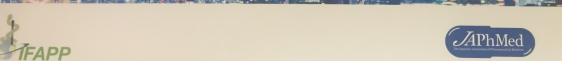




The 19th International Conference on Pharmaceutical Medicine (ICPM 2018)
 第9回日本製薬医学会年次大会

Main Theme
The Future of Medicines Development

• Date: September 27(Thu)~28(Fri), 2018(ICPM&JAPhMed)
 September 29(Sat)~2018(JAPhMed)



IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine

THIS ISSUE

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Leadership Transition in the Communication Working Group

As already introduced in our President's message delivered immediately after our House of Delegate meeting on June 28th, and reprinted in this issue of IFAPP TODAY, new leaders are elected for each of five working groups. Now it is my pleasure to introduce PD Dr Ghazaleh Gouya-Lechner, as a new standing officer of the Communication Working Group and hand over the leadership to her.

I've served the role as a temporary assignment since September 2020 due to the unexpected early departure of the predecessor. Having worked with our great group members, I'm strongly convinced that this working group must be a hub of all the news and information in and out of our national member associations which can be of our common interests throughout the world. New ideas keep popping up to figure out new manuscripts to be contributed by most knowledgeable experts for sharing by IFAPP TODAY and posting at the IFAPP website.

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Of course, constant communication with member associations is critically important, and we highly appreciate Ghazaleh's participation as the new group leader.

My very best wishes to Ghazaleh and the members of the Communication Working Group!

Kyoko Imamura, MD, PhD
Past-president of IFAPP

Being driven by a passion for science and clinical research, I am honored to take over the leadership in the Communication Working Group of IFAPP. Clinical research is all about people as the success of lies in communication between people, beyond our silos, transdisciplinary, and across the globe. Within the Communication Working Group we would like to provide all national member associations and IFAPP members the format to present their achievements, to learn from each other and to improve in the entire drug and device development process. The critical view in the clinical research landscape most important to education and training for clinical research and medical affairs professionals are the further focus of our future activities.

I welcome all volunteers to apply for collaboration within the Communication Working Group.

PD Dr. Ghazaleh Gouya-Lechner,
Head IFAPP Communication Working Group

Message from the IFAPP President, Dr Marco Romano, Italy

During the IFAPP House of Delegate meeting on 28th June 2021, a new IFAPP Board was elected as follows:

- Secretary: Anna Jurczynska, Spain
- Treasurer: Brigitte Franke-Bray, Switzerland
- Standing Officer/Chair Education and Certification WG: Birka Lehmann, Germany
- Standing Officer/Chair Communication WG: Ghazaleh Gouya, Austria
- Standing Officer/Chair External Affairs WG: Cordula Landgraf, Switzerland
- Standing Officer/Chair Ethics WG: Kotone Matsuyama, Japan
- Standing Officer/Chair Young Professionals WG: Annette Mollet, Switzerland

The votes obtained by each of them are thus:

Candidate's name	Votes in favour	Votes against	Abstentions
1 Anna Jurczynska	29	0	3
2 Brigitte Franke-Bray	31	0	1
3 Ghazaleh Gouya	28	0	4
4 Birka Lehmann	27	0	5
5 Kotone Matsuyama	27	0	5
6 Cordula Landgraf	27	0	5
7 Annette Mollet	27	0	5



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Moreover, we decided to start a new WG dedicated to Young Professionals to develop a global network via the use of social media. I consider it of paramount importance to facilitate the career of junior colleagues by supporting them with a continuous education in Pharmaceutical Medicine.

We will continue to focus on the Ethics of Clinical Research and Development as this is the “sine qua non” of every successful drug development plan and Good Clinical Practice.

Finally, on behalf of the whole of IFAPP, I would like to thank the past Standing Officers who have now left the Board. These include: Honorio Silva, Domenico Criscuolo, Gustavo Kesselring, Sandor Kerpel Fronius and Peter Stonier. They represented IFAPP for more than a decade and their dedication will be an example for the new IFAPP Board of Officers.

Thank you all for your active participation in the House of Delegates. We look forward to your further contributions in the coming months. We will face many challenges in the future and your continued support is the best reward for our efforts.

I would like to congratulate each of them and wish them great success in their new roles. I am sure they will lead their respective Working Groups (WGs) well and with the ambition to increase member numbers and to foster closer interactions with our National Member Associations and Individual Affiliates.

One of the main objectives of this new Board is to contribute to the development of IFAPP across the globe with the support of as many regions and countries as possible. We will do our best to show Pharmaceutical Medicine Associations and related organisations that becoming a member of our International Federation brings many benefits.

Another important goal will be to increase communication and improve our relationship with external Institutions such as Academia, Pharma, CROs, Patient Organisations and Regulatory Authorities. We are thus aiming to become a point of reference for our National Member Associations and Individual Affiliates.

We intend to dedicate time and energy to the education and training of our members (especially our young colleagues) by implementing new online learning programmes offered globally. We also plan to explore additional certification possibilities.



Annette Mollet



Cordula Landgraf



Birka Lehmann



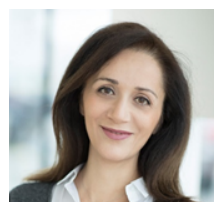
Anna Jurczynska



Kotone Matsuyama



Brigitte Franke-Bray



Ghazaleh Gouya



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Webinar COVID-19 and Bioethics - Pandemic and Research Ethics: Democracy, Placebo and Post-Trial Access

Feedback from the Participants

"This was a truly outstanding meeting with open and frank discussions on central issues at a critical time. The type of speaker and the quality of the debate was excellent." (Ulf Schmidt, one of the speakers)

"An extraordinary meeting with extraordinary speakers, discussants and interaction. It was a meeting that will drive major developments in the ethics field." (Varvara Baroutsou, President Elect, IFAPP)

"The speakers addressed topics of high importance in today's world and I agreed very much with the statements." (Brigitte Franke-Bray, IFAPP)

"I was so excited to witness a historic moment. I'm sure it will receive much acclaim." (Keiko Inoue, lay person with expertise in public engagement)

"With the analysis, insights and energy of all speakers, we must find a new way forward for bioethics, adhering to the principles established in the Nuremberg Code in 1947, just after World War II, all the way through to the experience of this pandemic, and consider the more critical emergent issues of our time." (Rihito Kimura, Japanese professor, one of the founders of global bioethics at the Kennedy Institute of Ethics at Georgetown University)

The webinar entitled "COVID-19 and Bioethics - Pandemic and Research Ethics: Democracy, Placebo and Post-Trial Access", held on June 4 and 11, 2021 was highly acclaimed as a memorable, historical turning point in research ethics. The event was co-organised by the COVID-19 Task Force, the Japan Association for Bioethics and the Brazilian Society of Bioethics, supported by the Japanese Association of Pharmaceutical Medicine (JAPhMed) and the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP). The video-recorded version is available at the following websites:

June 4, Day 1

<https://www.youtube.com/watch?v=eD8mF9mKTIQ>

June 11, Day 2

<https://www.youtube.com/watch?v=jpgd3jzVCD4>

All invited speakers (table), including Dirceu Greco, Chair of the Brazilian Society of Bioethics, played historically critical roles in the entitled topics. The ethics of "placebo-controlled trial" and "post-trial access" to the intervention proven to be effective in the trial have provoked international debate since the 1990s, during the world pandemic of HIV/AIDS, and led to revisions of the World Medical Association's (WMA) Declaration of Helsinki (DoH). Our objective is to revisit these topics considering the experience of the COVID-19 pandemic. Two guests from the WMA participated in discussion: Ramin Parsa-Parsi, Working Group Chair of 2013 revision of the DoH and Otmar Kloiber, Secretary General of the WMA. Moderator Takeo Saio congratulated the WMA for having received the Golden Arrow Award from the Vienna Congress, representing doctors combatting COVID-19 (1).

[i] Duncan N. WMA Wins Prestigious Award; Otmar Kloiber Acceptance Speech; David Barbe Acceptance Speech. World Medical Journal. 2021; 67(1): 11-14.



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Table: Webinar speakers and moderators:

June 4

Chieko Kurihara, BSocSc., Specially appointed Professor, Kanagawa Dental University.: Opening remarks and situation in Japan and the world: Proposal on "Ethics of Placebo-Controlled Trials and Post-Trial Access in the Declaration of Helsinki"

Ruth Macklin, Ph.D., Distinguished University Professor Emerita at Albert Einstein College of Medicine in New York City: "Ethics in Vaccine Research: The COVID-19 Pandemic"

Peter Lurie, M.D., MPH., Center for Science in the Public Interest, Washington, DC: "Revisiting the Debate over Placebo Use in Developing Countries in the Age of COVID-19"

Ulf Schmidt, Ph.D., Professor of Modern History, University of Hamburg: "From Nuremberg to Helsinki: Historicising Research Ethics during Health Crisis"

June 11

Ames Dhai, M.D., Ph.D., Specialist Ethicist at South African Medical Research Council, Johannesburg: "Ethics in Vaccine Allocation in Developing Countries"

Tammam Aloudat M.D., Ph.D., "Médecins Sans Frontières (MSF) Access Campaign for Equitable Access in the World"

Dirceu Greco, M.D., Ph.D., Professor Emeritus, Infectious Diseases and Bioethics, Federal University of Minas Gerais: "Post Trial Access for all Perspective of Achieving Universal Access to Adequate Public Health"

Francis P. Crawley, BPhil., Executive Director of the Good Clinical Practice Alliance – Europe: "Special Comments"

Moderators: **Takeo Saio**, M.D., COVID-19 Task Force, Japan Association for Bioethics and **Kyoko Imamura**, M.D., Ph.D., Past President of IFAPP and JAPhMed.

*Co-authored by Takeo Saio, Kotone Matsuyama, Kyoko Imamura

In the Day 1 session, Kurihara and Macklin provided criticism of an article authored by a group of experts appointed by the World Health Organization and published in the New England Journal of Medicine. The article stated that, following emergency use authorisation of effective vaccines, placebo-controlled trials were permissible in regions where access to these vaccines did not exist or was severely limited (2). This resulted in a double-standard, in which it was acceptable to conduct placebo-controlled trials in low- and middle-income countries but impermissible in wealthier countries. That double standard has been criticised for at least the past two decades. Lurie (3, 4), Greco (4, 5) and Macklin (6, 7) are global leaders of this argument. The discussion based on the COVID-19 experience clarified that placebo-controlled studies after the establishment of effective and safe interventions must be limited to the situations in which this intervention has not been shown to be effective and safe (e.g., populations excluded from the clinical trials). It was also clarified that post-trial access to proven interventions must be ensured for those who need it in the world. Thus, DoH only to suggest to "make provisions" for post-trial access in study protocols and informed consent forms is not enough.



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Schmidt described the history of the Nuremberg Trial 1946/47 to punish the War Crime of Nazi Doctors' human experimentation and the establishment of the DoH. He mentioned the importance of the DoH to ensure protection of vulnerable research subjects, presenting one example of unethical influenza vaccine trial by global companies involving homeless people. Kimura underlined Japanese war crime of human experimentation in China. Greco mentioned an unethical observational study of the United States on Hiroshima bombing survivors without providing care. The debate led to our determination to avoid exploitation of vulnerable study participants.

In the Day 2 session, Dhai and Aloudat strongly argued for unequal allocation of COVID-19 vaccines and need of humanitarian, alternative framework of medicines development and health systems to ensure fair, equal access to effective interventions for all who need it. It was timely that discussions on the TRIPS (Trade-Related Aspects of Intellectual Property Rights) waiver for COVID-19 related products have made a big progress at the beginning of June this year. Dhai is a founder of the Steve Biko Centre for Bioethics overcoming apartheid and now engaged in vaccine allocation programmes in African countries. Aloudat is a Syrian physician who has been engaged in Access Campaigns of Médecins Sans Frontières (MSF). Greco articulated the statements of international documents regarding post-trial access, in most of which he had participated during the development process. Showing the successful experience of Brazil, he argued the need for changes in these important documents to make sure it is a right of the participants of post-trial access to products that have shown to be effective and safe. He added that this right to access at the post clinical trial should help establishment of a more difficult but needed fight for equal access in public health to needed products to all.

Kloiber stressed that inequity in this world was not happening since the COVID-19 pandemic, but it has been existing and revealed by this pandemic. Both Kloiber and Parsa-Parsi expressed the importance of a continuous discussion and suggested the possibility of future DoH revisions. Crawley stressed the importance of research ethics by more focusing on public health responding to actual problems. All the discussants agreed in the continuing discussion. Johanna Schenk, member of the IFAPP Communication Working Group, extended "Congratulations on this thought-provoking meeting, looking forward to future collaborative efforts of IFAPP".



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Screenshot at the end of the second day, just a little bit edited, and including photos of some speakers and active participants who could not stay until the end of the second day, under their permission of using images. There were 110 registrants and about 60 participants were confirmed, and most of them participated at both dates. The proceeding of this webinar is to be published in the Journal Clinical Evaluation.

http://cont.o.oo7.jp/specialissue_e.html

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5. Greco DB. Ethical limits to placebo use and access to Covid-19 vaccines as a human right. Indian J Med Ethics. 2021 Apr-Jun;VI(2):1-14. doi: 10.20529/IJME.2021.027. PMID: 33908350.
6. Macklin R. Double standards redux. Indian J Med Ethics. 2021 Apr-Jun;VI(2):1-7. doi: 10.20529/IJME.2021.021. PMID: 33908355.
7. Macklin R. Against Relativism: Cultural Diversity and the Search for Ethical Universals in Medicine. Oxford University Press (1999)

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

The Brazilian Association of Pharmaceutical Medicine (SBMF) Completes 50 Years in 2021

The SBFM is an entity that brings together health professionals who work in the Pharmaceutical Industry. Fifty years ago, it was formed only by physicians who worked especially in the regulatory area and clinical research. As years went by, other professionals, especially pharmacists, joined it, as the technical complexity of drug regulation increased, and because of the emergence of a rigorous pharmacovigilance and quality control.

Since the beginning, the SBFM has always praised the importance of clinical research and ethics as a fundamental pillar for drug development. Therefore, we have placed ourselves as a bridge between the pharmaceutical industry, authorities and medical societies to develop education and participate in the

discoveries of innovative products, sometimes for unmet medical needs. We also brought home the ambitions of these stakeholders for a conduct of excellence in compliance, their yearnings for a strong value-added relationship, which led to the emergence of the Medical Science Liaison (MSL) professional.

In Brazil, we had an active participation in the introduction of "Good Clinical Practice" in clinical research. We followed the regulatory initiatives of clinical research and participated in numerous meetings with the authorities to explain the importance of having a technical regulation that aimed, for the benefit of the patients, to have quick access to innovative therapies.



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We have been heavily involved in education for establishing research ethics committees across the country. We are currently engaged in strong advocacy for drafting a law to regulate clinical research in Brazil. For this, we participate in joint meetings with other entities that represent CROs and researchers.

The SBMF has a history of partnership with INTERFARMA, the official entity that represents the Pharmaceutical Research Industries, that are involved in research and launch new medicines. We jointly participate in educational campaigns for the population and we support the entity in meetings in need of scientific support. Currently, we have jointly set up a course for legislative professionals on the development of medicines. The aim of this course is to provide politicians with knowledge about the phases of medicines development, human research, drug regulation, patents and the incorporation of medicines into government lists. The aim of this course is to bring greater knowledge in the policy environment about how pharmaceutical science participates in the health of the population. This need was evident in the political environment of COVID-19, where numerous discussions occurred as a result of misinterpretations of clinical results from research with vaccines or other drugs without proven efficacy.

The SBMF also contributes to the education of authorities who decide on the incorporation of medicines in the public sector. We received a request to design a course on pharmacoeconomics and clinical research in rare diseases. This course also takes place in partnership with INTERFARMA and arises from the pharmaceutical industry's difficulty in promoting authorities' understanding of the complexity involved in interpreting scientific data related to rare diseases. This course will take place in the second half of 2021.

SBMF has promoted several update courses on relevant topics in Pharmaceutical Medicine such as pharmacovigilance, career in Pharmaceutical Medicine, patient advocacy for patient associations, compliance, and vaccines. In addition, we organise meetings to discuss topics on legislation and regulation. Most of these courses have been done in collaboration with medical associations like AMB (Brazilian Medical Association). The strong relationship built between SBMF and AMB during the last 20 years turned into a direct collaboration of SBMF members to become official representatives of AMB in the World Medical Association matters such as Medical Ethics Committees and the Revision of the Declaration of Helsinki.

SBMF also works in close collaboration with the Academy of Pharmaceutical Sciences of Brazil (ACFB) with their academic and educational activities.

SBMF has institutional and individual members whose membership fees ensure the sustainability of its offices in São Paulo.

Helio Osmo, MD, MBA, GFMD
President SBMF



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DIRETORIA SBMF
GESTÃO 2020 - 2021

 Heli Osma Presidente Zambon Brasil	 Charles Schmidt Vice-Presidente TCM Santa Casa SP	 Marcelo V. Lima Secretário Geral Bleu Farmacêutica	 Abner Leão Secretário Adjunto Takeda	 Stevie Zung Tesoureiro Aché	 Wellington Briques Tesoureiro Adjunto Canopy Growth	 Gustavo Kessabing Diretor para Assuntos Institucionais IFAPP Academy	 Bernarda Barros Diretor Científica
 Dagberto Brandão Conselheiro Consultivo PKC do Brasil	 João Massad F. Conselheiro Consultivo	 Sonia Dalmeida Conselheira Consultiva Recapta Biopharma	 Angela King Conselheira Consultiva Pfeizer Nafar Advogados	 Eduardo Motti Conselheiro Consultivo			

PESQUISA CLÍNICA NO BRASIL
acelerando para o futuro

LIVE DIA 25 DE JUNHO ÀS 18H

 Heli Osma Presidente SBMF	 Charles Schmidt Vice-Presidente SBMF	 Nelson Mussolini Presidente ABRAFARMA	 Rodrigo Guimarães Diretor Presidente Abraxis
 Freddy Goldberg Diretor Clínico	 Jorge Raimundo Advogado(a) de Negócios SBMF Assessoria		

Informações e inscrições:
joanna@taoassessoria.com.br ou +55 11 98156.0361
Acesso pelo site www.sbfm.org.br

O Compliance JUNHO 26
no trabalho desenvolvido pelo MSL

WEBINAR GRATUITO DAS 9H ÀS 10H30

PROGRAMAÇÃO

Administrando o conflito entre as expectativas comerciais e as orientações de compliance.
André Bressan - Insulin & Biopharm Medical Manager - Novo Nordisk

Nível atual de satisfação do HCP. O que mudou em relação ao compliance frente ao novo cenário.
Ana Paula Neves - Diretora Executiva de Ética & Compliance - Takeda

Como encontrar e abordar novos médicos, dentro das premissas de compliance.
Sandra Franco - Consultora Jurídica referência nacional em Direito Médico e da Saúde.

Mesa redonda com os palestrantes
Coordenador: Charles Schmidt - Vice Presidente - SBMF

Acesso pelo site www.sbfm.org.br

VAGINAS COVID-19
DESAFIOS E ESTADO ATUAL
29-07 19h30 às 21h

Coordenador: **Dr. Eduardo Motti**

Das instituições:  

INTRODUÇÃO
Dr. Heli Osma (Presidente da SBMF)
Presidente da Comissão Coordenadora da Interfarma

DESAFIOS REGULATÓRIOS DOS ESTUDOS CLÍNICOS DE VACINAS CONTRA COVID-19 NO BRASIL
Conferenciantes: **Martina Alves de Souza** - Coordenadora do CORIC - ANVISA

VACINA SINOUSAC: PARCERIA INSTITUTO BUTANTÁ (OSIATIS), FAPESP, PRODUÇÃO
Prof. Dr. Roger Kalish - Professor de Doenças Infecciosas do ICM-PUSP e Investigador no estudo de vacina Sinovac em Brasil

VACINA OXFORD-ASTRAZENECA: PRODUÇÃO SINOSAC-ASTRAZENECA, OSIATIS, FAPESP, PRODUÇÃO
Dra. Maria Augusta Bernardes - Diretora Médica Astra-Zeneca

Inscrições e acesso no site www.sbfm.org.br

COVID-19
Desafios dos Centros de Pesquisa Participantes
31-08 19h30

Das instituições:  

PALESTRANTES

 ANA CAROLINA DE MORAES Diretora Médica de Pfizer Brasil	 DR. CRISTIANO ZANETTI Diretor de Centro Pesquisa de Investigação Clínica - IDPO	 DR. EDUARDO COLUCCI Professor Associado, Dept. de Clínica Médica, Faculdade de Medicina de Ribeirão Preto - USP	 DRA. LUANA FERRAZ Coordenadora de Pesquisa Clínica - IC-IMP
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Inscrições e acesso no site www.sbfm.org.br



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COVID-19 Pandemic in the Mediterranean Area: Experience in Spain, Italy and Greece

Many countries in Europe and all over the world were severely affected by the coronavirus pandemic. To better understand both the natural course of the disease and the best therapeutic options to be offered to patients in the different stages of the disease, several clinical trials were initiated both in Europe, in the United States and in other countries worldwide. The webinar held on June 17, 2021 gave an overview of the pandemic in Spain, Italy, and Greece and the most relevant research activities which were implemented.

The introduction to the webinar was carried out by Dr Isabel Sanchez-Magro, the President of the Spanish Association of Pharmaceutical Medicine (AMIFE). In her short presentation, Dr Sanchez-Magro underlined three phases of COVID-19 in Spain: in the initial phase the Spanish healthcare system was mainly dedicated to COVID-19 patients thus reducing other specialties consultations to minimal or phone consultations; when the recovery started: hospital specialists recovered delayed consultations and virtual or limited presential meetings ensuring safety distance were initiated; finally, back to normal: hospitals recovered normal activity and face-to-face meetings were allowed. The pharmaceutical industry strongly supported all these measures, organised virtual meetings with Medical Directors aimed at sharing vision and experiences and allowed some pharma professionals to participate voluntarily in hospitals.

The first presenter was Dr Cesar Hernandez, Head of the Department of Medicines for Human Use at the Spanish Medicines Agency who gave an overview of the COVID-19 pandemic in Spain and the role of the Medicines Agency. Starting with concerns about supply and availability of certain products coming from China, from January 2020, they tried to build an emergency stock for lopinavir/ritonavir, ribavirin, remdesivir (very far from what was finally used) and first international meetings (ICMRA, WHO) on preparedness, vaccines, etc. were initiated.

There were so many challenges to overcome: to secure supply of medicines needed; to facilitate options for treatment and prevention; to solve operative barriers both internal and external. All these challenges required timely action in a very changing environment and work closely with all stakeholders and integrate work at national and international level.

The Agency worked towards sales control, stock control and forecast on product release (by implementing an obligation for the industry and a new IT tool to report daily), adapting production and distribution processes to the needs (crossing information with ICU admissions, for daily contact with Healthcare Providers (HCPs), hospital and regional managers for the NHS, and scientific societies), incentivising evidence generation while satisfying a health demand by HCPs; rolling review of Clinical Trials (CT) in close collaboration with Ethics Committees and supporting larger CTs through the Innovation Office.

The main objective of the Agency was to support R+D (Research + Development) for vaccines development, secure access to medicines, define needs and scenarios, promote capacity for production and build international alliances. Dr Hernandez concluded his presentation highlighting the following points: As a Medicines Agency, they are at the service of the society; more preparedness means more resilience; right balance between urgent need and evidence generation; need to close the circle between research and authorisation; more cooperation and less competition.



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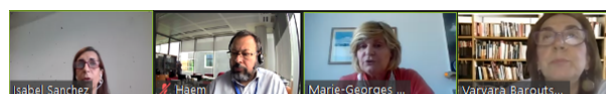
The next presenter was the President of SIMeF, Dr Marie-Georges Besse, who focused on Italy's experience with COVID-19 as well as the role of SIMeF during the pandemic.

The presentation included demographic data related to Italy's experience with COVID-19 (number of cases, casualties, etc) as well as vaccination data at the European level. More specifically, Dr Besse illustrated data from Italy and other European countries, discussing the percentage of the population vaccinated with at least one dose of the vaccination as well as the share of population fully vaccinated per country. It was interesting to learn the percentage of the fully vaccinated population is 20.5%, which translates into 12.4 million as per ourworldindata.org (data as of June 3, 2021) during this presentation.

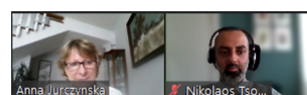
Regarding the actions taken by SIMeF to engage and maintain contact with its member base, through a number of web-based activities (webinars, online live discussions, and others) the organisation managed to successfully network with other scientific societies, initiate a debate with the academic world and reinforce the capacity to involve institutions.

Dr Varvara (Barbara) Baroutsou, President of EL.E.F.I. and IFAPP President Elect was the next presenter who focused on Research, Pharmacoepidemiology and Pharmacovigilance response to the COVID-19 pandemic in Greece.

The presentation included epidemiology data specific to Greece providing a high-level overview of the situation in Europe. The next topic covered was the National Campaign of COVID-19 Vaccination also known as Project "Eleftheria", a fully digitalised programme with appointments booked solely online, SMS notifications and e-vaccination certification issued upon completion of the vaccination. As part of this topic, the vaccination progress in Greece was also discussed.



COVID-19 Pandemic in the Mediterranean Area: Experience in Spain, Italy, and Greece



In addition, Dr Baroutsou illustrated the activities carried out by EL.E.F.I. since the beginning of the pandemic, which had a positive impact on the relevant stakeholders involved. Some of such activities included a Clinical Research Position statement published March 2021, COVID-19 impact on Pharmacovigilance, COVID-19 Clinical Research Forum established April 2021, RWE, MSL Day and Patient Support Programmes during the COVID-19 pandemic.

The end of the presentation focused on the lessons learnt during these challenging times and the room for improvement available. More specifically the findings included (but are not limited to) the need for closer collaboration via the concept of virtual trials and full use of available technology, adopting a patient-centric approach and have new technologies assessed and adopted faster by regulators, to ensure successful clinical trials even during a pandemic.

We would like to thank the organisers IFAPP and IFAPP Academy for the opportunity, as well as all the speakers and participants for their contribution.

Anna Jurczynska, MD, AMIFE Board, IFAPP Delegate

Nikolaos Tsokanas, Biomedical Scientist MSc, MBA, EL.E.F.I. Board Member



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Research Perspectives at the Newly Established Clinical Research Coordinating Centre of Semmelweis University, Budapest, Hungary

Semmelweis University (SU) has always been defined by the threefold mission of education, research and patient care, which has been woven into its more than 250 years of history. Ever since its foundation in 1769, SU has stayed true to its core values and has not only become Hungary's leading health care provider, but also an internationally recognised research institute. SU is an excellent location for the development of novel drugs and medical devices and it supports the biopharmaceutical and life science services industry by conducting clinical trials ranging from first-in-man to post-marketing studies.

Recently, SU identified the need to further develop the internal R&D and innovation support system (management and new infrastructure) and to further motivate and assist researchers to boost their scientific performance. The newly established Research Development Innovation (R&D&I) support system, incorporating the Clinical Research Coordinating Centre (CRCC), is involved in optimising their workflow and ultimately contributes to the efficiency, quality, and success of SU's overall output.

Adapting to an increasingly complex research environment goes hand in hand with the increasing need for dedicated and experienced clinical study personnel. Having a staff of high professional standards and boasting cutting edge instrumentation, SU provides optimal circumstances that attract drug development companies to the university. The more industry partners SU attracts, the more contracts for clinical trials it can secure, thus boosting the university's scientific performance. This enables the university to advance in rankings and to get to the forefront of international research.

It also allows SU's patients to be provided with the latest therapeutic and diagnostic options and doctors to gain first-hand experience.



János Filakovszky

The aim of CRCC within the university's R&D&I ecosystem is to simplify and streamline the administration of the clinical trial start-up process, to support patient recruitment, to implement new technology and digitalisation and to strengthen collaboration with industry players.

Speeding up administrative and authorisation procedures is also an important factor in providing efficient and seamless operation. The contract negotiation and signature process, for example, should not take longer than 20 days. CRCC seeks to have the institutional contract signed parallel to the Health Authority approval to accelerate site initiation and to make more time for patient recruitment. A hot wire to the sponsor will keep trials on schedule and costs within the budget. CRCC additionally provides internal quality management. Overall, CRCC monitors and supports the entire clinical development process from the initial inquiry throughout the contracting and conducting phases to the closure of the trial.



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For early-stage clinical developments, SU established three Phase I Units accredited by the competent authorities. In accordance with the current regulations in Hungary, all Phase I Unit leaders are qualified clinical pharmacologists. The Phase I Units are at the Department of Internal Medicine and Oncology, the Heart and Vascular Centre, and the 2nd Department of Paediatrics. Along with the Phase I Units, SU clinical departments perform close to 200 clinical trials every year. More than 3,000 active clinical trial patients per year benefit from innovative diagnostics and therapy. SU also works in close cooperation with key opinion leaders to support scientific oversight and to decide on the optimal operational delivery and clinical trial execution.

The most important research projects are translational research of cardiovascular and oncological diseases, diseases of the central nervous system and immunological disorders, molecular biomarkers and molecular medicine, the development of imaging procedures and devices, bio-engineering, big data, e-health, and personalised medicine. Besides clinical trials in new therapeutic areas CRCC's core strategic objectives are implementing digitalisation, supporting the application of new technologies, such as remote monitoring possibilities, decentralised clinical trials execution, e-consents, e-patient internal recruitment, and referral systems.

The new R&D&I system's approach to coordinate clinical trials at the university, its ability to react promptly to internal and external environment changes and its flexibility give a competitive advantage for SU among the university networks and professional clinical research sites.

With the establishment of CRCC along with the involvement of other new and existing organisational units, the entire R&D&I support system at SU has been renewed and strengthened. Its goal is to increase the quality, efficiency, volume, and income-generating capacity of scientific activities at the university, which is essential for future success.

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From left to right: Dr. Domokos Csukás, Dr. Péter Hegyi, Dr. János Filakovszky, Dr. Renáta Papp, Dr. Péter Ferdinandy, Dr. Zoltán Benyó, Peter Szluca, Dr. Gyula Péter Szigeti, Dr. Zoltán Vokó



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