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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

Regional Update: AUSTRIA

GPMed: Strong Leadership in Clinical Research

The Austrian Society for Pharmaceutical Medicine (GPMed) was founded in 1992 and to date has around 160 full members. The majority of them are physicians and scientists across big, mid-size and small pharmaceutical companies, academic institutions and sites, authorities and clinical research organizations. All of them are heavily involved in clinical research activities in Austria – from protocol development to trial implementation as well as trial execution and quality control.

GPMed President Dagmar Doby MD, MBA, Eli Lilly, together with a diverse leadership team, assembled by team members who represent all the needs and perspectives of pharmaceutical/research companies as well as of academic institutions, are focusing on a regularly updated, strong and solid plan of professional, high quality, cross-functional educational meetings (approximately 400 attendees per year), accompanied by other activities, covering a huge variety of important topics in clinical research.

Based on these established and continuous activities throughout the years, GPMed has not only become a highly valued platform for communication and networking within and beyond its own membership community, but on top of that also has grown into a respected partner for the Austrian authorities and academic institutions running meaningful activities together – e.g., the Austrian "Best Inspectee Site Award" to name just one.

The defined goal of GPMed is to further >>>

Specialist in Medicines Development (SMD) Project

Advancing Competent Professionals in Medicines Development

In June 2015 IFAPP will celebrate its 40th anniversary at a conference in Rome, Italy [1]. The main conference issue is education and training in pharmaceutical medicine and competencies in clinical research. An IFAPP working group has defined "Core competencies for pharmaceutical physicians and drug development scientists" [2] in great detail in a paper published in August 2013. Dr Peter Stonier is a member of this working group as well as of the Scientific Committee of the Rome conference; and he kindly provided an insight regarding the need for specialist in medicines development in an interview with the IFAPP WORLD Editor, Eckhard Böttcher-Bühler, Germany.

Dr Peter Stonier
PharmaTrain Federation

IFAPP WORLD • Dr Stonier, do you spot inappropriate education and training, or a new demand for particular skills?

Dr Peter Stonier • Throughout its 40-year history IFAPP has held high in its aims and agenda the education and training (E&T) of members of its constituent professional associations, working in the field of pharmaceutical R&D, medicines' development and the growing discipline of pharmaceutical medicine.

The essence of this E&T has been to follow a curriculum, success rewarded by a certificate, diploma or degree, to cover the syllabus of a field of endeavor which is not represented in undergraduate or postgraduate programs, and to which doctors, scientists and others are first exposed through their work in a pharmaceutical company, in a clinical research organization or a regulatory agency.

The basic need for E&T and continuing learning in the complex and ever-changing world of medicines' development – innovative, high-risk, lengthy, costly, multi-disciplinary and with patient benefit and welfare at its very public end – should not need to be emphasized. Additionally the value of E&T, to learn from the past to prepare for a changed and different future, to offer assurance to the public that the development of its medicines is in the hands of appropriately-trained, up-to-date and competent professionals, should be recognized.

IFAPP has promoted this agenda vigorously over the years, through recognition and accreditation of established courses and qualifications meeting appropriate standards, through acceptance and promotion of the common (IFAPP) syllabus, through encouragement and support of E&T in its worldwide network of member associations, and through focus and update of latest science and medical developments at its international conferences. IFAPP has also supported the adoption of developments in E&T methods appropriate to >>>

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>>> strengthen Austria's position as a highly attractive place for investing in and running of clinical research. In this regard GPMed is taking a strong leadership role: bringing all partners together, professionally driving the topics, engaging in transparent communication, thus preparing the ground for impactful joint actions and decisions.

Dr Dagmar Doby
GPMed President

Dr Dagmar Doby: "The new EU Clinical Trial Regulation is an underestimated huge upcoming change: The way the topic has been prepared, brought-up, shared within our meetings and discussions, all the subsequent professional communication, using several channels around the implications of this new process, have triggered a huge and open dialogue in Austria – as a consequence a lot of projects from all sides are currently ongoing to implement the new Clinical Trial Regulation in a 'role-model' way in our country."

Dr Doby stresses that in order to succeed in the worldwide competition in clinical research now and even more in future, a lot of effort needs to be made to communicate the strengths of Austria as a great place to do clinical research, such as highly professional centers, study sites, very experienced and well-trained investigators, very specific know-how and excellent track records in some important areas, e.g., Phase I trials. In addition to that, there are lean structures and a solid, strong, and positive professional collaboration between sponsors and study sites with the Austrian authorities and Ethics Committees (Institutional Review Boards – IRB) ensuring high speed and high quality data generation. Furthermore, there are already a lot of activities ongoing to evaluate, address and overcome existing small hurdles, like time to contract finalization.

To ensure transparent and up-to-date communication with its members and to build a "strong knowledge and experience library" GPMed runs a professional webpage, including an official study site data base at www.gpmed.at as well as a Twitter feed.

In this way GPMed is continuously driving the clinical research landscape in Austria and is very optimistic that with keeping this mindset and level of excellence the future of clinical research will be bright.

Professor Dr Gerfried Nell
IFAPP Treasurer,
IFAPP Delegate, Austria

THE INTERVIEW • Specialist in ...

>>> workplace-based, adult education and part-time, flexible delivery, and meeting learner and employer needs.

However, the uptake of the E&T agenda has over the years been patchy to say the least, both nationally and throughout the IFAPP member associations. So it might be possible to conclude – with regard to your question –, that a purposeful education is deficient and targeted training is inappropriate, whilst at the same time there is recognition of the demand for new skill-sets. This is, however, more a statement of a challenge for which a set of solutions is available given the support of employers, the active engagement of all stakeholders and the promotion of the view, held for example by the Innovative Medicines Initiative (IMI) [3], by PharmaTrain [4], LifeTrain [5] and other high-level international bodies that E&T is an essential component of all R&D programs with a will to survive long-term, including those such as medicines development that cross the boundaries of industry, academia and government.

IFAPP WORLD • Are the "core competencies" [2] a common standard in the world of clinical research already or do you still struggle for global acceptance?

Dr Peter Stonier • The paper, resulting from a joint working group of IFAPP and PharmaTrain [4] (of the IMI [3] joint undertaking between the European Union and the European Federation of Pharmaceutical Industries and Associations – EFPIA [6]), sought to consolidate a competencies curriculum – and statement of competence – for those engaged in medicines development. This was to reflect the importance of transformative learning (as delivered through outcomes-based/competency-based education – CBE) as well as its arrival in and relevance to the field of medicines development and pharmaceutical medicine.

CBE has been progressively introduced into the healthcare sector over 30 to 40 years but not widely to that part of it relating to pharmaceutical R&D and medicines development.

CBE, with curricular input dependent on meeting learner needs (not teacher demands) and on assessments of learning based on what the student is expected to know (learning outcomes) or be able to do (competency, performance), arguably, fills the gap between what employees have learnt in their education and what employers expect them to know and be able to do to accomplish a particular job role.

This paper [2] is arguably a significant step forward in defining the core competencies and statement of competence for a (general) medicines development and pharmaceutical medicine professional. It is one amongst a growing number of such endeavors to develop competency profiles for specialties, sub-specialties and related fields in medicines development and clinical research [7].

None has reached a global acceptance, or indeed audience, but perhaps together they have a better chance of moving forward, and being accepted as a solution for the challenges of E&T and continuing learning and professional development in the field of medicines R&D.

IFAPP WORLD • Sharing the syllabus and quality standards for E&T and gaining global recognition of the certification needs a strong organization with a global reach – IFAPP seems to fit perfectly?

Dr Peter Stonier • Given its 40-year history, its global reach of over 30 member associations of pharmaceutical professionals, its primary involvement in the field of pharmaceutical R&D, medicines development and pharmaceutical medicine and its principle aim of support for training and continuing learning, especially on the vocational track of professional development, it would appear that IFAPP should be well-placed to be the agent for continuing support of E&T in this field in whatever form it takes.

Clearly it is always necessary that IFAPP keeps itself engaged, up-to-date and invigorated in terms of its aims and objectives, and it can never be said that it is doing so on every front. More than anything IFAPP needs the commitment and support of its member associations, and the strategies and capabilities to address regional healthcare priorities, biomedical industry agendas, and cultural divergence. Having said that, there is within the global environment of medicines development today a widespread agreement >>>

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>>> of what basic medicines development E&T should be. Its syllabus, its curricular content, its modular, flexible and learner-centric delivery designed to meet the joint requirements of employer and learner needs, E&T academic and quality standards.

So with help on the consumer side, there should be a welcome for IFAPP to promote a unified syllabus and core-competency and workplace-centered training curricula meeting quality standards, together with the appropriate accreditation of courses and providers and certification of successful participants – a learner-centric program in keeping with the needs of the changing world of medicines development, of employers and their job profiles and levels, and of vocational and career development of individuals.

IFAPP WORLD • The IFAPP-PharmaTrain-SSFA conference on June 10-11, 2015 in Rome, Italy [1], will set a focus on certification in pharmaceutical medicine and clinical research and will explore the visions of stakeholders – e.g., pharma companies, CROs, medical and pharmaceutical associations, regulators, academia. Which visions do you expect? Will it be compatible? And how far away is the set-up of a globally recognized certification board?

Dr Peter Stonier • Well, that is certainly a lot of very different stakeholders to reach with a unitary vision! We start with the proposal, not visionary but already tried, of an E&T program in medicines development, which will meet the needs of professional scientists and practitioners and of their employers. Along the way we develop a unified syllabus, a practical curriculum, an adult, flexible, outcomes-based/competency-based, workplace centered certification program with the consent of uneasy bedfellows of industry employers, trade associations, professional bodies, government regulatory agencies and the universities.

This comes down at this conference to a proposal for the Specialist in Medicines Development (SMD) as the unifying approach to all of the above. Will it be compatible – yes it will, as all stakeholders have had some say, over the years, in the development of the program, of the syllabus, and of the curriculum. Will it be universal, quick and easy – well, if it makes sense, is logical, is easy to engage in and undertake, is resource efficient (time, support and cost), then why should it not gain traction and spread?

At the end it is the patients, an active and vociferous stakeholder, who are waiting for new medicines, developed by an industry-academic-government complex with past success but no guarantees for the future, but who need to demonstrate that they are a trained and professional workforce to be trusted, keep up-to-date, meet rigorous quality standards and are constantly challenged and tested.

Moving in those circles and with those intents is no bad thing to engage IFAPP and its agenda for the next 40 years.

IFAPP WORLD • Thank you for your detailed answers.

References and Literature

[1] Advancing Competent Professionals in Medicines Development – A PharmaTrain-IFAPP-SSFA Conference. Rome, Italy, 10-11 June 2015.

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[3] Innovative Medicines Initiative (IMI)

[4] PharmaTrain

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

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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First-hand Report from EMA November 2014 Workshop

Investigation of Subgroups in Confirmatory Clinical Trials

Our readers surely know that the European Medicines Agency (EMA) is distributing a draft version of each new guideline, asking for comments. IFAPP regularly receives these drafts (on average 2/month), and I have offered to provide comments. Based on this long lasting collaboration, which has improved IFAPP's visibility at the EMA, I was invited to join the EMA workshop on subgroup analyses (SA). Since the topic is important, EMA has organized this workshop in order to obtain detailed comments on the draft of the "Guideline on the investigation of subgroups in confirmatory clinical trials" [1] and to reach consensus for the final version.

As indicated in the program, the objectives of the workshop were:

- To discuss the role of SA and subgroup findings in clinical trials submitted for marketing authorization (MA).
- To receive input on the position outlined in the EMA draft guideline [1] from experts and stakeholders.
- To provide an open forum for discussion of subgroup issues in planning and assessment of Phase III clinical trials.

About 100 experts, who met in the new EMA facilities at Churchill Place, Canary Wharf, London, United Kingdom (UK), have been welcomed by Marisa Papaluca, EMA.

The first speaker, Jens Heisterberg, Health and Medicines Authority (HMA), Denmark, opened the workshop with a crucial argument supporting SA: "Women get medicines tested in men". He presented several good reasons to run an SA, e.g., to obtain information about different drug effects concerning patients whose baseline status may differ. However, there also are less good reasons to run an SA, e.g., to save a failed trial, to obtain claims for the summary of product characteristics (SmPC), or to reach a compromise. Heisterberg added that biomarkers led the way to SA (e.g., estrogen receptors determine endocrine therapy in breast cancer, CD117 antigen determines imatinib medication >>>

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>>> in gastrointestinal stromal tumours – GIST). SA should be pre-specified, but this is not always done. SA are definitely increasing, however, they should be limited to well-defined groups.

Robert Hemmings, Medicines and Healthcare Products Regulatory Agency (MHRA), UK, continued to state that an MA is based on a solid benefit/risk evaluation, and regulators have discomfort when confronted with unplanned SA, especially because often there is no rationale but a statistical risk of multiple testing. He continued with three scenarios in Phase III trials: clear results, borderline results with evidence of SA effects, and negative results with evidence of SA effects. In fact many clinical trial designs assuming patients' homogeneity, but bio-logy and clinical practice address their diversity. That's why Hemmings clearly re-cognizes the need for an SA guideline to better define the possible scenarios.

Armin Koch, Hannover Medical University, Germany, commented that sometimes it is important to identify subgroups of patients with an unfavorable benefit/risk ratio, as this may be crucial for rescuing an MA of a new drug. This issue was enforced by Yuki Ando, Pharmaceuticals and Medical Devices Agency (PMDA), Japan; she provided several examples for clinical outcomes in subgroups of Japanese patients, which were considerably different to the overall outcomes. To conclude the first session, Estelle Russek-Cohen, Food and Drug Administration (FDA), USA, stressed that SA can inflate type I error, and it should not be applied to save a failed trial. She underlined that companion diagnostic tools can be helpful to stratify patient populations, but in the EMA draft guideline is no mention of them.

The second and third sessions were planned as an opportunity to hear the sponsors' opinions. Albert Radimaier and Christine Flechter, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium, illustrated the comments from 14 EU pharma companies. When there is only one Phase III confirmatory trial, SA definitely should be limited. They suggested four priorities to be included in the EMA guideline: consistency of subgroup effect, defining subgroups, exploratory subgroups, and power of SA. They strongly recommend an agreement on SA with regulators before a confirmatory trial starts. Alan Philips, European Federation of Statisticians in the Pharmaceutical Industry (EFSPI), UK, said it is a good guideline, but it should better define the issue of consistency, the impact on reimbursement and the consequences of dose adjustments. Claudia Schmoor and Frank Langer, International Biometric Society (IBS), Germany, said there should be a strong focus on few rationally selected subgroups. They also raised some criticism on the three proposed levels of SA, and on the required statistical power.

Geert Molenberghs, Integrated DEsign and AnaLysis of small population group trials (IDEAL), Belgium, said that it should be better to look for new drugs rather than running SA, as frequently SA fails to provide a convincing proof of efficacy. Alex Dmitrienko, Quintiles, USA, presented the results of a simulation he has conducted with trials on antibiotics in pneumonia, and expressed serious concerns about the conclusions. In fact, he ended with the message: Proceed SA with caution.

Many speakers raised additional issues for the benefit of the audience. In conclusion, it was a useful and informative workshop. The results will be incorporated in the EMA guideline.

Dr Domenico Criscuolo
IFAPP Delegate, Italy

References and Literature

[1] Guideline on the investigation of subgroups in confirmatory clinical trials. EMA/CHMP/539146/2013; 23 January 2014.

• NEWS FROM IFAPP MEMBERS • NEWS FROM IFAPP MEMBERS • NEWS FROM IFAPP MEMBERS •

GERMANY: New DGPharMed Board

The German Society of Pharmaceutical Medicine (DGPharMed) has held elections at the General Assembly on March 19th, 2015 in Berlin, Germany. The new DGPharMed President is Dr Susanne Kienzle-Horn, MD, Diploma in Pharmaceutical Medicine and in Computer Sciences, Managing Director of SCRATCH Pharmacovigilance GmbH. New DGPharMed delegate to IFAPP is Dr Michael Hübschen, MD, Swiss Specialist title in Pharmaceutical Medicine, MBA, Director Medical Affairs, Merck Serono GmbH.

SOUTH KOREA: New President

Dr Jongho Ahn was elected as new President of the Korean Society of Pharmaceutical Medicine (KSPM). He is successor of Dr Myunghoon Kim and his term will be from 01.2015 to 12. 2016.

FINLAND: New President

The Finnish Association of Pharmaceutical Physicians (SuLL/FiAPP) has elected Dr Juhana J. Idänpään-Heikkilä as new President.

SWITZERLAND: SwAPP President and Delegate

Dr Mirjam Eglin, President of the Swiss Association of Pharmaceutical Professionals (SwAPP), is the new SwAPP delegate to IFAPP.

IFAPP: Join us on ...

IFAPP kindly invites all individuals from IFAPP's National Member Associations to join the LinkedIn group "IFAPP – International Federation of Associations of Pharmaceutical Physicians & Pharm. Medicine".

To register is simple and free. Just visit IFAPP's website at www.ifapp.org and scroll down. At the bottom click the in button and follow the instructions. Start right now!

IFAPP Conferences

Please pay attention to the information on current IFAPP events on the next page!

Conference presentation and aims

Quality in the pharmaceutical industry is a must: we have the mission to discover, develop and manufacture drugs for sick people, so all our activities must implement the best levels of quality systems.
Indeed the quality process in the pharmaceutical industry started at the times of the "industrial boom of the '60s": GMP, GLP and finally GCP defined in clear terms the quality standards of our complex activities.
Now, it is time to consider the quality level of the education of professionals involved in drug development: this issue was already well considered by some pioneers, who established the first master or diploma courses in Pharmaceutical Medicine back in the '70s. However only in the last 20 years these courses have been established almost in every country with a significant tradition in drug development.
The IMI founded project named PharmaTrain, which lasted from 2009 to 2014, had the vision to harmonize these courses in the European Union: it was very successfull in establishing the quality standards of education, and to identify several Centres of Excellence all over the European Union. In addition, it raised a global interest, so that in 2014 the PharmaTrain Federation was established, with the mission not only to continue in the harmonization process, but also to establish the title of Specialist in Medicines Development (SMD), a voluntary 4 years path to guarantee the correct implementation on the job of the principles acquired with the diploma title.
Our international conference aims at celebrating the first 40 years of IFAPP, a global Federation strongly devoted to education in Pharmaceutical Medicine, and to disseminate the culture of the SMD program, which will be implemented soon in Italy, Japan and other countries.

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SBMF Associação Brasileira de Medicina Farmacêutica