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IFAPPWORLD

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS

QUESTIONS & ANSWERS

IFAPP President Takes a Stance

An Interview with IFAPP President Dr Rudolf van Olden, The Netherlands

IFAPP WORLD: Dr van Olden, when considering research, development and safety monitoring of medicines: What is the role of physicians and of non-physician experts in the field of Pharmaceutical Medicine?

Dr Rudolf van Olden: The role of Pharmaceutical Medicine experts in R&D of new medicines and in pharmacovigilance – these experts are likewise physicians *and* non-physicians – is to contribute an in-depth knowledge concerning pharmacology, ...

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Partnerships Between Academia, Industry and Government(s) in the Development of New Medications

International Models and Experience: A North American Perspective

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Questions & Answers

IFAPP President Takes a Stance

An Interview with IFAPP President Dr Rudolf van Olden, The Netherlands

The IFAPP Presidency of Dr Rudolf van Olden, The Netherlands, is reaching its mid-point, approximately. By now he has launched an "initiative to modernize the IFAPP structure to better cope with future challenges – this initiative is on track now within the Executive Committee and will be communicated soon," he said. Indeed, there are several points to consider for getting IFAPP prepared for future tasks. Dr Rudolf van Olden stated his position on these issues at a face-to-face meeting in December 2011 with the IFAPP WORLD Editor in Chief, Eckhard Böttcher-Bühler, Germany:

IFAPP WORLD: Dr van Olden, when considering research, development and safety monitoring of medicines: What is the role of physicians and of non-physician experts in the field of Pharmaceutical Medicine?

Dr Rudolf van Olden: The role of Pharmaceutical Medicine experts in R&D of new medicines and in pharmacovigilance – these experts are likewise physicians *and* non-physicians – is to contribute an in-depth knowledge concerning pharmacology, toxicology, medicine, pathophysiology, specific disease areas, trial design techniques, statistics, epidemiology and a lot more. Overall they have to explore and monitor the impact of medicines on health outcomes and what it means with regard to pharmacoeconomics. They also have to generate sufficient data packages required not just for marketing approval of a new drug but also for setting a reasonable price and obtaining reimbursement.

IFAPP WORLD: Physicians and non-physician experts in Pharmaceutical Medicine – what do they have in common and what differentiates them from each other?

Dr Rudolf van Olden: What they have in common is their knowledge part of pharmacology, pathophysiology, trial designs, epidemiology and statistics. The added value of physicians is their in-depth knowledge of medicine, their contact to patients and bed-side experience, their capability to evaluate health outcome and adverse events on an individual basis which relate to a particular medicine, to co-medication or even to a certain disease and to keep an eye on any possible clinical sign of an interaction of medicines in individual patients. Physicians are vital to make proper clinical evaluations and decisions.

IFAPP WORLD: IFAPP uses 'Pharmaceutical Physician' in its name; however, it clearly represents physicians and non-physician experts in Pharmaceutical Medicine. Do they both compete with each other or do they complement each other?

Dr Rudolf van Olden: Physicians as well as other life science specialists – for instance toxicologists, chemists, pharmacologists, biologists, pathologists – they all may become outstanding experts in Pharmaceutical Medicine. ▶

Dr Rudolf van Olden, IFAPP President, The Netherlands:

"The field of Pharmaceutical Medicine these days is much too broad to give any specialty the right to say it is the superior or the one-and-only specialty in this field."

And they all contribute their particular knowledge and focus based on their respective education, training and experience.

The field of Pharmaceutical Medicine these days is much too broad to give any specialty the right to say it is the superior or the one-and-only specialty in this field and to allow only these specialists to use the title of a Pharmaceutical Medicine expert. The knowledge and driving forces are within the team consisting of various specialists or Pharmaceutical Medicine experts with different insights and in-depth knowledge about certain areas within the broad field of Pharmaceutical Medicine.

IFAPP WORLD: What makes an expert in Pharmaceutical Medicine – education and training, knowledge and practice or certification?

Dr Rudolf van Olden: A combination of all – education, training, knowledge and practice in the different fields of Pharmaceutical Medicine is essential to become a Pharmaceutical Medicine expert. Certification is only a signal of proven expertise. To my knowledge and in my perception, a majority of experts active in Pharmaceutical Medicine are educated in life sciences or in medicine and passed final examinations, but have never gained any specific certification for their training and in-depth knowledge as a Pharmaceutical Medicine expert.

Acquiring and sharing up-to-date knowledge is particular essential for experts in the field of Pharmaceutical Medicine. Courses and conferences facilitated by IFAPP or IFAPP's national member associations are essential tools to keep oneself up-to-date for being aligned in the field of expertise and for building networks within Pharmaceutical Medicine.

In this regard I strongly recommend to attend the International Conference on Pharmaceutical Medicine – ICPM 2012 – coming off in Barcelona, Spain, from November 14th to 16th this year which now is open for registration! [For details please notice page 11]

IFAPP is also planning the 2nd Science-to-Business – S2B – Conference, which might be held in the Asia Pacific region soon.

These are opportunities not just to acquire up-to-date knowledge but also to exchange information, to share experience and to create networks.

IFAPP WORLD: Is there a world-wide recognized certification in Pharmaceutical Medicine? And what is IFAPP's place in such a certification?

Dr Rudolf van Olden: No, there is no such universal certification. The key question for me is whether such a world-wide recognized certification in Pharmaceutical Medicine is a necessity? I doubt this. Just consider, a certification as a physician in one country is not necessarily a guarantee to get this certification recognized in another country.

Within IFAPP it seems much more important to develop and increase the knowledge of all the different aspects of Pharmaceutical Medicine world-wide. That is what IFAPP's active national member associations do. Their members, namely Pharmaceutical Medicine experts, foster a fruitful dialog with clinical colleagues, pharmaceutical reviewers and regulators. And also, Pharmaceutical Medicine experts are particularly accountable to the society with regard to the provision of safe and effective medicines and of monitoring safety during the whole life-cycle of a drug.

IFAPP WORLD: Clinical investigator – is it conceivable to establish a recognized certification for them? And members of ethics committees and institutional review boards – do they also need a particular certification in Pharmaceutical Medicine? What is IFAPP's position on that?

Dr Rudolf van Olden: It is pivotal that a clinical investigator has an in-depth knowledge of the specific disease area, which is in the focus of the particular clinical trial. And – of course – he necessarily needs to understand and to recognize Good Clinical Practice and all other formal issues for

Dr Rudolf van Olden, IFAPP President, The Netherlands:

"Pharmaceutical Medicine experts are particularly accountable to the society with regard to the provision of safe and effective medicines."

conducting a clinical trial. With this in mind, it is easy to understand that a general practitioner involved in a clinical trial phase III needs to have different knowledge and experience as compared with an oncologist performing a phase I trial. How to handle one-sort of certification for them all? Probably, we need to differentiate – not just a general practitioner versus an oncologist, but also a trial nurse versus a principal investigator.

The role of IFAPP is to advocate that training and expertise in Pharmaceutical Medicine are essential for all of them – clinical investigators, members of ethics committees and institutional review boards – and adds value to drug development, pharmacovigilance and patients' safety and welfare.

IFAPP WORLD: IFAPP is firmly linked to PharmaTrain, the European Pharmaceutical Medicines Training Programme. Could PharmaTrain, actually a European Innovative Medicines Initiative, be extended globally by an IFAPP initiative?

Dr Rudolf van Olden: It really is worthwhile that the PharmaTrain initiative is taken by a lot of well-known experts in the field of Pharmaceutical Medicine. IFAPP is the co-founder of PharmaTrain. Although PharmaTrain is constituted in Europe, there are in principle no physical borders to training in Pharmaceutical Medicine and to disseminate the PharmaTrain concept. The main hurdles for exporting this concept are funding and management capacity.

However, as a federation of national member associations, the strength of IFAPP is its network. So far IFAPP has no ambition to organize its own Pharmaceutical Medicine training center.

IFAPP WORLD: What is IFAPP's position and role in the globalization of R&D for new medicines?

Dr Rudolf van Olden: As already stated, IFAPP is a network organization and primarily follows the initiatives and activities of IFAPP's member organizations.

The main strength of IFAPP is to connect the member associations.

With regard to the changes in the globalization of R&D, we need to put some additional focus on the member associations in the South-East-Asia-Pacific region and the so-called BRIC countries – Brasil, Russia, India and China. Besides, it is important to stay connected with our colleagues in the United States of America and in Japan. Europe will always have a strong backbone in Pharmaceutical Medicine activities based on the home-based industries.

IFAPP WORLD: Health economics is gaining ever more importance and influence on R&D decisions. If so, then how is health economics linked with Pharmaceutical Medicine and further on with IFAPP?

Dr Rudolf van Olden: Health economics is, in essence, part of the Pharmaceutical Medicine spectrum. In a lot of activities of our member associations and also in the last International Conference on Pharmaceutical Medicine – ICPM – and other IFAPP conferences, various topics of health economics were addressed as matters of high importance.

IFAPP WORLD: What other challenges is IFAPP currently facing?

Dr Rudolf van Olden: The main challenge is the limited time available to our individual members to spend on IFAPP activities. Just consider our individual members – nearly all of

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Bild: Fotolia

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them are working for the pharmaceutical industry or related service providers, which face ever more budget constraints and change their priorities. As a consequence, IFAPP’s individual members have to spend ever more time to cope with this, and have less and less time to spend for IFAPP activities e.g., professional international networking and knowledge sharing.

However, international networking and knowledge sharing becomes more and more important not least as a means to better cope with these dynamics within the pharmaceutical industry sector.

In order to retain IFAPP as a strong and reliable partner on behalf of our member associations around the globe, and to better cope with future challenges, I have launched an initiative to modernize the IFAPP structure. This initiative is on track now within the Executive Committee and will be communicated soon.

IFAPP WORLD: Thank you very much for your detailed answers and your description of your positions. ■

The Flag

IFAPP World is a publication of the

International Federation of Associations of Pharmaceutical Physicians (IFAPP)

IFAPP, founded in 1975, is a non-profit organization with 30 national member associations 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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Dr Greg Koski:

"Academia, government(s) and industry must build a tripod structure where the limits will be more flexible and able to face new challenges."

The International Perspective

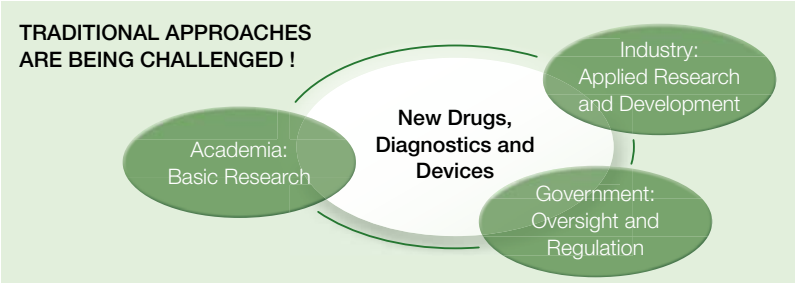
Partnerships Between Academia, Industry and Government(s) in the Development of New Medications

International Experience and Models: A North American Perspective

By Prof Dr Greg Koski, Harvard Medical School, Boston, USA, member of the IFAPP Executive Committee

Despite frequent ethical lapses, widespread financial conflicts of interest and disparities in healthcare resources and services, clinical research and drug development offer hope. There are ways to develop safe and effective therapies, accessible to those who need them without exploitation or harm. It is not a dream to pursue eradication of neglected and endemic diseases, the prevention of many acquired diseases and to enhance health, productivity and quality of life for all.

Traditionally, investigation and development of drugs, diagnostic tools or devices meant separated tasks: academia has looked essentially for basic research, industry was most focused on applied research and development. Government is naturally engaged in oversight and regulation (figure 1). Many people recognize that a new kind of relationship between these stakeholders is urgently needed. Academia, government(s) and industry must build a tripod structure where the limits will be more flexible and able to face new challenges (figure 2).



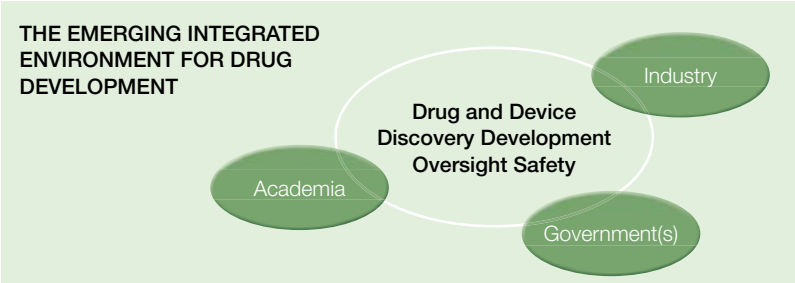


Figure 1 (on top) and 2 [Koski 2011]

There are three kinds of aspects to be considered:

1. Economics

- Depleted pipelines: big pharmaceutical companies are lacking of products that can shine and displace older ones.
- Diminishing profitability due to extended and strong competition.

2. Science

- Genomics, proteomics and lipomics are very promising fields.
- New targets for drug action must be identified.

3. Society

- Longstanding ethical concerns involving different matters going from subject protection to commercial practices.
- Growing anti-regulatory sentiment.

There are several relevant US-American initiatives focused on improving the clinical trials process. Among them are the Critical Path Initiative (CPI/C-Path), the Clinical and Translational Science Awards (CTSA), the Clinical Trials Transformation Initiative (CTTI), the Multi-Regional Clinical Trials (MRCT) Initiative and the Alliance for Clinical Research Excellence and Safety (ACRES).

New Relationships Between Stakeholders in Clinical Research

Dr Paulo Aligieri, Executive Secretary of the Brazilian Society of Pharmaceutical Medicine, São Paulo, Brazil, is pleased to expand the 9th Brazilian Forum and to bring the keynotes to the attention of the global audience of IFAPP WORLD:

Public-private partnerships are a reality in virtually all areas of knowledge and in several countries. Academic researchers, the governments as well as pharmaceutical companies work together to find solutions for some unmet medical needs, and the clinical trials arena is certainly an important point of interest in this scenario.

The adjacent article summarizes a lecture given by Dr Greg Koski from Harvard Medical School, Boston, USA, at the symposium "Partnerships between academia, industry and government in the development of new medications" during the "9th Brazilian Forum on Ethics in Clinical Research", held in Sao Paulo, Brazil, in August 2011. ■

Critical Path Initiative

"The Critical Path Initiative (CPI) is FDA's [United States Food and Drug Administration's] national strategy for transforming the way FDA-regulated medical products are developed, evaluated, and manufactured." [1]

The acronym CPI must be distinguished from Certified Physician Investigator exam process offered by the Academy of Clinical Research Professionals. That's why the author chooses to use the name C-Path for Critical Path.

The C-Path Initiative was launched in March 2004, with the release of FDA's landmark report "Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products" [2]. The report identified reasons for the widening gap between scientific discoveries and their translation into innovative medical treatments.

Selected objectives:

- Developing better evaluation tools like biomarkers and new assays.
- Streamlining clinical trials by modernizing clinical trial sciences to make trials safe and efficient.
- Harnessing bioinformatics (e.g., moving from a paper-based to electronic environment for exchanging information and overseeing the safety of FDA-regulated products.

Specific key areas of focus:

- Moving manufacturing into the 21st century, using tools such as process analytic technology and nanotechnology.
- Seeking products to address urgent public health needs, including improved antimicrobial testing, new animal models to test bioterrorism countermeasures and vaccine testing.
- Paying more emphasis on at-risk populations, such as pediatrics. ▶

Although the Clinical Trials Transformation Initiative was created to address a crisis for US clinical research, it seeks to identify practice improvements that can be applied internationally.

C-Path recommendations are twofold:

1. Collective action needed to modernize scientific and technical tools as well as harness information technology to evaluate and predict the safety, effectiveness, and manufacturability of medical products.
2. A national effort to identify specific activities all along the critical path of medical product development and use, which, if undertaken, would help transform the critical path sciences.

C-Path 21st century challenges:

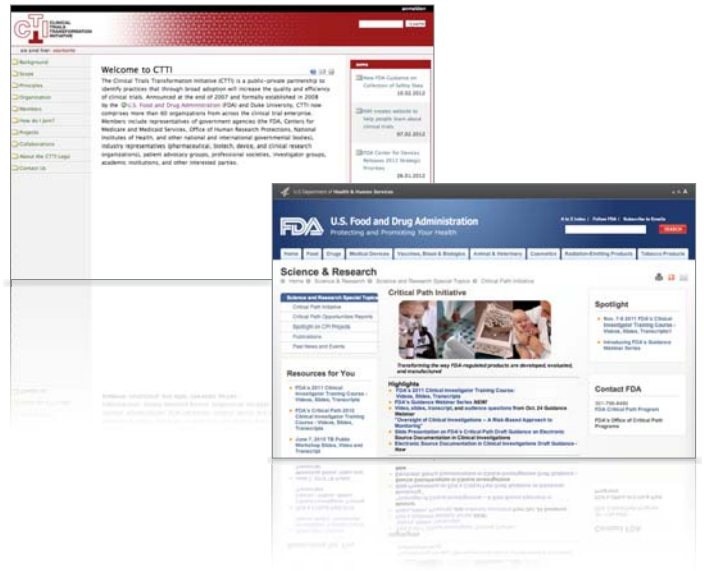
- Globalization, rapidly evolving technologies, and emerging areas of science are having a major impact on FDA-regulated medical products.
- C-Path is leveraging the knowledge we've gained from these emerging scientific fields to enhance the tools the FDA uses to evaluate drugs, biologics, and medical devices.

Detailed information is available at www.fda.gov/CriticalPath

Clinical Trials Transformation Initiative

The Clinical Trials Transformation Initiative (CTTI) was created in 2007 between the United States Food and Drug Administration (FDA) and Duke University as a public-private partnership for the purpose of identifying practices that will increase the quality and efficiency of clinical trials. It is a major spin-off from the C-Path Initiative.

The clinical trials system in the United States has been suffering as a result of increasingly longer study start-up times, slowing enrollment of patients into trials, increasing clinical trial costs, and declining investigator interest in participating in clinical trials. Although CTTI was created to address a crisis for US clinical research, it seeks to identify practice improvements that can be applied internationally, and is therefore engaging international collaborators with international efforts that have similar objectives.



CTTI seeks to involve all sectors in the selection, conduct, and interpretation of its projects to keep the dialog open across sectors, to provide evidence that can influence regulatory guidance, and to attempt to create a "level playing field" when recommending change.

A broad and diverse data-driven discussion of the important issues in clinical trials will lead to meaningful change for the benefit of all concerned, and importantly for patients.

Detailed information is available at www.trialstransformation.org

Clinical and Translational Science Awards

The Clinical and Translational Science Awards (CTSA) program is an initiative that represents a strong government-academia partnership and was launched in 2006 with US$ 465 Million funding appropriated by Congress from tax revenues. The main players are the National Institutes of Health (NIH) and the National Center for Research Resources (NCRR).

The CTSA program currently supports a national consortium of 55 academic health centers. These centers share a ▶

The Multi-Regional Clinical Trials Initiative explores ways to improve the conduct of global clinical trials and addresses the challenges of conducting research in the developing world.

common vision to reduce the time it takes for laboratory discoveries to become treatments for patients, to engage communities in clinical research efforts, and to train the next generation of clinical researchers. NCRR anticipates the addition of at least five new CTSA awards in 2011.

Detailed information is available at www.ctsapharmaportal.org or www.ncrr.nih.gov in the menu "Clinical Research" and "Clinical and Translational Science Awards"

ResearchMatch.org is an informatics innovation that was launched in October 2009 by the CTSA consortium. There is a national subject recruitment registry. Volunteers register their interest in potentially participating in research. CTSA provides health and medication information. Their profiles are matched in a de-identified manner with the needs of Institutional Review Board-(IRB-)approved enrolling studies. When a match is found, an IRB-approved message can be sent to the potential volunteer. Only if the volunteer agrees, the researcher will have access to the volunteer's contact details and identifiable health information.

More information can be found at www.researchmatch.org

Another innovation, the CTSA Pharmaceutical Assets Portal is sponsored jointly by the NCRR and Pfizer Inc. The consortium looks for collaborations between pharmaceutical companies and researchers in the area of drug repositioning. It is managed by the UC Davis Clinical and Translational Science Center. One of its goals is to leverage existing compounds to advance mechanistic understanding of human disease, resulting in novel treatments for patients. Another is to increase the knowledge base and the pool of methodologies available for proof-of-concept studies.

More information can be found at www.ctsapharmaportal.org

Multi-Regional Clinical Trials Initiative

The Multi-Regional Clinical Trials (MRCT) Initiative is an academic-industry partnership, hosted by Harvard University. It was initiated and initially sponsored by Pfizer Inc. but now is based on diversified funding with a pay-to-play model.

MRCT explores ways to improve the conduct of global clinical trials and addresses the challenges of conducting research in the developing world. Some working groups presented excellent papers enhancing quality and efficiency of ethics review, data and safety monitoring besides site selection and investigator team expertise. One of its strongest areas of focus is professionalism of monitors. Dr Edson Moreira of the Oswaldo Cruz Foundation, Brazilian Ministry of Health, has participated in the meeting. MRCT is currently working to substantiate a continuing presence and support for its activities.

A number of organizations have signed on as members of the executive and steering committees.

A website is currently under development. The initial MRCT Project Report [3] is available at www.pfizer.com/files/research/research_clinical_trials/mrct.pdf

Alliance for Clinical Research Excellence and Safety

The Alliance for Clinical Research Excellence and Safety (ACRES) is a private, non-profit organization currently planning formal incorporation. The alliance brings together like-minded people and organizations around the world to build a robust, shared global network infrastructure for clinical research, modeled after the international air transportation system. 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 envisions a global network of many thousands of clinical research sites that are accredited by independent local agencies according to internationally recognized standards, operated and staffed by fully trained, certified, professional research teams. This network will be supported by a robust, web-based shared information system to promote safety, quality and efficiency.

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.

More information about ACRES is available at www.acresglobal.net

Of course there are several other initiatives underway that are worthy of discussion, including MAGI and the work of the Health Improvement Institute (HII).

"Model Agreements & Guidelines International (MAGI) is standardizing best practices for clinical research operations, business and regulatory compliance" [4].

The "Health Improvement Institute is a non-profit, tax exempt, 501(c)3, educational organization dedicated to improving the quality and productivity of America's health care" [5]. ■

Greg Koski

Greg Koski, MD, PhD, is Senior Scientist at the Morgan Institute for Health Policy, Associate Professor at the Department of Anesthesiology, Critical Care and Pain Medicine, Massachusetts General Hospital at Harvard Medical School, Boston, USA, and Associate Editor, Journal for Empirical Research on Human Research Ethics.

He also is Co-Founder of the Alliance for Clinical Research Excellence and Safety (ACRES), and he was the first director of the Office for Human Research Protections (OHRP) at the US Department of Health and Human Services (HHS). ■

SOURCES

[1] U.S. Food and Drug Administration: Critical Path Initiative. Detailed information is available at www.fda.gov/CriticalPath

[2] U.S. Department of Health and Human Services – Food and Drug Administration: Challenges and Opportunities Report - March 2004. Available at www.fda.gov following the menu: > Science & Research > Science and Research Special Topics > Critical Path Initiative > Critical Path Opportunities Reports > Challenges and Opportunities Report - March 2004.

[3] MRCT Project Report – Enhancing Respect for Research Participants, Safety, and Fairness in Multi-Regional Clinical Trials. Addressing the Globalization of Clinical Trials. 18 March 2010. Available at The Initial MRCT Project Report [3] is available at www.pfizer.com/files/research/research_clinical_trials/mrct.pdf

[4] Information about Model Agreements & Guidelines International (MAGI) is available at http://magiworld.org

[5] Information about the Health Improvement Institute (HII) is available at http://www.hii.org

IFAPP's Calendar

16th International Conference on Pharmaceutical Medicine

14-16 November 2012, Barcelona – Spain

ICPM 2012

On behalf of the organizing committee the Presidents of IFAPP and of the Spanish Association of Pharmaceutical Medicine (AMIFE) kindly invite any and all interested persons and parties worldwide to attend the 16th International Conference on Pharmaceutical Medicine – ICPM 2012 – to be held in Barcelona, Spain, from Wednesday through Friday 14th-16th November 2012. ICPM 2012 is jointly organized by IFAPP and AMIFE.

ICPM 2012 is 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 associations' goal to make key contributions towards procuring better medicines to patients.

ICPM 2012 will ensure a top-level scientific program with expert presentations, additional debates, discussions, an interchange of ideas and sharing of information and good practices.

www.ICPM2012.com: Please join us at this important event for Pharmaceutical Medicine

ICPM 2012 Main Topics

- Plenary Lecture: Health Care Improvement Through Clinical Research
- Drug Advertising – Ethics and Compliance
- Pharmacovigilance Legislation in the European Union
- Current Patent Issues – Implications, Developments and Possible Solutions
- Patient Associations
- Pharmaceutical Medicine's Role Within the Companies' Medical Departments
- On the Edge of Therapeutic Innovations: New Ways of Developing Medicines and the Regulators' View
- The Impact of the Economic Crisis and the Changing Economy on Conceptions and Opportunities for Market Access
- Clinical Research Associates' (CRAs) Workshop

Please join us at this important event for Pharmaceutical Medicine, which already is open for registration at http://ifapp2012.com – looking forward to seeing you in Barcelona!

Dr Rudolf van Olden
IFAPP President, The Netherlands

Dr Jose Maria Taboada
President, AMIFE, Spain

Dr Belén Sopesen
Vice President, AMIFE, Spain

If you wish to be alerted to updates of the ICPM 2012 program and details of each roundtable and the panel of experts and speakers immediately upon availability, just click here and subscribe at www.ifapp.org/subscribe For details see "e-Mail Alert" on page 5 of this IFAPP WORLD issue.

Reports and Concepts

LifeTrain for a Lifelong Learning

Shaping a Common Framework for Continuous Professional Development in Medicines Research and Development – Off to a Flying Start

Bild: Fotolia

In October 2011 the European Medicines Research Training Network (EMTRAIN) invited the European Professional/Scientific Bodies (29 European scientific associations and research organizations) to explore the development of a harmonized framework for lifelong learning (LLL) under the auspices of the Innovative Medicines Initiative (IMI). The summit aimed at …

- obtaining an overall agreement for the components of the common framework
- agreeing on next steps and define an implementation plan
- understanding the role and potential of "on-course"
- agreeing on a communication plan.

Forty European professionals, representing the majority of the invited bodies, convened in the Sir James Black Conference Centre, Macclesfield, south of Manchester, United Kingdom, to share opinions and to define the future structure of the European Continuous Professional Development (CPD).

What the Event was All About

The motto of the event was "YOU CAN'T DO TODAY'S JOB WITH YESTERDAY'S METHODS AND BE IN BUSINESS TOMORROW" which was explained in detail by Martin Mackay, President of R&D at AstraZeneca, and Dr Mike Hardman, Vice President Science Policy (UK) at AstraZeneca, EMTRAIN Coordinator and PharmaTrain Co-Coordinator. In particular, both speakers underlined the great importance that the European Union (EU) is attaching to training and education: the program of the European Innovative Medicines Initiative (IMI), which will support different projects for a total of two billion euro, already had granted its support to four training projects which are:

- EMTRAIN – European Medicines Research Training Network: focused on general aspects of training and CPD; awarded a grant of 7.7 million euro [www.emtrain.eu]
- EU2P: focused on pharmacovigilance and pharmacoepidemiology; awarded a grant of 7.2 million euro [www.eu2p.org]

Sir James Black Conference Center, Macclesfield, United Kingdom, in October 2011

Representatives of European scientific associations and research organizations met to explore the development of a harmonized framework for lifelong learning

- PharmaTrain – Pharmaceutical Medicines Training Programme: focused on training programs in Pharmaceutical Medicine; awarded a grant of 6.6 million euro [www.pharmatrain.eu]

- SafeSciMet – European Modular Education and Training Programme in Safety Sciences for Medicines: focused on modular education and training programs in safety sciences for medicines, and awarded a grant of 6.3 million euro [www.safescimet.eu].

Objectives of all these projects are to promote pan-European standards in education and training. All these projects must follow a common framework for CPD programs based on three principles: quality criteria, mutual recognition and review process.

Life Long Learning

The key points of Life Long Learning (LLL) were then underlined by three speakers:

Peter Baur, Directorate-General Education and Culture, European Commission (EC), reported that LLL is a matter of attention from EC since 1996. EU experts predicted that by 2020 Europe will have some 35 percent jobs requiring a high level qualification, and under the present system they anticipate a shortage in information and communication technology (ICT), sciences, engineering and health. EU objectives are to move LLL from 9.3 percent in 2009 to 15 percent by 2020. But unfortunately a 2010 EU report stated that LLL remains a peripheral concern in many countries.

Peter Zervakis, German Rectors' Conference, the voluntary association of state and state-recognized universities and other higher education institutions in Germany, reiterated the high value of the Bologna principles, based among other issues on the acceptance of the progression from baccalaureate to master to doctor and finally to employment. He also illustrated the Nexus project, which is being implemented in Germany.

Antony Payton, Manchester University, United Kingdom, demonstrated the new website portal named "on-course" (www.on-course.eu) which was launched in December 2011. This new instrument will offer a catalog of all European courses and masters related to scientific topics, and should help students not only in their selection, but also stimulate a pan-European mobility of them.

"The **Innovative Medicines Initiative (IMI)** is Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients.

IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe.

IMI is a joint undertaking between the European Union and the pharmaceutical industry association EFPIA." [www.imi.europa.eu]

"The **European Medicines Research Training Network (EMTRAIN)** establishes a sustainable, pan-European platform for education and training (E&T) covering the whole life-cycle of medicines research, from basic science through clinical development to pharmacovigilance.

EMTRAIN is funded by the Innovative Medicines Initiative Joint Undertaking (IMI JU)." [www.emtrain.eu]

LifeTrain motto:

"You can't do today's job with yesterday's methods and be in business tomorrow."

Dr Mike Hardman at his LifeTrain presentation. He is, inter alia, EMTRAIN Coordinator and chaired the LifeTrain workshop steering committee.

Two Working Groups With Well Defined Tasks

The participants then were divided into two working groups (WG) with well defined tasks.

WG 1 had to elaborate on LLL framework, quality and review. The results of this WG can be summarized in three points as follows:

- CPD must be implemented, and should have a broad objective (not only to include scientific aspects, but also topics like leadership and team working);
- It is critical to convince all EU MS to implement a CPD program;
- For its success, CPD should be encouraged by all parties.

WG 2 had to elaborate on LLL benefits and challenges; conclusions can be summarized as follows:

- Most important benefits are a European platform, the quality review process, the identification and support of talents, the reference point of National Associations and the opportunity to increase reputation and professionalism.
- Most critical challenges are funds, a shared program, the agreement on key points, the review and acceptance of programs already implemented.

The final part of the morning of the second day was devoted to a possible definition of an implementation plan for a pan-European CPD. Conclusions were that in 12 months time it should be possible to finalize the strategic plan, which should become operational during the subsequent 12 months. In short, according to the whole group agreement, by the end of 2013 Europe should have implemented a mutual CPD program.

Status of the Innovative Medicines Initiative

The meeting was concluded by an institutional presentation: Fatiha Sadallah, Principal Scientific Manager of IMI, gave a short report of the IMI status and its achievements. Until now, IMI had three calls, in 2009, 2010 and 2011.

2011 projects are under scrutiny, but results of the first two calls indicate that a total of 15 plus 8 projects were approved, for a total budget of 281 plus 172 million euro. Most frequently represented EU countries in the approved projects are the United Kingdom (75 partners), Germany (55), France (44), The Netherlands (29), Spain (22) Italy (19) and Belgium (18).

As an example of an interesting result already achieved, Fatiha Sadallah reported that a study group in schizophrenia was able to combine results from different clinical trials including a total of 23,401 patients, and to get important genetic information from 1,800 of them. Similar programs are under way in other diseases, such as pain and severe asthma.

The Author's Conclusion

Special thanks are due to AstraZeneca for arranging and hosting the meeting. It is a reassurance, which underlines that a big pharmaceutical manufacturer is so heavily committed to support a EU Continuing Professional Development (CPD) program. In my view, this may have its roots in the Swedish-British souls of AstraZeneca – in fact, both Sweden and Britain have always largely invested in both education and research.

Continuing Professional Development (CPD) – and no more Continuing Medical Education (CME) – might take some more time to spread out but it will become reality for quality assurance. It seems similar to the implementation of Good Clinical Practice (GCP), Good Laboratory Practices (GLP) and Good Manufacturing Practice (GMP): once implementation was started, it took several years but finally it got well established and at present nobody doubts its value.

IFAPP was identified as a player of this process, so this federation should maintain its role and promote the CPD culture among IFAPP's National Member Associations.

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

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