2013 April

IFAPPWORLD

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS & PHARMACEUTICAL MEDICINE

PRESIDENT'S LETTER

Dear Colleagues

I am glad to address my words to you and to all IFAPP members through IFAPP WORLD again. I like to use IFAPP WORLD properly as an efficient and effective tool to communicate with all of you in so many different countries. And I hope we can share more information through ...

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IFAPP'S ETHICS CORNER

Ethical Quandary: How Much Should We Ask Before Site Selection?

Irrespective of where you stand on the question above – please notice IFAPP's Ethics Corner article "Ethical Quandary: Site Selection Dilemmas" which provided two case studies exploring ...

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THE INTERNATIONAL PERSPECTIVE

Pharmaceutical Physicians and PM Professionals – Partner on a Par

Physicians and non-physician pharmaceutical medicine (PM) professionals – How are IFAPP member associations dealing with it? IFAPP WORLD presents answers form the United States, Japan, Mexico, Australia, Brazil, Romania and Greece.

▶ page 4 + 14

17th 'International Conference on Pharmaceutical Medicine'

March 20-21, 2014 in BERLIN, Germany
Please note the date

▶ page 18 + 19

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WWW.IFAPP.ORG

Dr Yil-Seob Lee, IFAPP President, South Korea

"IFAPP WORLD is a great communication platform to share news from IFAPP's member associations and news from IFAPP."

President's Letter

Dear Colleagues

IFAPP's communication platform: IFAPP WORLD

I am glad to address my words to you and to all IFAPP members through IFAPP WORLD again. I like to use IFAPP WORLD properly as an efficient and effective tool to communicate with all of you in so many different countries. And I hope we can share more information through IFAPP WORLD. With this in mind, I would like to update you on what has happened in IFAPP since my last communiqué of January.

The IFAPP secretariat, namely Ilse van der Woude from the Netherlands, has contacted all national member associations to figure out changes made on any of their matters. It is not that easy to reach out to all our appreciated members, however, it is good to know what goes on within their organizations and to offer help where help is needed.

The majority of our members are doing fine and are active. However, some of us were challenged or have even experienced difficulties in certain matters and some are still working hard to cope with it, e.g., with ethics, compliance or financial issues, the latter due to the global economic crisis. We are all trying to find ways for IFAPP to support these members concerned.

Meanwhile, we have learned that this kind of close networking is very important to all of us – for the national member associations as well as for IFAPP. Moreover, since a two-way communication is always the best, I also would like to kindly invite you and all IFAPP members to update each other on any activities regarding your association in particular and on pharmaceutical medicine in general. In this regard please pay extra attention to page 14–17 where you can read several responses from IFAPP members to the question about their composition of memberships.

I believe IFAPP WORLD is a great communication platform to share news from IFAPP's member associations and news from IFAPP. Please participate and consider sharing what is ▶

At the 25th Annual DIA EuroMeeting in Amsterdam on March 4-6, 2013, IFAPP had an exhibition booth to promote IFAPP activities, members and pharmaceutical medicine: Dr Gustavo Kesselring, IFAPP President Elect, Caroline van Bruggen (center) and Ilse van der Woude (left) from the IFAPP secretariat at the IFAPP exhibition booth (right).

new and what is going on in your association. Therefore, please send a respective message to the IFAPP secretariat or the IFAPP WORLD Editorial Board (for contact details see "The Flag" on page 18). This will allow IFAPP to distribute it through IFAPP WORLD to colleagues all over the world.

In the meantime, some colleagues of the IFAPP Executive Committee and me are contacting national associations on pharmaceutical medicine, which are not yet members of IFAPP, to encourage them to join our federation. Moreover, we also assist our colleagues in a few countries in setting up an association for pharmaceutical medicine and joining the IFAPP. By doing so, we further promote pharmaceutical medicine and will hopefully gain new IFAPP members, which will strengthen our global network and improve our position.

At the 25th Annual DIA EuroMeeting in Amsterdam on March 4 – 6, IFAPP had an exhibition booth where we promoted IFAPP, our activities, our members and pharmaceutical medicine (above photos). In fact, a lot of visitors at the booth showed an interest in IFAPP, IFAPP activities and its global network.

Last but not least, the IFAPP Governance Committee, which is working on a proposal for new IFAPP procedures and structure is making progress and will present a draft soon. Then, it will be discussed in the IFAPP House of Delegates and finally, when approved, we will share it with all of you.

Wishing you a successful and fruitful performance in 2013 combined with the best regards.

Dr Yil-Seob Lee, IFAPP President, South Korea

Please remember to share with IFAPP and IFAPP WORLD what is new and what is going on in your association. ■

Dr Chris P. Allen, President of the Academy of Physicians in Clinical Research (APCR), USA

"ACRP is open to physicians and non-physicians. APCR is an affiliate of ACRP and being a physician is a condition of membership."

By Dr Chris P. Allen, APCR President, USA

Clinical Research in the United States: APCR and ACRP

The Academy of Physicians in Clinical Research (APCR – www.apcrnet.org) began as the medical section of the Pharmaceutical Manufacturers Association (PMA). In 1993 PMA was reorganized as the Pharmaceutical Research and Manufacturers of America (PhRMA) to concentrate on advocacy. The medical section became the American Academy of Pharmaceutical Physicians (AAPP), an independent professional organization of industry physicians. In 2005, AAPP entered into an affiliation with the Association of Clinical Research Professionals (ACRP; see later), an organization of healthcare professionals based at health research sites, with physician investigators who were members of ACRP becoming members of AAPP.

At that time the name of the organization was changed to the Academy of Pharmaceutical Physicians and Investigators (APPI). The proportion of the physician membership who work as clinical investigators increased over time, and on January 1, 2012 the organization was renamed the Academy of Physicians in Clinical Research – APCR.

Academy of Physicians in Clinical Research – APCR

APCR Members are pharmaceutical physicians, physician investigators, and other physicians in good standing who, in addition to their other professional work, devote a portion of their time to …

- performing studies of drugs, biologics, devices, vaccines or diagnostics,
- activities related to research, development or regulation of these products, or
- teaching the subject of pharmaceutical medicine.

The stated mission of APCR is, "To advance medical innovation and public health by providing advocacy, promoting competence and encouraging exchange for and among physicians involved in or affected by clinical research."

The Monitor appears six times a year as a APCR and ACRP member benefit.

APCR has developed a complete curriculum in pharmaceutical medicine and provides annual meetings and courses. In 2008, APCR joined the Clinical Trials Transformation Initiative (CTTI), a partnership between the U.S. Food and Drug Administration and Duke University, established the previous year to modernize clinical trials. One of the initiative's goals was to increase clinical trials in the U.S. because the number of trials had fallen 30 percent since 2001.

APCR and ACRP are also known for its Code of Ethics & Professional Conduct. Physician investigators have a responsibility to support "the dissemination only of scientifically sound information from clinical trials and other investigations, without regard to study outcomes […] for the benefit of medicine, patients, science and society" [Code of Ethics & Professional Conduct – available here].

APCR has also held a seat as a medical specialty society in the American Medical Association House of Delegates since 2002.

Further to its mission promoting competence, APCR maintains a certification program for Physician Investigators who complete required education, work experience and an examination covering knowledge and skills related to clinical research. The Certified Physician Investigator (CPI) qualification is a renewable time-limited designation. The examination is administered by an independent Academy within the Association of Clinical Research Professionals (ACRP – see next). On September 30, 2012, the National Commission for Certifying Agencies (NCCA) granted accreditation to the Certification Program for demonstrating compliance with the NCCA Standards.

Association of Clinical Research Professionals – ACRP

The Association of Clinical Research Professionals (ACRP – www.acrpnet.org) was founded in 1976 to address the distinct educational and networking needs of research nurses and others who supported the work of clinical investigations. With its own professional society came the recognition of a new distinctive profession – that of the clinical researcher.

More than 35 years later, ACRP is a global association comprised of more than 18,000 individuals in over 70 countries dedicated to clinical research and development. ACRP members are professionals actively engaged in clinical research endeavors, including clinical monitors, clinical research associates, nurses, pharmacists, pharmacologists, physicians, regulatory professionals, clinical research coordinators and clinical research service providers.

Physician and Non-Physician Pharmaceutical Medicine Professionals – How Are IFAPP Member Associations Dealing with It?

Answers to this question are presented on page 14 – 17 in this IFAPP WORLD issue.

Would you think of ethics when selecting investigational sites to place a clinical trial?

IFAPP's ETHICS CORNER

Ethical Quandary: How Much Should We Ask Before Site Selection?

Irrespective of where you stand on the question above – please notice IFAPP's Ethics Corner article "Ethical Quandary: Site Selection Dilemmas" which provided two case studies exploring real-life scenarios pertinent to ethics relevant to pharmaceutical physicians and health professionals (see IFAPP WORLD 2-2012-June – click here). These cases have raised two ethical issues:

First, do we as pharmaceutical physicians have a responsibility to check the workloads of the clinical investigators involved in a study and to check if they have adequate staff?

And second, is it the Contract Research Organization's (CRO's) responsibility to insist that action be taken against investigators who transgress even if the sponsor's organization paying the CRO chooses not to?

It should be appreciated that each scenario was expressed as a vignette, thus, our IFAPP WORLD readers, the pharmaceutical physicians and pharmaceutical medicine professionals can learn and gain from the experience. And a panel of IFAPP's Pharmaceutical Medicine Ethics Councils (PMEC) and our readers were asked for their clinical, regulatory, country and cultural perspective and opinion. Our panelists have no vested interest in the outcome but they believe that the IFAPP ethics principles stimulate a base for a meaningful debate.

Dr Sander Becker, Australia, co-chair of IFAPP's Pharmaceutical Medicine Ethics Council (PMEC)

The debate on ethical quandary on site selection highlighted:

1. "… most critical is that the patients have been enrolled without consent, which is by far the most significant violation of fundamental ethics …."

2. "… it would be totally improper and would not be in accordance with the protection of personal rights […] to inquire about the doctor's private life."

3. The case also sheds light on the difficulty which pharmaceutical physicians face when a colleague is compromised albeit with alcohol, drug dependence, or family life problems.

4. "… avid researchers involved in (too) many trials may be susceptible to money fraud."

5. "...need to acknowledge record and report the transgression to the sponsor. Whether or not the sponsor takes heed thereof…"

European, Asian and Latin American Ethics Flavor

As you can see below – our PMEC panelists from Germany, Argentina and Japan provide European, Latin American and Asian ethics flavor.

Dr Hans Weber, Germany

Case 1: Of course, an investigator who is alcoholic should not be recruited for a study. But alcoholism is not always obvious, and it would be totally improper and would not be in accordance with the protection of personal rights for a company monitor to inquire about the doctor's private life. Thus, in my opinion the arguments brought forward by the lawyer are nonsense unless alcoholism of the doctor would have been a generally known issue and mentioned to the monitor.

Case 2: Usually, a pharmaceutical physician should not do own workload checks but follow the advice of a monitor – a CRO's monitor in case of outsourcing has the same function as the company's internal monitors – and respect his assessment of site workload. In this case immediate action does not seem to be necessary other than closing the site and carefully reporting the findings and possibly excluding the patients from analysis in the final report. As the bottle-neck in workload appears to be the study nurse the investigator may stay as first author if he admits the time for his responsibilities according to the publication rules. This would not depend on own patients in the study.

Dr Luis Collia, Argentina

Case 1: The sponsoring company and the monitor are not responsible for knowing the private life of a researcher. However, when analyzing the capacity of the site and the investigator, I think you should investigate the ability of the researcher and this may arise from the interview with the investigator or the sub-investigator's comments. I think with this type of behavior, there is no doubt that the researcher's colleagues would know the behavior of the person.

Case 2: Again, it falls into a poor selection of the research center. Those responsible on the CRO's side and the monitor should alert the sponsor and should not allow a center, which is already involved in too many research projects, to start another study.

Not to forget that unwillingness, overload and inability of researchers and research staff might turn down the conduct of a study on the one hand and on the other hand avid researchers involved in (too) many trials may be susceptible to money fraud.

It should also be a matter of the agreement between CRO and Sponsor that a very busy research center gives rise to concerns regarding voluntary or involuntary mistakes.

Dr Jane Barrett, United Kingdom, co-chair of IFAPP's Pharmaceutical Medicine Ethics Council (PMEC)

Professor Dr Yuji Sato, Japan

Case 1: First, I do believe that monitors should assess the site and investigator therein primarily in terms of their scientific, ethical and operational suitability. This case vignette refers to the alleged drinking problem of the investigator, but as I happen to be a psychiatrist I would maintain that the investigator's personal problems, be it a past history of substance abuse or persistent depression following divorce, are relevant only in so far as they affect the said suitability. If they do, the nature or details of the problems aside, the site and the investigator should be deemed unsuitable. In the vignette, what is most critical is that the patients have been enrolled without consent, which is by far the most significant violation of fundamental ethics, and is already grave enough to close the site. This judgment and decision should be made irrespective of the 'causality' of the violation.

Case 2: Here one should also focus first and foremost on the quality of the trial conduct, apart from whether or not the site is 'very busy'. Busy sites are no more malfunctioning in clinical trials than the sites with few patients are. Most critical is the fact that there was significant doubt as to the veracity of the heart rate recorded, in other words suspicion of data forgery at worst. The closure of the site is a necessary first step, and whether or not the company takes further action so as not to instigate the 'important' investigator, merely reflects the company's scientific and ethical standard, obviously inferior to the marketing and sales perspective.

Two answers for the questions raised:

1. Do we, as pharmaceutical physicians, have a responsibility to check workloads and make sure that sites commit only to studies for which they have adequate staff?

   Again, the workload should be taken into consideration in so far as it can affect the trial conduct in terms of operational, scientific and ethical quality.

2. Is it our responsibility to insist that action be taken against investigators who transgress, even if the organization paying them chooses not to?

   Pharmaceutical physicians need to acknowledge, record and report the transgression to the sponsor. Whether or not the sponsor takes heed thereof is of secondary importance; even if the company neglects the report, the fact that the report was made, without any further resultant action from the sponsor, should also be recorded for future regulatory inspection.

Dr Sander Becker, Australia, and
Dr Jane Barrett, United Kingdom,
co-chairs of IFAPP's Pharmaceutical Medicine Ethics Council (PMEC)

Many thanks to the PMEC panelists from Germany, Argentina and Japan for their comments which are appreciated very much.

Now IFAP invites you to get involved! We would appreciate to receive your own case, or your experience, opinion, comment, or questions. Please respond to Dr Jane Barrett (janebarrett@doctors.org.uk) or to the IFAPP WORLD Editor in Chief Eckhard Böttcher-Bühler (boebue@boebue.de). With your permission, we might publish your response in full or in part and, upon your request, without disclosing your name. ■

IFAPP's International Code of Ethical Conduct

Please also pay attention to the poster of IFAPP's Pharmaceutical Medicine Ethics Council (PMEC), which is attached at the end of this IFAPP WORLD issue. This poster has been presented at the 16th International Conference on Pharmaceutical Medicine – ICPM 2012 – November 14-16, 2012, in Barcelona, Spain.

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From the ViS Website www.visresearch.org

"We enable research centers to easily share their disease-specific capabilities, and trial planners to efficiently find the best centers for their clinical trials."

Networks & Alliances

ViS Brings Game-Changing Analytics Platform to Global Clinical Research

Clinical research has become a global endeavor, generating a need for vast amounts of information, covering disease-specific technical capabilities of research centers and the environment in which they operate.

The Problem Today

Put most simply by the ViS Research Institute's website www.visresearch.org: "Trial planners spend much time and resources trying to decipher manually gathered information about research centers and the locations where they operate. Research centers, on the other hand, are inefficiently trying to attract trial planners by filling out non-structured requests for information – the so called 'feasibility questionnaires'" (figure 1).

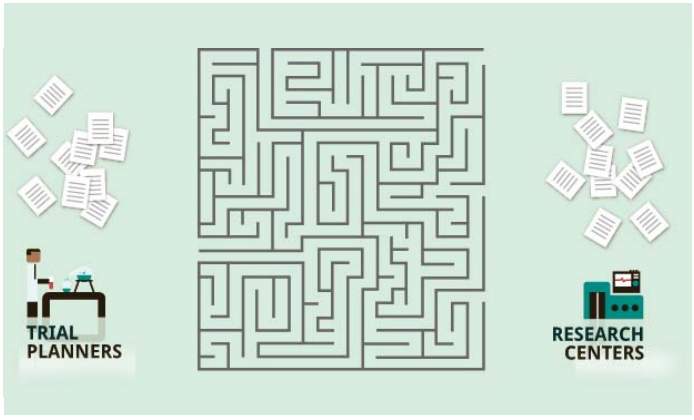


Figure 1: Dealing with a two-fold challenge (© ViS)

This Is where ViS Steps in

ViS addresses these inefficiencies through merging a social network with an analytics platform, integrating exceptional algorithms and using innovative visualizations. This creates an interactive map of global clinical infrastructure, where trial planners can quickly hone in on and find the right disease specific research centers for their needs. They can, for example, easily find information relevant to the locations where centers operate, e.g. (figure 2):

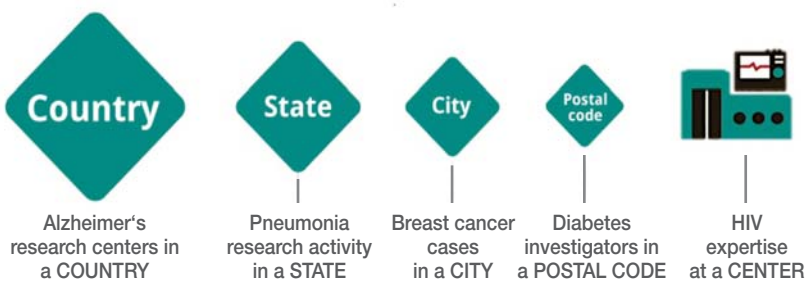


Figure 2: A robust yet simple mapping platform enabling disease specific analytics from country level all the way down to what is inside the research center facilities [© ViS]

- The number of Alzheimer's research centers in a country
- Pneumonia research activity in a state
- Breast cancer cases in a city
- Diabetes investigators in a postal code
- HIV expertise at a research center.

From the ViS Website www.visresearch.org

ViS interconnects emerging and traditional markets through its four regional hubs in New York City, São Paulo, Mumbai, and Frankfurt am Main, with team members spread across other cities worldwide.

- Trial planners also can see "who is doing what, where and how" by zooming in from the country level all the way down to what is inside the research center facilities, e.g.:
  - How many schizophrenia centers are there in Osaka?
  - How many Indian epilepsy centers have access to diffusion tension imaging?
  - Which US centers have access to the largest Alzheimer's patient population?

"The solutions provided by ViS enable clinical research centers for the first time to be seen and recognized globally, and to connect efficiently with pharmaceutical companies. This is something that will greatly help the field of clinical research". – Min Soo Park, MD, PhD, Director of Clinical Trials Center, Severance Hospital, Yonsei University College of Medicine, and Vice President, Korea National Enterprise for Clinical Trials (KoNECT), Seoul, Korea.

A Collaborative Analytics Approach

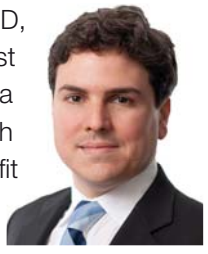
This zooming ability is enabled by ViS' collaborative analytics approach: ViS experts generate analytics relevant to the locations where centers operate, while centers upload their disease-specific profiles directly to the cloud-based ViS enterprise social network (figure 3).

Proposals from readers concerning the presentation of clinical research networks and alliances are welcome. Please contact the IFAPP WORLD Editor in Chief Eckhard Böttcher-Bühler (boebue@boebue.de) with your ideas.

Figure 3: Integrating location analytics, generated using ViS algorithms, with center analytics, submitted by centers in a social network [© ViS]

All together this creates a robust yet simple mapping platform, which – as promised by ViS – allows to harvest, harmonize, and generate vast amounts of information relevant to the conduct of clinical trials and fosters a fruitful collaboration between trial planners and research centers.

Visitors who have registered can easily browse a vast number of centers in the ViS platform and participate in the social network for free. More advanced disease-specific analytics on patient population, research activity and infrastructure are paid and accessed through the platform.



ViS founder and CEO Fabio Thiers, MD, PhD, a Harvard/MIT trained physician-scientist and IT entrepreneur, points out that "as a result, the overall process becomes much more cost-efficient. Trial planners benefit from a cheaper and better center selection process; research centers gain global exposure, using much less time and resources; and we all benefit from the accelerated development of much needed medicines".

BöBü according to an interview, press release and website content ■

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 and will follow on to shed some light on such initiatives by summarizing descriptions of the initiators without giving any rating or recommendation.

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 1-2013 p. 13

ViS Brings Game-Changing Analytics Platform to Global Clinical Research
IFAPP WORLD 2-2013 p. 9

Outlook

CDISC – Clinical Data Interchange Standards Consortium – a global, open, multidisciplinary, non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata.

OUTLOOK

IFAPP WORLD Report Preview

Medication-errors

"In Europe, the medication-error rate in ambulatory care is estimated at 7.5% at prescription and 0.08% at the dispensing stage, whereas in the hospital setting the rates vary between 0.3–9.1% and 1.6–2.1% respectively."

Quoted from the introduction to a "Medication-errors workshop" held by the European Medicines Agency (EMA) on February 28 and March 1, 2013, in London, United Kingdom. This unique event at the European Union (EU) level brought more than 150 people from all stakeholder groups together to determine a way forward for better reporting and prevention of medication errors.

Dr Domenico Criscuolo, IFAPP Delegate, Torino, Italy, will present a detailed report on this workshop for the next issue of IFAPP WORLD released in June/July 2013.

AMEIFAC and the Mexican Chapter of ACRP

Dr Marlene Llópiz, AMEIFAC President, Mexico, and IFAPP Officer will focus on AMEIFAC, ACRP and IFAPP – a combination of knowledge for the betterment of pharmaceutical medicine worldwide. ■

The next Cooperative European Medicines Development Course (CEMDC) will start end of April 2013. Participation might be individually determined until the start of the course.

Education & Certification

Cooperative European Medicines Development Course

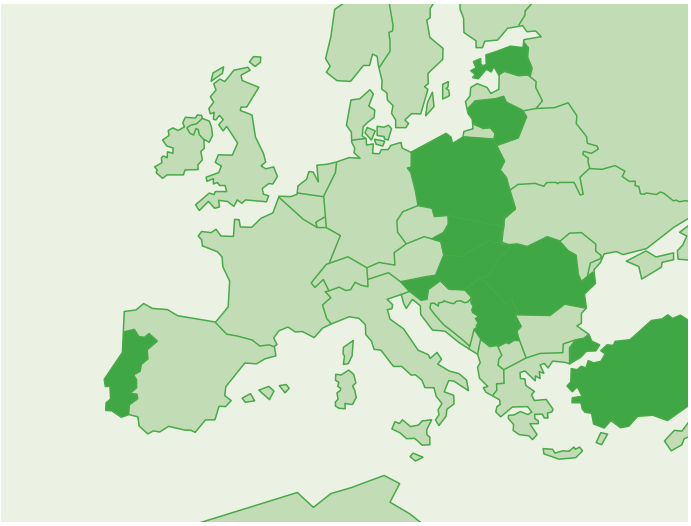
For covering the needs of countries with smaller populations and/or small-sized pharmaceutical industry the Cooperative European Medicines Development Course (CEMDC) was organized with the participation of ten universities located in the Central-East European region.

The aim of the course, which is accredited by PharmaTrain and IFAPP, is to train experts who understand the complex process of medicines development from molecule to health care and who can apply this knowledge working in large or small, innovative or generic pharmaceutical companies, small and medium sized enterprises, regulatory agencies as well as in health care and health insurance management. For this purpose academic and industry experts have carefully compiled the course material.

Students of all nationalities with a medical or pharmaceutical background and a Master of Science or equivalent degrees in natural and life sciences can apply for course participation. A satisfactory English knowledge is needed to follow the program.

The course coordinator is located at the Semmelweis University in Budapest, Hungary; the face-to-face teaching sessions of the various modules will be held at different locations in various Central-East European countries.

Detailed information about the education plan, participation fee, registration and contact details is available at http://cemdc.eu where the locations of course modules are listed.



CEMDC Partner Universities

Estonia: Tartu	Romania: Targu Mures
Hungary: Budapest	Serbia: Belgrade
Lithuania: Kaunas	Slovakia: Bratislava
Poland: Warsaw	Slovenia: Ljubljana
Portugal: Lisbon	Turkey: Ankara

The next modular CEMDC course will start at April 25, 2013. A participation and registration might be individually discussed until the start of the course. According to personal training needs a participation in individual selected modules is possible.

Professor Dr Sandor Kerpel-Fronius, CEMDC Study Director, Delegate to IFAPP, Budapest, Hungary

Linda Meyerson, retired Chief Operating Officer, ICON CR, Philadelphia

"While cost and time matter in clinical trials, ultimately success depends on quality, and site excellence is a hallmark of quality."

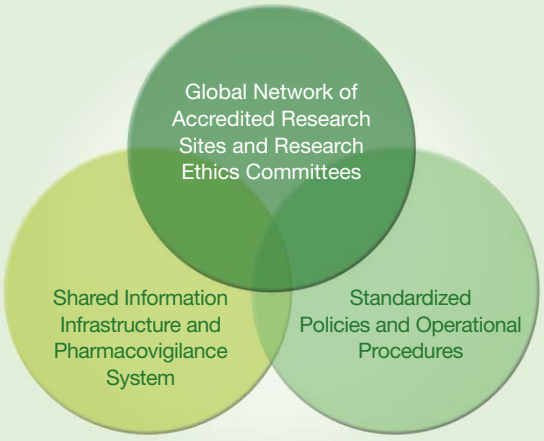
The International Perspective

Collaborative Initiative to Develop Standards for Clinical Research Sites

The Alliance for Clinical Research Excellence and Safety (ACRES) has announced a major step forward in efforts to re-shape the world of clinical research through a collaborative systems approach that leverages the expertise and resources of stakeholders world-wide.

ACRES' Site Accreditation Standards Initiative (SASI), inaugurated in December 2012, has teamed up with industry leaders Linda Meyerson, recently retired as the Chief Operating Officer at ICON CR, a Philadelphia-based pharmaceutical services company, and Tracy Blumenfeld, co-founder, president and CEO of RapidTrials, a leader in improving the efficiency of clinical trials. Both will serve as Co-Chairs of the SASI Steering Committee.

ACRES Global Network Concept



SASI brings together prominent representatives from the multi-sector biomedical research community to promote formal standards for globally recognized, third-party accreditation of clinical research sites worldwide in an attempt to ensure industry-wide inter-operability and enhance safety, quality and efficiency of drug development. Over the next two years, SASI working groups, representing all key stakeholder groups, will develop and pilot test standards in at least four areas: facilities, professional personnel, information technology and quality management.

The complete ACRES News release is available here. More information about ACRES is available at www.acresglobal.net or in IFAPP WORLD (see first point in the box on page 11).

BöBü

IFAPP Community

RSS or e-Mail Alert: Once Subscribed, Always Informed!

Are you interested in being alerted to the availability of IFAPP's latest news, IFAPP WORLD or upcoming IFAPP conferences to stay up-to-date with IFAPP?

1 You can subscribe to IFAPP's RSS feed click here

2 or join IFAPP's mailing list option click here

With your participation you will get (1) a feedreader added to the favorites of your internet browser or (2) an e-mail with a hyperlink to the latest IFAPP news and to the newsletter IFAPP WORLD upon availability.

Physicians and Non-Physician Pharmaceutical Medicine Professionals – How Are IFAPP Member Associations Dealing with It?

The International Perspective: JAPAN

JAPhMed Has Opened its Door to Non-MD Members in 2010

The Japanese Association of Pharmaceutical Medicine (JAPhMed – www.japhmed.jp) was founded in August 1968 by a small group of physicians employed by pharmaceutical companies in Japan. However, "In Japan, non-physicians, most of them pharmacists, have historically driven both pharmaceutical development and regulatory review", Dr Kihito Takahashi, former President of JAPhMed, said in an interview published in IFAPP WORLD 1-2008 available here **and providing a profound insight into major matters of pharmaceutical medicine in Japan.**

JAPhMed opened its doors to non-MD members in 2010 and several new members have joined the association ever since.

JAPhMed has recently performed a survey of its membership which revealed that it counts some 250 members including 10 non-MDs only. It appears that about 70 percent of the JAPhMed membership represents MDs who are employed by pharmaceutical companies, most of them being foreign-based companies. This means that another 30 percent of the members work as occasional consultants or temporary workers for the pharmaceutical industry.

JAPhMed started an on-line mail magazine a few years ago, which has attracted more than 600 subscribers to date. These subscribers largely seem to be non-members of JAPhMed and – as JAPhMed representatives believe – most of them are non-MDs.

The Japanese Ministries of Health, Education, and Economy have already been investing a lot of effort for several years in order to develop a strong infrastructure for the conduct of clinical trials in Japan. In particular, recent efforts to enhance investigator-initiated trials have created numerous positions in academic institutions and national medical centers. Dr Kyoko Imamura: "We will have to work hard to invite these people to join JAPhMed in order to increase our membership."

Dr Kyoko Imamura, Chairperson of JAPhMed's Board of Directors

The International Perspective: MEXICO

AMEIFAC Membership But Not the Board of Directors Open to Physicians and Non-Physicians

AMEIFAC stands for Asociación de Médicos Especialistas en la Industria Farmacéutica, A.C. in Mexico, the Mexican Association of Medical Specialists in the Pharmaceutical Industry (www.ameifac.com.mx). Currently, our membership is comprised of physicians and non-physicians – it is open to everyone working in the health sector and allied health fields.

The Membership is not restricted to any profession but it is required that the members are actively involved in pharmaceutical medicine (PM), e.g., in the design and conduct of clinical trials. Among the non-physicians, AMEIFAC has registered members who are professionals qualified as administrators, biologists, chemists, dentists and nutritionists – just to mention some of them.

However, there is one clause in our rules and regulations stating that only physicians can serve on the AMEIFAC Board of Directors, which is comprised of a President, a Vice-President, a Secretary and the Directors of various commissions: Academic (2 members), Finance (2 members), Regulatory/Normativity (2 members) and Communication (2 members).

This administration of AMEIFAC has recently proposed changing this rule and allowing at least one of the two Directors from each commission to be a non-physician in order to expand and share new thoughts within the Board of Directors at AMEIFAC. We believe there are many talented people out there in all fields related to pharmaceutical medicine who could make a valuable contribution to AMEIFAC's success.

Dr Marlene Llópiz,
AMEIFAC President, Mexico,
and IFAPP Officer

The International Perspective: GREECE

EL.E.F.I. Exclusively for Industry Experts, But Will Extend Membership to Public Domains Soon

First of all, I would like to congratulate IFAPP on the extension of its name into International Federation of Associations of Pharmaceutical Physicians & Pharmaceutical Medicine. This perfectly reflects the membership of the Hellenic Society of Pharmaceutical Medicine (EL.E.F.I. – www.elefi.gr) in Greece.

Both physicians and non-physicians as pharmaceutical medicine professionals are accepted as full members by EL.E.F.I., provided that they work in the pharmaceutical industry within medical or scientific departments. Also, physicians and non-physicians working within Contract Research Organizations (CROs) of various types can apply for a full EL.E.F.I. membership on condition that they are experts in the pharmaceutical medicine field.

Beside EL.E.F.I. there are no other associations for pharmaceutical medicine professionals, neither physicians nor non-physicians.

It is important to note – the Board of EL.E.F.I. Executives is planning to extend the EL.E.F.I. membership in order to accept pharmaceutical medicine experts working in the public sector, e.g., in universities, the National Health Services, the regulatory authorities and other organizations.

Katerina Papathoma, EL.E.F.I. President

The International Perspective: ROMANIA

SOMFAR is a Pharmaceutical Medicine Society for Industry Experts Exclusively

For the time being, the Romanian Society of Pharmaceutical Medicine (Societatea de Medicina Farmaceutica din Romania – SOMFAR – www.somfar.ro) is exclusively dedicated to members working in clinical research, either in the pharmaceutical industry or in clinical research organizations (CROs), having either medical or pharmaceutical background.

The SOMFAR by-laws ruling the terms and conditions of membership were adopted nine years ago. In the nearest future the SOMFAR Boarding Committee may decide to extend the eligibility criteria and admit those pharmaceutical medicine professionals to membership, who are working outside the pharmaceutical industry and CROs even without a medical or pharmaceutical background.

Dr Dumitru Uta, SOMFAR President

Other IFAPP member associations are kindly invited to provide details on their own organization and membership.

The International Perspective: BRAZIL

SBMF Accepts Physicians as Members and Since 2009 Non-Physicians As Well

The Brazilian Society of Pharmaceutical Medicine (Sociedade Brasileira de Medicina Farmacêutica – SBMF – www.sbmf.org.br) was founded in 1971 by physicians working for the pharmaceutical industry.

SBMF accepts physicians as members and since 2009 non-physicians as well. All in all, the SBMF membership includes physicians, nurses, pharmacists, biologists, lawyers and experts of other professions that are involved in the research, development, regulation, surveillance, delivery and marketing of pharmaceuticals, medical devices or related products.

SBMF is a non-profit organization. With its main office located in São Paulo City, it operates throughout Brazil. It offers guidance, support and leadership for the continual development of professionals devoted to pharmaceutical medicine.

SBMF is in continuous interchange with pharmaceutical industry associations, academic associations and institutions, the Brazilian health authorities, e.g. the Brazil Ministry of Health and the National Health Surveillance Agency, and the National Ethics Committee.

Struggling for the recognition of pharmaceutical medicine as a medical specialty, SBMF has a space in the Brazilian Medical Association Journal. Some time ago, a pharmaceutical medicine editorial board was created and the acceptance of articles on this medical field has improved now.

What should be highlighted is SBMF's close connection to and full support of the unique Pharmaceutical Medicine Post Graduate Course, which was launched in September 1999 (see IFAPP WORLD 2-2009, page 9, available here). It is an academic course at the Federal University in São Paulo accredited by IFAPP.

Dr Gustavo Kesselring, SBMF Vice-President, Brazil, Delegate to IFAPP and IFAPP Pesident Elect

The Flag

IFAPP World is a publication of the

International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (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 expert's professional's organizations worldwide by dealing with matters brought to its attention through national member associations.

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As a not-for-profit organization IFAPP appreciates the support it receives from institutions with a passion for enhancing the knowledge, expertise and skills of pharmaceutical medicine professionals worldwide.

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.

17th International Conference on Pharmaceutical Medicine – ICPM

March 20-21, 2014 in BERLIN, Germany – Details next page

IFAPP kindly requests all member associations and all readers to place the ICPM 2014 date announcement from the next page easily visible on their websites and in their associations' calendars and to distribute the respective hand-out – available for download at WWW.IFAPP.ORG – thank you in advance.


SAVE THE DATE
17TH INTERNATIONAL CONFERENCE ON PHARMACEUTICAL MEDICINE
in Verbindung mit / in combination with
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20.–21.03.2014 BERLIN
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Ethics Corner

IFAPP's International Code *of* Ethical Conduct

for Pharmaceutical Physicians & Health Professionals

...10 years on

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IFAPP's Pharmaceutical Medicine Ethics Council

Aims

- IFAPP's International Code of Ethical Conduct is a voluntary code which one hopes will give standards of good Pharmaceutical Medical practice for us as Pharmaceutical Physicians and Health Professionals to follow when facing and dealing with ethical dilemmas
- IFAPP continually re-evaluates ethics behaviours relevant in our contemporary global society
- IFAPP's Ethics Corner brings proactive thinking, real-world issues and progressive debate
- Informed decisions and ethics consideration

Constitution Update

- PMEC invites ethics orientated, experienced, like minded Pharmaceutical Physicians to sit on our panel
- Since 2008 PMEC have 7 councilors – Argentina, Austria, Australia, Germany, Japan, UK, and USA
- Currently Bangladesh, Hungary, Greece, Italy, Mexico, Korea & South Africa have expressed interest

Achievements - *C Factors*

- IFAPP Corner and Concept (IFAPP World – June 2011)
- Capitalising on IFAPP World and IFAPP web communication capability and capital
- Ethics Corner Explores:
  - "Ethical Dilemmas: Beyond Clinical Trials - A Case Study" (IFAPP World June 2011)
  - "Ethical Quandary: Site Selection Dilemmas" (IFAPP World June 2012)

Controversial Decisions - *What have we learned?*

- Responsibility matters beyond Prescription Medicines
- Physician Investigators' ***competence***, ***capability*** & ***compliance*** are relevant
- Personal rights and responsibilities of Pharmaceutical Physicians
- As Pharmaceutical Physicians do we have the responsibility to check workload?
- Errors of omission or commission

Truth, Transparency, Trust

Future Advances

- Medical Doctors vs. Health Sciences graduates vs. PhD
- IFAPP & nMAs - Value added vs. Added Value
- Update Guidelines

IFAPP's Ethics Corner *brings proactive thinking, real-world issues and progressive debate to the table*

IFAPP
International Federation of Associations of Pharmaceutical Physicians