IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine

THIS ISSUE

1. A New Asset to the IFAPP Communication Working Group
2. Sharing Positivity in these Challenging Times
3. IFAPP Recommendations for the Revision of the Declaration of Helsinki, Version 2013
4. Post-COVID-19: Ethical Challenges in Clinical Research
5. IFAPP Webinar on COVID-19 in Sub-Saharan Africa 18 November 2021
6. IFAPP Survey of NMAs' Interests in Benefits for Members
7. Clinical Trial Disruption: Getting Back on Track, Part 2
8. 20th ICPM 1st Announcement

A New Asset to the IFAPP Communication Working Group

After obtaining my medical degree at the University of Leiden, the Netherlands, I started my traineeship to become an anaesthesiologist with special interest in the field of pain management. During that time there was an opportunity to combine it with the field of pharmaceutical medicine (clinical research).

The many fields in which one can contribute within pharmaceutical medicine has led to the fact that after more than 25 years of working in the field of clinical research as well as clinical safety and pharmacovigilance, I still enjoy the new challenges each day brings. During those years I was able to work both academically and in the for-profit field. Starting out as Medical Manager working for AstraZeneca with local responsibilities to Global Director at the Janssen Research Foundation in Belgium.

IFAPP TODAY
The Global Newsletter on Pharmaceutical Medicine

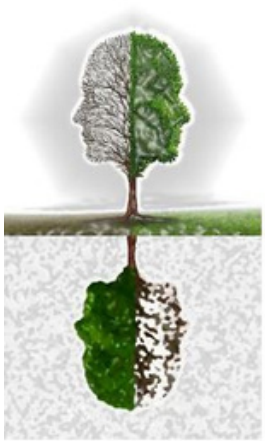
Having worked in various therapeutic areas such as anaesthesiology and pain management, oncology, infectious diseases and currently working in the challenging field of rare diseases as Senior Medical Director Pharmacovigilance, Pharming Group N.V.

To enhance my knowledge, I obtained a master's degree in Public Health. Being responsible for contacts with various branches as well as Health Authorities, my daily activities focussed on daily management and crisis management in several countries, amongst others in the U.S.A., Norway, and Japan. In the past years I worked as an independent executive supervisor for pharmaceutical companies (Novartis, Astellas) as well as for various Dutch Biotech start-ups.

As a board member of the Dutch Association for Pharmaceutical Medicine (NVFG), I reside on the Communication Committee. In this capacity I look forward to being able to contribute in the IFAPP Communication Working Group at an international level.

Rita Lobatto MD MPH
Senior Medical Director Pharmacovigilance, Pharming Group N.V.
Leiden, South Holland, Netherlands

Sharing Positivity in these Challenging Times



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We often heard of people saying, "I tested positive for COVID screening test. I heard that she is positive for COVID symptoms". Yes, you heard it right that the entire family got infected with COVID-19. But we seldom hear of people saying, "It's good to have a positive mindset despite being in this time of pandemic".

We often ask ourselves when will this pandemic end. How will the new normal look like in the field I am currently in? Should I set sail or stay still and not move in this mist of uncertainty?

The choices are always presented and it's up to us to decide the course of our action. Exerting effort and staying positive in terms mindset is challenging in this time of pandemic. Negative discussions in social media have been flowing with posts of negative articles and news about COVID-19, COVID-19 deaths, declining economy, companies declaring bankruptcy, people losing jobs and families relationship being strained because of all these pressures brought about by the pandemic.

The first step is accepting the brutal truth that COVID-19 is here and is real. We are now going the third year into this pandemic. COVID-19 statistics have been a regular item in the news. With the new Omicron variant of COVID-19 spreading, tension and anxiety are rising again. Negative emotions and outlook are gaining grounds. But should we let this eat us and control us? If we will look at the principles of nature, like poles repel each other and opposite poles attract each other.

IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine

Like Poles Repel each other....

Living at the time of the pandemic is like living in an environment of negativity. Keeping a negative mindset will be going against the current state we are in at present. We will be going against the force we are living at right now. But keeping a positive mindset will most likely keep us tuned with the situation while keeping another pole of our thinking at bay. This will keep us in balance - performing within capacity with our negative side making us on the guard. Our negative side should still work for us in a positive way, by keeping our health and our loves' safety. A little amount of anxiety will keep you grounded in the reality but keeping a mindset of positivity will make you functional.

Time has come that we should be facing the brutal truth that forces of nature is teaching us. We should learn to live positively in a world where negative forces are existing and learn to control our thinking, our perception of the world we are all living in. Nature is teaching us a lesson on how to conform and live in harmony with our current state. Keeping one another at a safe distance should give us an advantage because it will give us a chance to look at things in a bigger perspective.

The year 2022 is a good time to start if we have not decided yet on which side we want to be.

Rodelio C. Bito, MD
Member, IFAPP Communication Working Group,
Associate Medical Director, Pfizer Philippines

IFAPP Recommendations for the Revision of the Declaration of Helsinki, Version 2013

In the previous issue of IFAPP TODAY (No. 19, Nov/Dec 2021) (1), an article entitled "Proposal for Future Revisions of the Declaration of Helsinki" introduced the achievement and continuing discussion of the Ethics Working Group (WG) of the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP). It seeked to clarify the necessary revision points for the future version of the Declaration of Helsinki (DoH) of the World Medical Association (WMA), considering recent evolution of research ethics. Our paper (2) introduced in the previous issue of IFAPP TODAY made a proposal focusing on "data-driven research", showing the "infographic" (1) of our proposal.

The ethics of placebo-controlled trials and post-trial access have been critical topics with long-term international debates. IFAPP supported discussions among world experts at a webinar back in June 2021, which was reported in No. 16 of IFAPP TODAY (3). The proceedings of this webinar were also published in Clinical Evaluation (4).

Moving into 2022, we would like to introduce the "List of the topics recommended by IFAPP for the Revision of the Declaration of Helsinki, Version 2013" in more detail, as shown below (Figure and the list in the Appendix). This list was prepared by the WG and submitted to the WMA in 2019 under a Memorandum of Understanding of mutual cooperation of both organisations.

IFAPP TODAY
The Global Newsletter on Pharmaceutical Medicine

Our next focus is the new trend of research ethics. WMA's DoH was first issued in 1964 considering mostly the relationship between an individual physician and a patient. However, recent evolution of research ethics has come to be seen as a multidisciplinary enterprise: planned, conducted, and achieved by teams of various stakeholders, involving patients and the general public.

From such perspective, we wish to stimulate discussions on the future framework of research ethics. We look forward to further discussions with various stakeholders.

Figure: Categories and related IFAPP achievements and perspectives considering the topics to revisit the Declaration of Helsinki

Appendix

This list was prepared by the WG and submitted to the WMA in 2019, here published with slight linguistic modifications.

The list of IFAPP recommendations for the revision of the Declaration of Helsinki, version 2013, in detail:

1. Connection between Declaration of Helsinki (DoH) and Declaration of Taipei (DoT)

The scope of the DoH is "human research"; and the scope of the DoT is "health databases and biobanks". But it remains unclear, whether data and/or biological material collected as a part of the research and used for secondary analysis, fall under the scope of the DoT. IFAPP believes it should be in the scope of the DoT, in case of intended data/material sharing and/or secondary use. This should be clarified in the "General Principles" of the DoH.

IFAPP TODAY
The Global Newsletter on Pharmaceutical Medicine

2. Ethical approval and consent for secondary use

If future secondary analyses of data/material collected in research is expected, it should be written in the research protocol and informed consent form, to be assessed by an ethics committee. Once approved, the candidate subject can then make a decision whether to accept or refuse this secondary use. This should be clarified by revisions of **paragraphs 22 (protocol) and 26 (informed consent)**. This consent to future secondary use should be separated from the consent to participation in the proposed research, and this consent could be valid on condition that the above connection between the DoH and DoT is clarified.

3. Incidental findings

The last sentence of **paragraph 26** of the DoH states that "All medical research subjects should be given the option of being informed about the general outcome and results of the study.", but "incidental findings" are not mentioned. Meanwhile, paragraph 11 of the DoT states that returning results including incidental findings is one of the conditions of valid consent. The right of an individual of taking option of knowing/not knowing the results should be the same in both frameworks of the DoH and DoT, thus it should be clarified that the "results" in the DoH includes "incidental findings".

4. Registration of "data sharing plan" and "result" in publicly available database

Study registration requirement was included in **paragraph 35** of the DoH in 2008 with no further revision in 2013. "Result registration" has become to be a legal requirement in many countries but many cases of non-compliance have been reported. Responsible data sharing is considered by the International Committee of Medical Journal Editors (ICMJE) to be an "ethical obligation" and considered necessary in the WHO's list of items but registration of data sharing plan has not been well facilitated. These registrations should be promoted by **paragraph 35**. In addition, if the secondary use plan is registered in the same registry, an individual can track it.

5. Shared responsibility

Recently, especially related to the development of advanced medicinal products, non-medically qualified personnel became increasingly involved in the work of clinical drug development teams. Frequently their activities directly influence the well-being of the trial subjects. Therefore, IFAPP recently recommended that also non-medically qualified personnel should jointly share the ethical responsibility of such trials. We suggest including additionally one sentence into **paragraph 12** of the DoH: "All medically or non-medically qualified members of a research team having direct effect on the well-being of the trial subjects should share jointly the ethical responsibility for their welfare."

6. Patient and public involvement plan

An increasing number of research projects in the world has come to have a "patient and public involvement (PPI) plan" in their medicine development project. Although there is no international consensus, there is one guideline (in Canada) recommending it to be described in a protocol for assessment by the concerned ethics committee. To avoid misuse of a PPI plan and as a physician's responsibility to protect a patient involved in a research project even not as a study subject, it should be recommended in **paragraph 22** that a PPI (if any) should be described in the research protocol.

IFAPP TODAY
The Global Newsletter on Pharmaceutical Medicine

7. Diversity of membership and qualified expertise of Research Ethics Committees
It is considered international standard that the membership of research ethics committees is required to provide multiple perspectives, e.g., scientific and non-scientific, include all genders, and affiliated and not affiliated to an institution. As for the non-scientific perspective, there are a variety of aspects to be considered, e.g., expertise of humanities, perspectives of lay persons such as study volunteer, citizen, or patient, religion, law, etc., **paragraph 23** mentions "qualification", "transparency" and "independence" of Research Ethics Committees. It is recommended that "diversity" is added as one of the necessary characteristics. Sufficient education in topic and process of research is recommended for the qualification of the committee, and additional experts should be consulted when expertise is not within the core ethics committee competency.

8. Terminology of key concepts: human subjects, humans, participants, patients, etc.
There have been substantial discussions on the correct wording of "human subject". It is recommended that the WMA in cooperation with other organisations and patient representatives agree upon a mutually acceptable nomenclature.

9. Terminology of key concepts: medical research
Previously the DoH had changed the terminology from "clinical research" to "biomedical research" and then to "medical research". CIOMS has changed from "biomedical" to "health-related" with inclusion of epidemiological research and expansion of the scope. The wording "medical" in the DoH should be revisited. Some types of research may involve physicians but are not strictly considered "medical": for example, behavioural or educational research using MRI (for which physicians take responsibility for safety); social science research (to which physicians contribute with medical knowledge). These types of research should be well defined within the scope of the DoH.

10. Vulnerable populations
CIOMS 2016 took position that vulnerable people should be included in research unless there is justifiable reason for exclusion. This stance arose because routine exclusion had led to a lack of evidence in these populations, but this principle of protecting the vulnerable should not be abused. Meanwhile, **paragraph 20** of the DoH justifies research with vulnerable groups only when the research is responsive to the health needs, or priorities of this group and the research cannot be carried out in a non-vulnerable group. This may exclude participation of vulnerable patients who are willing to participate in research with expected direct benefit to an individual but not directly responsive to health needs or priority of this group. It is recommended that the WMA should discuss these two opposite views and clarify its position.

11. Use of placebo
CIOMS 2016 took the standard of "minor increase above minimal risk" as the limit of acceptable risk of placebo control, when there is an established effective intervention. The standard in **paragraph 33** of the DoH "no additional serious or irreversible harm" is almost the same as CIOMS 2002 and ICH E10 in 2000. Considering the revised standard (or wording) in CIOMS, WMA should discuss these two different standards (or wordings) and clarify its position.

IFAPP TODAY
The Global Newsletter on Pharmaceutical Medicine

12. Post-trial access

Paragraph 34 recommends making provision for appropriate post-trial intervention in advance of the trial. If the meaning of "an intervention identified as beneficial in the trial" is not limited to the tested drug/intervention, but any intervention identified as beneficial for each participant, it would be the physician's obligation to provide such intervention to each participant who needs it after the completion of the trial. In addition, community involvement strategy to make the proven intervention available in the host community would be important. These two points should be clarified in this paragraph.

References:

1. Kurihara C. Proposal for Future Revisions of the Declaration of Helsinki. IFAPP TODAY 2021; (19): 13-15. https://ifapp.org/static/uploads/2021/12/IFAPP-TODAY-19-2021.pdf

2. Kurihara C, et al. Linking the Declarations of Helsinki and of Taipei: Critical Challenges of Future-Oriented Research Ethics. Front. Pharmacol. 2020, 11: 579714. https://doi.org/10.3389/fphar.2020.579714

3. Kurihara C. Webinar COVID-19 and Bioethics - Pandemic and Research Ethics: Democracy, Placebo and Post-Trial Access. IFAPP TODAY 2021; (16): 4-6. https://ifapp.org/static/uploads/2021/07/IFAPP-TODAY-16-2021.pdf

4. Clinical Evaluation. 2021; 49 (Suppl 38): COVID-19 and bioethics Part 3: Pandemic and research ethics—Democracy, placebo and post-trial access http://cont.o.oo7.jp/49sup38/49sup38contents_e.html

Chieko Kurihara, BSocSc. Specially appointed Professor, Kanagawa Dental University, and member of the IFAPP Ethics Working Group

Post-COVID-19: Ethical Challenges in Clinical Research

Meeting Summary of 5th EL.E.F.I. Clinical Research & Clinical Trials Innovation Forum

The online meeting on ethical challenges faced during the COVID-19 era triggered an insightful scientific exchange among clinical research professionals working in academia, research institutions, patient engagement consultancies, ethics committees and Forum members.
The open dialogue was moderated in a partnership of EL.E.F.I. with BioMedLex, an organisation with expertise in legal and ethical provisions, from genetic testing and advanced therapies to clinical trials and precision medicine research.

IFAPP TODAY
The Global Newsletter on Pharmaceutical Medicine

The key highlights of the scientific discussions cover few critical components presented here below.

The pandemic directly affects the status and full spectrum of clinical trials. On the one hand, it has highlighted new possibilities, in particular through procedures for remote participation of volunteers and their monitoring. However, it raises issues of accelerating clinical trials in terms of COVID-19 research, but also a relative downgrade of clinical research priorities in other areas.
Emerging collaborations, tools, technologies and services are evolving at a phenomenal pace raising research ethics challenges. In view of the observed phenomenon, it is particularly important to adhere to the principles of ethics, so as not to diminish the protection of patients' rights.

Controlling the processing of personal data, especially in pandemic conditions, where international data flows from clinical trial procedures have increased and accelerated, is an additional critical problem. To some extent, the GDPR addresses the necessity of data exchange, but it is necessary to further clarify several of its provisions by regulators, but also by national laws.

COVID-19 disease tends to overturn the conventional therapeutic approach in medicine and surpasses the comparison with influenza and any precedent. The new disease requires an innovative strategy to detect rapidly deteriorating patient subgroups prone to severe respiratory failure on the basis of molecular risk standards, biomarkers such as suPAR (soluble urokinase plasminogen activator receptor) or an equivalent risk categorisation system, with the aim of providing timely ICU admission, which would improve the management of the seriously ill and reduce pandemic mortality.

Repurposing development of the immunosuppressive medicine Anakinra, hindering action of IL1α and IL1β, as COVID-19 treatment in adult patients with pneumonia requiring supplemental oxygen (low or high flow), was based on

SAVE Ph II & **SAVE MORE Ph III** clinical trials.
The authorisation of the above extension of indication of **Anakinra use by the European Commission** on the 17th of December 2021, is a noteworthy research outcome of the Hellenic Institute for the Study of Sepsis by Prof. E. Giamarellou-Bourbouli, Principal Investigator, Professor of Internal Medicine – Infectious Diseases at Athens Medical School of National Kapodistrian University of Athens.

IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine

The willingness and altruism shown by the volunteers participating in the clinical trials of the vaccines are a paradigm shift in the recruitment of individuals in clinical trials, which should be developed with the principles of diversity and health equity, based on gender, age range, minorities, socio-economic status, neurodiversity, special paediatric populations, the elderly and other populations.

Simultaneously, health literacy and awareness around clinical trials, along with the confidence in science and medicine gained during the pandemic, are seen as a momentum of encouragement from the community and healthcare staff to participate in clinical trials.

In parallel, the strengthening of the consent process of the candidates for their recruitment in studies by trained research staff and access to modern educational audiovisual material that will explain comprehensibly the protocol & procedures will contribute to the effective understanding of participants' rights and obligations.

On behalf of EL.E.F.I. Clinical Research &Clinical Trials Innovation Forum
Dr Varvara Baroutsou, Internist, GFMD, Independent Medical Consultant, Pharmaceutical Medicine Consultant, EL.E.F.I. President, IFAPP President Elect.

IFAPP Webinar on COVID-19 in Sub-Saharan Africa 18 November 2021

Speakers:

Professor Rhoda Wanyenze, Dean of Makerere University School of Public Health (MakSPH), Kampala, Uganda; “Covid-19 – Experiences from Uganda, Democratic Republic of Congo, Senegal, and Nigeria”

Professor Charles Wiysonge, Director of Cochrane South Africa, Medical Research Council, Cape Town, South Africa: “Vaccine Policy, Usage and Vaccine Hesitancy in SA”

Professor Elmien du Plessis, Associate Professor, Faculty of Law, Northwest University, Potchefstroom, South Africa: “Legal Responses to the Pandemic in South Africa, including Human Rights Considerations”

Moderators:

Dr med Bernd Rosenkranz, FFPM, Prof. em. (Stellenbosch University), President, Fundisa African Academy of Medicines Development, Visiting Scientist, Institute for Clinical Pharmacology and Toxicology, Charité Universitätsmedizin, Berlin, Germany

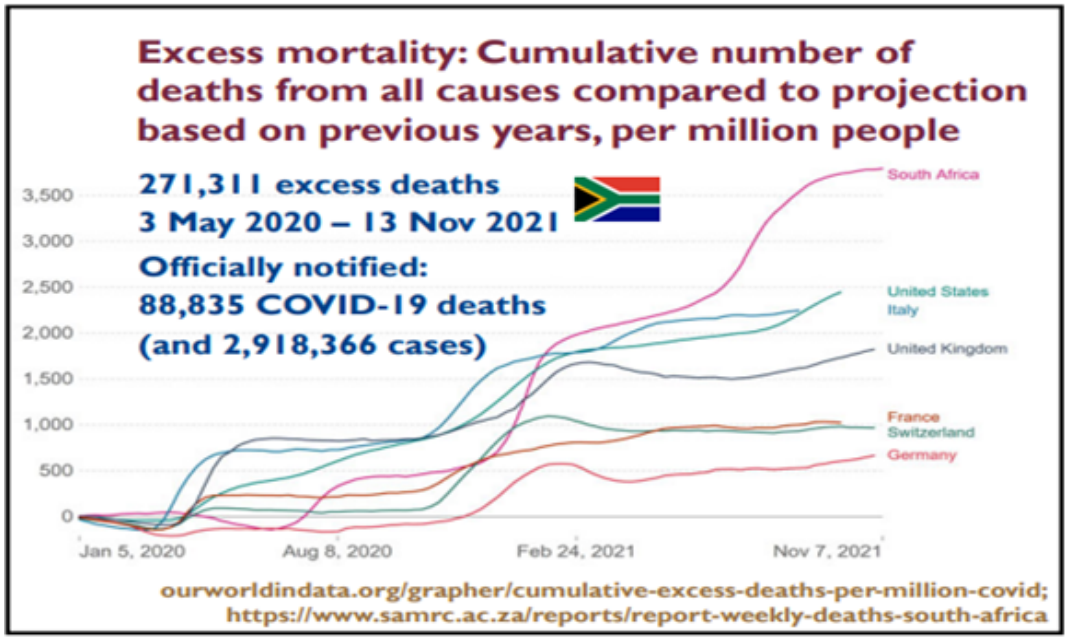
Professor Wolfgang Preiser, Head: Division of Medical Virology, Faculty of Medicine and Health Sciences, Stellenbosch University and National Health Laboratory Service (NHLS), Tygerberg, South Africa

IFAPP TODAY
The Global Newsletter on Pharmaceutical Medicine

Professor Bernd Rosenkranz, long-standing IFAPP member, introduced the speakers and moderated the webinar. He also mentioned that Professor du Plessis and he are currently convenors of two chapters of a COVID-19 country report for the South-African government.

Professor Wolfgang Preiser, a renowned Medical Virologist, opened the webinar with an introductory presentation. He discussed why it looked as if Africa had been (relatively) spared by the pandemic, and why this was not true.

Professor Preiser also presented data on the excess mortality of a variety of countries and these were clearly highest for South Africa in comparison:



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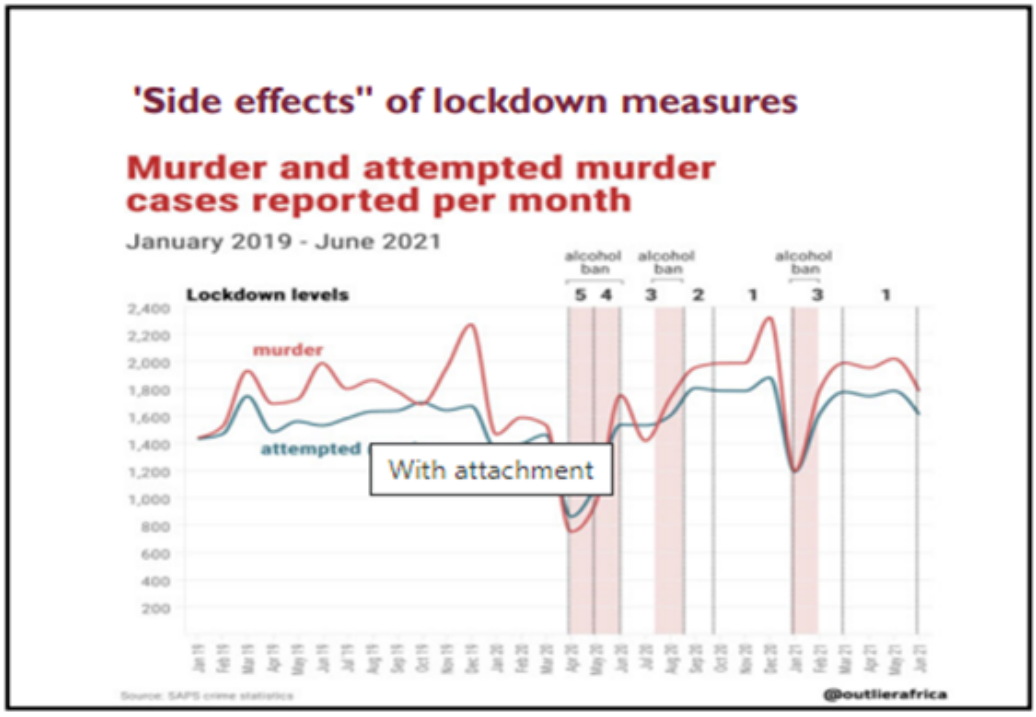
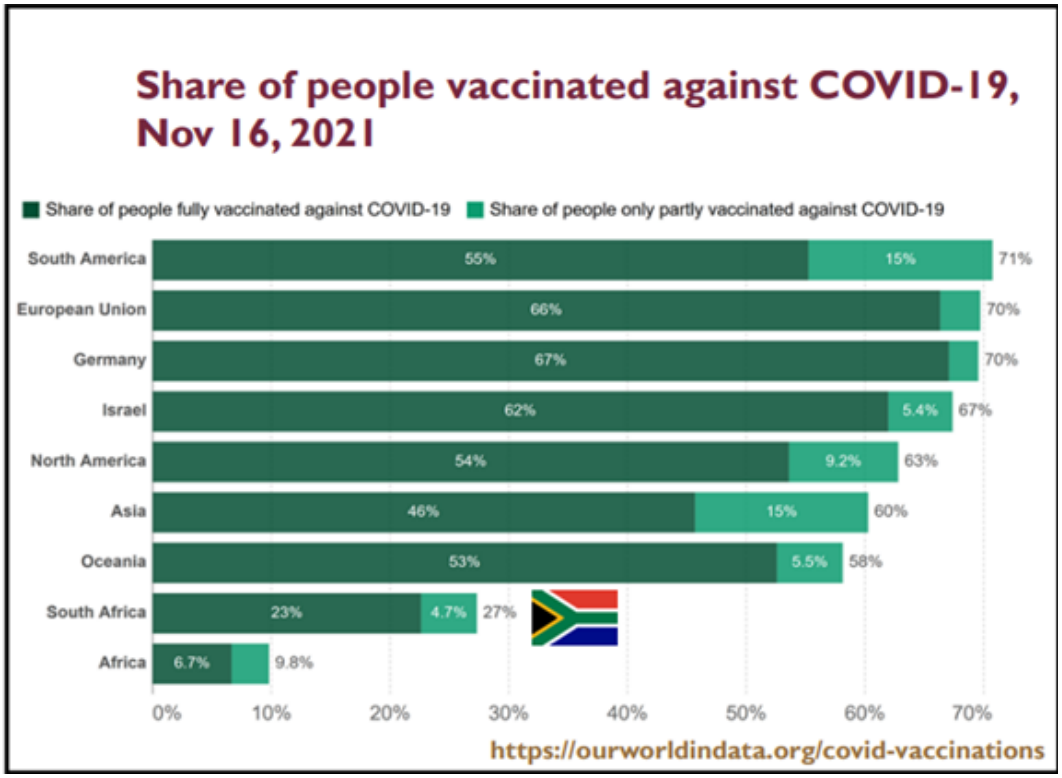
The Global Newsletter on Pharmaceutical Medicine

Positive side effects of the lockdown were the number of murders in South Africa being reduced:



Also, data on the share of people fully and partly vaccinated in South Africa and Africa in comparison to other parts of the world were presented:



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The Global Newsletter on Pharmaceutical Medicine

Professor Rhoda Wanyenze spoke about "COVID-19 – Experiences from Uganda, Democratic Republic of Congo (DRC), Senegal, and Nigeria"

Professor Wanyenze explained with whom they work and what they are developing in these countries to drive impact. One partner, for example, is the Bill & Melinda Gates Foundation. Whilst for 2021 near-term decisions and funding allocations played a role, the plan for 2022 is to shape guidance on future investments in pandemic preparedness and resilient health systems. A network of universities focused on pandemic preparedness and response will be established. The impact of COVID-19 on health systems and routine services will be assessed and the focus will lie on best practices for health system resilience. The various testing and surveillance strategies were framed and evaluated.

Vaccine readiness and implementation in Sub-Saharan Africa were evaluated and the optimal selection and implementation strategies for digital health tools in response to COVID-19, not only in the aforementioned four countries but also in Burkina Faso, Vietnam, Sri Lanka and India were discussed.

Public health emergencies like the COVID-19 pandemic cause disruption to essential health services beyond direct morbidity and mortality.

Fear of contracting COVID-19 and transport difficulties due to mobility restrictions have caused people to avoid health facilities, delaying routine health services.

Professor Wanyenze presented these high-level recommendations:

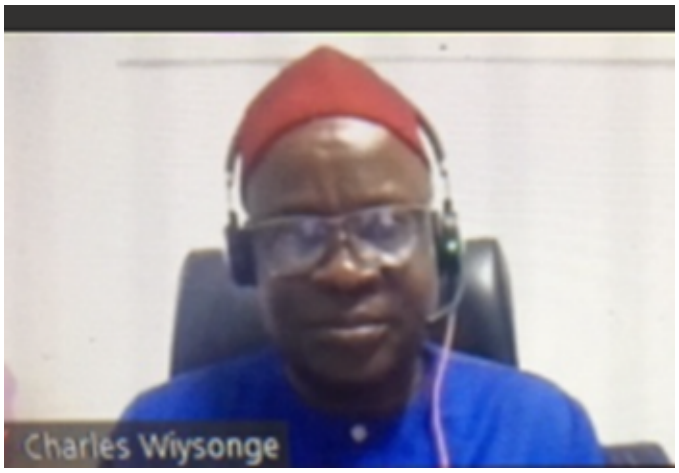
- Develop clear guidelines to promote maintenance of essential health services during crises and disseminate to all levels of the health system.
- In time of crisis, health systems should implement innovative health service delivery models and strategies
- Reliable, accurate and connected data reporting systems across health system levels enable effective evidence-based decision- and policy-making.
- Strong government coordination, public-private partnerships, and international cooperation are key to an effective COVID-19 response.

Professor Wanyenze further explained why Uganda, Nigeria, Senegal and DRC were selected for analysis, one reason being representation of Francophone and Anglophone countries to enhance South-South collaboration through learning networks and communities of practice.

IFAPP TODAY
The Global Newsletter on Pharmaceutical Medicine

She also presented on the context of population-based public health measures employed in the four countries, with regard to mobility restrictions, measures in public places and support for vulnerable populations. Graphs were shown in respect to relative change in mobility, self-reported mask use, the height of the various waves of daily new confirmed COVID-19 cases over time of the pandemic, and the number of daily new confirmed deaths.

Following Professor Wanyenze's presentation Professor Wiysonge gave an overview of lessons learned.



Professor Charles Wiysonge talked about the Vaccine Policy and Vaccine Hesitancy in South Africa. He presented the South African COVID-19 vaccine strategy and the licensures of the COVID-19 vaccines in South Africa and that the national regulatory agency, the South African Health Products Regulatory Authority (SAHPRA) can grant an emergency use authorisation for vaccines prior to full approval. By June 2021, SAHPRA had approved the AstraZeneca, Pfizer, and J&J vaccines for emergency use in South Africa. He showed the numbers of vaccination totals as can be derived under the following link https://sacoronavirus.co.za/latest-vaccine-statistics/. He also mentioned the WHO's definition of vaccine hesitancy as "the delay in acceptance or the refusal of vaccines despite the availability of vaccination services".

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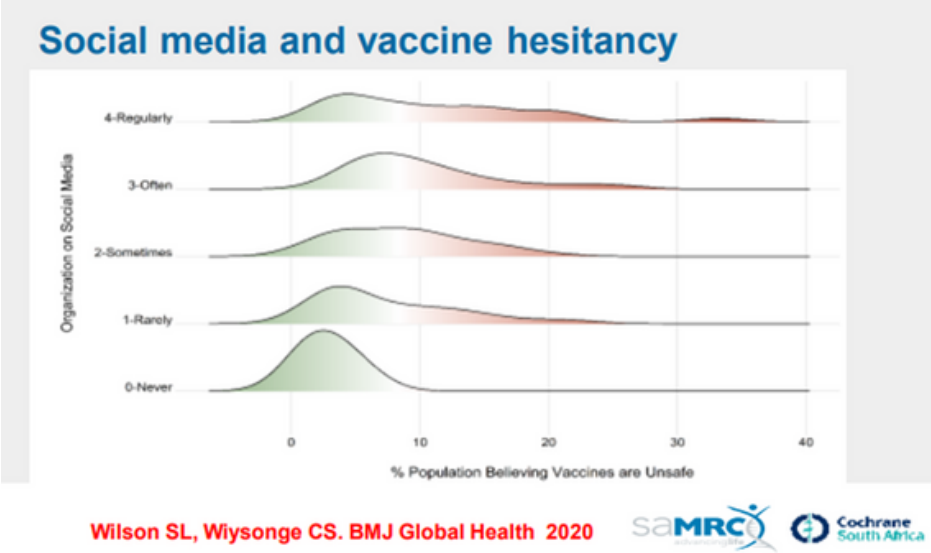
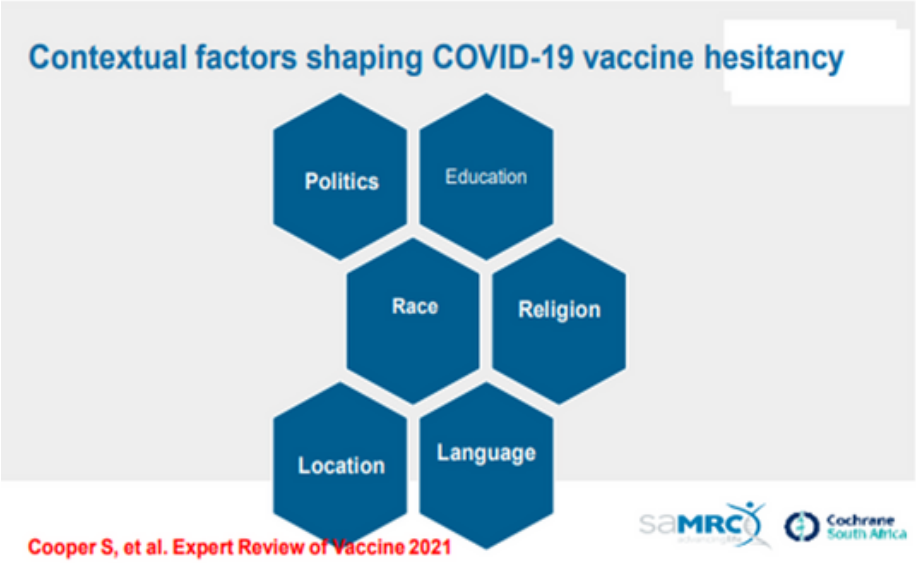
The Global Newsletter on Pharmaceutical Medicine

And the influence of social media:



He then showed the contextual factors influencing the COVID-19 vaccine hesitancy:



Professor Wiysonge concluded that South Africa was doing well with COVID-19 vaccination, but could do better!

IFAPP TODAY
The Global Newsletter on Pharmaceutical Medicine

Professor Elmien du Plessis concluded the webinar by talking about the legal background and human rights aspects, especially in the South African context. She spoke about the heightened interest in the field of disaster risk management but also emergency laws, i.e., the South African Disaster Management Act implemented in 2002. In addition, there is also the State of Emergency Act.

These two laws govern two different sets of exceptional circumstances. A state of emergency can only be declared when there is a threat on the nation's life. This is why the South African government chose the Disaster Management Act to deal with the pandemic in South Africa. The Disaster Management Act is only applicable when other legislation is inadequate. The National Health Act already makes provision for regulations and quarantine in the case of certain notifiable medical conditions. Over the past 20 months, South Africa learned a lot about the pandemic and what is needed to manage it.

The one big lesson learnt from COVID-19 is that the Disaster Management Act and the National Disaster Management Framework require disaster risk reduction planning to be in place in all ministries, all the time. This will reduce risks in the case of a hazardous event, which in turn means that ordinary legislation might be able to cope with its management, reducing reliance on states of disaster being declared in the future.

Post-webinar Note by Professor Bernd Rosenkranz

This webinar was prepared and given on 18 November 2021, i.e., before the detection and identification of a new variant of the SARS-CoV-2 called omicron. Of interest for the local South African context is a comment in The Lancet online on 3 December 2021 "The political theatre of the UK's travel ban on South Africa" by Marc Mendelson et al. This article describes the detection and spread of the various variants and, in particular, that, on 25 November 2021, "South African scientists reported a new SARS-CoV-2 variant, B.1.1.529, that was subsequently designated omicron…"

Two days after the identification of omicron, the UK Government promptly reapplied a travel ban on travel from South Africa and some other African countries. Several other countries, such as Israel and the USA, swiftly followed suit with travel bans from countries in Sub-Saharan Africa, citing this action as a precautionary measure. This unwarranted action has generated intense anger and frustration. Travel restrictions are unlikely to be able to stop the spread of coronaviruses unless countries are able to completely seal their borders to travellers from all nations.

IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine

Predictably, soon after the UK travel ban announcement, cases of the omicron variant were reported in Europe, the UK, North America, and, as of 2 December 2021, 25 countries in total..... South African scientists rapidly and transparently shared the findings of mutation and genomic sequences of the latest SARS-CoV-2 variant. Rather than applaud their generosity and openness, travel bans have had the opposite effect and could be damaging to the health response, economy, and freedom of movement. This situation puts countries such as South Africa in a difficult position, and potentially threatens future willingness to share information and weakens global solidarity. Once again, South Africa and other African countries have been stigmatised and will pay a heavy economic and societal price for sharing information. This experience is also likely to have detrimental impact on the behaviour of other countries going forward.... We call on the UK and other governments to reverse their damaging travel bans and follow the advice of WHO and the International Health Regulations in keeping international borders open."
(https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02752-5/fulltext)

Brigitte Franke-Bray, MD PhD, FFPM, GFMD, Consultant in Pharmaceutical Medicine, Switzerland, IFAPP Board Member

Bernd Rosenkranz, MD PhD, FFPM, Prof. em. (Stellenbosch University), President, Fundisa African Academy of Medicines Development, Visiting Scientist, Institute for Clinical Pharmacology and Toxicology, Charité Universitätsmedizin, Berlin, Germany

The next free COVID-19 webinar will be organised by SBMF, the IFAPP member association from Brazil, on Thursday January 20th (8.00-9.30 am Brazil time, 12:00-13:30 CET, 20:00-21:30 Japan (JST).

Click here for registration.

After registering, you will receive a confirmation email containing information about joining the webinar.

IFAPP TODAY
The Global Newsletter on Pharmaceutical Medicine

IFAPP Survey of NMAs' Interests in Benefits for Members

Upon kick-off of the new board of IFAPP as elected at the House of Delegates (HoD) Meeting on June 28, 2021, IFAPP asked all National Member Associations (NMAs) and Individual Affiliates (IAs) of their interests in Benefits for Members (*1) using Survey Monkey online questionnaires.

Three questions were asked whether IFAPP should continue or discontinue the current services for benefits, followed by questions asking their interests in 5 working groups.

More than half of the NMAs responded to the survey, together with IAs, and the results are summarised in the following table:

Questions	% Interested to continue (n=12)
【Q1】 Medical Affairs Online Training: An e-learning course offering professional certification in medical affairs in medicines development, with King's College London, UK and the IFAPP Academy (*2)	83.33%
【Q2】 Global Fellow in Medicines Development (GFMD): Professional certification recognised by IFAPP and IFAPP Academy awarded to senior and experienced members	91.67%
【Q3】 Heroes in Pharmaceutical Medicine: This title was created by the previous Council of Past Presidents and is to be awarded to colleagues who contributed significantly to Pharmaceutical Medicine	83.33%
Please let us know your future interest to help us enrich your national activities. Here you can tick off more than one box:	
【Q4】 Education and Certification • Recognition/accreditation of your national courses/trainings • Advice/support in developing your courses/trainings in your country • Sharing opportunities to learn about the courses/trainings offered by any NMAs	 36.36% 18.18% 45.45%
【Q5】 Ethics • List of potential issues for discussion to meet your national interests • Introducing your national thought leaders to international ethics events	 70.00% 30.00%
【Q6】 External Affairs • Development of joint opportunities with external organisations for shared interests and possible discount in participation fees • Sending your national representatives as team members to work with external organisations	 72.73% 27.27%
【Q7】 Communication • Sharing national/regional topics with global readers • Introducing hot topics/leaders in your country	 66.67% 33.33%
【Q8】 Young Professionals • Opportunities (social networks like LinkedIn, Facebook) to discuss a potential career path • Speakers to be invited as professional experts to talk at your national lectures/seminars	 36.36% 63.64%

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*1: https://ifapp.org/static/uploads/2020/07/Flyer_IFAPP_Membership_benefits_Jul2020.pdf
*2: https://ifapp.org/static/uploads/2020/07/IFAPPAcademyBrochure_for_web.pdf

In addition, positive interests were found to suggested activities such as:

- Recognition/accreditation of national courses/trainings
- Sharing opportunities to learn about the courses/trainings offered by any NMAs
- List of potential issues for discussion to meet national interests
- Development of joint opportunities with external organisations for shared interests and possible discount in participation fees
- Sharing national/regional topics with global readers
- Speakers to be invited as professional experts to talk at NMAs' national lectures/seminars

Results of this survey were shared at the HoD meeting on November 11, 2021 and will be incorporated in the planning of future activities by the Board of Officers (BoO) and the working groups.

Your participation is much appreciated, and active communication is encouraged.

Kyoko Imamura, MD, PhD, DrMedSci
IFAPP Past-President
Visiting Professor, The University of Tokyo

Clinical Trial Disruption: Getting Back on Track, Part 2

Prior to the pandemic, the Mexican Health System had already been affected due to political/administrative decisions and there were already fewer human and material resources available for patients. At the start of the health crisis, efforts were fundamentally focused on attacking the COVID-19 problem, while the distribution and availability of treatments for other diseases were placed on hold.

As for health personnel, whether physicians, nurses, or assistants, a great number requested temporary leave due to the pandemic, while others were reassigned to areas where patients with COVID-19 were being treated. This distracted a critical mass of personnel from assisting on clinical trials.

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It is also important to mention that the personnel at health institutions have suffered from physical and/or mental exhaustion, or burnout, which implies long working hours that are not carried out under the best conditions. It should be noted that Mexico has been one of the countries where the greatest number of health personnel have suffered from COVID-19 and even more have died. All of this has led to insufficient human resources for the development of trials. Therefore, there is a lack of investigators, sub-investigators and study coordinators to continue clinical trials, let alone starting new trials.

Continuing with the analysis of each of the factors and parts of a clinical study, patients participating in studies are now limited to being enrolled since the vast majority of the hospitals where the protocols are carried out were “converted" to sites where patients with COVID-19 are being treated. On the other hand, the Mexican population in general does not feel safe going to hospitals at the present time, regardless of whether it has been classified as a COVID or non-COVID care center. There is great fear of being infected. It should be noted that, in the development of clinical protocols, the interaction of health professionals with patients is relevant and currently, due to the rules of social distancing, now limited. This has also hindered, among other things, patients from going to their appointments.

‘Infodemia’

No less important is what is called "infodemia," or the "overabundance of information (some truthful and others false) on a subject." Media has been both a deterrent and an asset through the pandemic. Misinformation and fake news have cluttered people’s minds, leading crowds of people to wrong assumptions and to act inadequately when faced with this contagion. Other information has provided precise and exact explanations for people to stay safe and remain as far as possible from possible sources of contamination and infection.

A very valuable tool, but at the same time with certain limitations, has been the use of telemedicine, as well as the remote care of patients. It is important to mention that these tools are not yet in the domain of many sectors of the population nor are they available to all patients or at research sites.

Regarding the facilities where patients are regularly enrolled and treated when partaking in specific clinical trials, these have also been limited. Most hospitals have been changed to COVID-19 facilities and are no longer conducting trials. Likewise, the availability of medical equipment that most often is necessary for the implementation/development of research protocols is now limited due to delayed regulatory processing. It is important to mention that the federal budget cut for the health sector has also had an impact on the supply/availability/storage of medicines, as well as supplies of all kinds.

It is worth highlighting the role played by all those participating in clinical monitoring. At the moment, much of the work has been limited to teleworking, which limits the access to the actual source of the information.

Starting from the fact that all the information in a research protocol must be documented and all the evidence of the evolution of a clinical study should be protected, the situation of the pandemic has created a challenge to carry out essential additional steps for adequately recording and saving information on patients.

Most of the available resources have been focused on treating COVID-19, as well as developing vaccines to combat this disease. We know that the creation of vaccines against COVID-19 has broken the paradigm of the time required for development, since the whole process was accelerated; otherwise, it would have taken up to 15 years to create a vaccine against the new coronavirus. Even drug development has been altered. New drugs are now being tested to treat COVID-19.

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It is also worth noting that both the importation of supplies and medicines, as well as travel restrictions have had an impact on the development of clinical studies.

On Aug. 27, 2020, the US National Library of Medicine through Clinical Trials.gov reported 2,757 clinical studies related to COVID-19, 59 of them in Mexico. Today, Clinicaltrials.gov reports there are 6,884 trials related to COVID worldwide, 172 in Mexico. This highlights the importance this topic has had on clinical research and how it has overturned trials on a specific topic.
On a positive note, major pharmaceutical companies are working together with the Mexican government for the production of a vaccine against COVID-19. This vaccine expects to receive the endorsement of the US regulatory authority, the FDA, to later be endorsed by COFEPRIS and to be able to start administering it to the population very soon.

Having said the above, we must not forget a relevant point in this whole context, which is the patient protection, since the safety and well-being of the participants in the clinical trial must be guaranteed and preserved.

Here we will highlight the following: the Declaration of Helsinki and the Oviedo Convention state that “the well-being of the human being must prevail over the interest of society and science, haste cannot justify a decline in methodological rigor, it is better to have the uncertainty of ignorance than to have poor quality conclusions,” indicated Dr. Rosa María Wong Chew during her conference transmitted by Facebook Live at the Faculty of Medicine on May 22, 2020, as head of the Clinical Branch of the Research Division of the UNAM School of Medicine.

In terms of obtaining results, one must consider the implications of this situation, which includes the lack of the collection of real treatment effects for studies with little statistical power, or the misstatement of an effective treatment based on a surrogate endpoint.

It should not be forgotten that investigative protocols not related to COVID-19 have been somewhat delayed or suspended, or have had to be adjusted to the current circumstances. No less important, has been the pharmacovigilance that has been limited on other treatments.

Most of the investment in COVID-19 to date has been new funding, that is, not at the expense of the current healthcare budget, although possibly at the expense of the national economy or specific expenditure undertaken by the pharmaceutical firms.

Venture capital financing can be difficult to secure, adding challenges for the life sciences sector in bringing new innovations to market.

Conclusions

The new implementation/development of clinical studies worldwide should contemplate a redesign in the interaction of the research team and an update of plans.

It must be considered that this pandemic is here to stay for an uncertain period of time, so we will most likely not return to the way we used to work/interact in the near future. From now on, we must consider remote communication and the use of technological tools that will allow us to maintain strict control of the studies without putting the health of both the patient and personnel who interact with them at risk.

Corporate resilience will be a fundamental factor for overcoming and surviving the pandemic in the best way possible.

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This article has been reprinted from Mexico Business News (https://mexicobusiness.news/health/news/clinical-trial-disruption-getting-back-track-part-2) with kind permission of the publisher.

20th ICPM 1st Announcement

The **Greek Society of Pharmaceutical Medicine (EL.E.F.I.)** and the **International Federation of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP)** invite you to the international congress

20th International Conference on Pharmaceutical Medicine

in Athens, Greece, **next October.**

At a critical moment for the evolution of the pandemic, with optimism stemming from intensification of vaccination against SARS-CoV2

#EL.E.F.I. #IFAPP

are planning to deliver #ICPM 2022: an exceptional hybrid educational experience.

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The COVID-19 pandemic is likely to impact educational activities in 2022 and, as many of our guest speakers from Greece and abroad may face difficulties travelling to an in-person conference, we have already included the opportunity for online participation of congress faculty members and attendees.

We are aiming to cover all the latest developments in modern Pharmaceutical Medicine and will host dedicated Biomedical Research sessions. Additionally, we will focus on New Technology Platforms, Precision Medicine, Advanced Clinical Medicine, Career Development and Professional Competencies in Pharmaceutical Medicine.

We are optimistic that the digital and onsite format of the congress will provide opportunities for networking and interaction with our members, the academic community, researchers, clinical investigators, and other stakeholders and trigger lively discussions, either face-to-face (or “mask-to-mask”) or in online forums.

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The Global Newsletter on Pharmaceutical Medicine

IFAPP AGENDA

20 January - COVID-19 Webinar Brazil
(8.00-9.30 am Brazil time, 12:00-13:30 CET, 20:00-21:30 Japan (JST)
For more information and registration click here.

28 March - IFAPP House of Delegates Meeting

19-21 October - International Conference on Pharmaceutical Medicine (ICPM)
Athens - Greece. Hybrid Meeting

THE FLAG

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

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