2012 June

IFAPPWORLD

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS

PRESIDENT'S LETTER

Dear Colleagues

You might have downloaded this edition of IFAPP WORLD from our new website. Or you might have visited our website recently for other reasons. In this case you have probably noticed that we have renewed our digital portal behind our well-known address: www.IFAPP.org – we use new colors, a new lay-out, easy-to-use buttons, self-explanatory toolbars, and an environment up to the current standards. Our website is one of the important visual points of our ... ▶ page 2

IFAPP'S ETHICS CORNER

Ethical Quandary: Site Selection Dilemmas

Few pharmaceutical industry researchers think of ethics when selecting investigational sites to place their studies. It is widely accepted that the selection of the right sites to place a clinical trial is the most important step in the development of any drug. The costs are massive; over US$ 25,000 to open a site, up to US$ 2,500 per month to monitor it, and then over a third of sites fail to recruit more ... ▶ page 3

16th International Conference on Pharmaceutical Medicine

November 14-16, 2012, Barcelona – Spain

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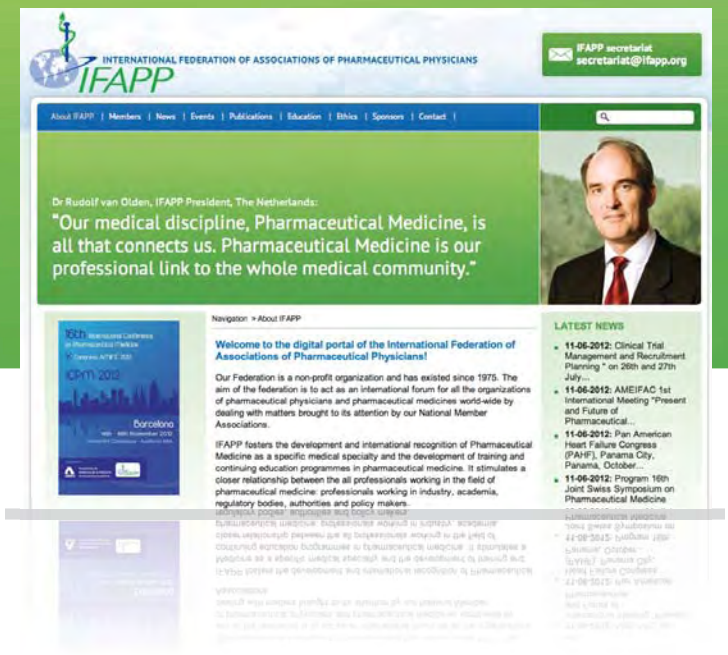
WWW.IFAPP.ORG

Dr Rudolf van Olden, IFAPP President, The Netherlands:

"We have renewed our digital portal where we all are connected: www.IFAPP.org"



President's Letter

Dear Colleagues

You might have downloaded this edition of IFAPP WORLD from our new website. Or you might have visited our website recently for other reasons. In this case you have probably noticed that we have renewed our digital portal behind our well-known address: www.IFAPP.org – we use new colors, a new lay-out, easy-to-use buttons, self-explanatory toolbars, and an environment up to the current standards. Our website is one of the important visual points of our federation where we all are connected.

Behind the digital portal www.IFAPP.org a lot of activities are going on in all our national member associations. Actually, the association in my own country, the Netherlands' Association of Pharmaceutical Medicine (Nederlandse Vereniging voor Farmaceutische Geneeskunde – NVFG), is celebrating their 50th anniversary this year! Congratulations on behalf of the whole IFAPP team! In the past 50 years the NVFG has grown and developed into an association of more than 550 members, including life-scientists and physicians, all of them with the ambition to learn, to connect, and to share the experience gathered in Pharmaceutical Medicine.

When you consider the fact that all IFAPP member associations organize at least their national conferences focused on different topics on and around Pharmaceutical Medicine every year, then you can easily imagine that IFAPP is constantly involved in a lot of activities all over the world, even though it is not always visible to all of us. However, by surfing within the different websites of IFAPP's member associations you learn a lot about their activities and experience, the atmosphere of Pharmaceutical Medicine around the different parts of the globe.

A conference, which is important for all our IFAPP member associations, is the upcoming International Conference on Pharmaceutical Medicine – ICPM 2012. Thanks to our Spanish colleagues from AMIFE, Asociación de Medicina de la Industria Farmaceutica Española, who organize this event, which is to come off in Barcelona on November 14-16, 2012, we all have the opportunity to join this important conference. I strongly recommend and kindly ask you to take a detailed look at the program on www.icpm2012.com and to join this great conference. You will meet a lot of colleagues from Spain and from all over the world. And you can expect a superb selection of relevant topics and excellent speakers. It is all with a focus on Pharmaceutical Medicine, our professional discipline, which is at least our connection in all our professional lives. I really hope to see a lot of you during this conference in Barcelona at the end of this year.

Last but not least: IFAPP also engages in professional development in another way. In the course of the upcoming weeks all the presidents and secretariats of our national member associations will receive a draft document entitled "Core Competencies for Pharmaceutical Physicians and Drug Development Scientists". This draft document was composed by a Working Group set up by IFAPP's Council for Education in Pharmaceutical Medicine (CEPM) under the leadership of Dr Honorio Silva. May we kindly request all the national member associations to review this document and provide feedback to us by the end of September this year 2012. Our objective is to get the document cleared and then present it at ICPM 2012 in Barcelona where we will also offer a handout to all of you!

Have a great summer – With kind regards – Dr Rudolf van Olden, IFAPP President, The Netherlands

The difficult task of selecting good sites for the recruitment of study subjects – two case studies

IFAPP's ETHICS CORNER

Ethical Quandary: Site Selection Dilemmas

Few pharmaceutical industry researchers think of ethics when selecting investigational sites to place their studies. It is widely accepted that the selection of the right sites to place a clinical trial is the most important step in the development of any drug. The costs are massive; over US$ 25,000 to open a site, up to US$ 2,500 per month to monitor it, and then over a third of sites fail to recruit more than one patient. We give training to pharmaceutical industry monitors in the mechanics of site selection, yet the ethics are not often discussed.

Two very different cases are presented here where site selection came to be a central ethical issue.

The First Case Study

The first case emerged during a disciplinary hearing relating to a doctor's fitness to practice. A principal investigator in a pharmaceutical company's clinical trial was accused of entering patients into clinical trials without their knowledge or consent. His lawyer argued that the doctor concerned was an alcoholic, and that the company monitor assessing his site's suitability should have asked questions that would have revealed this. Because these questions were not asked, the site was used, and according to the defense team it was therefore "the company's fault that patients were recruited because the doctor was not responsible for his own actions due to his drinking problem".

Many would say this argument is totally lacking in logic, but it raises questions. How far should monitors go in assessing suitability of the site and the investigator? Does an investigator's personal life impact on his ability to conduct a study, and is it right and proper to look into it?

The Second Case Study

The second case is very different. A contract research organization (CRO) was asked by a sponsor to open a specific site for a phase 3 study. Staff from the CRO felt that as the site seemed very busy it should not be used, but the sponsor was adamant about using it. When the CRO monitor had vague concerns during the study, he asked questions of the study nurse. When asked how she undertook various ▶

IFAPP WORLD invites you to get involved!

After reading the following case studies please share with us your ethical considerations and provide us your opinion, comment, experience or question. Thank you in advance.

study assessments, she said that she took the heart rate by counting the radial pulse for 15 seconds and multiplying by four. This was clearly not true as none of the recorded heart rates were divisible by four. When challenged she said that the site was too busy, she was the only member of staff doing studies, so she "made up the bits that don't matter". The sponsor, when told of this, agreed only to close the site. They refused to take action against the investigator as he was very important to them and was to be the first author on the study report.

This case raises two ethical issues: First, 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? And second, is it the CRO's responsibility to insist that action be taken against investigators who transgress, even if the organization paying the CRO chooses not to?

So here are two case studies, quite unconnected in type, but both stemming from the difficult task of selecting good sites for the recruitment of study subjects. Pharmaceutical Medicine experts were involved in both. Dear reader, how would you have handled matters?

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

As always, IFAPP WORLD would be delighted to hear the views and experiences of others. Please send your opinion, comment, experience or question to Dr Jane Barrett (janebarrett@doctors.org.uk) or the editor (boebue@boebue.de). Your response is appreciated. With your permission we might publish it completely or in parts and if you wish without disclosing your name. Thank you. ■

IFAPP's Regional Update

Pharma Mirror – Online Pharma Magazine

The Bangladesh Association of Pharmaceutical Physicians (BAPP) has recently launched the Pharma Mirror, an online pharma magazine at www.pharmamirror.com, which is the 1st online professional pharma magazine from Bangladesh with "cutting-edge peer reviewed contents over the pharma arena", as emphasized on the first page. As a BAPP representative has acknowledged, the publishers believe a website will be a very valuable option to get connected with the world of Pharmaceutical Medicine. Pharma Mirror is also present in facebook and twitter, which are linked on the publication's website www.pharmamirror.com.

The publishers said they would change the design of the website as a continuous development process. And – last but not least – they would invite Pharma Mirror visitors to make suggestions – just contact Dr Hasan Mahmood vial email: drmahmoodh@gmail.com. ■

The European Medicines Agency invited IFAPP and the Italian SSFA to join a consultation and discussion.

IFAPP News

Risk-Based Quality Management in Clinical Trials

European Medicines Agency, London, United Kingdom: The lobby (left), meeting of an EMA committee (center), EMA reception desk (right) [© EMA]

For some years now, the European Medicines Agency (EMA) has got into the regular practice of offering a public consultation and discussion of any new guideline or regulation in order to collect opinions of professional associations concerned as well as of other interested parties. The author of this report has repeatedly volunteered to share his experience and knowledge on behalf of IFAPP. That is the reason why he is regularly invited – twice a month on average – to comment on a newly drafted document posted on the EMA website.

As a result of his detailed comments and constructive criticism, he was invited by the EMA to join a meeting entitled "Workshop on the reflection paper on risk-based quality management in clinical trials", held at the EMA facilities in London, England, on May 22, 2012.

He felt honored to receive this invitation. And he successfully involved the Italian Association of Pharmaceutical Medicine (Società di Scienze Farmacologiche Applicate – SSFA). In fact Daniela Marcozzi, Head of Quality Assurance (QA) at Sigma-Tau Pharmaceuticals, Inc., readily accepted to give a presentation on her experience of the interaction between QA and Project Management.

The EMA Working Session was held in a large and well-equipped meeting room. Representatives of the US Food and Drug Administration (FDA), which showed a great interest in this issue, also participated via teleconferencing – this was remarkable especially considering the fact that the session started at 10 o'clock in the morning, which is 4 o'clock at night in Washington D.C.

The meeting was attended by the majority of EU Good Clinical Practice (GCP) inspectors, and also by some 40 delegates representing 24 different bodies: scientific associations of Pharmaceutical Medicine, Quality Assurance, Contract Research Organizations (CROs) and pharmaceutical companies.

Yet again, Dr Fergus Sweeney, Head of Compliance and Inspections at the EMA, proved to be an excellent and competent moderator. He provided ample time after each presentation to ensure that everybody had the opportunity to comment and to offer suggestions.

The main topics under discussion are listed below – based on their relevance and according to the author's personal judgement:

Complexity of Clinical Trial Protocols

All participating parties agreed that many protocols of clinical trials are too comprehensive, too long and too complicated to get accurately implemented. Many times ethics committees and clinical investigators underestimate this critical aspect, which often is the main reason for failures and findings at inspections. It was anticipated that more attention should be paid to this issue in future thus making sure that protocols only have one principle and maybe few secondary endpoints. Criteria for patients' selection should also be listed with a more realistic approach.

Training of CRAs and Investigators in the Focus

The sponsors should put a strong focus on the training of both clinical research associates (CRAs) and investigators. All participants agreed that training of all professionals involved in clinical trials was of vital importance. There is also the perception that training of CRAs is generally required as the quality of CRAs is an important aspect in the CRO competitive environment. The training of clinical investigators should be more accurate and with more attention to their roles whether as principal investigators or co-investigators.

A Better Approach to Risk Management

The sponsors of clinical trials should be encouraged to implement a risk-based approach to clinical trials. This is recognized as an essential prerequisite to get prepared for any new scenario which might evolve during the trial execution.

In closing the meeting, Fergus Sweeney expressed EMA and his personal thanks for a very fruitful meeting and he anticipated that all comments would be taken into proper consideration for the final draft of the EMA guideline, which was most likely to be released by this year end.

The author personally offered some contributions to the discussion and emphasized the fact that quality is an ethical issue in clinical trials, which cannot be compromised in any way. EU inspectors commented the same way stating that in their view quality was of paramount importance.

Report by Dr Domenico Criscuolo, Co-Founder and Chief Executive Officer of Genovax S.r.l., Torino, Italy, member of the IFAPP Executive Committee

IFAPP member associations are all invited to follow this generous initiative.

IFAPP's Regional Update

Participation in ICPM 2012 Granted by the Italian SSFA

The International Conference on Pharmaceutical Medicine – ICPM 2012 – is the leading global event in the fields of professional activities in Pharmaceutical Medicine. The Italian Association of Pharmaceutical Medicine (Società di Scienze Farmacologiche Applicate – SSFA), member of IFAPP, has always supported the active participation of SSFA members in this event, which is held every other year.

As in previous years, the Italian SSFA offers support for an active participation in this year's ICPM as well: Two grants of 1,000 Euros each are donated to the authors of two posters which will be presented at the ICPM 2012.

Get an International Exposure – Join ICPM 2012!

The International Conference on Pharmaceutical Medicine – ICPM 2012 – will be held in Barcelona, Spain, from November 14 to 16, 2012. For details see page 11 or visit www.ICPM2012.com

The rules for participation in this competition, specified by the Italian SSFA, are quite simple:

- The poster subject must be related to the topics of ICPM 2012.
- The first author of the poster must be member of SSFA.
- The abstract must be submitted to SSFA secretariat until August 31, 2012.

Poster presentation at ICPM 2006 in Seoul, Korea

- A committee, consisting of five members of the SSFA Executive Board will evaluate all posters submitted to SSFA and will identify the top two of them, which will receive the grants.
- The two awarded posters will be nominated by September 7, 2012, in time for the poster submission deadline to ICPM 2012, which is September 15, 2012.
- The first authors of the two awarded posters are committed to attend the ICPM 2012 and to display and present the awarded posters.

It is assumed by the SSFA Executive Board that the grants of 1,000 Euros each will be sufficient to cover all expenses (conference participation fee, travel and accommodation) to attend the ICPM 2012.

After ICPM 2012 the awarded posters will be published in full text in SSFAoggi, the official SSFA journal.

Dr Domenico Criscuolo, Italy,
member of the IFAPP Executive Committee, on behalf of the SSFA Executive Board

The time for an initiative like ACRES is now.

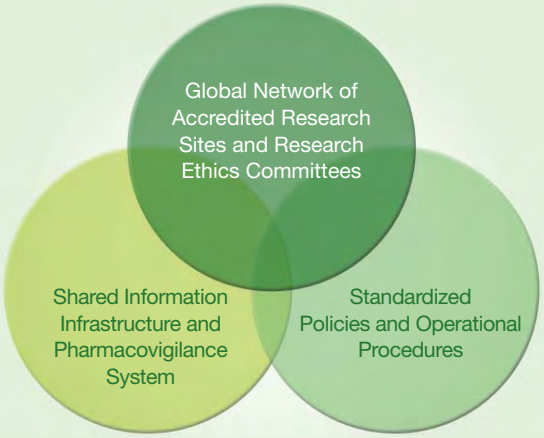
Remark from Dr Thomas Lönngren, Executive Director of the European Medicines Agency (EMA) from 2001 until the end of 2010, at the inaugural meeting of the ACRES Global Steering Committee

The International Perspective

ACRES Update: Alliance for Clinical Research Excellence and Safety, A Global Network for Clinical Research, Takes Off

The Alliance for Clinical Research Excellence and Safety (ACRES) is a private, non-profit non-governmental initiative that seeks to create a global network for clinical research (see figure) modeled after the international air transportation system. This network will consist of 150,000 or more independently operating clinical research units worldwide, each accredited to internationally accepted and globally uniform standards. These clinical research units will conduct clinical trials following Good Clinical Practice (GCP) on behalf of different sponsors. Therefore the units shall be equipped with well-educated, certified professionals and inter-connected via a web-based information system with a secure, robust data warehouse to enable real-time pharmacovigilance, operational performance metrics and remote risk-based monitoring.

ACRES Global Network Concept



The Vision of ACRES

The ACRES Global Network is similar to the system for international air travel built by the International Air Transport Association (IATA) over the past 50 years, a system that began with efforts to introduce and encourage uniform standards for air safety, operational excellence, regulatory harmonization and inter-operability. Today, the success of IATA is evident to all, as it has transformed global air travel. ACRES intend to similarly transform the world of clinical research.

IFAPP WORLD already has reported about ACRES twice [1+2]. In March 2012 IFAPP WORLD wrote: „The Alliance […] is a private, non-profit organization [which] brings together like-minded people and organizations around the world to build a robust, shared global network infrastructure for clinical research […]. Through standardization of policies and procedures, regulatory simplification, professionalism and information technology, this system will enhance safety, quality and efficiency while reducing the cost and time required to bring new medical products to the people of the world. […] ACRES seeks to positively align ethics, scientific integrity, good business practices and economics to provide incentives and opportunities that will advance drug and device testing and development in a safer, scientifically sound, socially responsible manner that rewards all participants and stakeholders and improves the quality of life for all." [1]

The ACRES Alliance is now gaining important momentum.

Professor Dr Greg Koski (right side), who is the father and co-founder of ACRES, chairs the meeting of the ACRES Global Steering Committee on March 28, 2012 in Copenhagen, Denmark – here beside Dr Thomas Lönngren, former Executive Director of the European Medicines Agency (EMA) [© DIA 2012]

Since these original reports, much has happened with ACRES. IFAPP WORLD now offers an update on the status of this ambitious and important global initiative.

From Concept to Reality

Since originally conceived in 2010, the vision of ACRES has been presented to several like-minded organizations and audiences around the world. These presentations have generated some enthusiastic support. In fact, IFAPP was the very first member of the ACRES Alliance, which is now gaining important momentum.

To enter into formal dialog with all interested parties, ACRES first needed to establish a formal status. This has been achieved primarily by Professor Dr Greg Koski, Senior Scientist at the James Mongan Institute for Health Policy and Associate Professor at Harvard Medical School, who also is the father of ACRES (see photo on the left). ACRES was formally incorporated as a non-profit organization in March, 2012. Meanwhile, the initiative is being spearheaded by the ACRES Executive Committee comprised of co-founders, Beat Widler, former Global Head Quality at Hoffmann-La Roche Ltd., now managing partner of Widler and Schiemann AG (Basel, Switzerland), Andrew Olmsted, Vice-President at IRBNet (Cambridge, MA, USA), along with Honorio Silva, Vice President, Inter American Foundation for Clinical Research (New York, NY, USA), Peter Goldschmidt, President of the Health Improvement Institute (Bethesda, MD, USA), and its most recent addition, Brian Edwards, Principal Consultant at NDA Regulatory Affairs Group AB (United Kingdom). Dennis LaCroix, formerly at Genzyme, is ACRES General Counsel.

On March 28, 2012 the inaugural meeting of the ACRES Global Steering Committee was held on the 24th DIA Euromeeting in Copenhagen, Denmark. More than 30 participants from all over the world joined the meeting – representatives from Pharma (NovoNordisk, Sanofi, Pfizer), Contract Research Organizations (CROs) (e.g., Covance, Parexel, Quintiles), expert associations (e.g., IFAPP) and organizations like the European Clinical Research Infrastructures Network (ECRIN), the Clinical Data Interchange Standards Consortium (CDISC) and the Pharmaceutical Medicines Training Programme (PharmaTrain).

The event was launched with a keynote address and “pep-talk” by Dr Thomas Lönngren, who was Executive Director of the European Medicines Agency (EMA) from 2001 until the end of 2010. In his encouraging remarks, Dr Lönngren highlighted the rationale and justification of this concept and noted, that the time for an initiative like ACRES is now.

The ACRES Global Steering Committee at its first meeting on March 28, 2012 in Copenhagen, Denmark [© DIA 2012]

The purpose of the meeting was to seek the advice of the Global Steering Committee members as ACRES more clearly defines its short- and mid-term goals, to discuss the work package tasks and to constitute two task-forces. Within the upcoming months the task-forces shall create templates and proposals regarding the ACRES infrastructure and development and regarding ACRES products and services. The recommendations from these task-forces will be incorporated into a final prospectus during the ACRES Strategic Planning Session to be held in Philadelphia on June 27-28, 2012. Already several cornerstone projects are in preparation for launch later this year to begin building the critical supporting processes and infrastructure to support the ACRES Global Network. ACRES has also signed a mutual letter of intent with PharmaTrain to explore opportunities for collaboration. IFAPP WORLD will keep you informed as events unfold.

Report by Dr Norbert Clemens, Managing Director & Head of CRS Clinical Research Services Mannheim GmbH, Germany, IFAPP Treasurer, Member of the ACRES Global Steering Committee

References

[1] Koski G: The International Perspective – Partnerships Between Academia, Industry and Government(s) in the Development of New Medications. IFAPP WORLD 2012 March; page 6-10. Online at http://ifapp.org/Publications/IFAPP-World available.

[2] Koski G, Olmsted A, Widler B; ACRES: Alliance for Clinical Research Excellence and Safety – A Global Network for Clinical Research Modeled after the International Air Transport System; IFAPP WORLD 2010 August; page 1 and 3-6. Online at http://ifapp.org/Publications/IFAPP-World available.

Detailed information on the ACRES is available at www.acresglobal.net.

IFAPP's Calendar

ICPM 2012 – 16th International Conference on Pharmaceutical Medicine

14-16 November 2012, Barcelona – Spain

ICPM 2012, jointly organized by the Spanish Association of Medicine in Pharmaceutical Industry (Asociación de Medicina de la Industria Farmaceutica Española – AMIFE) and IFAPP, will ensure a top-level scientific program with experts' presentations on well-differentiated and important dimensions of our professional endeavors, including debates, discussions, exchange of ideas and sharing information and good practices.

ICPM 2012 will provide a plenary lecture presenting renowned figures of the Pharmaceutical Medicine world. Dr José Gomes do Amaral, Brazil, President-Elect of the World Medical Association, has kindly accepted to deliver a Keynote lecture on "Health Care Improvement Through Clinical Research".

As described on the conference website, "ICPM 2012, a two-and-a–half-day journey through topics that have an undoubted impact on our professional activity, are of notorious relevance in today's environment and are core to our association's goal to make key contributions towards procuring better medicines to patients."

Excerpt from the program:

Wednesday, 14th November 2012

- Current Patent Issues. Implications, Developments and Possible Solutions
- Current Challenges in Clinical Research in Children
- CRA Workshop I + II: How to Prepare an Inspection by the FDA and EMA
- Patient Associations
- New EU Clinical Trials Directive

Thursday, 15th November 2012

- New Developments in Personalized Medicine
- New Pharmacovigilance Legislation in the European Union I + II
- Biosimilars, Regulation and Rules
- Recent Issues in the Design of Clinical Trials and Decisions Regarding Approval of Drugs
- Creating Collaborative Academy-Industry-Government Programs to Foster Drug Development: Past, Present and Future
- Health Care Improvement through Clinical Research
- The New Market Accesss Paradigm in the Scope of the Economical Crisis

Friday, 16th November 2012

- The Evolving Role of the Medical Science Liaison Function. New Roles and New Directions
- Future of the Pharmaceutical Industry
- Trends and Needs for Educational and Certification in Clinical Research and Pharmaceutical Medicine
- Ethics and Compliance

Details on the ICPM 2012 conference including the program are available at www.ICPM2012.com and at the end of this IFAPP WORLD issue.

Please join us at this important event for Pharmaceutical Medicine and register right now at www.ICPM2012.com. Looking forward to seeing you in Barcelona!

Dr Rudolf van Olden
IFAPP President, The Netherlands

Dr José María Taboada
President AMIFE, Spain

Dra. Belén Sopesen
Vice President AMIFE, Spain

Dates & Deadlines

1st World Conference on Pharmacometrics, WCoP

September 5-7, 2012, Seoul, Korea

Pharmacometrics is regarded as a core technology these days to reduce cost and time in drug development processes. The World Conference on Pharmacometrics (WCoP) is an opportunity to discuss future directions of pharmacometrics in the world from strategic perspectives.

The 1st World Conference on Pharmacometrics, a 2.5-day event, will provide 7 oral sessions and 2 plenary lectures, followed by 2 workshop sessions in parallel with tutorial and software demo sessions.

There have also been scheduled 6 satellite courses to provide WCoP participants hands-on opportunities to learn about various software tools related to pharmacometrics.

Moreover, as announced by the host, grants of up to USD 1,000 will be available for selected abstracts.

- Abstract submission due: June 30, 2012
- Early-bird registration due: June 30, 2012

Details regarding the program, the call for abstracts and the registration are available at the conference website www.go-wcop.org

WCoP 2012 World Conference on Pharmacometrics

The WCoP will be held every 4 years in changing locations.

Seoul, the 2012 conference venue, has been very active in hosting international conferences in recent years. Since it has been the capital city of Korea for more than 600 years since the last Korean dynasty, WCoP participants can expect a cultural experience with a mixture of old tradition and high technology. ■

Dates & Deadlines

1st International Meeting – Present and Future of Pharmaceutical Medicine and Health Regulation in Latin America

September 27-29, 2012, Mexico City, Mexico

Bild: Fotolia

The Mexican Association of Medical Specialists in the Pharmaceutical Industry (Asociación de Médicos Especialistas en la Industria Farmacéutica, A.C. – AMEIFAC) will host this meeting with distinguished members of the Pharmaceutical Medicine community including representatives of health regulatory agencies and Health Departments across Latin America, the USA and Europe. Representatives from pharmaceutical companies, contract research organizations and their associations, from academia and educational institutions, renowned specialized organizations in Pharmaceutical Medicine such as IFAPP, the Association of Clinical Research Physicians (ACRP), the Brazilian Society of Pharmaceutical Medicine (SBMF), the European PharmaTrain, and EduFarm will also actively participate. Countries represented by the meeting include the USA, Mexico, Spain, Panama, Colombia, Argentina, Brazil, etc.

The 3-day meeting provides a rich program with various topics, e.g.:

- Clinical Research: Present and Future
- Education in Pharmaceutical Medicine in the World
- Health Regulation throughout Latin America
- Legislation in Clinical Research in Latin America
- Ethics and Clinical Research in Special Populations
- Vaccines and New Molecules
- Marketing for Non-Marketing Specialists
- Risk Management and PharmacoVigilance
- Advertisement

On the third day of the meeting, a Certification Preparation Course will be organized by ACRP experts. Since admission is limited, those who are interested should register early.

Detailed information is available at www.ameifac.com.mx or by contacting the host under ameifac2010@yahoo.com.mx or mllopiz@hotmail.com.can directly.

A special discount registration fee is available for early registration and for members of IFAPP and AMEIFAC. ■

Dates & Deadlines

16th Joint Swiss Symposium on Pharmaceutical Medicine – SwAPP-SGPM Annual Meeting 2012

November 28, 2012, Bern, Switzerland

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (Schweizerische Gesellschaft für Pharmazeutische Medizin – SGPM / Association Suisse de Médecine Pharmaceutique – ASMP) jointly organize the 16th Joint Swiss Symposium on Pharmaceutical Medicine.

Beside a State of the Art lecture on Translational Medicine – Turning Chemical and Biological Discoveries into Drugs – four session will be held:

Session I: Clinical Trials
Session II: Patient Presentations
Session III: Medical Devices and Combination Products/ Companion Diagnostics
Session IV: Benefit-Risk Assessment/Safety

The detailed program will be published soon at www.swapp.ch – for inquiries the host kindly ask to contact the administrative secretariat under sgpm@congress-plus.ch.

IFAPP's Sponsors

IFAPP gratefully acknowledges generous sponsorships and financial support from the following companies:

Platinum Sponsor:
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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 experts 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. ■

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 29 national member associations 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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16th International Conference on Pharmaceutical Medicine

X Congreso AMIFE 2012

ICPM 2012

Barcelona

14th - 16th November 2012

Hotel NH Constanza - Auditorio AXA

Organized by:

AMIFE

Asociación de Medicina de la Industria Farmacéutica Española

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International Federation of Pharmaceutical Physicians

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PRELIMINARY PROGRAMME

WEDNESDAY, 14TH NOVEMBER 2012

NH Constanza Hotel

08:30 Documentation delivery

AXA Auditorium

10:00 WELCOME
José María Taboada, AMIFE President
Rudolf van Olden, IFAPP President

AXA Auditorium

10:15 INAUGURAL SESSION
Speakers: To be confirmed

NH Constanza Hotel – Exhibition and Poster Area

10:45-11:15 Coffee Break

AXA Auditorium

11:15-13:00 **CURRENT PATENT ISSUES – IMPLICATIONS, DEVELOPMENTS AND POSIBLE SOLUTIONS**
Chaired by: **Irene Gascón**, GENOMICA S.A.U. (Grupo Zeltia)

20 YEARS OF SUPPLEMENTARY CERTIFICATES OF PROTECTION (SPCS) – RETROSPECT AND OPEN QUESTIONS
Speaker: **Dr. Klemens Stratmann**
Hoffmann & Eitle, Munich - Germany
German and European Patent Attorney at Hoffmann & Eitle.

IMPLEMENTATION OF THE U.S. PATENT REFORM
Speaker: **Dr. Anthony Tridico**
Finnegan, Brussels - Belgium
Managing partner of Finnegan's European office in Brussels, Belgium.

EUROPEAN UNITY PATENT - CURRENT SITUATION
Speaker: **Dr. Miguel Vidal Quadras Trías de Bes**
Amat & Vidal-Quadras, Barcelona - Spain
Head of Intellectual Property and Pharmaceutical Law Department Amat & Vidal-Quadras

Discussion and closing remarks

NH Constanza Hotel

11:15-13:00 **CURRENT CHALLENGES IN CLINICAL RESEARCH IN CHILDREN**

Chaired by: **César Sanz**, MSD, Spain and co-chaired by: **Domenico Criscuolo**, Genova, Italy

REGULATORY FRAMEWORK FOR THE ASSESSMENT OF PEDIATRIC INVESTIGATION PLANS (PIPS) AND PEDIATRIC TRIALS
Speaker: **Dr. Thorsten Olski**
European Medicines Agency's Human Medicines Special Areas, UK

THE ROLE OF RESEARCH NETWORKS IN PEDIATRIC CLINICAL RESEARCH
Speaker: **Dr. Nick Croft**
Chair of the NIHR Medicines for Children Research Network (MCRN), UK

ETHICAL CHALLENGES IN CLINICAL RESEARCH IN CHILDREN
Speaker: **Dr. Martine Dehlinger-Kremer**
Global VP Regulatory Affairs, RPS & Chair of Pediatric Working Group EUCROF, Germany

Discussion and closing remarks

NH Constanza Hotel – Exhibition and Poster Area

13:00-14:30 **Cocktail Lunch**

NH Constanza Hotel – Barcelona meeting room

14:30-16:00 **CRA WORKSHOP (I)**
HOW TO PREPARE AN INSPECTION BY THE FDA AND EMA

Chaired by: **Marta Arias Salgado**, MSD, Spain

EMA INSPECTION DATABASE AND STATISTICS OF FINDINGS
Speaker: **Dr. Carmen Tristan**
Inspector, AEMPS, Spain

INTERACTIONS BETWEEN AEMPS – EMA – FDA. HANDLING OF DEVIATIONS DURING INSPECTIONS
Speaker: **Dr. Ernesto Vera**
Inspector AEMPS, Spain

Discussion and closing remarks

AXA Auditorium

14:30-16:00 **PATIENTS ASSOCIATIONS**

Chaired by: **Anna Jurczynska**, AMIFE and co-chaired by: **Rudolf van Olden**, IFAPP

EMA FOCUS ON RESEARCH AND ROLE OF PATIENTS ASSOCIATIONS
Speaker: **Juan García Burgos**
Section Head for Public Information and Stakeholder Networking in Medical Information, EMA, London

DISSEMINATING YOUR MESSAGE THROUGH PATIENT ORGANIZATIONS AND SOCIAL MEDIA
Speaker: **Christina SanInocencio**
President/Executive Director
LGS Foundation – Lennox-Gastaut Syndrome, US

PATIENT'S PERSPECTIVES ON DRUG SAFETY. CASE STORY FROM HONG KONG
Speaker: **Kin Ping Tsang**
Chair Elect of International Alliance of Patients Organizations (IAPO)

PATIENTS ASSOCIATIONS IN RARE DISEASES
Speaker: to be confirmed (EURORDIS)

Discussion and closing remarks

NH Constanza Hotel – Exhibition and Poster Area

16:00-16:30 **Coffee break**

NH Constanza Hotel – Barcelona meeting room

16:30-18:00 **CRA WORKSHOP (II)**
HOW TO PREPARE AN INSPECTION BY THE FDA AND EMA
Chaired by: **Marta Arias Salgado,** MSD, Spain

ANNUAL PLAN OF INSPECTIONS IN SPAIN. REGIONAL CLINICAL TRIAL INSPECTIONS
Speaker: **Fernando Antúnez**, Inspector Junta de Andalucía, Spain

Discussion and closing remarks

AXA Auditorium

16:30-18:00 **NEW EU CLINICAL TRIALS LEGISLATION**
Chaired by: **Domenico Criscuolo**, Genovax, Italy and co-chaired by: **Oscar Fillat**, Sanofi

RELEVANT CHANGES AND ADAPTATIONS IN THE EUROPEAN CLINICAL TRIAL DIRECTIVE
Speaker: **Vincenzo Salvatore**
EMA, London

DEVELOPMENT OF THE NEW EU DIRECTIVE IN DIFFERENT COUNTRIES
Speaker: **Maria Antonia Serrano**
Head Clinical Trials Department, AEMPS, Spain

IMPACT OF THE NEW EU DIRECTIVE ON PHARMACEUTICAL INDUSTRY
Speaker: to be confirmed (Farmaindustria, Spain)

Discussion and closing remarks

18:00-20:00 **IFAPP EXECUTIVE BOARD MEETING**

THURSDAY 15 NOVEMBER

NH Constanza Hotel – Barcelona meeting room

09:00-10:30 **NEW DEVELOPMENTS IN PERSONALIZED MEDICINE**

Chaired by: **Jaime del Barrio,** Instituto Roche, Madrid, Spain and co-chaired by: **Yil-Seob Lee**, GSK, Korea

GENOME ANALYSIS IN THE AGE OF PERSONALIZED MEDICINE
Speaker: **Ivo Gut**
Director, Centro Nacional de Análisis Genómico (CNAG), Barcelona, Spain

STRATIFIED CANCER MEDICINE: THE UK EXPERIENCE AND GLOBAL THOUGHTS
Speaker: **James Peach**
Director of Stratified Medicine at Cancer Research, UK

BIOMAKERS IN PERSONALIZED MEDICINE
Speaker: **Joan Albanell**
Head Medical Oncology Department & Director of Cancer Research Program, Hospital del Mar, Barcelona, Spain

IMPACT OF PHC ON EFFICIENT HEALTHCARE SPENDING
Speaker: **Thomas Szucs**
Professor of Pharmaceutical Medicine and Director of The Institute of Pharmaceutical Medicine / European Center of Pharmaceutical medicine at the University of Basel, Basel, Switzerland

Discussion and closing remarks

AXA Auditorium

09:00-10:30 **PHARMACOVIGILANCE WORKSHOP: NEW PHARMACOVIGILANCE LEGISLATION IN THE EUROPEAN UNION (I)**

Chaired by: **Almudena Del Castillo,** Azierta, Spain and co-chaired by: **Dolors Querol**, Sanofi

NEW EUROPEAN PHARMACOVIGILANCE LEGISLATION OPPORTUNITIES AND CHALLENGES
Speaker: **Stella Blackburn**
Risk Management Development and Scientific Lead EMA, EU

NEW CHALLENGES FROM A MULTINATIONAL COMPANY PERSPECTIVE
Speaker: **Laurent Auclert**
EU QPPV Sanofi

Discussion and closing remarks
Workshop continues at 11:00

NH Constanza Hotel – Exhibition and Poster Area

10:45-11:00 **Coffee break**

AXA Auditorium

11:00-12:30 **PHARMACOVIGILANCE WORKSHOP: NEW PHARMACOVIGILANCE LEGISLATION IN THE EUROPEAN UNION (II)**

NEW SPANISH ROYAL DECREE FOLLOWING THE NEW EUROPEAN LEGISLATION AND GOOD PHARMACOVIGILANCE PRACTICES. WHAT'S NEW?
Speaker: **Dolores Montero**
Head of Pharmacoepidemiology and Pharmacovigilance Department, AEMPS, Spain

NEW CHALLENGES FROM THE SUBSIDIARY COMPANY PERSPECTIVE
Speaker: **Dolores Calderón**
Merck Serono, Spain

Discussion and closing remarks

NH Constanza Hotel – Barcelona meeting room

11:00-12:30 **BIOSIMILARS, REGULATION AND RULES**
Chaired by: **Marlene Llopiz,** AMEIFAC (Association of Medical Specialists in the Pharmaceutical Industry), Mexico and co-chaired by: **Carlos Bañado**, Chemo, Spain

BIOSIMILARS: LATIN AMERICA´S COMING ON BOARD
Speaker: **Marlene Llopiz-Aviles**
IFAPP/AMEIFAC

THE POSITIVE EXPERIENCE OF BIOSIMILAR REGULATION
Speaker: **Ulrike Jaegle**
Novartis International AG, Switzerland

Gonzalo Calvo Rojas
Consultor of Pharmacology Department of Hospital Clinic i Provincial de Barcelona
Associate Professor of Clinical Pharmacology, Barcelona University
President of the European Society of Clinical Pharmacology and Therapeutics

Miguel Ángel Calleja
Head Pharmacy Service University Hospital Virgen de las Nieves, Granada
Associate Professor, Granada University

Discussion and closing remarks

NH Constanza Hotel – Exhibition and Poster Area

13:00-14:30 **Cocktail Lunch**

NH Constanza Hotel

14:30-16:00 **RECENT ISSUES IN THE DESIGN OF CLINICAL TRIALS AND DECISIONS REGARDING APPROVAL OF DRUGS**

Chaired by: **Erik Cobo**, Department of Statistics and Operations Research at the Polytechnic University of Catalonia (Barcelona, Spain)

Speakers:

Steven Julious
(BSc, MSc PhD FSS FRIPH CSi CStat), Medical Statistics Group, ScHARR, The University of Sheffield

Michael J. Campbell
(BA,MSc, PhD, CStat), Professor of Medical Statistics Health Services Research, ScHARR, The University of Sheffield and member of National Institute of Health and clinical Excellence (NICE)

Sue Todd
Professor of Medical Statistics, University of Reading

Discussion and closing remarks

AXA Auditorium

14:30-16:00 **CREATING COLLABORATIVE ACADEMY-INDUSTRY-GOVERNMENT PROGRAMS TO FOSTER DRUG DEVELOPMENT: PAST, PRESENT AND FUTURE**

Chaired by: **Gustavo Kesselring**, ViS Research Institute and co-chaired by: **Enrique Jiménez**, Imclone, Spain

USA EXPERIENCE
Speaker: **Greg Koski**
Associate Professor Anesthesiology at Harvard Medical School

EUROPEAN EXPERIENCE
Speaker: **Fritz Buhler**
Coordinator of IMI Pharma Train and ECPM at University of Basel

KOREAN EXPERIENCE
Speaker: **Min Soo Park**
Director Clinical Trials Center and Chair, Department of Clinical Pharmacology, Severance Hospital. Associate Professor, Department of Pediatrics, Yonsei University College of Medicine. Vicepresident of Konect.

Discussion and closing remarks

NH Constanza Hotel – Exhibition and Poster Area

16:00-16:30 **Coffee break**

NH Constanza Hotel – Barcelona meeting room

16:30-18:00 **HEALTH CARE IMPROVEMENT THROUGH CLINICAL RESEARCH**
Keynote lecture by: **José Luiz Gomes do Amaral**
President of the World Medical Association

AXA Auditorium

16:30- 18:00 **THE NEW MARKET ACCESS PARADIGM IN THE SCOPE OF THE ECONOMICAL CRISIS**
Chaired by: **Xavier Badía**, IMS Health, Spain and co-chaired by: **Carme Piñol**, Bayer HealthCare, Spain

FROM THE POINT OF VIEW OF PATIENTS
Speaker: **Albert Jovell Fernández**
President of " Foro Español de Pacientes "

FROM THE POINT OF VIEW OF THE REGIONAL ADMINISTRATION
Speaker: **Antoni Gilabert**
Pharmaceutical Care Manager and Supplemental Services Catsalut

FROM THE POINT OF VIEW OF THE PHARMACEUTICAL INDUSTRY
Speaker: **Javier Urzay**
Farmaindustria, Madrid, Spain

FROM THE POINT OF VIEW OF DOCTORS
Speaker: **Adolfo Díez Pérez**
Hospital del Mar, Barcelona, Spain

Discussion and closing remarks

18:00 **AMIFE GENERAL ASSEMBLY**

18:00 **IFAPP HOUSE OF DELEGATES**

FRIDAY 16 NOVEMBER

AXA Auditorium

09:00-11:00 **THE EVOLVING ROLE OF THE MEDICAL SCIENCE LIAISON FUNCTION. NEW ROLES AND NEW DIRECTIONS**

Chaired by: **Giovanna Tocco**, Allergan and co-chaired by: **Gerfried Nell,** NPC Nell Pharma Connect GmbH, Germany

RATIONAL, BEST PRACTICES AND STRATEGY FOR SUCESS IN MSL ROLE
Speaker: **José Antonio Sacristán**
Medical Director, Lilly Spain

JANSSEN CILAG'S EXPERIENCE: CREATION OF A NEW ROLE, LESSONS LEARNED AND FUTURE PLANS
Speaker: **Guadalupe Martínez**
Medical Director, Janssen Cilag España

ESTABLISHING STRATEGIC INTERACTIONS WITH INTERNAL AND EXTERNAL STAKEHOLDERS UNDER CHANGING REGULATORY ENVIRONMENTS
Speaker: **Xavier Puig**
Chief Scientific Officer, Clinical Development & Medical Affairs, Novartis Farmacéutica

MSL INSTITUTE'S INITIATIVES AND CONTRIBUTION
Speaker: **Jane Chin**
MSL Institute

Discussion and closing remarks

NH Constanza Hotel

9:00-11:00 **FUTURE OF THE INNOVATIVE PHARMACEUTICAL INDUSTRY / IMPACT OF THE CRISIS IN THE PHARMACEUTICAL INDUSTRY IN SPAIN**

Chaired by: **José María Taboada**, Sanofi Aventis and co-chaired by: **Belén Sopesén**, Noscira, Spain

HOW TO CREATE VALUE IN HEALTHCARE SYSTEM MAINTAINING ITS SUSTAINABILITY
Speaker: **Nuria Más**
Adjunct Professor of Economy at IESE and Research Fellow PPSRC, Spain

CHALLENGES AND OPPORTUNITIES FOR THE PHARMACEUTICAL INDUSTRY
Speaker: **Ignacio Riesgo González**
PriceWaterHouse Consulting

INNOVATION AND ITS ACCESS TO THE MARKET: ARE THEY COMPATIBLE?
Speaker: **Marc Antoine Lucchini**
President, Sanofi Iberia, Spain

EQUITY AND SUSTAINABILITY OF THE NHS: BUILDING A CONSTRUCTIVE RELATION BETWEEN ALL STAKEHOLDERS
Speaker: **Carlos Lens**
General Deputy Director of Pharmacy, MSPSI, Spain. (To be confirmed)

Discussion and closing remarks

NH Constanza Hotel – Exhibition and Poster Area

11:00-11:30 **Coffee break**

NH Constanza Hotel

11:30-13:00 **TRENDS AND NEEDS FOR EDUCATIONAL AND CERTIFICATION IN CLINICAL RESEARCH AND PHARMACEUTICAL MEDICINE**

Chaired by: **Gerfried Nell,** NPC Nell Pharma Connect GmbH, Germany and **Peter Stonier** and co-chaired by: **José Luis Bravo,** Tigenix, Spain

EMERGING NEEDS FOR TRAINING AND EDUCATION IN MEDICINES DEVELOPMENT
Speaker: **João Massud** MD

PHARMATRAIN: A HARMONIZED APPROACH TO POSTGRADUATE EDUCATION IN MEDICINES DEVELOPMENT
Speaker: **Fritz Buhler** MD

ALIGNMENT OF PROFESSIONAL COMPETENCIES IN CLINICAL RESEARCH AND MEDICINES DEVELOPMENT
Speaker: **Honorio Silva** MD

GLOBAL STATUS OF CERTIFICATION IN CLINICAL RESEARCH AND PHARMACEUTICAL MEDICINE
Speaker: **Jean-Paul Deslypere** MD

Discussion and closing remarks

AXA Auditorium

11:30 -13:00 **ETHICS AND COMPLIANCE**

Chaired by: **Roberto Ruiz,** Glaxo, SmithKline, Spain and co-chaired by: **Sander Becker**, AOL, Australia

INTRODUCTION. ETHICS AND COMPLIANCE IN THE PHARMACEUTICAL BUSINESS
Speaker: **Dr. Roberto Ruiz**
Medical Affairs Director, GSK Spain

ETHICS AND COMPLIANCE IN EU: ROLE OF MEDICAL FUNCTION
Speaker: **Dr. Else Høibraaten**
European Medical Director, Lilly

ETHICS AND COMPLIANCE IN LATIN AMERICA: NEW CHALLENGES FOR OLD PRACTICES
Speaker: **Dr. Marlene Llopiz-Aviles**
AMEIFAC, Mexico

EVOLUTION OF KOREA IN ETHICS AND COMPLIANCE
Speaker: **Dr. Won-Sik LEE**
Medical Director, Pfizer Korea

SELF-REGULATION IN THE PHARMACEUTICAL INDUSTRY: TRENDS AND EVOLUTION
Speaker: **Mr. José Zamarriego**
Director of Farmaindustria's Code of Practice Surveillance Unit, Spain

Discussion and closing remarks

13:00-13:30 **AWARDS TO THE BEST POSTERS**

13:45 **PRESENTATION OF ICPM 2014 AND CLOSING CEREMONY**

14:15 GENERAL ASSEMBLY IFAPP

GENERAL INFORMATION

CONGRESS DINNER

The ICPM / AMIFE Congress Dinner will take place at Palau Nacional, the emblematic building of the 1929 International Exhibition, which is the home of the Museu Nacional d'Art de Catalunya: MNAC. It is situated on the mountain of Montjuïc, a privileged site from where you can enjoy a magnificent and unique view of the city of Barcelona
The MNAC embraces all the arts (sculpture, painting, drawing, engraving, posters, photography and coinage) and has the task of explaining the general history of Catalan art from the Romanesque period to the mid-twentieth century.

All attendants will have the opportunity to enjoy an exclusive private tour at the Romanesque Art galery. After the visit, the official cocktail dinner will take place inside the Cupula room.

With such an inviting venue for an already much-anticipated event; we're confident the Congress Dinner is one event you won't want to miss.

Additional fees apply, see registration page

LOCATION

Just 10 minutes walk from Plaça Espanya (Green line metro station) the nerve centre for the main urban and regional transport routes), the MNAC is also easy to get to by private transport as it has a large parking area for cars and buses.

REGISTRATION

	Until 15/09/12	From 16/09/12
MEMBER AMIFE or IFAPP	400€	480€
AMIFE or IFAPP non member	500€	580€
FEE OFFICIAL DINNER (if registered at congress)	20€	
CRA SATELLITE SYMPOSIUM	100€	

PAYMENT METHODS

Full payment of fees is required in order to attend the Congress.

Payment can be made online at the time of registering, or at a later time upon receipt of invoice. A Confirmation of Registration will be sent to you upon completion of the online registration form. If you do not receive this within 3 days, contact the Congress Office to find out why.

Payment can be made in the following manner:

- Bank Transfer Detailed banking information will be provided automatically by e-mail. Transfers must be made in € Euros to the account of VIAJES PACIFICO SA.
- Credit Card Online You will be redirected to a Bank secure page. VISA, Mastercard and American Express are accepted.
- Credit Card Authorization form: You will receive automatically by e-mail our credit card authorization form. Please mail or fax your completed credit authorization form to **amife2012@pacifico-meetings.com** or fax it to +34932387488

ORGANIZED BY:

AMIFE
Asociación de
Medicina de la Industria
Farmacéutica Española

IFAPP
International Federation of
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