive Committee and as a member of IFAPP's Council for Education in Pharmaceutical Medicine (CEPM) and was recognized before as the highly esteemed host of the International Conference on Pharmaceutical Medicine – ICPM 2006 – in Seoul, South Korea, during his presidency of the Korean Society of Pharmaceutical Medicine (KSPM).

He was elected in April 2011, then started as President-elect and just took over the Presidency on November 15, 2012, at the 16th 'International Conference on Pharmaceutical Medicine' – ICPM 2012 – in Barcelona, Spain. For details about his person please note the information on page 3 of this IFAPP WORLD issue. His current term of office will run for two years.



IFAPP Presidents: (left to right) Dr Rudolf van Olden (Past President), Dr Yil-Seob Lee (President), Dr Gustavo Kesselring (President-elect) at the office handover during IFAPP's House of Delegate meeting, 15th November 2012, at the 16th 'International Conference on Pharmaceutical Medicine' – ICPM 2012 – in Barcelona, Spain.

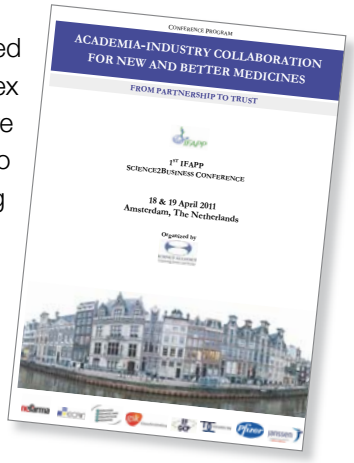
Further on, during his Presidency Dr Rudolf van Olden initiated and completed a relaunch of the IFAPP website WWW.IFAPP.ORG in May 2012. The new digital portal of the federation is equipped with a new menu framework, in new colors and is easy to navigate. Four IFAPP WORLD issues were published during his Presidency, which he supported with several contributions.

IFAPP News

Past President

Dr Rudolf van Olden, The Netherlands, handed over his IFAPP Presidency to his successor Dr Yil Seob Lee, South Korea, on November 15, 2012.

Dr Rudolf van Olden was instrumental in the development of a new IFAPP event format: the IFAPP Science2Business (S2B) Conference. The first S2B two-day conference was held in April 2011 in Amsterdam, The Netherlands, under the banner "Academia-Industry Collaboration for New and Better Medicines". The success of this conference encouraged IFAPP to follow on – the next S2B conference is planned for September 2013 in Seoul, South Korea, under the leadership of the new IFAPP President, Dr Yil-Seob Lee.



And, particularly important, he initiated and most actively pursued in a complex process the renewal of IFAPP's structure of operational boards and tasks to better cope with the currently changing environment of Pharmaceutical Medicine. This process is on its way, further pushed by the new IFAPP President, Dr Yil-Seob Lee, and IFAPP WORLD will keep its readers posted.

Meanwhile, Dr Rudolf van Olden has released his proposal for a new IFAPP structure, which is being discussed and partly executed. Furthermore, a Governance Committee has

According to its designation IFAPP now stands for the International Federation of Pharmaceutical Physicians & Pharmaceutical Medicine.

been set up to draft a proposal concerning transparent and clear principle rules and procedures for all IFAPP office-holders.

And he has recently obtained approval by the House of Delegates to extend the name of IFAPP to International Federation of Associations of Pharmaceutical Physicians & Pharmaceutical Medicine (see header bar above). This became necessary to better reflect and represent IFAPP's membership of Pharmaceutical Medicine professionals, who are likewise physicians and non-physicians. On page 16 in this issue IFAPP WORLD starts to draw a picture of the complete IFAPP membership and its composition – the first focus is on the particular situation in Switzerland.

IFAPP News

President-elect

Dr Gustavo Kesselring was elected IFAPP President-elect by the House of Delegates. He is currently Vice-President of the Brazilian Society of Pharmaceutical Medicine (SBMF – Sociedade Brasileira de Medicina Farmacêutica), an IFAPP member association, and he is the SBMF delegate to IFAPP. In 2014 he will succeed the IFAPP President-in-Office, Dr Yil-Seob Lee.

Dr Gustavo Kesselring (right) on the day of his election for IFAPP President-elect – here beside Dr João Massud Filho, SBMF President.

In 2011 Dr Kesselring received the Honorary Lifetime Membership Award of the Academy of Pharmaceutical Physicians and Investigators (APPI) for his leadership in Pharmaceutical Medicine and his contributions to APPI (see IFAPP WORLD 1-2011).

http://ifapp.org/Publications/IFAPP-World

IFAPP News

ICPM 2014

In 2014, the 17th 'International Conference on Pharmaceutical Medicine' – ICPM 2014 – will take place in Berlin, Germany, on March 27th-28th, 2014. Dr Axel Mescheder, President-elect of the German Society of Pharmaceutical Medicine (DGPharMed – Deutsche Gesellschaft für Pharmazeutische Medizin), will chair the ICPM 2014 Organizing Committee.

IFAPP kindly requests all member associations and all readers to place this event information easily visible on their websites and in their associations' calendars and to distribute the respective hand-out – attached at the end of this IFAPP WORLD issue and available for download at WWW.IFAPP.ORG – thank you in advance.

IFAPP News

New IFAPP Member

The Philippine College of Pharmaceutical Medicine (PCPM) has been newly accepted as an IFAPP member association and is warmly welcomed. The PCPM President is Dr Sonia E. Bongala. On the next page the PCPM provides detailed information concerning its status quo.

Dr Sonia E. Bongala

Dr Alexander Tuazon, PCPM Immediate Past President

The Philippine College of Pharmaceutical Medicine (PCPM) has 106 members which work in the industry, in the academy or in hospitals.

IFAPP's Regional Update

The Philippine College of Pharmaceutical Medicine (PCPM) – The History in Brief

The Philippine College of Pharmaceutical Medicine (PCPM) traces its beginnings in 1969 when the Association of Medical Directors in the Philippine Pharmaceutical Industry (AMDPPI) was founded.

The AMDPPI held partnerships with the Philippine Medical Association, the Drug Association of the Philippines and the Department of Health. The AMDPPI published the Philippine Drug Reference. Its recommendations led the drug regulatory agency to mandate that no pharmaceutical company should operate without a medical director. The medical director primarily then served as the liaison officer between the pharmaceutical company and the government. In 1988, AMDPPI was part of the consultations with the Drug Regulatory Agency, the Congress and the Senate in drafting the Generics Act of 1988 in an attempt to reduce the price of medicines.

In 1991, the association's name was changed to the Philippine College of Pharmaceutical Medicine (PCPM) and the character of the association changed from one representing the pharmaceutical industry to a full medical organization with emphasis on professionalization and continuing professional education. Its role as an expert body in Pharmaceutical Medicine continued as the association is constantly consulted by the Drug Regulatory Agency, educational institutions and other professional associations, including the Philippine Medical Association to which the PCPM is an affiliate society.

Hand in hand with training sessions, the PCPM has conducted its annual convention and regularly scheduled continuing professional education meetings serving as venues to keep its members updated on industry developments. These meetings continue to this day as the forum for updates and sharing best practices.

The PCPM takes an active part in healthcare issues of national interest and freely take a stand on matters that affect the welfare of the industry in general and the patients in particular. It works with the Philippine Society of Experimental and Clinical Pharmacology (PSECP) and the Philippine Clinical Research Professionals (PCRP) on three common goals:

1. advocacy against counterfeit drugs
2. research initiatives
3. continuing medical education programs.

PCPM also works with the new Philippine Food and Drug Administration (PFDA), the newly constituted National Formulary Executive Council and the Philippine Research Ethics Board in establishing guidelines on proper conduct of clinical trials, pharmacovigilance, post-marketing surveillance and medical information.

To date, the PCPM has 106 members, 99 of which work in the pharmaceutical industry and 7 in academia or in hospitals.

Dr Alexander Tuazon, PCPM Immediate Past President, Philippines

Focus on South Korea

A Short History of Trial Conduct in South Korea

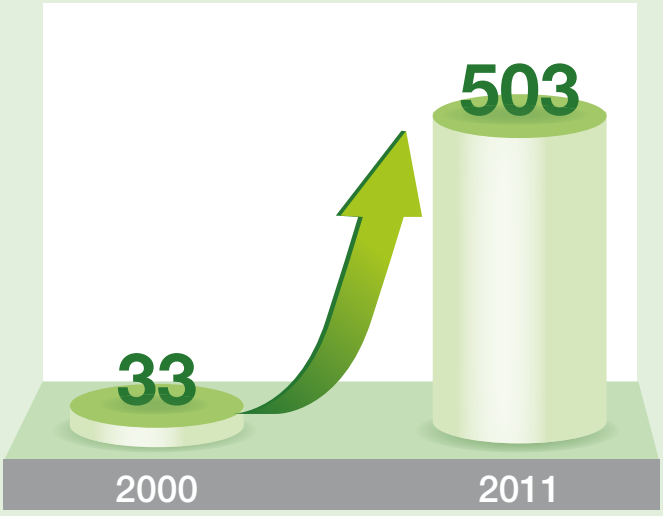
There is a joint effort behind South Korea's significant achievements and remarkable successes in clinical research (see the bullets in the box) with people involved from academia, industry and administration. In 2002 South Korea adopted ICH-GCP and separated the approval of trial protocols regarding investigational new drugs (IND) and new drug applications (NDA). At the same time, the Korean Association of Institutional Review Boards (KAIRB) was established. Since 2007 the Korean Ministry of Health and Welfare (MoHW) has supported the KAIRB; so far, three IRB institutions in South Korea have been accredited by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP – www.aahrpp.org) and more than 15 institutions have been recognized by the Forum for Ethics Review Committees in the Asian and Western Pacific Region (FERCAP – www.w.fercap-sidcer.org) or the Strategic Initiative for Developing Capacity in Ethics Review (SIDCER – www.who.int/sidcer/en).

In 2004, an industry-academia-government co-operation was established by the Korea Food and Drug Administration (KFDA), which has resolved many regulatory hurdles for clinical research. At the same time, a Regional Clinical Trial Center (RCTC) program supported the set-up of clinical trial centers at academic institutions throughout the nation that meet the international quality standards regarding trial conduct and subject protection.

This all together has improved the clinical research environment in South Korea and the number of clinical trials conducted has increased rapidly (see in the box).

Significant Achievements and Remarkable Successes

During the last decade, the number of clinical trials in South Korea has tremendously increased: In 2000 the conduct of 33 phase I-IV clinical trials was approved by the Korea Food and Drug Administration (KFDA); this number increased up to 503 in 2011.

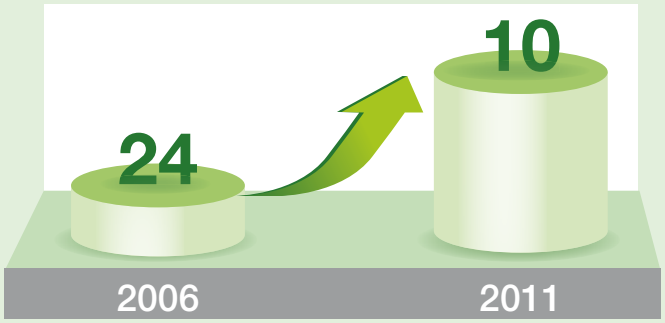


South Korea: Number of clinical trial conducts approved by KFDA

Dr Min Soo Park, South Korea,

"We are well aware that it is important to care about ethical issues, the protection of patients and the quality of data we produce."

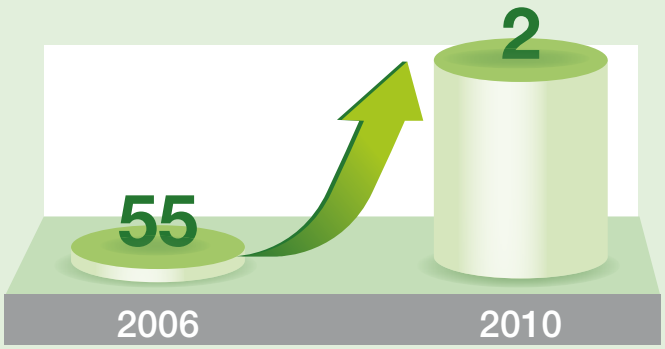
In 2006, the total number of approved industry sponsored clinical trial protocols puts South Korea in position 24 in a global ranking according to the US ClinicalTrials.gov registry. In 2011, this was lifted up to position 10, which is position 2 in Asia-Pacific countries, close behind Australia in position 1.



South Korea in a global ranking by the number of clinical trial conducts approved by KFDA according to ClinicalTrials.gov

All major international operating pharmaceutical companies and contract research organizations were engaged as trial sponsors or operators; by far the most trials were conducted in oncology.

In March 2011, the country counted 132 KFDA certified trial sites. In a global comparison by the number of trial sites per city, Seoul was on position 55 in 2006 and reached position 2 in 2010 behind Berlin in Germany.



South Korea in a global ranking by the number of clinical trial sites according to ClinicalTrials.gov

South Korea also has established domestic pharmaceutical companies, which are relatively small and initially depended on the investments from the global pharma industry. However, they steadily developed new drugs and by the year 2010 South Korean companies had developed and registered 18 new drugs; in these terms, South Korean reached the 10th position worldwide.

In 2007, the clinical trial centers had to be coordinated for creating synergy and for raising new professionals to tackle with the increasing number of trials. That's why a body called KoNECT – Korea National Enterprise for Clinical Trials – was established in order to consolidate the infrastructure for a global clinical trial hub (see page 13).

"We have increased our capacity in conducting clinical trials in Korea tremendously. At the same time we are well aware that it is important to care about ethical issues, the protection of patients and the quality of data we produce. Today, Korea is one of the few countries in the world that certifies clinical trial sites before they are allowed to conduct clinical trials." Dr Min Soo Park, Director of the Clinical Trial Center and the Department of Clinical Pharmacology at the Yonsei University in Seoul, KoNECT vice president, South Korea, stated in his presentation at ICPM 2012 in Barcelona, Spain.

What also matters is the Korea Drug Development Fund (KDDF), established in 2011; it is funded by three South

Korean Ministries with a total of 1 billion US$ for giving grants to academia and industry in South Korea to develop new drugs for the global market. With regards to a news release in October 2012, there are 16 awarded projects in the portfolio, which span the whole drug development continuum and various therapeutic areas [Peter Mansell; Pharma Times online 23 October 2012].

Overview by Eckhard Böttcher-Bühler based for the most part on a presentation given at the International Conference on Pharmaceutical Medicine – ICPM 2012 – in Barcelona, Spain, in November 2012 by Dr Min Soo Park, Director of the Clinical Trial Center and the Department of Clinical Pharmacology at the Yonsei University in Seoul, South Korea. ■

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IFAPP is in search of further Gold and Silver Sponsors.

Detailed information on sponsorship opportunities is available at www.IFAPP.org, section "sponsors" in the menu. ■

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 30 national member associations representing ca. 5,500 Pharmaceutical Medicine professionals worldwide.

IFAPP acts as an international forum for all Pharmaceutical Medicine experts' organizations worldwide by dealing with matters brought to its attention through national member associations.

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KoNECT paid its efforts to create synergy among related industries, professionals and technology on clinical trials in South Korea.

The International Perspective

KoNECT – South Korean Enterprise

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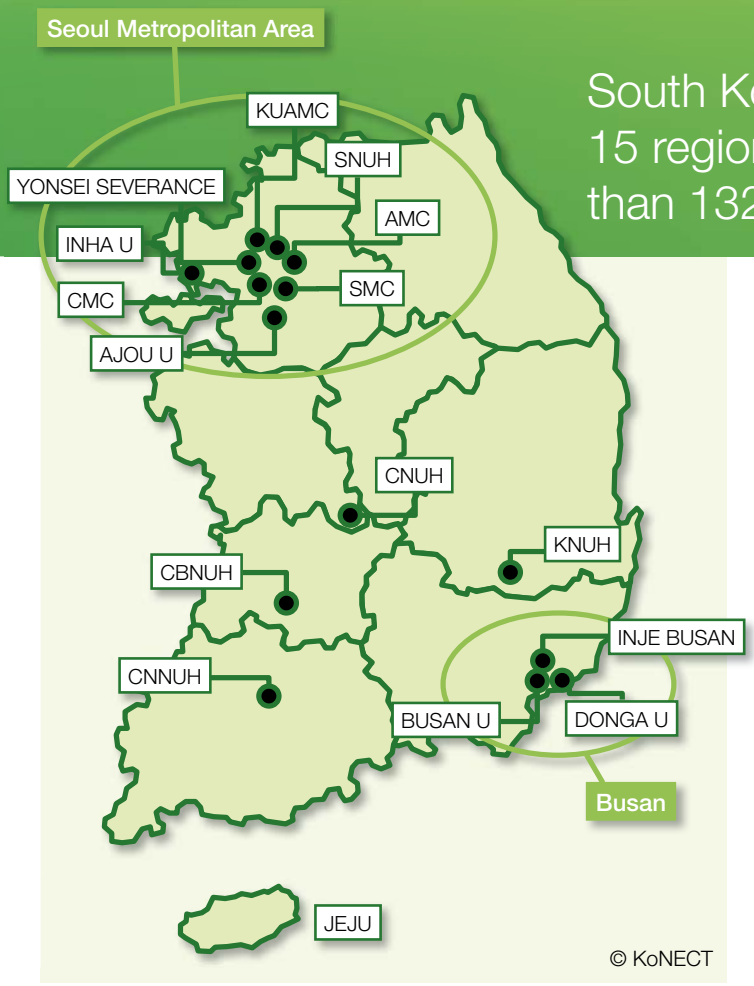
South Korea entered the international clinical research scene as a serious international partner around the turn of the millennium 2000. Due to its joint efforts, the country was very successful in trial participations, and the number of trials conducted constantly increased, which challenged the infrastructure available in the country ever more.

In 2007, a body called KoNECT – Korea National Enterprise for Clinical Trials – was established with "support from the South Korean government, academics and related business industries in order to meet the increasing demands for clinical trials and to raise national competitiveness by fostering necessary human resources, developing core technology, and building a solid infrastructure to become a global clinical trial hub." [KoNECT website www.konect.or.kr – Professor Dr Sang-Goo Shin, KoNECT President; President's Message]

Clinical Research Networks and Alliances

Clinical research for new medicines is an international business and more than ever needs globally organized structures, networks and alliances. In fact, several such initiatives have already been established, and IFAPP WORLD has introduced some of them (see the box on page 15). In the current and in the following issues, IFAPP WORLD will follow on to shed some light on such initiatives by summarizing descriptions of the initiators without giving any rating or recommendation.

Since then, KoNECT has established a network of 15 regional clinical trial centers (RCTC – see the map) with 132 investigational trial sites in major university hospitals nationwide, all of which are certified by the Korea Food and



South Korea: Locations of KoNECT's 15 regional clinical trial centers with more than 132 KFDA certified trial sites.

Drug Administration (KFDA). KoNECT has also enacted three programs to further foster clinical research in South Korea:

1. The Regional Clinical Trial Centers Support Group was established to coordinate the 15 regional clinical trial centers (RCTC).
2. The Clinical Trial Training Academy was set-up to educate and train clinical trial specialists. In 2008 the academy ran 19 education centers with eight different programs.
3. Grants are provided by the Korean Ministry of Health and Welfare to support the development and propagation of new innovative technologies for the clinical trial conduct, e.g., biomarkers.

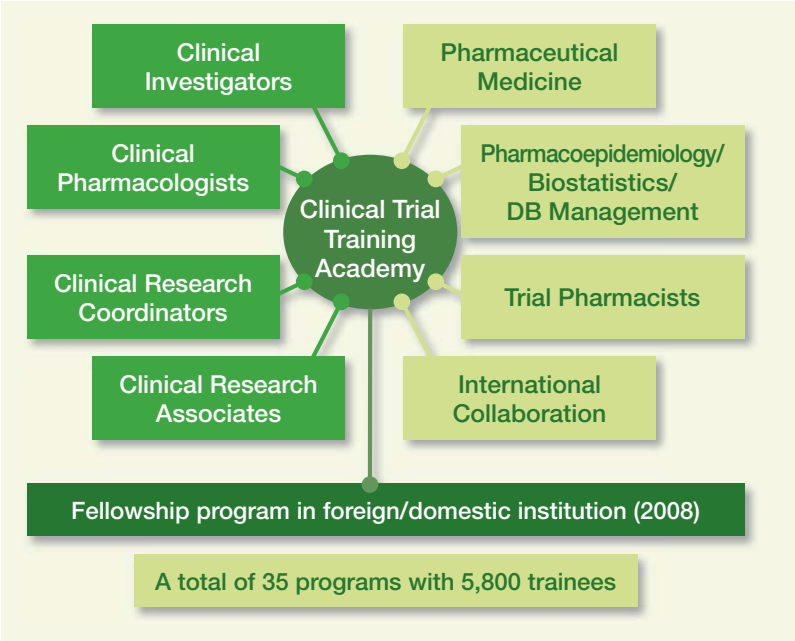
Along with that, KoNECT runs an information center and provides support that has been utilized for the improvement of clinical development in South Korea .

Recently, KoNECT has started a Global Center of Excellence in Clinical Trial Program that will support two trial centers for five years in an attempt to shape them as peer leaders.

Training Core Competencies

The Clinical Trial Training Academy offers systematic training programs, tailored for different professionals involved in clinical trials – clinical investigators, clinical research coordinator (CRC), clinical research associates (CRA), clinical pharmacologists, trial pharmacists, and pharmacoepidemiologists, biostatistician and data manager.

Recently, KoNECT has tackled on a certification system for three different trial professionals: physician investigators, CRC and CRA.



KoNECT educates and trains clinical trial specialists *© KoNECT*

Proposals from readers concerning the presentation of clinical research networks and alliances are welcome. Please contact boebue@boebue.de with your ideas.

Dr Min Soo Park (right) in the discussion and answer session after his presentation – beside Dr Enrique Jiménez, Spain (left), Professor Dr Greg Koski, USA, and Professor Dr Fritz Bühler, Switzerland (hidden).

KoNECT has also created training programs in Pharmaceutical Medicine:

- A Master's program in Yonsei University, which is accredited by the IFAPP Council for Education in Pharmaceutical Medicine (CEPM) and is an affiliate of PharmaTrain, the European Pharmaceutical Medicines Training Programme (www.pharmatrain.eu).
- The Advanced Course on Pharmaceutical Medicine at Seoul National University.

In collaboration with global pharmaceutical companies and contract research organizations, (CRO) KoNECT is also continuing to organize special fellowship training programs for South Korean clinical research professionals in foreign institutions. By 2011, the number of such education and training programs had already increased to as much as 35, with a total of 5,800 trainees.

"All this came about through the joint efforts of the industry, academia and government in South Korea. Together, we will further develop the environment to build global competitiveness for the highest quality in science and ethics and the most efficient system for clinical research and development" – Dr Min Soo Park, Director of the Clinical Trial Center and the Department of Clinical Pharmacology at the Yonsei University, KoNECT vice president, Seoul, South Korea, stated in his presentation in ICPM 2012 in Barcelona, Spain.

Overview by Eckhard Böttcher-Bühler based on a presentation given at the International Conference on Pharmaceutical Medicine – ICPM 2012 – in Barcelona, Spain, in November 2012 by Dr Min Soo Park, Director of the Clinical Trial Center and the Department of Clinical Pharmacology at the Yonsei University in Seoul, South Korea. ■

IFAPP WORLD Reports on Networks and Alliances

ACRES – Alliance for Clinical Research Excellence and Safety
IFAPP WORLD 2-2012 p. 8; 1-2012 p. 10; 1-2010 p. 1

CTTI – Clinical Trials Transformation Initiative
IFAPP WORLD 1-2012 p. 8

CTSA – Clinical and Translational Science Awards Program
IFAPP WORLD 1-2012 p. 8

MRCT – Multi-Regional Clinical Trials Initiative
IFAPP WORLD 1-2012 p. 9

KoNECT – South Korean Enterprise
IFAPP WORLD 3-2012 p. 13

http://ifapp.org/Publications/IFAPP-World

Preview

The ViS Research Institute – a "Collaborative Analytics for Clinical Research" platform will be presented in the next IFAPP WORLD edition. Its website www.visresearch.org promises "A game-changing analytics platform for clinical trial planning". ■

Reports and Concepts

Pharmaceutical Physicians and Pharmaceutical Medicine Professionals – Two Sides of One Coin

Recently, IFAPP has extended its name – according to its designation, IFAPP now stands for the International Federation of Pharmaceutical Physicians & Pharmaceutical Medicine. This reflects the memberships of IFAPP's member associations. Several of these associations include Pharmaceutical Medicine professionals who are likewise physicians and non-physicians. Others limit their membership to physicians only.

IFAPP WORLD hereby starts to draw a picture of the complete IFAPP membership and its composition. The first focus is put on the particular situation in Switzerland.

Photo © Fotolia

Switzerland: SwAPP and SGPM

In Switzerland there is an association and a society representing professionals in Pharmaceutical Medicine: the Swiss Association of Pharmaceutical Professionals (SwAPP; www.swapp.ch) and the Swiss Society of Pharmaceutical Medicine (SGPM; www.sgpm.ch). Both are member associations of IFAPP.

SwAPP was founded in late 1995 whilst SGPM officially started its activities in June 1997. SGPM was created as a prerequisite for the creation of a physicians' specialization in Pharmaceutical Medicine as was also legally required by the Swiss Society of Physicians FMH (Foederatio Medicorum Helveticorum). This specialization was granted by the FMH in 1999, and Switzerland was the first country worldwide to introduce a specialist title in Pharmaceutical Medicine for physicians.

- SwAPP counts about 300 members; physicians are welcomed.
- In SGPM there are about 150 members, physicians only.

These are good membership figures for a small country such as Switzerland with its approximately 8 million inhabitants. ▶

The SGPM postgraduate training for the title in Pharmaceutical Medicine takes five years and consists of practical and theoretical training and a written and oral examination at the end. Foreign physicians with a non-Swiss physician certificate can also apply for the Swiss specialization in Pharmaceutical Medicine provided they fulfill the entry criteria according to the official Swiss postgraduate training program.

Invitation

Other IFAPP members associations are very welcome to portray their own rules and principles with regard to their membership composition. Please contact boebue@boebue.de with your contribution.

Investigators treating patients at trial sites are not obliged to be physician Specialists in Pharmaceutical Medicine, but need to be certificated in Good Clinical Practice (GCP) according to the specifications of SwissMedic, the Swiss agency for the authorization and supervision of therapeutic products.

SwAPP also offers so-called Specialty Diplomas in specific areas as, for example, in Pharmaceutical Medicine (PM), Regulatory Affairs and Study Management. The written examination for the SwAPP Diploma in PM and for the SGPM physician's title 'Specialist in PM' is identical.

The SGPM specialist exams are held at the University of Basel in Switzerland once a year at the same time as the non-physicians' exams for the SwAPP Specialty Diploma in Pharmaceutical Medicine.

SGPM is a member of the Swiss Society of Pharmacology and Toxicology (SSPT), and participates in their annual spring conference with one or two sessions. In addition, each year since 1996, SwAPP and SGPM have co-organized an annual symposium which always takes place at the end of November and is held in English language due to Switzerland's multi-lingual status. This also helps to attract external speakers and attendees who additionally benefit from a relatively low registration fee (CHF 200 for members, CHF 300 for non-members).

In spring, in addition to the annual symposium in autumn, SwAPP conducts a half-day meeting with stakeholders from the Swiss health system and representatives from the authorities. Both SwAPP and SGPM provide mutually recognized accreditation and hold joint board meetings once or twice a year.

Overall, SwAPP and SGPM maintain a fruitful cooperation and collaboration without any unnecessary competition. Both of them are members of IFAPP, where they are represented by their delegates Dr Annette Magnin for SwAPP and Dr Brigitte Franke-Bray for SGPM.

IFAPP WORLD thanks Dr Brigitte Franke-Bray (photo), Member of the SGPM Board and SGPM Delegate to IFAPP, for the detailed information she has provided for this synopsis.

IFAPP's ETHICS CORNER

Would you think of ethics when selecting investigational sites to place a clinical trial? Whether you are yes or no – please notice IFAPP's Ethics Corner article "Ethical Quandary: Site Selection Dilemmas" (see IFAPP WORLD June 2012 page 3).

http://ifapp.org/Publications/IFAPP-World

IFAPP WORLD has already collected opinions on that from different countries and will publish them in the next IFAPP WORLD issue to be released in spring 2013.

We would appreciate to receive your opinions, comments, experience or questions. We therefore invite you to respond to Dr Jane Barrett (janebarrett@doctors.org.uk) or to the editor (boebue@boebue.de). With your permission, we might publish it completely or in parts and, upon your request, without disclosing your name.