IFAPP TODAY

The Global Newsletter on Pharmaceutical Medicine

THIS ISSUE

Introducing a New IFAPP Board Member: Dr Birka Lehmann

Dr Birka Lehmann was elected Chair of the IFAPP Education and Certification Working Group (ECWG) and therefore became a member of the IFAPP Board of Officers in June 2021. She has been a Senior Expert for Drug Regulatory Affairs and Lecturer at the University of Bonn, Germany, since 1998.

Dr Lehmann studied Medicine at the Free University Berlin and trained at the paediatric clinic (Kinderklinik) Norderney in Germany. Her working experience includes 9 years of preclinical assessment in the division 'Pharmacology and Toxicology' of the German Medicines Regulatory Agency (BfArM, 1) and she served as Head of Unit 'Decentralised Procedure' (1996 - 2002) and as Deputy Head of the EU Division (2000 - 2002). She was a member of and chaired the Mutual Recognition Facilitation Group and served as expert to the Committee for Human Medicinal Products (CHMP) of the European Medicines Agency (EMA).

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From 2002 – 2006 she joined the Directorate-General Enterprise and Industry of the European Commission as expert on secondment to the unit 'Pharmaceuticals' responsible for inter alia Marketing Authorisation and implementation of the Clinical Trials Directive.

From September 2006 to October 2011 Dr Lehmann was Head of Division 3 Marketing Authorisation procedure at the BfArM comprising several indication areas including cardiovascular and pulmonary diseases, antibiotics and dermatology. Dr Lehmann was then Head of the Executive Department EU and International Affairs of the BfArM from October 2011 till the end of 2015, and she was a member of the Paediatric Committee at the European Medicines Agency from 2007 to 2016. Dr Lehmann is a member of the German Society of Pharmaceutical Medicine (DGPharMed, 2).

Lecturing activities

Since 1999:	University of Bonn (Rheinische Friedrich-Wilhelms-Universität Bonn), Germany
2008 - 2016:	University of Copenhagen (Medicademy), Denmark
2006 - 2014:	Ruhr University Bochum, Germany
2002 – 2016:	University Duisburg/Essen (formerly Witten/Herdecke), Germany

Dr Birka Lehmann MD PhD GFMD
Member IFAPP Board of Directors and Chair of Education and Certification Working Group

1 BfArM: Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices)
2 DGPharMed: Deutsche Gesellschaft für Pharmazeutische Medizin e. V.

The Swedish Society of Pharmaceutical Medicine

The Swedish Society of Pharmaceutical Medicine - an Association for Doctors and other Medical Experts in the Pharma Industry Interested in Research and Drug Development

The Swedish Society of Pharmaceutical Medicine (SSPM) was founded in 1998. It was a complement to the Foundation of Pharmaceutical Medicine, created in connection to the 9th International Conference on Pharmaceutical Medicine (ICPM), held in Stockholm 1996. This conference was organised by the Swedish Pharmaceutical Industry Medical Society. In 2003, this society was integrated into SSPM.

SSPM is a society of medical expertise and expertise from other relevant areas in clinical science, medical affairs and drug development. Members of the society belong mainly to the pharma industry but also to authorities, academia and health care. The mission is to contribute to providing patients with access to adequate treatment and to contribute to create optimal conditions for drug development in Sweden. To be able to achieve our goals, we are offering regular educational seminars and symposia within current important areas. We also stress the importance of building and maintaining a strong network within our community to be able to faster increase and spread competence. The networking part has, over years, become one of the most important pieces in our work.

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In the past we used to have a number of physical meetings with invited lecturers and possibilities for members to interact. During the late years with the ongoing pandemic, we adapted our educational programmes to digital meetings, which has worked remarkably well. In order to maintain the very important objective of networking, we also started a web-based activity called Dialogforum, around areas of interest to discuss. The main focus is a dialogue among attendees, triggered by an invited person setting the scene by a short presentation of a topic of common interest, e.g., what does big pharma need to show interest in Sweden? How do HTA bodies interact - any experiences? Differences working in small and big companies - what can we learn? The Dialogforums have been short (not more than one hour) with intensive and inspiring discussions.

We are looking forward to further developing the way we work together with our members and in the light of the European/global network, continue to contribute to the best for patients and health.

Ulf Jersenius Chairman
Margareta Olsson Birgersson Board member

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Chairman

Mikael Holst
Treasurer

Andreas Fasth
Board Member

Margareta Olsson Birgersson
Board Member

Ulla Sollenberg
Board Member

How do Real World Data become Real World Evidence?

This current topic has been discussed on November 25, 2021 as an online-event organised by GPMed, the Austrian Society for Pharmaceutical Medícine. The following aspects have been covered:

- **Real World Data and the role of patients (Univ. Prof. Dr. Tanja Stamm, Medical University Vienna)**
- **Value and quality of Real World Data in Austria: an industry perspective (Mag. Bernhard Mraz, Medical Director Novartis)**
- **Real World Data from the authority's point of view – an overview of European initiatives (DI Arnold Herzog, AGES - Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH)**

In the first presentation, Tanja Stamm emphasised the role of patients in the generation of Real World Data (RWD). This requires a change in perspective for investigators to consider the issues relevant for patients. As an example, quality of life becomes more and more important the longer the duration and the observation period are. To involve patients, the value of RWD for the patient needs to be communicated while building up trust and confidence (key word: data protection).

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Solid RWD can be reliably generated using patient-oriented and outcome-standardised questionnaires. The most useful approach is to apply generic questionnaires, which allow to compare different disease entities, e.g., always stick to the same method to evaluate pain. Moreover, clinical questionnaires often omit central aspects of the patient's daily life such as fatigue, sexual activity, and others. This advocates to involve patients, to let them take part and to give them direct access to the data they generate together with other patients. This entitles patients to compare their own situation with aggregate data sets further motivating them to contribute.

To ensure this access, data systems hosting the RWD should be located at national authorities. Documentation of RWD should preferably rely on apps; in Austria there is a high level of willingness to contribute.

Tanja's summary: Real World Data provide insights, which go well beyond the knowledge obtained by randomised clinical trials. As such, RWD complement the randomised setting in a meaningful way.

Bernhard Mraz started his presentation from the industry perspective with the statement that Real World Evidence (RWE) is nothing new: we use this approach since decades in post-marketing, in case reports and non-interventional studies. There are, however, several reasons why RWE has become so important in the last time.

- Resource utilisation and allocation
- Ageing demographics with multimorbid patients
- Health Technology Assessments becoming more and more sophisticated.

Although randomised clinical trials will remain the gold standard, this approach is not well suited to fill some sorts of gaps, e.g., effectiveness in a whole population or in different countries.

He explained that compounds have been approved by the regulatory bodies without randomised clinical trials, per example in the field of precision medicine in oncology.

This leads to the use of new sources of data derived from social media, networks or blogs. With this approach, the data analyses face completely new challenges as large amounts of unstructured data have to be processed. Moreover, RWE is demanded over the whole life cycle of a pharmaceutical product (key words: patient adherence, long-term effect, sub-populations, ...) and is becoming increasingly important for decision-making in the health care sector.

Regarding availability and maturity of data, Austria is on an average position despite considerable efforts to collect data. In the academic setting, these data are per examples documented in „Health Outcome Observatories" (H2O). Their motto is: put the patient in the centre of the healthcare system! As a consequence, the initiative is conferred to patients who directly enter data into the system. This in turn would one day allow to observe online and simultaneously status and conditions, which is as relevant for the pharma industry as it is for the patient himself.
His conclusion: that's why initiatives such as H2O have the potential to induce an altered perception of RWD, their utilisation and to eventually ameliorate patient care. Hence, the industry and their advocacy groups actively support this development.

It seems, therefore, logical that in the area of RWE European initiatives have been founded as detailed in the presentation of Arnold Herzog. Europe is behind the international trend, particularly in standardised data sets for data exchange, which has prompted a new strategy. Their cornerstones are the areas "accessibility – data quality – data protection – analytical competence".

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To this aim, Europe has defined nine data rooms including a health data space to share efficiently health data across countries of the Union based on data protection as the essential prerequisite for patient acceptance. This has spurred an update in the networking strategy of EMA in order to facilitate the application of RWD/RWE in the future, e.g., in the surveillance of safety and efficacy after drug licensure. This approach comes with new challenges. The EMA Big Data Steering Group has therefore issued ten recommendations to enhance competitiveness and released a pro-active work plan covering the period up to 2023. DARWIN (Data Analytics and Real-World Interrogation Network) is one of these initiatives, designed to meet these requirements.

How do we translate RWD into RWE?

- Analysis and integration of different RWD sources
- Application of the FAIR principles to ensure data quality (FAIR=findable, accessible, interoperable, reusable)
- Transparent data analysis algorithms.

Arnold Herzog concluded in his speech: RWE is on its way and has to be implemented on a national level – there is definitely a medical need!

To summarise the online meeting: there was consensus and common understanding that the big topic „from Real World Data to Real World Evidence“ is high on the agenda. Likewise, all speakers agreed that there is still a long way to go, because we talk about a complex problem, which will not have a simple answer. To consider all necessities, sensitivities, and different motivations, is the only approach to create the acceptance needed and to convince all involved people that everybody can be on the winning side.

Univ. Prof. Dr. Robert Mader, Member of GPMed (Austrian Society for Pharmaceutical Medicine); Director for Translational Research, Department of Medicine I, Medical University of Vienna.

Electronic Medical Record Integration for Clinical Trial Purposes in Greece - Part I

The EL.E.F.I. Clinical Research and Clinical Trials Innovation Forum has tried gearing the knowledge gained from trial conduct during the pandemic and identify an area on which to focus to ensure continuity and future longevity of Clinical Research in Greece. The focus of this effort is the development and implementation of the Electronic Medical Record (EMR) for clinical trial purposes. The experts, Assistant Prof. H. Karanikas, Computer Science, University of Thessaly and member of e-healthnet.gr, and Mr. D. Zografopoulos, Data Privacy Officer (DPO) of the Ministry of Health, gave us their input on the current EMR implementation progress and the next steps. The EMR development for clinical practice is underway with high priority by the Ministry of Digital Governance as part of the “Digital Transformation Bible” project of the Greek Government.

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Prof. Karanikas analysed that technologically we are capable of collecting and interpreting Big Data in healthcare. Such data are useful and necessary to ensure valuable review of clinical effectiveness. Registries and EMRs, in addition to the patient reported information, are the main sources of such data. Clinical decisions also use secondary analysis to update efficacy and real-world evidence data. The sources that will feed into the EMR are the main electronic prescription application e-Rx (IDIKA) platform, hospital patient data, the telemedicine network, patient registries and the national health insurance payor EOPPY datasets. What we should work on is the interoperability of all these systems as we would need to have the outcome of the medical action and not only the fact that, e.g., a prescription was provided and used, or a set of laboratory tests was requested and executed.

To have reliable health data there is need to develop an EMR centrally based in IDIKA, on ICD10 classification, where validated health data will feed into. The input will include private and public health data as 60% of health information is collected in the private health provider setting. Hence the need of a multi-modular EMR that will include: i) the international standard patient summary, ii) a registry of data collected in any other health provider unit, iii) a repository of all necessary documents such as the lab results, imaging, executed prescriptions and hospitalisation discharge documentation, iv) a central metadata index and v) a connection to central repositories of patient data by use of the personal health insurance registration number, so-called AMKA and coded nomenclature (e.g., ICD10). The EMR implementation is already budgeted, and it is a priority target in the programme implemented to digitally upgrade the health system and will be complete in its entirety in 2025.

Two Use Cases (UCs) have already been tested and their specifications will be entered in the EMR. These UCs were the exchange of laboratory results in the primary care context and the Intra-Hospital Ordering and Exchange of lab results. Next UCs include the interoperability of the medical imaging domain, sharing of discharge documentation, e-prescription cycle in the intra-hospital domain, DRG (Diagnosis Related Group) information exchange, claim management from Health Payor EOPYY, e-appointment interoperability, cancer management, national telemedicine, business intelligence and digitised and scanned documents integration.

Digital implementation is not enough, however, we need legislation, funding, infrastructure, motivation and user training. To include clinical trial considerations in the EMR, we should work on a User Case to determine the specification for integration in the EMR.

D. Zografopoulos underlined that the digital implementation was accelerated by the COVID-19 pandemic. The EMR implementation has been delayed, however, due to the weight being shifted on developing digital tools for COVID management. Now we are at a breakthrough to re-focus on the EMR development. The current information in the patient records is compartmentalised and lacking some information. Needless to say, GDPR is to be implemented in all aspects of patient data collection. The issue is that there is no DPO in some hospitals, this will have to be rectified before the full implementation of the EMR. Legislation-wise, we are a step ahead, but we are catching up digitally and an EMR is expected in the next two years.

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On behalf of EL.E.F.I. Clinical Research & Clinical Trials Innovation Forum

Konstantina Papageorgiou, Molecular Biologist, PhD, Assoc. Director Clinical Project Delivery at Covance, EL.E.F.I. Board Member

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

A Critical Retrospective on the COVID-19 Pandemic in Brazil (2020-2021)

On 20 January 2022, the Brazilian Society of Pharmaceutical Medicine (SBMF) organised together with IFAPP a Webinar about the two-year retrospective on the COVID-19 pandemic.

The meeting was chaired by Dr. Hélio Osmo, President of SBMF, and three distinguished guests have participated as lecturers:

1 – Gustavo Mendes – General Manager of the sector of Medicines and Biological products from ANVISA – Agência Nacional de Vigilância Sanitária: "THE MEDICINES APPROVAL AND REGISTRATION"

2 – Dr Rosana Richtmann – Infectiologist from Hospital Emilio Ribas (São Paulo): "THE HEALTH PROFESSIONALS ENGAGEMENT AND CHALLENGES"

3 – Dr Charles Schmidt – Coordinator and Professor of the Post-Graduation Course on Clinical Research from Santa Casa de São Paulo (São Paulo): "THE BIOETHICS PERSPECTIVE"

Mr Mendes discussed the urgency of approvals for vaccines and other drugs, as well as the approval of clinical trials. ANVISA has managed to maintain, despite this emergency situation, all the necessary steps for approving medicines to ensure the safety of the population. Numerous meetings have taken place not only with the manufacturers but mainly with journalists and politicians asking for clarification. AstraZeneca, Pfizer, Coronavac (Sinovac) and Janssen vaccines were approved. Other vaccines are still under review.

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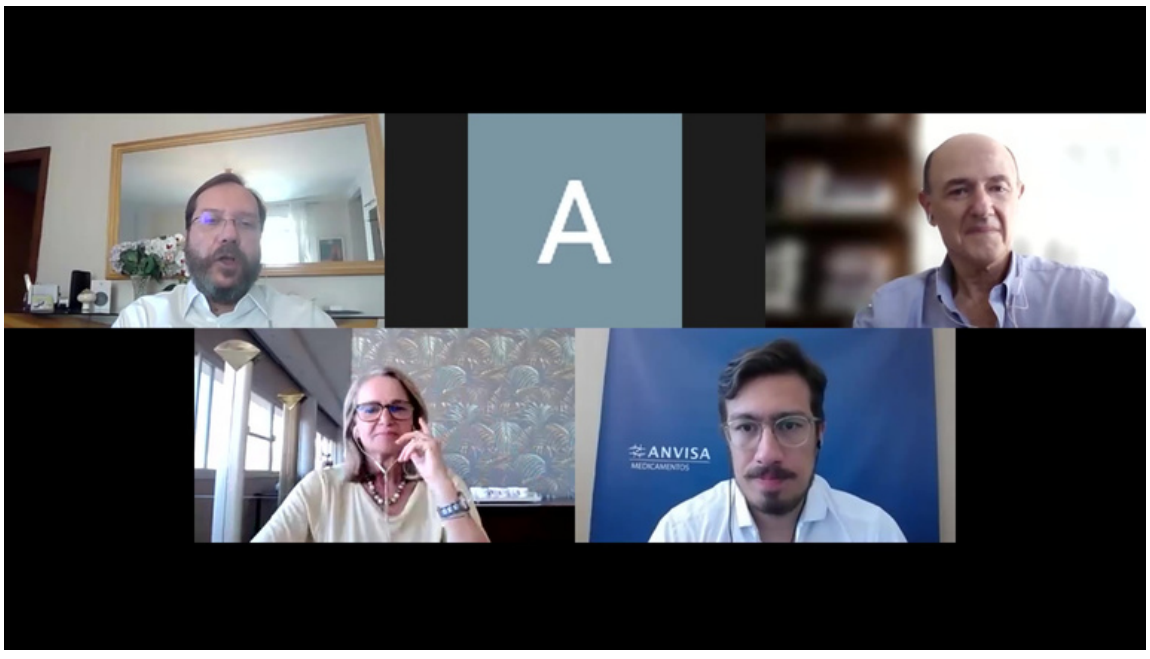
Dr Rosana Richtmann exposed the side of health professionals. Their routines were abruptly modified, and they were faced with an unimaginable challenge. They dealt with the fear of contamination of themselves and their families. They lived with the lack of resources of medicines, protective equipment, oxygen, and anaesthetics. The relationship with the population also changed. People lived in constant terror and were afraid to be close to health professionals on public transport. Health professionals were the first to be vaccinated, and this brought great relief and motivation. The pandemic was a test of life for extremely challenging situations both physically and mentally.

Dr Charles Schmidt has lived with the challenge of maintaining ethical regulation in both vaccine research and dubious medical conduct in times of crisis. Research ethics approvals that previously took at least six months were now approved in less than a week. This proved the urgent need for the approval of a specific official regulation for clinical research. On the other hand, clinical trials conducted by unprepared people without proper approval from ethics committees eventually occurred. The diffusion of treatments without scientific evidence was also a serious problem and it is still happening in Brazil. Denialist doctors spread fake news and challenged medical societies, leaving the population confused.

In this meeting we had around 80 participants from all parts of the world. Many questions were addressed to the speakers.

The meeting was also supported by other national organisations like INTERFARMA, SINDSFARM, CBDL and ANCF (Academia Nacional de Ciências Farmacêuticas)

Hélio Osmo, MD, MBA
President SBMF (Sociedade Brasileira de Medicina Farmacêutica)
GFMD IFAPP, Member of the IFAPP Communication Working Group



Dr Hélio Osmo, Dr Rosana Richtmann, Gustavo Mendes, and Dr Charles Schmidt (from left to right)

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20th International Conference on Pharmaceutical Medicine - ICPM 2022

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

"What lies ahead in 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.

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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Marlene Llópiz, IFAPP Individual Affiliate from Mexico, has been invited to speak about **Population´s Health Transitioning Trend**s at the **Mexico Health Summit** taking place 16th-18th February 2022.

The specific question of her presentation is:

"What are the current disease and population trends shaping the health priorities of Mexico?"

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This year the Dutch Association for Pharmaceutical Medicine (NVFG) celebrates its **60th anniversary** on June 16. In one of the forthcoming issues of IFAPP TODAY they will tell you more about this special event.

Does your member association also have a special celebration or event, please let us know by sending an e-mail to secretariat@ifapp.org.

28 March 2022 - IFAPP House of Delegates Meeting

1:00-2:30 pm CET, 7:00-8:30 am EST, 8:00-9:30 pm JST

THE FLAG

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

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