2014 NOVEMBER • NUMBER 3

IFAPPWORLD

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS & PHARMACEUTICAL MEDICINE

C O N T E N T

"The potential of integrated alliances remains elusive …"

After submission of the IFAPP WORLD Editorial "The Ever-Increasing Importance of CROs in Drug Development" by Dr Johanna Schenk (on this page) the journal Applied Clinical Trials has published an article entitled "Is 'Open Integration' Beyond Our Reach?". This article from Kenneth A. Getz, MBA, Director of Sponsored Research at the Tufts University, confirms Dr Schenk's view, extends it by research data, which concluded: "The primary causes of relationship failure include a long-established culture of mistrust in vendors and service providers and poor communication."

The complete article is available at www.appliedclinicaltrialsonline.com in the menu "Archives > October/November 2014".

NOTE FROM THE EDITORS

With regard to the Editorial on this page: What is your experience with the relationship between sponsors and service providers? Could you challenge the Editorial author's view? What is your opinion on these issues?

Please write to the Editors at boebue@boebue.de
With your consent IFAPP WORLD might publish your letter either wholly or in part. **You are all kindly invited!**

E D I T O R I A L

The Ever-Increasing Importance of CROs in Drug Development

Dr med Johanna Schenk, FFPM, Dipl. Pharm. Med. DGPharMed, IFAPP World Editorial Board Member, Managing Director & COO, PPH plus GmbH & Co. KG, Frankfurt am Main, Germany

During my IFAPP presidency (2000 to 2002) I had the great pleasure of attending the II Pan-American Congress in Pharmaceutical Medicine in Buenos Aires, Argentina. The lecture I was invited to give from a CRO perspective was entitled "Outsourcing Clinical Trials: Ever, Never, Sometimes?" This was at a time when clinical CROs were nearing the capacity of biopharma clinical research with 55,000 staff in the US and Europe [1], ten years after I had joined the CRO industry subsequent to 15 years of big pharma employment. By 2001, the CRO industry had reached considerable maturity as defined not only by its staff number – compared to 1980 clinical CROs in the US and Europe were grown by the factor 6.6 – but also in terms of geographic presence and competency. The forecast was that outsourcing would further grow in importance.

This became undoubtedly a reality. Nowadays, the largest global CROs conduct more clinical trials than any pharma company. Fellow pharmaceutical medicine professionals have like me moved from being employed by study sponsors to providing customer services to their previous employers. Economy of scale in outsourced trials led to efficiency gains with shortened clinical development time cycles despite ever-increasing regulatory demands and complex study designs without compromising quality [2]. "CRO segment is integral – not peripheral – to the drug development enterprise" concluded the author, Ken Getz, in 2006 [2]. Survey results released by the Association of Clinical Research Organizations (ACRO), representing the eight world's leading clinical research organizations, in September 2014 impressively reflect today's role of CROs in clinical development [3].

Thus, having gained a further decade in upgrading breadth and depth of CRO services and the cooperation between pharmaceutical medicine professionals at both sides of the equation, can we as heavily involved players lean back and be satisfied with what we have reached? I sense considerable room for improvement on the soft side of effective clinical partnerships, including, but not limited to, mutual trust and respect, excellence in sharing relevant information timely, an inspiring 'we are one team' spirit of sponsor and CRO staff on common projects, no finger pointing and redundant oversight efforts exceeding quality management processes of internally managed projects to a ridiculous extent. An area of concern to all of us should be 'fake RFPs' (request for proposals) deriving from misinterpretation of internal policies. In order to reach compliance, CROs receive invitations to bid despite having a zero chance of winning the >

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> project due to a predetermined successful vendor. Being compliant by abusing a service provider's time and knowledge is by no means in line with sound business ethics.

On the CRO side of the clinical development enterprise, size should not divert from the service mission. Big is not necessarily best in class. Complacency is rarely appropriate. I am certain that colleagues working in biopharma can add further suggestions for improvement that would help moving forward most effectively.

In conclusion, since my presentation in Buenos Aires in 2001 the clinical development enterprise has left the era when 'never' or 'sometimes' were viable outsourcing options. Small- and midsize biopharma have for obvious reasons reached the 'ever' stage, and big biopharma has arrived at the 'most often' level. The productivity gains demanded from us will not only come from new outsourcing strategies, disruptive technologies, uplifted approaches to organizational paradigms and clinical trial methodologies but also from optimization of the soft-skill side at the multiplicity of sponsor-CRO interfaces. Fairness, trust and respect for each other as equals will be the enabler of true value delivery to clinical development and consequently to patients who are in need.

Please be aware of the "Note from the Editors" and invitation on page 1.

References

[1] Hughes, G, O'Neill, M, Annual Review of Contract Research Organisations, European Pharmaceutical Contractor, February 2001, 16-27.

[2] Getz KA, Insights from Today's CRO Renaissance, Applied Clinical Trials, June 2006.

[3] ACRO (Association of Clinical Research Organizations) Survey Shows Strong Growth of CRO Industry, posted on 16 Sept. 2014 at www.acrohealth.org.

Questions & Answers

Shaping the Future of IFAPP

IFAPP's President Gustavo Kesselring, Brazil, Outlines IFAPP's Perspectives

IFAPP WORLD: Dr Kesselring, as the new IFAPP President you have proposed a new organizational structure for IFAPP. What is the concept and the procedure?

Dr Gustavo Kesselring: IFAPP was founded in 1975 and after almost 40 years it has achieved its maturity. It is time now to update its management and organizational structure without losing its essence, which is "the promotion of Pharmaceutical Medicine (PM) and Medicines Development by enhancing the knowledge, expertise and skills of pharmaceutical physicians and other professionals worldwide, thus leading to the availability and appropriate use of medicines for the benefit of patients and society".

The House of Delegates meeting held last March during the International Conference on Pharmaceutical Medicine (ICPM 2014) in Berlin, Germany, has approved the new IFAPP organizational structure. In its concept the House of Delegates consists of members from each National Member Association (President and delegate) and oversees the Board of Officers with its five members (President, Past-President, President-Elect, Secretary and Treasurer) that are responsible for the daily and operational activities. In order to attract more volunteers to actively participate and engage with IFAPP five Working Groups (WG: Finance & Fund-Raising, International Affairs & Conference, Education, Communications & Operations, Ethics) were defined and a call for volunteers has been made.

These Working Groups are the „brain and muscles" of the Board of Officers, and great collaborative work has been achieved so far.

I.W. Are there results already?

G.K. First results from these WGs in 2014 were:

- IFAPP's Institutional Presentation has been produced.
- IFAPP was represented and presenting at the 17th World Congress of Basic and Clinical Pharmacology in Cape Town, South Africa, in July 2014, and at the National PM Annual Conferences in Spain, Switzerland, and Argentina.
- IFAPP and PharmaTrain collaboration program is in progress.
- Two publications related to education in Pharmaceutical Medicine have been released:
  •• "Moving From Compliance to Competency: A Harmonized Core Competency Framework for the Clinical Research Professional", published June 2014 in the 'Clinical Researcher', and the 'Journal of Clinical Research Best Practice'
  •• "Education and Training Needs Among Clinical Investigators and Medicines Development Professionals from Two Latin American Countries", published October 2014 in the 'Clinical Researcher'
- Collaboration with the U.K. Faculty of Pharmaceutical Medicine for the revision of their "Code of Good Medical Practice in PM"

And there is much more to come in the next year.

I.W. What can IFAPP members expect from IFAPP? When and where could they meet each other?

G.K. In September 2014 we launched a Needs Assessment Survey to all our National Member Associations. Their feedback will serve IFAPP to better understand what its members expect from our federation and what is feasible to develop in the coming years. Results from this survey are expected for the first quarter of 2015. >

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> IFAPP is also mapping all PM related conferences for 2015 where an institutional presence can be delivered by means of presentations or symposia. In fact, more PM professionals should join their PM conferences.

I.W. What are other external policies?

G.K. The Board of Officers is in contact with the following institutions to develop collaboration agreements that will benefit all National Member Associations and PM professionals:

- Drug Information Association (DIA): development of a collaboration agreement for mutual membership recognition
- Pharmaceutical Research and Manufacturers of America (PhRMA) in the US: exploring an educational program in Drug Development Sciences
- World Medical Association (WMA): exploring the possibility to become a partner as an international organization and collaborate in educational programs in Drug Development Sciences

I.W. How can PM professionals and interested people from IFAPP Member Associations get involved?

G.K. One of the most frequent questions I hear is: "What can IFAPP do for us?" and my answer is: "What can we do for IFAPP?"

I am sure that all members we have in more than 30 countries can give a little piece of their time, expertise and network for a common objective that at the end will benefit all of us. Of course, it takes time, needs tenacity, resilience and hope.

This is the message that I give to all presidents and delegates through the personal contacts that I have been making since I started being IFAPP's President.

The best way to get involved with IFAPP is to volunteer for one of the Working Groups. To do so, just contact your National Member Association and the IFAPP secretariat at secretariat@ifapp.org – very simple.

I.W. Thank you for your answers.

IFAPP's Regional Update: PORTUGAL

The Portuguese Pharmaceutical Medicine Association

AMPIF (Associação Portuguesa de Medicina Farmacêutica – Portuguese Pharmaceutical Medicine Association) is a 25-year-old non-profit organization of currently 110 physicians working in Pharmaceutical Medicine, the majority of them within the pharmaceutical industry. AMPIF's main goal is to increase the technical and scientific level of its members with a focus on addressing the increasingly demanding ethical and compliance standards.

The year 2014 began with a new team within the Board of AMPIF. Since then, the 12 Board members are implementing a challenging program trying to increase the awareness of AMPIF across the pharmaceutical industry, inside and outside country borders.

Some years ago, medical jobs in pharma companies were mainly part-time collaborations devoted to field force and marketing teams' training and some scientific consultancy work supporting "license to operate" documents (regulatory submission dossiers, summary of product characteristics and patient leaflet revisions).

Today, the environment has changed dramatically and Medical Doctors (MDs) are pivotal in many of pharmaceutical companies' core activities, by increasing their scope beyond the past collaboration. They are involved frequently in patient safety and product complaints, medical information management, clinical trials activities, price and reimbursement discussions, as well as in key opinion leaders management plans, educational activities and compliance management.

"Medical Affairs" is now the name of the game and the role of MDs in product strategy is growing every day. With increasing challenges and hurdles to the traditional model of sales force medical visits, medical teams are, sometimes, the best party to raise awareness on unmet medical needs, as well as new products and related therapeutic areas. This growing role is changing every day and MDs are no longer enough to cover all the needs; other professionals, with different scientific backgrounds, mainly in life and health sciences, are now working in Medical Affairs.

Open the Door to Non-Medical PM Professionals

For Pharmaceutical Medicine Associations, the need to open the door to non-medical professionals, as IFAPP did recently, is strategic and reflects the changing pattern of required capabilities and skills in the pharmaceutical industry over the last years.

AMPIF has also been discussing it internally since long, but, until now, the associates decided to keep the Association exclusive to MDs. In the upcoming months, the current AMPIF board will bring this topic again to discussion, as part of a broader strategy of becoming more visible and representative, and in alignment with the recent change of the Association's name from "Portuguese Association of Pharmaceutical Industry Physicians" to "Portuguese Pharmaceutical Medicine Association". >

The Portuguese Pharmaceutical Medicine Association

> Meanwhile three major goals underpin AMPIF's vision and strategy:

- Consolidation of AMPIF's internal structure …

  •• … with regular visits to our associates and other medical employees in their working environment in pharma companies. AMPIF has a target of visiting 20 local and multinational pharmaceutical companies by the end of 2015.

  •• … with sponsoring of an academia-driven "real world study" with the main objective to have a baseline view on who in Portugal is working in the Medical Departments of pharma companies. Aveiro University, recently certified by IFAPP to provide accredited post-graduate training in Pharmaceutical Medicine, is working with AMPIF on this project and results are expected by third quarter of 2015.

- Increase awareness and visibility of AMPIF, network with the Portuguese pharma association, with health and regulatory authorities, parliament, patient´s and health care professionals´ associations, academia, hospital administration boards and the Portuguese Medical Association, with whom AMPIF is revising the current ethics code for pharmaceutical industry interactions with health care professionals.
- Leverage AMPIF's presence outside Portugal through increasing collaboration with IFAPP, mainly in international affairs & conferences and ethics working groups.

Luís Laranjeira, MD, MBA
AMPIF Vice-President &
IFAPP Delegate

Physicians Favor Transparency in Clinical Trials

Survey of the U.K. Faculty of Pharmaceutical Medicine

The U.K. Faculty of Pharmaceutical Medicine recently has surveyed its membership on transparency in clinical trials. A total of 430 persons have responded – 59% from pharma or biotech companies, 13% from CROs and 28% from other occupational fields. Most respondents (58%) are based in the U.K., 25% in other EU countries, 10% in the USA, and 7% elsewhere.

Registration of Clinical Trials

The vast majority of respondents (95%) believe, all clinical trials should be registered, and 74% say, registration should be mandatory. Only 45% believe that ClinicalTrials.gov, EU Clinical Trials Register, or any other existing requirements provide adequate transparency.

The analysis report distinguishes between trial "results", that means the clinical trial summary including information on the outcomes measured and the statistical analyses, and "data", which stands for the full reporting of clinical trial methods, analysis, results, individual patient data – in anonymized form –, and conclusions.

Sharing Results and Data

In this regard, the majority of respondents believes that increased publication of trial results (88%) and increased transparency with access to trial data (79%) "will ultimately lead to better medicines and better healthcare for patients". And 86% believe to strengthen the science by increased scrutiny of clinical trial data.

Most respondents (80%) see a moral duty on all trial sponsors to make data available to all – to trial participants, to the general public, and to the scientific community on trial completion.

Transparency of safety and efficacy data for phases I, II, III, and IV is also considered important by many respondents (38%-53%). Nearly half of respondents (43%) said, even historic data collected at least 5 years previously should be made available.

However, few respondents assume that increased dissemination of trial results (11%) and increased access to trial data (18%) will harm pharma companies' operations.

The question about who should get access to trial results and data and how has generated various answers. In this regard the respondents' majority favored a gatekeeper system.

The complete Analysis Report from 28 August 2014 is available at www.fpm.org.uk in the menu "Policy & Publications – Policy themes > Access to clinical trials results and data".

An interview on the subject has been scheduled with Dr Keith Bragman, President of the U.K. Faculty of Pharmaceutical Medicine, the institution, which conducted the survey, for the next IFAPP WORLD.

The Flag

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

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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IFAPP gratefully acknowledges generous sponsorships and financial support from:

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