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The Global Newsletter on Pharmaceutical Medicine

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Perspectives on Clinical Trials During Times of War

The Situation of Ukraine

#20DaysPeace



The only international
organisation for everyone
involved in Pharmaceutical
Medicine



The war in Ukraine has brought with it an unprecedented crisis in clinical trials. This is perhaps the first time in history where a country with such a large and important scientific, healthcare, and economic investment in clinical trials has suffered the trauma of war. This new and daily evolving situation challenges our established regulatory, ethics, and Good Clinical Practice standards. It raises new questions about the protection of the vulnerable, the right to inclusion in clinical trials, and even access to medicines. It is impossible for the international community of sponsors, researchers, patient organisations, and regulators to ignore these challenges and questions. In March (1) IFAPP expressed its condemnation of the war in Ukraine and argued in April (2) for the need for the continuation of investigational drug supplies for seriously ill research participants in times of war.

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Alongside strong input from the IFAPP membership, researchers and ethicists from Ukraine, Europe, the United States, Japan, and internationally have come together in a series of meetings to provide a situational analysis of clinical trials in Ukraine and the region as well as to develop a structured response to the needs of research participants and the continuity of research in such a disruptive situation. The following activities are being considered by this newly formed **Ukrainian Clinical Research Support Initiative** (UCRSI):

- Development of a structured ongoing **situational analysis** of the current clinical trials in Ukraine;
- Establishment of reliable **communication and information channels**;
- Provision of **support information** for displaced clinical trial participants, personnel, and scholars; and
- Development of specific **guidance** for addressing clinical trials during and following wartime: Good Clinical Practice Guidance; Ethics Review Guidance.

The IFAPP Ethics Working Group supports Ukrainian clinical trials and collaborates with the UCRSI. The UCRSI is intent on addressing the immediate challenges preliminarily identified during the meetings:

- Difficulties in continuing clinical trial protocols due to a lack of access to trial medications, a lack of access to laboratory and imaging facilities in some areas, and the displacement of physicians, investigators, patients, site staff, and sponsor/support staff.
- Difficulties with access to the standard of care, including diagnostics, medications, and other treatments (e.g., radiotherapy, surgery) for research participants. In some cases, investigational medicines have reached sites but “basic” medicines for clinical care have not. This impacts the overall health of research participants and may influence outcomes.
- Challenges with investigators and trial centre healthcare professionals being reassigned to care for the wounded, other health emergencies arising due to the war, and/or needing to be reintegrated into new healthcare settings due to being displaced.

The State Expert Center (SEC) of the Ministry of Health of Ukraine (the Ukrainian regulatory authority) has provided regulatory support for sponsors, contract research organisations, investigators, and ethics committees to assure as best possible continuity in conditions of war. This support includes:

- consistent support and coordination for the clinical research enterprises community;
- real-time and reliable communication through email, telephone, and video conferences;
- the implementation of guidance, including accelerated procedures for regulatory approval and registration of medicines through the electronic application system; and
- the close and active communication with clinical trial sponsors, international support agencies (e.g., the WHO, CIOMS), the Ukrainian European Business Association, clinical trial sites, ethics committees, and the academic community in ensuring coordination of the efforts to address issues as they arise regarding clinical trials and healthcare generally.



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On 25 April a small virtual meeting was held to discuss the ethics considerations that may need to be addressed. The meeting examined what may happen to study participants and clinical trials in conflict situations during humanitarian disasters and shared points to consider for ethics committees and sponsors. These points included:

- the impact of armed conflict on the conduct of clinical trials (on a case-by-case basis, e.g., the stage of a trial: whether a trial is ongoing, is planned, or has just been completed and is at the point of data cleaning);
- the availability of investigational medicinal products (IMPs) and potential supply chain issues;
- whether the study participants wish to continue in the trial;
- should there be a re-consent/continued consent;
- how the research participants' IMP-related safety can be monitored (e.g., blood tests) and any logistical challenges this may bring, including risk to the participants (e.g., leaving a safe place for a study visit);
- challenges when research participants are displaced (internally or to another country), in particular relocating the research participants to another study centre (with considerations for IMP supply, data collection, source data verification, benefit-risk assessment);
- what to do if no study centre is close by and an application has been made to open a study site at the closest hospital (e.g., how to care for the patients while waiting for ethics committee and regulatory approvals); should the IMP be continued (if it is available) and should data be collected as per protocol in anticipation of the re-inclusion of the research participant; what to do for placebo-controlled RCTs: should research participants be reassigned to the same randomised treatment arm they were initially randomised to;
- considerations for transferring research participants to a country with an open trial site (including logistic implications and costs, a need for re-consent, translation);
- if research participants need or wish to be discontinued from the study should an expanded access or compassionate use program be considered;
- differences in the possibility to respond to the challenges of armed conflict depending on sponsorship (academia, pharmaceutical industry); and
- the consequences of armed conflict leading to changes in the availability of healthcare systems / investigator centres for trial-related work.

With regard to ethics specifically, these points appeared important:

- discussions should include representatives of patients, investigators, sponsors, and ethics committees with input from regulators;
- consider the assessment of training needs of ethics committees, including how to prepare for humanitarian disaster (this may also be valuable for sponsors and investigators); and also consider the need for ongoing training of ethics committees during times of crises;
- consider the impact of humanitarian disasters on research participants and their ability to make informed decisions within a situation of a probable increase in vulnerability (e.g., the potential need for counselling/psychological support); and
- considering the impact of humanitarian disaster on investigators and healthcare practitioners at trial sites, e.g., their reassignment to other duties, displacement, need for counselling/psychological support.



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As a conclusion, the following activities in ethics are being considered:

1. The description of ethical challenges (scenarios) specific to armed conflict situations.
2. Developing ethics review and informed consent guidance during armed conflict situations (using Ukraine and the region as a first focal point).
3. An examination of wider ethical considerations (e.g., in the framework of GCP) to be considered in armed conflict situations (again, with Ukraine as a focal point).
4. Members of the IFAPP Ethics Working Group have participated in the founding of the UCRSI and continue to play a key role in supporting the initiative. The strong collaboration between IFAPP and UCRSI provide a firm basis on which to appreciate the critically important need for an appropriate and measured response to Ukrainian clinical trials' challenges during this war as well as providing a wider view on clinical trials in conflict situations.

References

1. IFAPP Deplores Russia's Aggression in Ukraine. IFAPP TODAY, 2022; March (Number 22): 1.
2. Kerpel-Fronius S, Baroutsou V, Franke-Bray B, Kurihara C, Matsuyama K, Naseem S, Schenk J, Members of the IFAPP Ethics Working Group. IFAPP TODAY, 2022; April (Number 23): 1-2.

Francis P. Crawley, Executive Director, Good Clinical Practice Alliance – Europe (GCPA) and Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Leuven, Belgium

Beate Aurich, Drug Safety Consultant, Methodological expert paediatric pharmacovigilance for the EU Paediatric Clinical Trial Project conect4children (c4c), France

Chieko Kurihara, Kanagawa Dental University, Kanagawa, Japan

Kotone Matsuyama, Nippon Medical School, Tokyo, Japan

'G'day' from the Australian Pharmaceutical medical and scientific Professionals Association (APPA)



Promoting best practices for Medical Affairs

Established in the late 1980s, APPA is the representative association for Medical Affairs in Australia and is dedicated to promoting excellence in the pharmaceutical, biotechnology and medical device industries. Members of our organisation include Medical Directors, Medical Advisors and Medical Scientific Liaisons working within Clinical and Medical Affairs departments. In recognition of the ever-evolving roles and responsibilities of these personnel (given both changes in treatment and regulatory landscapes, as well as constraints of a recent pandemic), APPA has remained committed to supporting the scope of Medical Affairs activities and advancing professional development.

A mission made possible through focussed efforts

At the core of our mission is to provide a national forum to advance our professional interests and enhance capacity to put science into practice. This is achieved through education events that provide an opportunity for knowledge sharing.



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Webinars that dive deep and drive discussion

In 2021, APPA members enjoyed access to a series of seven live webinars covering emerging and topical themes. <https://youtu.be/MJLzpt7K3uA>.

On the backdrop of a year into the COVID-19 pandemic, the first presentation, 'Reflecting on a year of crisis: Insights and Implications for the future of Pharmaceutical Medicine,' brought together high-profile experts from research, government, and industry to discuss the challenges, learnings, and agility of organisations to ensure continuity and accessibility to pharmaceuticals by patients.

In a welcome shift of focus from COVID-19, the second presentation, 'Keeping it Real. Real-World Evidence and Medical Affairs,' explored the value of RWE studies on patient outcomes and gain a real understanding of the value of medicines in real-life clinical settings. On the theme of 'value', the third presentation of the series, 'Medicos on Medical Affairs', invited a panel of healthcare practitioners (general physician, ophthalmologist, cardiologist, and neurological nurse practitioner) to share their expectations of engaging with those working in Medical Affairs and how they saw this relationship ultimately benefiting their patients. Interesting insights were provided.

One of the most well attended webinars hosted by APPA last year was 'Meet the Authors' session to discuss the seminal publication, 'Promoting best practices for Medical Science Liaisons: A Position Statement' jointly developed by APPA, MAPS, IFAPP and the Medical Science Liaison Society. The authors delved into the recommendations and rationale that informed the position paper and helped to contextualise the guidance provided. It is hoped that this publication will help inform industry standards on the role of the MSL.

The 'Women in Medical Affairs, Careers webinar' celebrated diversity and the contribution of women to the profession. The invited leaders shared their experiences, expertise, and insights into their journey

into Medical Affairs, providing valuable and inspiring accounts.

From careers to innovation, the implementation of digital technologies and their transformation of clinical trial design is becoming increasingly recognised. In the sixth presentation of the series, 'Unleashing Data to Accelerate our Future', the invited panellists shared examples of innovative approaches being used in clinical trials and regulatory approval processes and how these are helping to evolve the timeliness of drug development. Undoubtedly, the speed of digital innovation and capability is certainly a cause for much optimism for the future of the industry.

The webinar series culminated with the end of year APPA Annual General Meeting and a bold vision for future drug and healthcare delivery outlined by a Medical Futurist.

Awarding excellence in Medical Affairs

As an organisation, we believe it is important to recognise and celebrate individuals who are demonstrating commitment to excellence to the profession through the 'APPA Excellence Award'. This award is nominated by peers and granted to those who fulfil criteria related to the quality use of medicines and impact on patient outcomes; fostering relationships with KOLs; development and execution of a Medical Affairs strategy; teamwork and cross functional collaboration; leadership; and having a wider societal impact. As well as the accolade, the winner also receives a cash prize, trophy and a Certificate of Excellence.



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Strengthening ties, elevating the profession

In addition to education events, APPA holds networking events to allow the local Medical Affairs community to come together, engage and connect. Through these focussed efforts, APPA has garnered a membership base of over 630 individuals - estimated to account for approximately 90% of Australian professionals working within Medical Affairs. Moreover, APPA has built a strong alliance with the global, non-profit Medical Affairs organisation MAPS. With a shared vision to engage, empower, and educate, the two organisations enjoy partnering together to deliver on this objective. The APPA Executive Committee has currently 10 members who, in their day job, work in various roles across the industry and are located in two major cities – Sydney and Melbourne.

APPA is delighted to have joined IFAPP again and we hope that the members of both organisations will derive a lot of benefits from it. More information on APPA activities, events and partnerships is available at: <https://appa.net.au>.

Dr. Gisela Mautner, MD-PhD, MPH, MBA, FACPE, MAICD, FIIDM, CEO & Managing Director, Noxopharm Ltd, APPA Delegate to IFAPP



APPA Seminar: "Patients are e Virtue"

The banner features the APPA logo (Australian Pharmaceutical medical and scientific Professionals Association) on the left. The main text reads: **'Patients are a virtue'** Is 'patient-centricity a verb or noun' and what can Medical Affairs do in this area? Below this, it states: **Highlights from APPA Education Meeting Thursday 31st March 2022** hosted by award-winning Australian ABC medical reporter, Sophie Scott. A circular inset photo shows Sophie Scott in a red jacket. The background is blue with a white rounded rectangle for the text.



APPA held its first webinar of 2022 on the 31st of March – it was tackling the issue of patient engagement within Pharmaceutical Medicine and how Medical Affairs are placed to contribute to the vastly salient area. Over 110 APPA members and 70 non-members who had been approved to join came together for this meeting which brought together experts in patient engagement:

- Sophie Hibburd from Medicines Australia,
- Renza Scibilia from Diabetes Australia,
- Richard Vines from Rare Cancers Australia, and
- Matthew Britland - APPA President and Medical Director of Amgen.



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The premise of the webinar centred around the liberal use of the term ‘patient centricity’ within companies and what can be better done to ensure patient engagement can be authentically undertaken. It was a lively and packed hour with many questions and opinions, here are some of the highlights:

What does ‘patient-centricity’ mean to you?

The main feelings were that this was just a buzz word closer to a marketing term, than a culture or philosophy. Just repeating the term does not make it a reality and it has been overused to the point of diluting its intention. This term should define how we (as we are all patients) are at the centre of our own care.

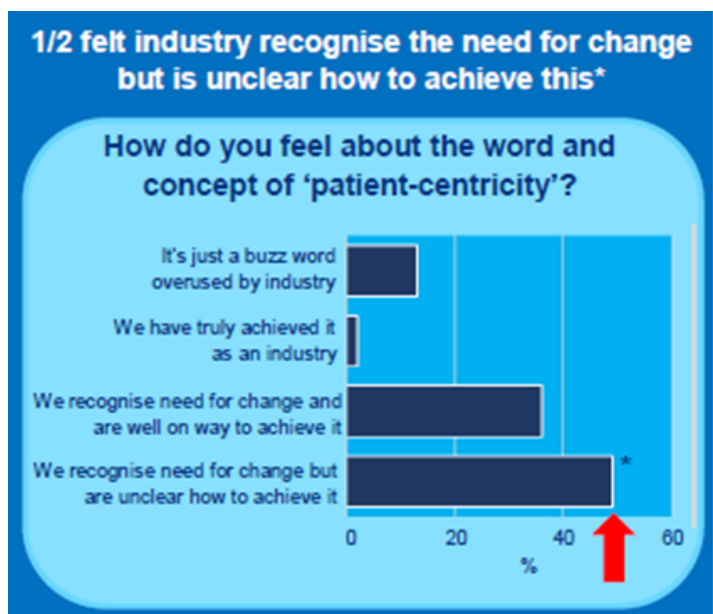
Where can patients have influence on the healthcare system?

This should occur at every stage of discussion. Our Industry can be more courageous, and we can engage better with patients. The new Industry Code of Conduct (from Medicines Australia) includes changes that refer to how industry can engage with patients: appropriate people within organisations can provide information to patient groups to help them in their role (e.g., clinical trial information, pipeline information, education). The patient voice has never been louder, and they are demanding an equal seat at the table. Patients can influence the healthcare eco-system at so many points, especially with Government. The patient access gap (between registration and reimbursement) is just one area where patients have an opportunity to make a difference. The registration and reimbursement process in Australia does not include a quantifiable measurement of the impact on patients – it should, and patients are the voice we need to listen to.

What are your thoughts on Medical Affairs involvement with patients?

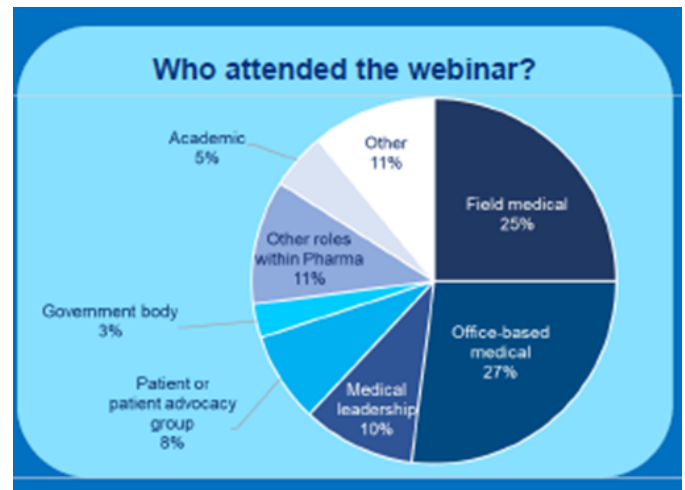
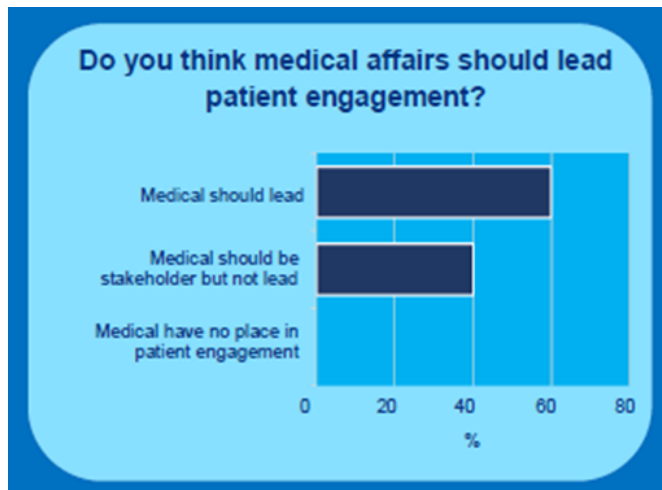
We need more engagement needed to bring together the data with the patient ‘heart’ story. Industry performance should be based on the expected number of people treated (e.g., with lung cancer) in a year rather than revenue. Our Code states that industry is the custodian of the information about the medicines we make and so we should be engaging with patients. We have an opportunity to be part of this engagement, not to lead the engagement but to help the patient own their own disease and treatments.

We held 3 main Polls during this meeting - here are the results [n=129].



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In summary, this APPA webinar exposed concerns about the liberal use of the term ‘patient-centricity’ and re-enforced the need to be courageous in this endeavour as we build truly patient informed medical strategies to better the quality use of medicine (QUM). Medical Affairs plays a critical leadership role in this regard and APPA look forward to taking this initial discussion to actionable change to bring patient engagement to the centre of every decision we make. Ensuring medical plans have a template specifically focussing on patient engagement, challenging norms, and ensuring companies have dedicated patient engagement leaders (working with Medical Affairs) are all steps in the right direction but we have work to do!

Matthew Britland – President of APPA and Medical Director at Amgen

NIGERIA - PPAN Introduction An Association with a Mission



Nigeria is an important player in the African and global scene for several reasons. With a population of more than 200 million, it is the most populous country in Africa and 7th in the world. In 2020, this population was almost entirely below 65 years, with 0-14- and 15-65-year age groups contributing 44% and 54% respectively. Having such proportion of a younger productive population is clearly an advantage in driving the economic machinery of the nation. The current per capita and nominal GDP of the country of \$2,272.84 and \$480.48 billion is the highest in the continent, contributed by economic activities in both oil and non-oil sectors.

Access to good quality healthcare is a common problem in most developing countries. Nigeria is still struggling to provide its teeming population with adequate healthcare, even with the apparent vibrant economy. Despite suboptimal funding, the country has great healthcare facilities managed by very enthusiastic and highly trained professionals.



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Though Nigeria is still considered poor by all standards, there is evidence that the population of the middle-class and standards of living have been increasing steadily in Nigeria since the late 1970s. This demographic-economic transition seems to correlate with the country's health burden. As in other sub-Saharan African countries, the epidemiological profile of Nigeria is changing. Decades ago, the region was considered as a predominant environment of infectious diseases. It still is. However, the rising living standard of the middle class, which gave rise to increase in international travels and acquisition of western cultural practices, related to diet for example, have collectively contributed to the current pattern of lifestyle diseases. It is therefore no surprise that the prevalence of cancer, cardiovascular and metabolic diseases have been going up amongst the young Nigerian population. The country is thus witnessing a trend towards endemism and increasing burden of both communicable and non-communicable diseases.

Major global pharmaceutical companies have always recognised Nigeria as an excellent business environment and many, like GSK and Novartis, have been in commercial operation in the country for decades. It is surprising to many that global pharma companies have not taken advantage of the highly skilled healthcare professionals and large population of treatment-naïve patients with cancer, for example, to consider Nigeria as one of the favourable countries for clinical trials. The COVID-19 pandemic has yet presented another opportunity for business growth to the global pharmaceutical industry, which some companies have realised and began to take gladly. Merck has recently moved towards establishing a vaccines manufacturing facility in the country.

The Pharmaceutical Physicians Association of Nigeria (PPAN) was established in 2021 with the realisation of the opportunities and challenges in the country. Thousands of Nigerian professionals are working in the pharmaceutical sector within and outside the country. Many physicians and other healthcare professionals are engaged in activities within local and international companies, but a significant proportion of Nigerian pharmaceutical industry professionals are in the diaspora, mainly in the EU and the USA. The aim is to bring these professionals, both physicians and non-physicians, to explore ways of supporting the Nigerian healthcare system.



To achieve its goals, PPAN planned to undertake activities aimed at the following:

- 1) Advocacy towards the promotion and recognition of pharmaceutical medicine as a medical specialty in the country. PPAN, with the support of the Faculty of Pharmaceutical Medicine (FPM) of the Royal Colleges of Physicians of the UK, has already approached the Medical and Dental Council of Nigeria (MDCN) and the Nigerian Postgraduate Medical College (NPMC) in this regard. We will continue the advocacy work by engaging with various stakeholders such as the African Union through the External Affairs Committee of IFAPP to ensure that PM get the deserved recognition across the African continent.



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2) Establishment of formal pharmaceutical medical training and capacity building system that will support manpower needs of the pharmaceutical sector in Nigeria. This is one of the critical areas of PPAN's activities. The number of contract research organisations (CROs) have increased in Nigeria in the last decade. NAFDAC, CROs, indigenous and global pharma companies will benefit from well-trained professionals that will drive the expansion in the scope of services and products these organisations can provide.

3) Encourage global pharma companies to invest in Nigeria. The Nigerian population with the current burden of disease is a ready market for pharmaceutical and other healthcare products. The sector is anticipated to grow to more than \$4 billion in 10 years according to prediction by Lagos Business School, thanks to various government's initiatives. Nigerian government has been creating agencies and formulating policies aimed at attracting and supporting foreign businesses. The Nigerian Investment Promotion Commission (NIPC, www.nipc.gov.ng) was established to "encourage, promote and coordinate investments" in the country. The Corporate Affairs Commission (CAC, www.cac.gov.ng), the Nigerian agency concerned with the registration and establishment of business entities has made incorporation of businesses easier and faster by going fully digital. The Nigerian banking sector is very vibrant and many banks either have presence or are in partnerships with global banks in major economies of Europe, the USA, Middle East, and Asia. Logistics and technology industry that support the pharma business are also booming in the country.

4) Engagement with global pharma companies to diversify their activities to include clinical research and manufacturing. Undertaking clinical trials in a country like Nigeria offers several

advantages. Studies will be considerably cheaper and recruitment faster compared to other developing countries since few trials are currently run in the country. The country can provide the diversity required in multinational studies. Bringing clinical trials to a country like Nigeria will help poor people with severe and rare diseases to have access to newer therapeutic products.

5) Encourage, facilitate and support local research and development. The COVID-19 pandemic has brought sustainability in healthcare sharply into focus once again. Developing countries have come to the realisation that it is unsustainable to rely on foreign support and donations to meet the ever-increasing demand for healthcare products, especially for the numerous endemic diseases with significant unmet healthcare needs. Addressing this will require substantial investment into local research and development of indigenous pharma companies and herbal products manufacturers. PPAN envisages provision of technical support to these establishments as well as further strengthening NAFDAC's capacity to regulate.

6) Networking and building strong relationship with various stakeholders in the effort to improve the Nigerian healthcare sector.



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PPAN appreciate that these are bold and ambitious objectives but the confidence in achieving them will depend on the keenness of its members and supports of other local and international bodies and agencies that share similar goals of promoting pharmaceutical medicine, best pharmaceutical practices, inclusiveness, and drive towards achievement of universal health coverage.

Agreeably, Nigeria is a developing country and has challenges which the government is working hard towards overcoming. However, the country offers significant opportunities to the pharmaceutical industry. PPAN is determined to bring meaningful change in Nigerian healthcare delivery for the good of the people. Though the association is still at its infancy there is a high level of optimism for the future, judging by the enthusiasm of its founders and encouragements from various national and international quarters.

Dr Ado H Muhammad, MD MSc MBA FFPM

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web: www.ppa-nigeria.org (launching soon)



Healixia – A Successful Convergence Resulting in the Largest Member Association for Belgian Pharmaceutical Professionals



Our legacy

The Belgian association of pharmaceutical medicine professionals (BeAPP) has been member of IFAPP for decades. BeAPP provided development, education, training and networking opportunities for its members active in the field of medical affairs in Belgium.

But today's challenges urge the need for cross-functional collaboration. Also, highly effective professionals bring a broad overarching view and combine expertise in multiple domains. Consequently, individual careers evolve more into horizontal development vs the siloed vertical development in the past, BeAPP experienced the need to broaden our scope beyond medical affairs.

This same need was experienced simultaneously by other member associations in Belgium: The Belgian regulatory affairs society (BRAS) and the Belgian branch of the association of clinical research professionals (acrp.be). The idea rose to join forces, expand the scope of our associations and generate a stronger value proposition for our members via a large offer of educational activities. This initiative was shared by the Belgian Association of Phase I Units (BAPU), resulting in the creation of Healixia in January 2020.

The convergence between ACRP.be, BAPU, BeAPP and BRAS resulted into Healixia which will continue as a joint new member association.



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Healixia

Our legacy

ACRP+ BeAPP bapu BRAS

Who we are

The professional is our member

640+ members coming from 170 companies or universities

Our members are professionals active in the following domains:

- Clinical Research
- Early Development
- Medical Affairs
- Regulatory Affairs

What we do

On an overall and domainspecific level:

Information

Weekly newsletter to more than 2400 contacts

Networking

Networking during our Annual Conference and other events

Education

We have an agenda full of valuable masterclasses, events, webinars...

Healixia is member of:

EFEMED IFAPP

Healixia is a Belgian non-profit organisation founded 1 January 2020

www.healixia.be

Who we are?

Healixia is the Belgian community of all professionals active along the life cycle of medicines, medical devices, in vitro diagnostics & other health related products. Members are active in research & development (including pre-clinical, early clinical and later phases), medical affairs, safety, regulatory affairs and market access in industry, academia, investigator sites, authorities, regulatory bodies or in consultancy. Today we represent over 640 members coming from 170 companies or universities.

Each domain is represented in the board of Healixia and has an educational working group.

Healixia has a worldwide network of organisations with which we cooperate.

What we do?

Healixia provides development, education, training and networking opportunities across all members and disciplines. We aim to further professionalize our members and concerned disciplines and are open to work with all relevant stakeholders towards a strong community of professionals in Belgium.

Recently we were delighted to be able to organize our first annual conference since our foundation (no need to explain why this wasn't possible for the past two years). We talked about current and future trends in patient centric solutions for healthcare and - of course - enjoyed the great vibes of a live networking event.



The Healixia educational workgroups and board



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Networking at our annual conference

Apart from overall Healixia events there are events and trainings for each of the four Domains: regulatory (formerly by BRAS), medical (formerly by BeAPP), clinical research (formerly by ACRP.be) and early development (formerly by BAPU). We also have a weekly newsletter reaching 2400 professionals and co-developed with Pharma.be (the Belgian trade organisation) a brochure detailing career options in the pharma industry, which was distributed at Belgian universities.

Please visit www.healixia.be for more information and for our educational program.

Dr Erik Present, President Healixia

Koen Raeymaekers, Board Member Healixia

Annual Meeting of the Bulgarian Association of Drug Information (BADI)



Under the title "Revolution in Regulatory Affairs - How the pandemic is shaping the regulatory field and science" the Bulgarian Association for Drug Information, BADI, is pleased to announce their annual meeting to take place in Sofia on 2 June 2022 with some of the most renowned speakers on up-to-date topics. The meeting will be a hybrid event.

- **Dr Christa Wirthumer-Hoche**, Head of the Austrian Medicines and Medical Device Agency at AGES - Austrian Agency for Health & Food Safety (AGES), Former Chair of the EMA Management Board, will speak on **The regulatory field for pharmaceuticals is changing - lessons learned from the COVID-19 pandemic.**



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- **Professor Dr Barbara Sickmüller**, Senior Scientific Adviser to the German Federal Association of Pharmaceutical Industry (BPI) and President of the German Association for Regulatory Affairs (DGRA), will address the **EU pharmaceutical strategy: important goals and milestones - where are we now?**
- **Professor Burkhard Sträter**, Sträter Lawyers for Health Legislation in Germany and the EU, will talk about **New Regulatory and Legal Framework in Clinical Research in the EU. Regulation EU No 536 (EC) 2014 on repeal of Directive 2001/20/EC.**

- **Dr Birka Lehmann**, Senior Expert Drug Regulatory Affairs, Instructor at the University of Bonn, Germany, Board Member IFAPP and Chair of IFAPP Education and Certification Working Group, will give an **Update on paediatric medicinal products.**
- **Professor Dr Folker Spitzenberger**, Centre for Regulatory Affairs in Biomedical Sciences (CRABS), Technische Hochschule (University of Applied Sciences), Lübeck, Germany, will address **Medical Devices, an update on the Medical Device Regulation (EU) 2017/745 and the In-Vitro Diagnostic Device Regulation (EU) 2017/746.**
- **Dr Alexander Natz, LL.M.**, Secretary General, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), will address **The Implications of the New EU HTA Regulation for companies.**

The speakers from Bulgaria comprise a representative from the Bulgarian Drug Agency (BDA; to be confirmed) who will talk about Variations, and Professor Dr Radka Argirova (virologist, Chairperson of the Bulgarian Association for Medical Virology) and Dr Margarita Strokova (member of the Management Board of BADI, PharmaLex) who will speak about COVID-19 Epidemiology and provide an Update with regard to Risk Management. Professor Dr Tatyana Benisheva, University of Sofia, President of BADI, will conclude the meeting by talking about The Evolution of the EMA-EUnetHTA collaboration and the new HTA Regulation (EU) 2021/2282 of 15 December 2021.

Professor Dr Tatyana Benicheva, University of Sofia, President BADI
Bilyana Polyakova, Communication expert, BADI

Registration to the event:

https://www.badibg.org/2022/REG%20FORM%2002%2006%202022_April_Final.doc



The exact meeting location in Sofia will be provided soon.

Contact:

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 E-mail: office@badibg.org
 Website: www.badibg.org



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SAVE THE DATE:
IMPORTANT HOUSE OF DELEGATES MEETING ON 21 JUNE 2022
1:00-2:30 pm CET, 7.00-8.30 am EST, 8:00-9:30 pm JST

Dear IFAPP Delegates,

I am writing to you to awaken your interest in attending all future House of Delegates (HoD) meetings, and in particular in attending the next one, which will take place on 21 June 2022 (rather than 28 June as previously announced).

Several important topics are on the agenda to be discussed at this June meeting including IFAPP's International Conference on Pharmaceutical Medicine, the ICPM 2022 in Athens (19 to 21 October 2022) on which IFAPP is working very hard in collaboration with our President elect, Barbara (Varvara) Baroutsou, as she is also President of EL.E.F.I., the Pharmaceutical Medicine Association in Greece. Both Barbara and I are excited to open and run this International Conference and we are confident that you will enjoy the programme which is already available on our website and via the following link <https://www.icpm2022.gr/>.

Another topic on the agenda for which your presence would be greatly appreciated concerns the revision of IFAPP's Constitution: the IFAPP Board determined a few months ago that this document needs to be updated and revised to meet the requirements of our ever-changing world. To this end, the Board will provide to you by email both the current Constitution and the revised one which we will propose well in advance of this next HoD meeting in June.

This will give you time to review the proposed new Constitution so that you can either approve or reject it or provide comments.



The last topic for this June HoD meeting I want to draw your attention to is a new initiative of the IFAPP Board which decided to provide to senior professionals an opportunity to apply for recognition of outstanding experience in one or several areas of Pharmaceutical Medicine by awarding the title of "Global Fellow in Pharmaceutical Medicine (GFPM)". Additional information on this topic will follow during the next few weeks.

Thank you very much for your continuous support to IFAPP!

Marco Romano, MD, PhD, GFMD
President IFAPP



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key dates

- **June 10th, 2022:**
Call for speakers – due date for submissions
- **June 12th, 2022:**
Abstract submission deadline
- **June 19th, 2022:**
Early registration deadline



Hybrid Meeting
19-21 October 2022
SNFCC, Athens – Greece

THE FLAG

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

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