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IFAPPWORLD

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS & PHARMACEUTICAL MEDICINE

C O N T E N T T H E I N T E R V I E W

Pharma-CRO Collaboration: Where Are We?

Response to the EDITORIAL of Dr Johanna Schenk in IFAPP WORLD November 2014

Dear Dr Schenk, I read your Editorial "The Ever-Increasing Importance of CROs in Drug Development" with great interest. And I am pleased to accept the invitation for comments.

First of all, let me say only that I have a large experience in clinical research: big pharma (27 years), global CROs (4 years) and small biotechs (8 years, ongoing). During these years, I dealt with several CROs and sponsors, so my comments are based on a large series of negotiations, sitting on both sides of the table. Anyway, let me confirm your opinion: I too feel the need for improvement, which must be addressed to both parties.

I will focus on few aspects of your analysis.

The first one is the "we are one team" spirit. I heard this concept hundreds of times, but ... is it true? I doubt it. Over the years, CROs learnt to prepare their offers using the "salami slicing" method: to describe one major activity, i.e., the complete management of the clinical study, in great detail. This approach not only generates very complex offers (10 pages or even more just for cost descriptions only) and a significant increase of costs, but as a consequence, it also creates CRO people with the attitude of "working with the contract on their desk". CROs are for-profit organizations, but I learnt that they love out-of-scope activities, which are tasks, that are not included in the initial offer and are charged above and beyond to the sponsor, which must accept it without any option to refuse. >>>

IFAPP's Role in PharmaTrain and Medicines Development Education

Training of Drug Development Scientists Needs Competence, Harmonization, Accreditation and Certification

IFAPP is traditionally committed to the promotion and harmonization of the education and training of pharmaceutical physicians and drug development scientists. In this regard IFAPP got prominently involved in the formation of PharmaTrain, which today "provides accreditation and professional certification to ensure the competence of medicines development scientists and clinical investigators." [1]

What is behind that and what is the way forward? This is explained by Dr Honorio Silva, IFAPP President Elect, USA, who is much involved in PharmaTrain, and Dr Ingrid Klingmann, President, PharmaTrain Federation, Europe, in an interview with the IFAPP WORLD Editor, Eckhard Böttcher-Bühler, Germany.

IFAPP WORLD • Dr Klingmann, Dr Silva, could you please outline the history of the common spirit, cooperative role, and close relation between IFAPP and PharmaTrain?

Dr Ingrid Klingmann • The need for a structured, harmonized approach to top-level education and training of pharmaceutical physicians and other experts working in medicines development, based on a shared syllabus and quality standards was a long-standing goal of IFAPP and its National Member Associations. Fritz Bühler in Switzerland with support from other colleagues from the IFAPP Board tried several avenues to enable concrete pan-European collaboration like assembling most of the European course providers into a joint European Federation of Course Providers in Pharmaceutical Medicine (EFCPM).

But only achieving need awareness of senior management in the pharmaceutical industry and the European Commission enabled the inclusion of this topic into the Innovative Medicine Initiative (IMI) [2] with the respective substantial funding opportunity and collaboration infrastructure. It was thus just natural that EFCPM and IFAPP were the core public consortium members for the PharmaTrain inception.

Dr Honorio Silva • IFAPP representatives were appointed to the PharmaTrain Board of Directors and helped in the adaptation of the IFAPP syllabus to the PharmaTrain syllabus and curriculum as well as in the creation of shared and jointly accepted quality standards. In addition, a Working Group including representatives from either organization prepared the Core Competencies for Pharmaceutical Physicians and Medicines Development Scientists [3] which were aligned with the PharmaTrain Learning Outcomes and ensured that >>>

Response to the EDITORIAL ...

>>> And I saw out-of-scope bills for a few hundred euro linked to a multi-million contract. Is this the "one team spirit"? Not in my view.

The second comment refers to the role of the CRO project manager (PM): I am sure everybody will agree that he/she is the most important player for a successful study. Now, what I experienced so many times, that it is almost the rule: In the bid defense meeting a very experienced PM is introduced to the sponsor. He/she will eventually start in this role, but ... after a few months, a CRO communiqué informs the sponsor that the PM has been promoted, and you are left with a less experienced PM. This happened so many times, that I start to believe, that I am the one who brings luck to the PMs of my studies – in fact, after just a few months of work all of them got a promotion!

The third and final comment is related to the "fake" requests, which sometimes sponsors address to CROs, although having already decided which one will win the project. This is of course a very unethical approach, which I would definitely discourage. On the other side, sponsors usually request 3 to 5 proposals for each study in order to identify the best quality/cost ratio. In a very competitive arena like the one of CROs, an ethical and unbiased approach to compare different proposals must be the way to go.

In conclusion, let me only say that the sponsor-CRO collaboration is mandatory today, but there is huge potential for improvement. Indeed, I would welcome the UEFA logo in our world too: RESPECT!

Domenico Criscuolo
IFAPP Delegate, Italy

What about you?
What is your opinion on these issues?
Please write to the Editors at boebue@boebue.de

The Flag

IFAPP WORLD is a publication of the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP).

IFAPP, a non-profit organization founded in 1975, acts as an international forum for all pharmaceutical medicine professionals' organizations worldwide by dealing with matters brought to its attention through national member associations.

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THE INTERVIEW • IFAPP's Role in PharmaTrain ...

>>> graduates from the PharmaTrain base course (Diploma) are fully competent at the cognitive level. The Working Group is currently cooperating with the implementation of the Competency Based Certification program in pilot countries, partly financed by the PharmaTrain successor program in IMI called IMI-TRAIN.

IFAPP WORLD • Thus, it is all about education and training on the highest possible level of competence. Where do you see the greatest needs for this and why?

Dr Silva • Surveys conducted among the IFAPP National Member Associations showed that the majority of pharmaceutical physicians and professionals working in medicines development have not received formal postgraduate education in the discipline.

On the other hand, traditional education does not meet the needs of key stakeholders in medicines development and thus outcomes based education, based upon learning outcomes and competencies has become the standard for undergraduate and postgraduate education as well as for continuing professional development activities. A competent pharmaceutical physician would be able to function effectively in the 3 areas and 7 competence domains defined by the Working Group [3]. Better-trained professionals would be able to develop better medicines for improved health care.

IFAPP WORLD • PharmaTrain is made in Europe but operates worldwide. What about the acceptance of this initiative – is acceptance right there, where you see the greatest needs.

Dr Klingmann • The news about the PharmaTrain project spread very quickly around the world amongst course providers leading to spontaneous requests to become member of the PharmaTrain consortium. IMI rules did not allow for this but PharmaTrain created the PharmaTrain Global Network and thus enabled interaction, collaboration and recognition as "PharmaTrain Centre" or "PharmaTrain Centre of Excellence" according to the PharmaTrain rules beyond the PharmaTrain Consortium.

The Pharmaceutical Medicine Course in Stellenbosch, South Africa, is the first Centre of Excellence in Africa and the course in Osaka, Japan, has applied for starting the recognition process. Being able to be recognized as a Diploma or Master Course demonstrating adherence to the "gold standard" obviously is of major interest for the course providers and enables attractivity for trainees looking for options to proactively develop their career and for pharmaceutical companies looking for top-quality, flexible course offerings for their employees.

IFAPP WORLD • Completing the circle – what is IFAPP's role and position in PharmaTrain today and further on?

Dr Silva • IFAPP continues to be a key strategic partner within PharmaTrain and is committed to help in expanding the affiliation of education providers from all over the world with an aligned curriculum and harmonized education standards, so that graduates from different countries are equally competent.

Dr Klingmann • And IFAPP will be a key enabler for the implementation of the structured educational infrastructure required for the job-based competence development pathway to a Specialist in Medicines Development in those IFAPP National Member Associations interested in establishing such career opportunities.

IFAPP WORLD • Are there any competitors to PharmaTrain providing such education in different countries and if yes, do their education standards differ?

Dr Klingmann • While some international not-for-profit organizations like the Association of Clinical Research Professionals (ACRP) have developed concepts and programs for professional education of CRAs or investigator site staff on a transatlantic basis, the large pharmaceutical company initiative TransCelerate is in the process of implementing agreed minimal standards for GCP training, and ACRES, the Alliance for Clinical Research Excellence and Safety, is establishing a global network of accredited top-quality performing investigator >>>

THE INTERVIEW • IFAPP's Role in PharmaTrain ...

>>> sites, no other organization has engaged in establishing an international infrastructure for competence in medicines development.

Dr Silva • On the other hand, the Core Competencies for Clinical Research Professionals have been identified by a Joint Task Force including representatives from IFAPP and PharmaTrain [4]. An international survey aimed to validate such competencies and define competency-based job portfolios and educational needs assessment in clinical research is underway.

IFAPP WORLD • How should IFAPP National Member Associations – NMAs – become actively involved and what can they expect?

Dr Silva • The IFAPP NMAs play a fundamental role in the planning and implementation of local educational and training activities for their members as well as for clinical research professionals by adopting and adapting the PharmaTrain programs. The NMAs also help in the interface with academic institutions and local regulatory agencies to create further awareness on the need for formal certification of professionals involved in medicines development. The IFAPP strategic objectives for the period 2014-2018 have been defined and the participation of the NMAs is absolutely critical to achieve specific goals.

All this is what Ingrid Klingmann has claimed above to be IFAPP's role – IFAPP is no more than the sum of IFAPP NMAs.

Dr Klingmann • The PharmaTrain developed concepts for investigator training (CLIC – Clinical Investigator Course) and Master programs in regulatory affairs (MRA) are further options for NMAs to provide attractive educational infrastructures for their members and their employers in industry and academia.

IFAPP WORLD • What is the main success so far? What are the challenges?

Dr Klingmann • It was a political and organizational master piece of all parties involved to enable the PharmaTrain global infrastructure, constructive collaboration in developing the shared standards and ready to use concepts for globally harmonized, improved education in medicines development, regulatory affairs and clinical trial management within five years including the sustainability concept as an independent not-for-profit organization, the PharmaTrain Federation.

The current challenges for PharmaTrain and IFAPP are the creation of the implementation infrastructure for these concepts, the ongoing and growing voluntary involvement of the different stakeholders in using and growing this unique opportunity and to find reliable funding for further developments.

Thank you for your detailed answers.

References

(Websites last accessed: Jan 17, 2015)

[1] PharmaTrain Website

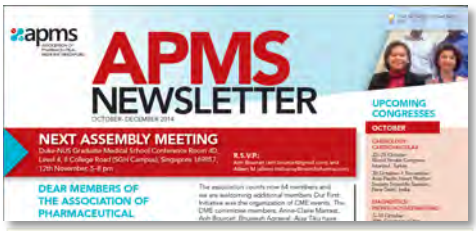
[2] Innovative Medicines Initiative (IMI)

[3] Silva H et al for the IFAPP WG: Core competencies for pharmaceutical physicians and drug development scientists. Front Pharmacol 2013; 4(105): 1-7.

[4] Sonstein, S.A. et al.: Moving form compliance to competency: A harmonized core competency framework for the clinical research professional. J Clin Res Best Practices 2014.

IFAPP's Regional Update: SINGAPORE

The Association of Pharmaceutical Medicine Singapore – APMS



It has just been over a year since the revival of the Association of Pharmaceutical Physicians in Singapore and the election of the Board, which recently held its 2nd General Assembly.

Based on member feedback, the association was officially renamed Association of Pharmaceutical Medicine (Singapore) (APMS) to reflect the broader participation of membership beyond physicians.

We built APMS as a professional non-profit organization aiming to promote pharmaceutical medicine by enhancing the knowledge, expertise, and skills of pharmaceutical professionals, thus leading to the availability and appropriate use of medicines for the benefit of patients and the society. APMS Board members are the APMS President Elena Rizova, MDPhD, VP Johnson & Johnson Innovation (Former Head of AP Medical Affairs Janssen); the APMS President-Elect Aileen Dualan, MD, Chief Scientific Officer Asia Cluster Novartis; APMS General Secretary Abhishek Bhagat, MBBS, PGDBM, Regional Medical Director CH Asia Merck Consumer Health, and the APMS Treasurer Suhail Ali, Project Director, Oncology-Hematology Asia Pacific INC Research.

APMS counts 65 members and is welcoming additional members.

One of the foremost areas in focus was to organize Continuing Medical Education (CME) events, renamed Pharmaceutical Medicine Forums (PMFs). This was a huge success due to the dedicated work of the PMF Committee: Ajay Tiku (GSK), Anne-Claire Marrast (DIOSCORIDES), Anh Bourcet (Janssen), and Bhuwesh Agrawal (Veladx). They developed an effective program and established a fantastic exchange platform. Topics included: The Evolving Market Access Landscape in Asia Pacific – Impact for Pharma; The Changing Landscape of Pharma in Asia and the Evolving Role of the Pharmaceutical Physician; Real World Research in Asia – its Evolving and its Importance.

We also successfully launched a quarterly newsletter thanks to the Communication Committee: Dr Arti Dhar (MedTech Media), Viabhav Joshi (Quintiles), and Ranga Prakash (Biogen Idec). The objective of the Newsletter is to provide news on relevant topics concerning pharmaceutical medicine with a focus on Singapore, including upcoming PMFs, and to offer a platform >>>

IFAPP's Regional Update: SINGAPORE

>>> for sharing experience, concerns and ideas.

The PMFs will continue to remain a key objective and a focus for APMS in 2015 in addition to the organization of a one day Medical Affairs Seminar with the following objectives: exchange on specific local and regional opportunities and challenges; share best practices on capability building in the region; leverage the importance, value and integration of Medical Affairs for patient access; better refine roles, responsibilities and contributions of scientific/medical operations (Medical Science Liaison – MSL) and discuss opportunities to strengthen relationship with academic institutions and local/regional medical associations.

Our APMS is still young and we count on all members to enrich it by contributing ideas and initiatives and sharing experience.

We are excited about the launch of "JADE" in the near future, which is a certified educational program in Medical Affairs to strengthen core functional competencies and therapeutic/disease area knowledge for medical and healthcare professionals who are interested in developing their career in the pharmaceutical industry or related fields.

On behalf of the APMS Board
Elena Rizova
APMS President

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IFAPP gratefully acknowledges generous sponsorships and financial support from:

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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 sponsors. Detailed information on sponsorship opportunities is available at www.IFAPP.org – section "sponsors".

A Testimony from GERMANY

Hosting ICPM 2014 in Berlin – a great success for IFAPP and the Hosting Association

IFAPP's 17th International Conference on Pharmaceutical Medicine (ICPM 2014) has been held in March 2014 in Berlin, Germany. When it came to organizing ICPM 2014, the German Society of Pharmaceutical Medicine (DGPharMed – Deutsche Gesellschaft für Pharmazeutische Medizin) approached the preparation of this high ranking meeting with professional attitude both for the scientific and the organizational aspects. The association could benefit from the profound experience in successfully setting up large-scale national conferences over the past years. In addition, based on previous management of hosting earlier ICPM meetings (1984, 2000) an experienced team was set up to plan and execute the meeting together with the colleagues from IFAPP.

The challenge was to set up a program, which could attract national and international participants at the same time, each with their particular needs and expectations towards a continuation of their usual biannual (ICPM) and annual (DGPharMed annual meeting) events for information, training and dialogue. How has this challenge been mastered?

A group of outstanding international pharmaceutical medicine experts from IFAPP National Member Associations under the leadership of the IFAPP and DGPharMed Presidents Dr Yil-Seob Lee, South Korea, and Dr Axel Mescheder, Germany, constituted an organizing and a scientific committee which have supported the organization of the event.

In collaborative efforts a comprehensive program was completed including eleven symposia with 34 expert-to-expert presentations on different pharmaceutical medicine issues and a round-table discussion on data protection in drug development. "Smart development for better drugs" was the maxim of the conference. At the conference the program matched the expectations of national and international needs.

In another effort clinical research and pharmaceutical medicine professionals as potential conference participants from all over the world have been individually invited to join the conference. Companies and service providers in clinical research and pharmaceutical medicine have been wooed and invited to present their services and business at a booth at the ICPM 2014 exhibition. And media representatives have also been invited to join the conference for reporting. They all together – more than thousand particular selected individuals – have been contacted from October 2013 until March 2014 seven times with seven different "Announcement & Invitation" letters each including a particular "Reference to the Scientific Program" and a "Glance at Berlin".

The considerable amount of work which has gone into this project finally paid off at the conference, which was well attended by more than 350 participants and came out as a lively, versatile, practice-oriented dialog between presenters from industry, service providers, authorities, ethics committees, academia, and conference participants. IFAPP's 17th International Conference on Pharmaceutical Medicine (ICPM 2014) was successfully completed in March 2014 in Berlin, Germany. On behalf of the organizing and scientific committees I like to send a cordial thank-you to all of those who made this successful meeting happen.

Dr. Axel Mescheder
DGPharMed Board Chairman and President of ICPM 2014

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

IFAPP
Pharmaceutical Medicine

SOCIETÀ DI SCIENZE FARMACOLOGICHE APPLICATE
SOCIETY FOR APPLIED PHARMACOLOGICAL SCIENCES

A PHARMATRAIN – IFAPP – SSFA CONFERENCE

Advancing Competent Professionals in Medicines Development

Rome, Italy | 10-11 JUNE 2015

Dear Colleague
We are pleased to inform you that IFAPP, in collaboration with SSFA (the Italian Association of Pharmaceutical Medicine) and the PharmaTrain Federation, is organizing an international conference on the Specialist in Medicines Development (SMD) project. This project is being implemented in Italy, but all other countries will follow. In addition, this event will celebrate the 40th Anniversary of the IFAPP Federation. Please plan to be in Rome, Italy, on 10-11 June 2015 and be part of this global initiative.

Wednesday | June 10 | Afternoon

Session Title: Celebrating the First 40 Years of IFAPP
Chairpersons: *Honorio Silva (IFAPP) & Marco Romano (SSFA)*

14:00 Introduction from the Chairs
14:10 The History of IFAPP | *Herman Lahon*
14:30 The Development of PharmaTrain | *Sam Salek*
14:50 Back to the Future – Round Table with some Former IFAPP Presidents: *LM Fuccella, P Stonier, J Schenk, D Criscuolo, G Nell*

16:00 Tea

16:30 IFAPP Future Strategies for Competence Development (Round Table)

- Competencies in Pharmaceutical Medicine *Dominique Dubois*
- Addressing Expectations from National Associations | *Daniel Sehrt*
- Plans for 2015-2018 | *Gustavo Kesselring*
- ICPM 2016 | *Joao Massud (via Skype)*
- The Role of the Faculty of Pharmaceutical Medicine *Keith Bragman*

18:30 Cocktail
20:00 Dinner (by invitation only)

Thursday | June 11 | Morning

Session Title: Education in Pharmaceutical Medicine: Present and Future
Chairpersons: *Ingrid Klingmann (PTF) & Gustavo Kesselring (IFAPP)*

9:00 Public and Private Partnerships to Advancing Education in Medicines Development *Mike Hardman*
9:20 PharmaTrain: an EU Initiative Going Global *Ingrid Klingmann*
9:40 The PharmaTrain Centres of Excellence in Italy *Pierluigi Navarra (Rome), Antonio Torsello (Milano)*
10:20 The Concept of Specialist in Medicines Development *Peter Stonier*

10:40 Coffee

11:10 Developing a Global Certification Board *Heinrich Klech*
11:30 SMD Implementation in Japan *Kyoko Imamura (via Skype)*
11:50 Medicines Development Education in Low-Income Countries *Sandor Kerpel Fronius*
12:10 Competencies in Clinical Research: A Global Perspective | *Honorio Silva*
12:30 The CLIC Project | *Jean Marie Boeynaems*
12:50 Round Table | *all speakers*

13:30 Lunch

Thursday | June 11 | Afternoon

Session Title: Certification in Pharmaceutical Medicine and Clinical Research
Chairpersons: *Peter Stonier (PTF) & Domenico Criscuolo (SSFA)*

14:30 The Vision of Regulators *AIFA (awaiting confirmation)*
15:00 The Vision of Pharma Companies *Farmindustria (awaiting confirmation)*
15:20 The Vision of Italian Pharmacologists *Francesco Rossi (SIF)*
15:40 The Vision of CROs *Mariapia Cirenei (AICRO)*
16:00 Perspectives from the Italian Association of Medical Oncology *Massimo Di Maio (AIOM)*
16:20 Discussion | *all speakers*
17:00 Conclusions and Wrap-Up | *from the Chairs*