IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine

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Patient Christmas Letter

Dear Santa,

An event has suddenly challenged my world and the very core of every nation, community and families.
Physically, mentally, emotionally and spiritually we became vulnerable, lost in space.
Continuously moving and looking for answers, questioning: Why has it happened? What went wrong, who has started it all, when will it end?
Seeking stability, access to solutions and longing to be understood and cared for!
Learning to adjust to the ever-changing threat to life and existence.

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Building a future in times of uncertainty and vulnerability.
Battling fears that ourselves have tried to search for a solution and determined to avoid reinfection.
Searching for the path that history has not thought of in our modern world.
Looking up to the sky and fighting for my breath… with the hope of being beside a loving soul to ease the transition.
Pain itself has become a solution to the hope that was lost.
Many lives have been sacrificed before an initial solution was introduced to address our concerns.
Not everyone was able to wait for that glimmer of hope that we were waiting for. Control was never in our hands….we were just waiting and living each day…
Social distancing has become a new norm and practice within family circle and in public places.
A separation that has brought distance to others but closeness to some…
Impacted in all directions, work, finances, relationship, living in the new normal…
Positively seeking and focused to celebrate Christmas with a New Cheer this season!

Be my North Star, lead us to the place where our hope was born and give us a reason for the celebration!

Yours truly,
Patient

Rodelio Camesa Bito, MD
Associate Medical Director
PSSR- Pfizer Inc. (Philippines)
Member of the IFAPP Communication Working Group

The IFAPP Communication Working Group Welcomes a New Member

I trained as a Biomedical Scientist in University of Ulster and worked in the clinical laboratories of Musgrave Park Hospital Belfast, UK. In 2011, I completed my PhD studies in the Centre for Cancer Research and Cell Biology at Queen's University Belfast studying small molecule therapies and genetics in haematology and leukaemia.

Upon completion of my PhD, I moved to Dublin and began work as a postdoctoral researcher in the Royal College of Surgeons in Ireland (RCSI). As a member of the Drug Delivery and Advanced Materials Team, I worked in gene therapy development and became pharmaceutics lecturer and principal investigator in RCSI in 2015. During this time, I obtained my qualifications in Health Professions Education.

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Since 2019, I have been Assistant Professor in Pharmaceutical Medicine in Trinity College Dublin, the University of Dublin where I manage our postgraduate diploma and MSc in Pharmaceutical Medicine courses. My research focus has also expanded into medicinal lifecycle and regulatory impacts. Within the department, we coordinate with pharmaceutical healthcare bodies and agencies based in Ireland and the EU, as well as members of the Association of Pharmaceutical Physicians of Ireland. Our courses are educationally supportive of the Higher Specialist Training programme with Pharmaceutical Medicine as a recognised medical specialty in Ireland since 2005.

Having followed the work of IFAPP for a long time I was delighted to become an individual affiliate in 2021 and in particular a member of both the Communications Working Group and the Education and Certification Working Group. Through this, I hope to contribute to IFAPP ambitions as well as to the advancement and dissemination of Pharmaceutical Medicine matters.

Joanne M Ramsey PhD DPP
Assistant Professor in Pharmaceutical Medicine in Trinity College Dublin, University of Dublin

Get Acquainted with the Italian Society of Pharmaceutical Medicine

A Bit of History
SIMeF was established in 2018 from the Society of Applied Pharmacological Sciences, founded in 1964. The change of name was an important decision, taken to represent the reality of the Society that had evolved over the years and also to symbolically underline the link with the international world of Pharmaceutical Medicine.

The Mission
With approximately 1,000 members, SIMeF is the reference Italian association for all professionals involved in the development of therapeutic agents and related disciplines. SIMeF's mission is to support the research and development of new therapeutic agents; to foster the dissemination of knowledge in both the preclinical and clinical fields; to help the scientific and professional training of young professionals in the field of the development of therapeutic agents.

SIMeF represents a unique reality in the field of Scientific Societies; it is characterised by multidisciplinary expertise and the fact that its members come from different areas: industry, contract research companies, universities, administrative institutions.

It is precisely the multidisciplinary nature of our Society that allows us to be an authoritative scientific and regulatory reference for those working in the world of medical devices and food supplements, and to provide information for those working in roles of growing interest such as patient partnership and medical science liaison.

SIMeF is a meeting point between professionals working in the industry and representatives of the institutions and authorities that regulate the world of pharmaceuticals, medical devices and healthcare in general.

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The Council and the Working Groups

To address its multiple activities, SIMeF is organised into twelve working groups (see table). The working groups plan and carry out the scientific and educational activities of SIMeF under the guidance of the Council, elected by the Members every three years, and the President, elected by the Council.

The Working Groups of SIMeF		
Clinical Research & Medical Affairs	Italian Biostatistics Group (IBIG)	Italian Group for Quality Assurance in Research (GIQAR)
Institutional Affairs	Food Supplements	Legal Affairs
Market Access & HTA	Medical Devices	Observational Studies - RWE
Patient Partnerships	Pharmacovigilance *"E. Montagna"*	Press Relations

Marie-Georges Besse, SIMeF President

and Salvatore Bianco, SIMeF Delegate to IFAPP

In addition to the Working Groups, it is to be mentioned the SIMeF Giovani section, which is not a specific working group, and mainly aims to bring together young members under 35. The SIMEF Giovani section deals with cross-cutting issues that are of interest to younger members, such as how to approach the world of work or training. The SIMeF Giovani also promote the active collaboration of its members with the existing working groups.

The Journal

The official journal of SIMeF is “Il Giornale della SIMeF”. The "Il Giornale della SIMeF" is more than a society bulletin. In addition to reporting on the activities of its many working groups, each issue of the SIMeF journal publishes extensive articles on topics of relevance and hosts authoritative contributions from commentators who are members of SIMeF or external to the Society, both Italian and foreign. The "Il Giornale della SIMeF" is published online and is now a

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widely read journal even beyond the Society. SIMeF activities are also presented through the website www.simef.it and our LinkedIn page.

SIMeF and IFAPP

As we wrote at the beginning of this short article, one of the reasons for changing the name of the Society was to emphasise the link with Pharmaceutical Medicine at an international level and in its broadest sense. The President of IFAPP, Dr Marco Romano, is the Past President of SIMeF, and SIMeF participates with its national delegate in the meetings of the IFAPP House of Delegates. The IFAPP bulletin IFAPP TODAY is distributed to our members via the SIMeF website. In the last issue of "Il Giornale della SIMeF" Dr Marco Romano presented the activities of IFAPP to our members. We think this is good and that more can be done. This article aims to make SIMeF better known to IFAPP members, and we hope to develop more and more collaborations and common activities in the future.

Dr. Salvatore Bianco, MD PhD, Founder and Chairman, AKROS Bioscience Srl, SIMeF Delegate to IFAPP, Pomezia (Rome), Italy
Marie-Georges Besse, Director Medical Affairs, Servier, and SIMeF President, Rome, Italy

How does Medical Device Regulation Translate in Real Life: Sharing Learnings

4 November 2021, EL.E.F.I.& GPMed Network Webinar Summary

The new EU Medical Device Regulation (MDR) 2017/745 and In Vitro Diagnostics Regulation (IVDR) 2017/746 took finally effect in the European Union on 26 May 2021 after approximately 13 years of consultation and preparation.

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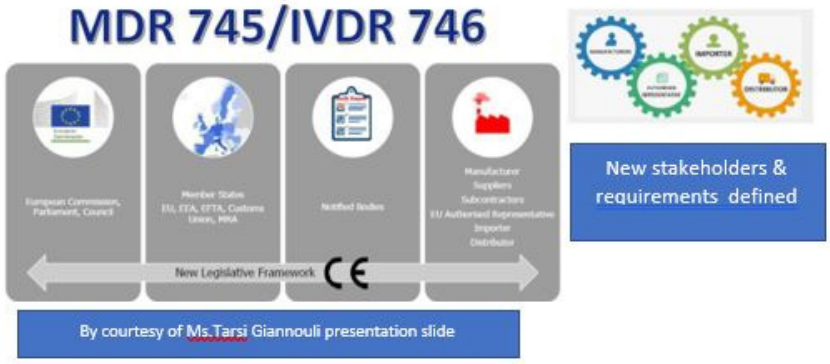
The new rules introduced significant changes to enhance the quality and safety of medical devices by strengthening how they are evaluated and certified ahead of market entry; make the data used for approvals more transparent; improve post-marketing surveillance with the expectation to reduce administrative burdens.

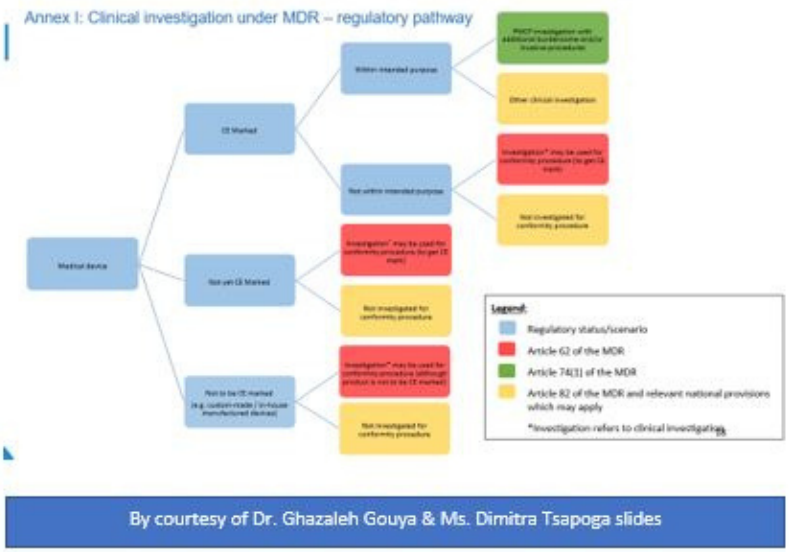


By courtesy of Ms.Tarsi Giannouli presentation slide

Despite the beneficial changes of both regulations, challenges to implementation remain according to the real-life experience of EL.E.F.I., Greek Pharmaceutical Medicine members and stakeholders, who had a webinar exchange on 4 November 2021 with the participation of

- **V. Safra**, PharmD, Deputy Head of the National Medical Devices Regulatory Agency,
- **Tarsi Giannouli** Physics BSc, Biomedical Engineering, MSc, DIC, Deputy Manager PC Medical, TÜV HELLAS (TÜV NORD),
- **EL.E.F.I. Experts: Marianna Karafoulidou** PharmD, **Vassiliki Kliafa**, Chemistry BSc, **Joseph Athanassiadis**, Chemistry BSc, **Dimitra Tsapoga**, Biotechnology MSc, **Varvara Baroutsou**, MD, PhD, Internist, GFMD, EL.E.F.I. President and IFAPP President Elect,
- **Ghazaleh Gouya-Lechner**, MD, Founder of Gouya Insights, GPMed (Austria) Board Member and Head of the IFAPP Communication Working Group.

Ninety-four participants engaged in an intensive dialogue with speakers and moderators sharing their learnings and challenges with stricter rules in force and unknowns of their implementation.



By courtesy of Dr. Ghazaleh Gouya & Ms. Dimitra Tsapoga slides

Everyone welcomed the improvements that new regulations bring, namely greater involvement of scientists, clinicians, and engineers in the scrutiny of evidence and certifications, stronger safety and surveillance requirements and access to clinical performance data, particularly for high-risk medical devices and for in vitro diagnostics.

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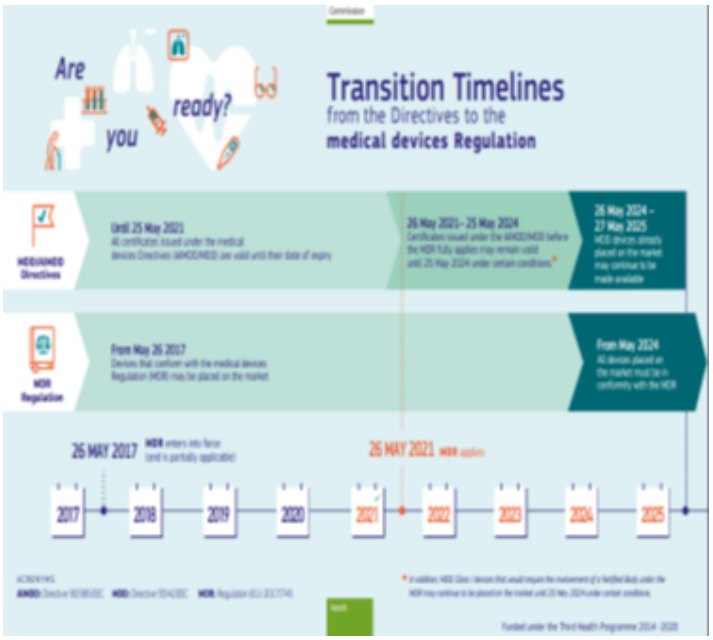
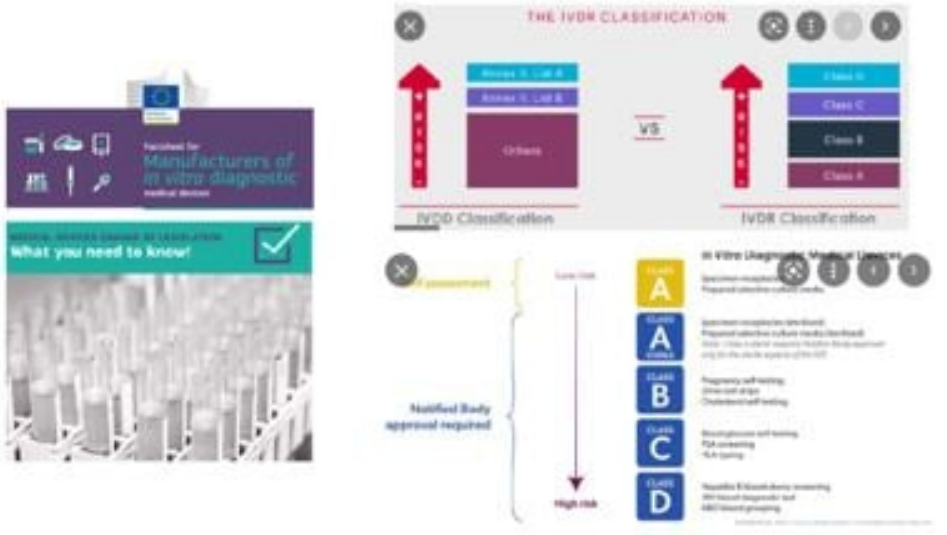
A number of common challenges between Greece and Austria were detected and are listed below:

- Transition period to MDR for existing products
- EUDAMED not being fully operational
- Uncertainties around the procedures for high-risk devices
- Major changes in clinical evaluation and clinical development
- Lack of guidance for mandatory requirements regarding clinical investigations becoming a burden for sponsors, ethics committees, authorities, and investigational sites due to clinical trial complexities



By courtesy of meeting presenters slides

A general concern from the audience about whether adequate resources are available to implement the MDR, due to the insufficient number of 23 currently approved notified bodies to certify medium-high risk medical devices. A higher capacity concern was expressed for the in vitro diagnostics conformity assessment by only 6 approved notified bodies so far.



By courtesy of Ms. Tarsi Giannouli presentation slide

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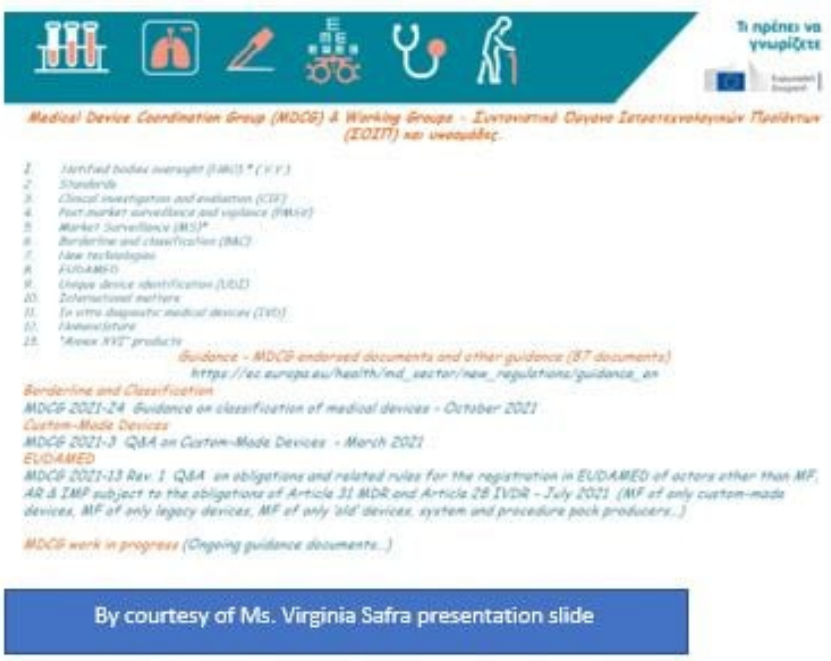
It was clear from the meeting discussions that despite remaining uncertainties on various fronts, it is important that MDR operates, and by gaining experience on how it works and which issues arise, Medical Device Coordination Group (MDCG) reviews and further updates may be the state of play.



By courtesy of Ms. Virginia Safra presentation slide

The meeting concluded on the lessons learnt during these challenging times and the need for a continuous dialogue & training. More specifically the findings included the need for closer collaboration of stakeholders and crosstalk with regulators for needed guidance and resources, adopting a patient-centric approach under the current complexities and have the fast-evolving new technologies robustly assessed to ensure a safe transition with the MDR 2017/745 & IVDR 2017/746 Regulations and successful outcomes even during an ongoing pandemic.

As a matter of fact, the Greek-Austrian networking exchange was greatly appreciated by the attendees not only as part of the middle size perspective of two European Union countries but also from the interactive impact of two Pharmaceutical Medicine associations, members of the IFAPP organisation showcasing a collaborative spirit and connectivity interest.

For your reference to the meeting presentations please visit EL.E.F.I.'s website.

As author of this article and member of the organising committee of the event, I wish to express my sincere thanks and gratitude to all speakers, moderators, and colleagues for their contribution to an engaging and highly insightful meeting.

Dr Varvara Baroutsou, Internist, GFMD, Independent Medical Consultant, Pharmaceutical Medicine Consultant EL.E.F.I. President, IFAPP President Elect.

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Clinical Trial Disruption: Getting Back on Track, Part 1

The coronavirus pandemic is having a major impact on initiating, conducting, and completing clinical trials. There has been lesser enrollment of patients into ongoing or new studies (not related to the pandemic), while continued treatment and follow-up of patients already in trials have been curtailed or adapted to minimize risk. This may have a significant impact on the timeliness of clinical trial data gathering, as well as potentially introducing risk to the resulting evidence base (for example, lack of statistical power, important missing data or altered outcome measures).

Latin America is no different than the rest of the world when it comes to clinical trials. Over 80 percent of the Latin America market share of pharmaceutical sales and growth is distributed among Mexico, Argentina, and Brazil, in addition to new opportunities in other Latin America countries, such as Chile, Peru, Costa Rica, the Dominican Republic, Ecuador, Guatemala, and Panama.

However, it is important to take into consideration what Latin America has to offer with respect to types of prevalent diseases, a diversity of sites for trials, timelines, availability of resources – researchers, hospitals, and patients – or pharmaceutical companies and Contract Research Organizations (CROs) to conduct trials. Latin America is a vast region that includes Mexico, Central America, the Caribbean and South America. The average annual growth rate of trials in Latin America was 20 percent in other topics not related to the pandemic. Nowadays, most clinical trials are directly related to treating COVID-19, finding a cure, or winning the race to getting a vaccine on the market.

Latin America provides an attractive environment for conducting clinical trials because it holds an excellent geographical location, a diverse population of over 560 million inhabitants, with massive patient populations with all possible therapeutic indications, a ready and professional supply of research facilities, and contract research organizations offering professional services for partnering solutions in clinical studies.

As a vastly varied and populated region, Latin America provides large drug-naïve patient populations with common and special disease profiles, rapid compliant patient recruitment, motivated and experienced researchers, US and EU equivalent medical standards, and well-prepared and experienced monitoring and project management teams thoroughly trained in the International Conference on Harmonization (ICH) Good Clinical Practices (GCP) guidelines. Placing trials in Latin America provides pharmaceutical companies and CROs an array of countries and races for testing drugs, as well as a reduction in costs with strategic multicenter studies.

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The year 2020 took us all by surprise in practically every field, whether in the economic, social or political spheres and, shockingly enough, in the health sector.

Clinical trials are no exception and have been impacted in every aspect.

The COVID-19 pandemic has had global repercussions but the effect and handling of the situation has been different worldwide. The pandemic has forced all sectors to find other mechanisms and to follow new strategies, in most cases disruptive from "normality," that require adaptation to the surrounding circumstances.

Contract Research Organizations

The CROs in Mexico, as well as in other countries, slowed down at the start of the pandemic. This hindered any trial from continuing or new studies considered appropriate for Mexico from starting. At the beginning of the outbreak, minimal work was done by the CROs. Ongoing trials were halted, and new studies were put on the back burner for the time being. No new sites could be visited to see if they were adequate for trials, hospitals were switched from regular, fully staffed centers to COVID facilities, researchers were not physically visited and if at the hospitals, they were treating COVID patients. Even monitors and staff were kept from having any contact with other important trial participants – most all employees were conducting business from their homes.

Regulatory Agency

A fundamental factor in implementing and developing any clinical study has to do with the local and global regulation. The pandemic caused a paralysis in the system. The regulatory body in Mexico – the Federal Commission for the Protection against Sanitary Risks (COFEPRIS) – halted most services and in some instances stopped working altogether. It placed its attention on everything related to the pandemic, whether treatment schemes or vaccine development. This has considerably slowed down new registrations, paperwork, and submissions, as well as the monitoring of those sites that were already working. Processes were severely backed up. Now, it seems to be getting slowly back on track with new digital developments being put in place.

In addition to the above, a restructuring of COFEPRIS is underway by the federal government, which has generated a great deal of uncertainty as to the way in which this institution will be managed in the future while questioning its autonomy.

Both the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have offered and provided guidance and advice to sponsors regarding ongoing trials and the initiation of new ones. However, how the new government will handle the overall structure of the health sector is still unknown for many.

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Healthcare System

The healthcare system in Mexico encompasses both the public and private hospital sectors. According to the design of most clinical studies, these are carried out mainly in public hospitals, due to the availability of large numbers of patients at these institutions, the feasibility of recruiting them due to their meeting inclusion and exclusion criteria, and the attractiveness of a study where patients are provided all the benefits of participating in a clinical study (access to laboratory tests, treatments, and close medical follow-up).

In Part 2 of this article, we will continue examining each of the factors and parts of a clinical study, including speaking on patients participating in studies that are now limited to being enrolled since the vast majority of the hospitals where the protocols were being carried out were “converted" to sites where patients with COVID-19 are being treated.

Marlene Llópiz Avilés, MD
CEO, Clínica Responsable Operativa, S.C.
San Felipe 230 Bis, Colonia Xoco, CDMX, CP 03330, Mexico

This article has been reprinted from Mexico Business News (https://mexicobusiness.news/health/news/clinical-trial-disruption-getting-back-track-part-1) with kind permission of the publisher.

Joint Annual Symposium of the Two Swiss Societies in Pharmaceutical Medicine SwAPP and SGPM

Musikschule Florhof, Zurich, Switzerland, 17 November 2021
Expediting Drug Discovery and Development through Translational Medicine
Chairs: Jeannette Achermann, Mepha, and Nadine C. Martin, Inselspital (University Clinic) Bern
Programme Organisers: Annette Mollet, ECPM, University of Basel, SwAPP and IFAPP, and Brigitte Franke-Bray, SGPM and IFAPP

At this 26th annual Swiss symposium a welcome address was given by the SwAPP President Frank van den Ouweland, and the new IFAPP Board Member Cordula Landgraf delivered a welcome address on behalf of IFAPP outlining its new strategy since the election of new board members on 28 June 2021.

The official programme started with a presentation by Caroline Haefliger, Debiopharm, on Translational Medicine and its Impact on Drug Development. Bryan Roberts, Roche, then talked about Data Science and its impact on Expediting Drug Development.

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The next session focussed on the development from Animals to Humans with presentations by Kasper Renggli, Philip Morris, on Re-Engineering Non-clinical Testing, and Martin Wehling, University Clinic Mannheim, Germany, on Closing the Gap Between the Experimental and Basic Pharmacology and Medical Practice. Julian Gray, NC Neuroconsulting, ended the session with an overview on Determining the First Dose in Humans.

Just before the lunch break, there was a brilliant musical interlude. The performers were Les Papillons (piano and violin). Have a look at the picture.

The afternoon started with a session on Clinical Trials and with Paulo Fontoura, Roche, talking about Changing the Clinical Development Process – Translational Approaches in Spinal Muscular Atrophy. Frank Bretz, Novartis, gave an overview on Optimising Clinical Trials through Adaptive Design.

Finally, with regard to Regulatory Aspects, Enrica Alteri, just previously a senior director at the European Medicines Agency EMA, reported on the Regulatory framework for First-in-Human Trials.

As there was no escape from the current pandemic, the last presentation was given by Pietro Vernazza, formerly Cantonal Hospital St. Gallen, Switzerland, who gave a COVID-19 Update.

At the end of the afternoon, Martin Traber, Roche, SGPM President, summarised the meeting and thanked the organisers, chairs and speakers. Finally, an apéro with drinks and nibbles was offered to all.

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SwAPP: Swiss Association of Pharmaceutical Professionals – www.swapp.ch
SGPM: Swiss Society of Pharmaceutical Medicine – www.sgpm.ch
IFAPP: International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine – www.ifapp.org

Brigitte Franke-Bray, MD PhD, FFPM, GFMD, Consultant in Pharmaceutical Medicine, Switzerland, SGPM Member and IFAPP Board Member
Martin Traber, MD PhD, GFMD, Roche, Basel, Switzerland, SGPM President

Proposal for Future Revisions of the Declaration of Helsinki

The Ethics Working Group (WG) of the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) is continuously discussing critical issues of ethics in medicines development. Now, in a newly constituted WG we are scrutinising the priority setting of ethical issues which we are confronting. Data-driven research and privacy protection is one of the prioritised topics. In the previous WG, we published a paper entitled “Linking the Declarations of Helsinki and of Taipei: Critical Challenges of Future-Oriented Research Ethics” (1). That paper made a proposal for future revisions of the World Medical Association’s (WMA) Declaration of Helsinki (DoH) (2). We acknowledge that the DoH is the gold standard of ethical principles of research involving humans. Besides, in 2016, the World Medical Association (WMA) issued the Declaration of Taipei (DoT) (3) on the topics of health databases and biobanks to complement the DoH. In our above publication we proposed items considered to be necessary revisions in the DoH by linking to the DoT.

We prepared a Poster as an “infographic” of this paper and planned to publish it at the International Conference of Pharmaceutical Medicine (ICPM) in Rome, Italy, in 2020. As this event was finally cancelled due to the COVID-19 pandemic, we have decided to publish this poster in this issue of IFAPP TODAY (see page 15).

Taking this opportunity, we would like to provoke discussion on what may be necessary revisions in other sections of the DoH. In 2019, we submitted to the WMA, under a Memorandum of Understanding of mutual cooperation of both organisations, several areas to be amended in the DoH. The most recent revision of the DoH is from 2013 and, considering the rapidly evolving situation of the research landscape, especially with experience from COVID-19, it is perhaps a good time for updating our gold standard of research ethics.

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We would be grateful if we could receive feedback from our colleagues from around the world with regard to future revisions of the DoH.

Points to be revisited in the DoH:

1. Connection between DoH and DoT
2. Ethical approval and consent for secondary use
3. Incidental findings
4. Registration of “data sharing plan” and “results” in publicly available databases
5. Shared responsibility
6. Patient and public involvement plan
7. Diversity of membership and qualified expertise of Research Ethics Committees
8. Terminology of key concepts: human subjects, humans, participants, patients, etc.
9. Terminology of key concepts: medical research
10. Vulnerable populations
11. Placebo
12. Post-trial access

References:

1. Kurihara C, et al. Linking the Declarations of Helsinki and of Taipei: Critical Challenges of Future-Oriented Research Ethics. Front. Pharmacol. 2020. 11: 579714. doi: 10.3389/fphar.2020.579714.
2. World Medical Association. Declaration of Helsinki: Ethical Principles for Medical Research involving Human Subjects. Adopted Jun 1964, last amended in Oct 2013. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
3. World Medical Association. Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks. Last revised in 2016. https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/
4. Kurihara C. Webinar COVID-19 and Bioethics - Pandemic and Research Ethics: Democracy, Placebo and Post-Trial Access. IFAPP TODAY 2021; (16): 4-6.
5. Clinical Evaluation. 2021; 49 (Sup 38).

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

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Original Poster:

XX International Conference on Pharmaceutical Medicine (ICPM), 2020, Rome

Prepared for ICPM 2020 which was cancelled, then published in this IFAPP TODAY No. 19, Dec 2021

A Proposal for the Revision of the Declaration of Helsinki

to promote data-driven science and strengthening human subject protection

Chieko Kurihara, Varvara Baroutsou, Sander Becker, Johan Brun, Brigitte Franke-Bray, Roberto Carlesi, Anthony Chan, Luis Collia, Sandor Kerpel-Fronius, Peter Kleist, Luís Filipe Laranjeira, Kotone Matsuyama, Shehla Naseem, Johanna Schenk, Honorio Silva

Ethics Working Group of the International Federation of Pharmaceutical Physicians and Pharmaceutical Medicine

https://ifapp.org/working-groups/ethics-and-professionalism Search: IFAPP ethics

Background:

- The Declaration of Helsinki (DoH) was revised in 2013 and the Declaration of Taipei (DoT) was adopted in 2016 by the World Medical Association (WMA).
- DoH is for research involving human subjects including individual identifiable data or material.
- DoT is for health databases and biobanks, developed in response to expansion of data-driven research in the 21st century.
- However, ethical principles for secondary use of data/material obtained in research remain unclear.

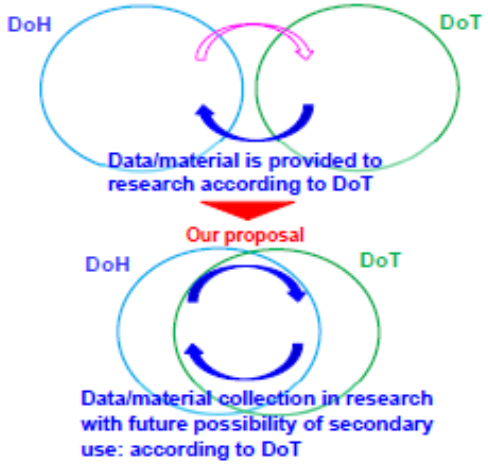
Objectives:

- IFAPP's recommendation for DoH on its necessary revisions to promote data-driven research, while continuing to strengthen human subject protection.
- This recommendation is based on official request from the WMA under the MoU for mutual cooperation.

Recommendations:

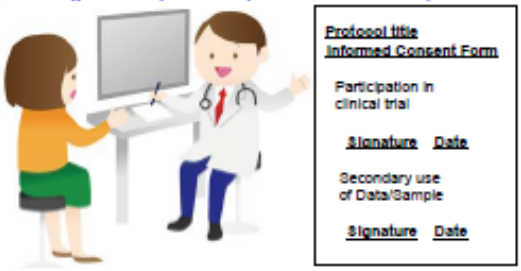
1. Connection between DoH and DoT

Data and/or biological material collected as a part of the research, which may be used for secondary analysis, should be in the scope of DoT, and this should be clarified in the "**General Principles**" of the DoH.



2. Ethical approval and consent for secondary use

- If the data/samples collected in research is anticipated to be used for other purposes after the research (="secondary use"), it should be included in the research protocol for ethical approval.
- Informed consent should be obtained separately.
- This should be clarified by revisions of **paragraphs 22 (protocol) and 26 (informed consent).**



3. Incidental findings

- The right of an individual of taking option of knowing/not knowing the research results should be assured.
- "Incidental findings" (IFs) during the research should follow the same principle, which should be clarified in **paragraph 26.** Examples:

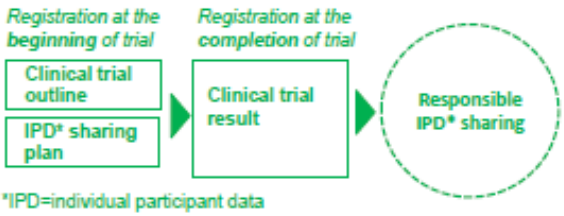
◆Imaging of brain of healthy volunteer in AD* drug study.
◆IF of brain tumor.

◆Pharmacogenetics clinical trial.
◆IF of unproven genetic factor.

*AD=Alzheimer disease

4. Sharing of study results and individual data

- In addition to registration of study outlines in public databases, registration of "data sharing plan" and "result" should be added to **paragraph 35.**



*IPD=individual participant data

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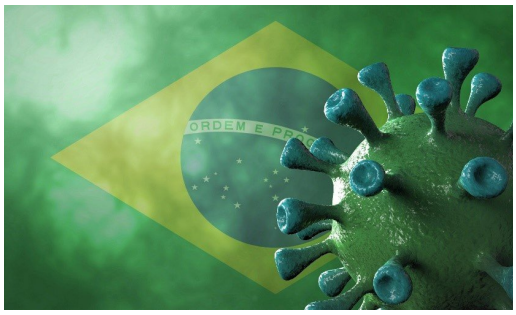
Announcement COVID-19 Webinar Update from BRAZIL: Critical Retrospective of the COVID-19 Pandemic in Brazil (2020-2021)

20 January 2022
8:00-9.30 Brazil time, 12:00-13:30 CET, 20:00-21:30 Japan (JST)

Coordinator Helio Osmo, President of SBMF – Associação Brasileira de Medicina Farmacêutica

- The Medicines approval and regulation (20 minutes) – Gustavo Mendes (ANVISA)
- The Health Professionals engagement and challenges (20 minutes) – Rosana Richtman (infectiologist - Hospital Emilio Ribas – São Paulo)
- The Bioethics perspective (20 minutes) – Celina Dias (President of Bioethics Committee Hospital Sirio Libanês – São Paulo)
- Interaction with the audience (30 minutes)



Introduction to Medical Affairs and Pharmaceutical Medicine

MEDICAL UNIVERSITY OF VIENNA | Vienna Healthcare Group University Hospital Vienna | GPMed GESELLSCHAFT FÜR PHARMAZEUTISCHE MEDIZIN E.V.

- Comprehensive overview and insights on one of the central roles in the pharmaceutical industry
- Medical Affairs as a major player in the pharmaceutical industry

Course description
Medical Affairs is an independent function in a pharmaceutical company that closely cooperates with other functional areas. The main responsibilities of Medical Affairs include Medical Information & Communication, Training & Education, Establishing of Networks with Healthcare Professionals, Medical Planning & Operations, Interventional & Non-Interventional Trials, Gathering of Insights and many more. The aim of this course is to provide a comprehensive picture of Medical Affairs in the context of pharmaceutical industry while reflecting all current national and international regulations and guidelines. It provides insights into the role of Medical Affairs in drug development and the cooperation with Marketing & Sales, Regulatory & Pharmacovigilance as well as with academic institutions.

Students will get an understanding of the international pharmaceutical market and of the importance of internal and external communication and team- and networking on national and international level.
The course provides details on different job profiles and practical tasks in Medical Affairs and furthermore on collaboration with healthcare professionals and other stakeholders.

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Target audience

- Academic & non-academic employees in the pharmaceutical industry
- Job applicants for the pharmaceutical industry
- Physicians and other professions interested in the perspective of the pharmaceutical industry

Information on the course

This part-time blended learning program allows professionals to remain on their job and to integrate the training with professional activities.

It is structured in 2 parts of blocked workshops.

Workshops are offered online through engaging webinars.

Location: Online
Language: All courses are held in English
Duration: 125 hours/5 ECTS
Certificate: Basic „Introduction to Medical Affairs and Pharmaceutical Medicine“ certificate after successful completion of Part 1. Advanced certificate after completion of Part 2.
Tuition fee: Euro 1,600 per part. Euro 3,200 in total.
10 % discount for Medical University Alumni Club members, members of the GPMed („Gesellschaft für Pharmazeutische Medizin“), members of IFAPP (The International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine) at the time of application.
Start: Yearly

Application:clinical-research@meduniwien.ac.at
Apply now: Introduction to Medical Affairs and Pharmaceutical Medicine | GPMed

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Year End Message from Our President

Dear IFAPP members,

This year has seen very important changes in our Federation: last June with the elections you have appointed new Officers who have replaced the previous ones to whom I express my gratitude for what they did for IFAPP in the past, in terms of contribution to our development and visibility in Pharmaceutical Medicine at a global level.

In parallel, I take this opportunity to wish all the best for a successful future to the new Chairs of IFAPP Working Groups (WG) and to welcome back Anna Jurczynska as Board Secretary.The new Chairs, i.e., Birka Lehmann for the Education and Certification WG, Cordula Landgraf for the External Affairs WG, Ghazaleh Gouya for the Communication WG, Kotone Matsuyama for the Ethics WG and Annette Mollet for the Young Professionals WG, will certainly ensure the continuity with the past as well as bring their expertise and enthusiasm to renovate and to give fresh stimulus to IFAPP growth and global strategy.

This year IFAPP started the Young Professionals WG to attract young members (< 40 years old) with the goal to connect them with senior and expert colleagues and to foster their continuous education and preparation in Pharmaceutical Medicine.

The main objective for this year and especially for 2022 is to engage more and more the attention and the participation of our current National Member Associations (NMAs) and Individual Affiliates (IAs) as well as to catch the interest of new ones, as it happened with the approval - during our last November House of Delegate meeting - with Sweden, Nigeria, and Australia and with IAs as new IFAPP members.

From 19 to 21 October 2022, we will hold our International Conference in Pharmaceutical Medicine (ICPM) which will take place in Athens where the President Elect, Varvara Baroutsou, will replace me as current IFAPP President. ICPM 2022 will be a great opportunity to get in contact with our colleagues both in person and virtually as the Conference will be a hybrid one to allow a wide participation at lower costs and from those countries where COVID-19 could still be present, though we all trust that in October 2022 the pandemics should have come to an end. I am sure you will take part in large numbers at this event that we sadly missed since 2018 when it was held in Tokyo while the following one did not take place in Rome in March 2020 because of the pandemics.

Let me also thank a lot for their dedication to IFAPP our Treasurer, Brigitte Franke-Bray, always committed, precise and very supportive as well as our Secretary, Caroline van Bruggen, who is always very helpful with all our members as well as with the Board.

Finally, I would like to wish you and your families a very Happy Holiday season and a joyful New Year!

Dr. Marco Romano MD PhD GFMD

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THE FLAG

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IFAPP Communication Working Group
Ghazaleh Gouya-Lechner (Chair), Varvara Baroutsou, Rodelio Bito, Brigitte Franke-Bray, Rita Lobatto, Kotone Matsuyama, Helio Osmo, Joanne Ramsey, Johanna Schenk and Peter Stilting.

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

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