IFAPP TODAY

The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

THIS ISSUE:

President's New Year Message

Let's remember the best moments of 2023 and carry these experiences forward into 2024.

Dear Colleagues,

It is with great pleasure that I wish you all a Happy New Year full of health, happiness, and success in your personal and professional lives.

In this farewell message for 2023 and welcome to 2024, I would like to emphasise the power of IFAPP's passionate and dedicated efforts towards innovation and new horizons, unlocking new potential for excellence and creating opportunities for more community-driven content and advancements for our members' professional development.

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On 5 December 2023, we reviewed the performance of the Federation at the House of Delegates (HoD) and General Assembly, where we summarised the achievements and challenges of 2023 and the priorities for 2024 and committed to their implementation.
The HoD validated the work and mission of our Working Groups, led by the Scientific Officers of the IFAPP Board, and the mandate of the IFAPP Executive Board members.

On 14 December we also welcomed to the IFAPP Board the new IFAPP Board members elected by the House of Delegates at the above meeting:
Dr Eric Klaver - President Elect, Dr Robert Lins - Scientific Officer and Chair of the External Affairs Working Group, and Assoc. Prof. Joanne Ramsey - Scientific Officer and Chair of the Young Professionals Working Group, as well as the re-elected IFAPP Board members, Anna Jurczynska PhD, IFAPP Board General Secretary, Dr Birka Lehmann, IFAPP Scientific Officer and Chair of the Education and Certification Working Group,
Dr Ghazaleh Gouya, IFAPP Scientific Officer and Chair of the Communication Working Group, Prof. Kotone Matsuyama, IFAPP Scientific Officer and Chair of the Ethics Working Group.

I am also proud to announce the publication of the Springer book "Ethical Innovation for Global Health" in the first half of December 2023, to which IFAPP contributed as a collaborating partner with authors and editor-in-chief from the IFAPP Board & IFAPP Ethics Working Group members.

During my first year as IFAPP President, I realised the importance of professional identity formation for our members, which is a complex and transformative process of internalising the core knowledge, skills, values and beliefs of an IFAPP member, resulting in an individual 'thinking, acting and feeling' as a member of the IFAPP professional community and increasing the impact of the profession.The process of a professional identity formation begins before the first day of health, biomedical or medical school and continues throughout an individual's career.

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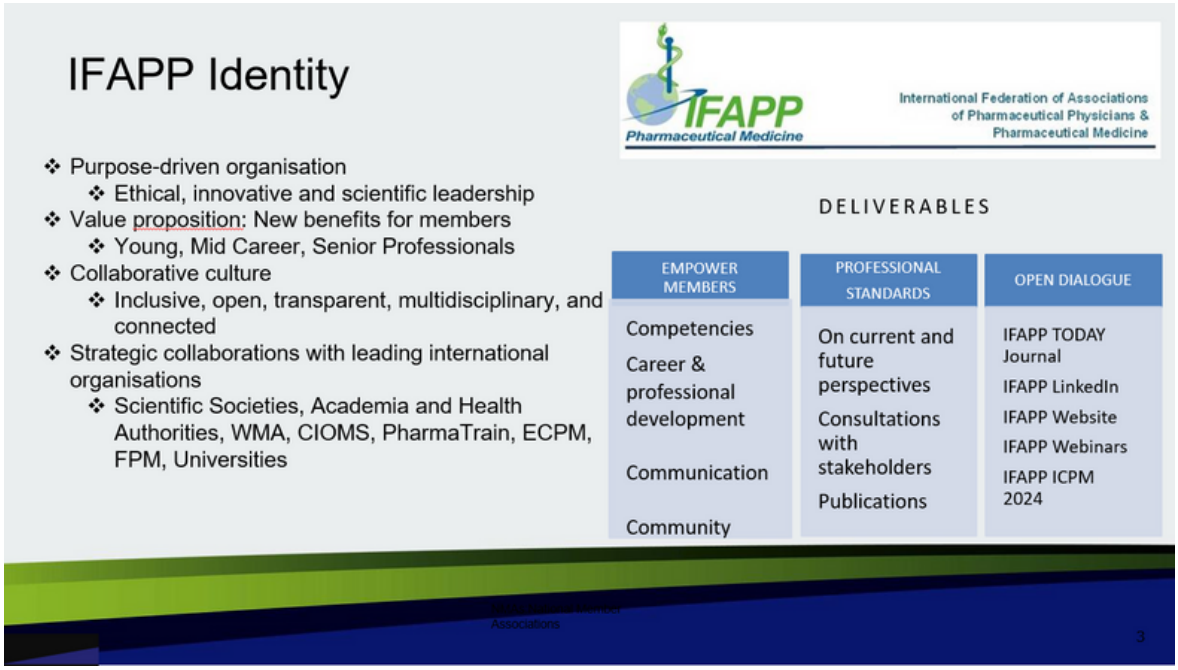

In 2024, I will advocate the priorities and continue to support the innovative projects of the Working Groups with a focus on patient engagement aspects, strengthen IFAPP's commitment to our NMAs and work to attract new NMAs and individual members to the Federation.

My personal flagship remains the professional identity, the next generation of IFAPP leaders, and in particular the growth and development of the IFAPP talent community.

This year, as announced in the December 2023 HoD, we will unfold the 2024 annual series of educational webinars with innovative content, select and award the 2024 IFAPP Fellows, hold the 21st IFAPP International Conference on Pharmaceutical Medicine (ICPM) in Amsterdam next September and I will work closely with Eric Klaver to prepare for a smooth succession.

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I am confident that in 2024 with the bundle of wit, resilience, dedication and team spirit of the IFAPP Board, we will meet the challenges and do all we can with the IFAPP community to achieve the future-proof growth and successful modernisation reform of IFAPP.

Let us join hands and continue to improve the talent cultivation, scientific rigour, and moral spirit of pharmaceutical medicine professionals.

My best wishes and sincere appreciation to all IFAPP Board Members, IFAPP Working Group Members, NMAs, IAs, esteemed stakeholders and supporters from various organisations.

Dr Varvara Baroutsou

Varvara Baroutsou

IFAPP President

Discover the Future of Digital Health in Africa

// Digital Health Africa 2024

… offers the conference with the theme «Discover the Future of Digital Health in Africa" that will take place on 23-24 February 2024 at the Biomedical Research Institute of Stellenbosch University in Cape Town, South Africa. You can join virtually or in person.
This is an international conference hosted by Fundisa African Academy for Medicines Development, Stellenbosch University (School for Data Sciences and Computational Thinking and Division of Clinical Pharmacology) and Pharmacometrics Africa.

The conference will offer an overview of recent advancements in digital health, telemedicine, and artificial intelligence within Africa's healthcare sector and their transformative potential on the future of healthcare in Africa. This event is designed to be a dynamic forum for collaboration and networking among local stakeholders and international partners to promote knowledge exchange and mutual growth (https://www.fundisa-academy.com/).

Here is the link to register: https://digitalhealthafrica.org/. Sponsorship opportunities are also available on the website.

Author: **Prof. em. (Stellenbosch University) Dr. med. Bernd Rosenkranz, FFPM**
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Summary of the 28th Swiss Annual Symposium in Pharmaceutical Medicine on 29th November 2023

Optimising Patient Engagement and Ensuring Access to Treatment

On 29th November 2023 the 28th Swiss Annual Symposium in Pharmaceutical Medicine took place at the Musikschule Florhof in Zurich organised by members of the Swiss societies SwAPP (Annette Mollet, ECPM) and SGPM (Brigitte Franke-Bray, Raoul Giger, Sanofi, and Martin Traber, Roche). The symposium focused on optimising patient engagement and ensuring access to treatment.

The morning session was chaired by Alexandra Kundert from Pfizer, while the afternoon session was chaired by Jean-Marc Hoffmann from the Clinical Trial Center at the University Hospital Zurich.

Welcome Addresses

The symposium began with a welcome speech from **Martin Traber, SGPM President**, followed by a presentation from **Birka Lehmann, Chair of IFAPP's Working Group on Education and Certification**, who gave an update on IFAPP's recent activities. Birka Lehmann highlighted the 2023 webinars that were delivered successfully and gave an outlook on 2024 webinars as well as on IFAPP's engagement in Ethics, the monthly journal IFAPP TODAY, and IFAPP's participation in the WMA, CIOMS and ICH. **Brigitte Franke-Bray, SGPM Board Member**, conveyed the welcome message from the German association DGPharMed which was planned to be given by Klaus-Gustav Beinhauer, its President-elect, absent due to illness.

Presentation Highlights

Ingrid Klingmann, PharmaTrain President and EFGCP Chairwoman, gave the **Keynote Lecture** on ***"Patient Involvement in Medicines Development - Progress and Gaps"*** with a focus on EUPATI (eupati.eu), the European Patients' Academy on Therapeutic Innovation, a public private partnership which had been founded as an IMI (EU Innovative Medicines Initiative) project in 2011.

The EUPATI Strategy tackled the unmet need of patients and the public for information on therapeutic innovation. EUPATI developed education options targeted at different knowledge levels, e.g. an EUPATI Patient Experts Training Course, the EUPATI Educational Toolbox plus the Internet library for patient advocates and the public.

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From 2016 to 2020 over two hundred graduates from 196 countries and 197 disease areas completed the 14-month training course. Since 2021 there has also been an online, open access course with the EUPATI Open Classroom. About 25 % of the participants also applied for the certificate to become a EUPATI Fellow. The involvement of the EUPATI Fellows and trainees is evidenced in R&D projects, with regulators, ethics committees, academia and industry. EUPATI national platforms have now been established in 25 European countries and in Japan. Several hundred EUPATI Fellows in Europe are available and keen to contribute and there are also first EUPATI Fellows in USA, Canada, India, Japan, Korea, Singapore, and South Africa.

There is now awareness of the benefits of patient involvement in the pharmaceutical industry (sadly, less so far in the medical device industry), in competent authorities, in medical development funding bodies, in professional societies involved in therapeutic innovation, and in academia. Unfortunately, and this is one of the gaps, the EU Clinical Trials Regulation (negotiated in 2012-2014 and launched in 2022) does not make patient involvement mandatory but just mentions that the patient voice should be taken into consideration by ethics committees.

Additionally, there is limited expertise in academia, ethics committees, regulatory authorities and HTA bodies on how to make best use of patient input. There is still a lot to do and much more public awareness of the importance and benefits of patient involvement in the development of new therapeutic options needs to be raised.

Annette Magnin, Managing Director of the Cantonal Ethics Committee KEK Zurich, talked about "Informed Consent – View of an Ethics Committee".

Annette Magnin presented the origins of informed consent (e.g., the Belmont Report, the Nuremberg Code, the Declaration of Helsinki, the Swiss Federal Act on Research Involving Human Beings, the Swiss Ordinance on Clinical Trials, the ICH E6 Guideline for Good Clinical Practice, Ethics Committees/Institutional Review Boards) and she pointed out that ICH E6 clearly says that the informed consent procedure is an investigator responsibility.

The Swiss Human Research Act, Art. 53 1b, outlines that Swiss Ethics Committees (ECs) should have at least one person representing patients. All Swiss ECs have more than one member with this function. The new permanent swissethics (Swiss association of research ethics committees) working group for patient representation in the Swiss ethical review processes in clinical research has been established with the aim to better coordinate and harmonise patient involvement in the ethical review of clinical trials, as well as in the review of clinical research projects in general and Participant Information/Informed Consent in particular. Annette Magnin also addressed the patients' needs for simple/lay language and short but concise explanations of clinical trials. Vulnerable groups such as minors/children, prisoners, pregnant women, foetuses, elderly, migrants, people with reading impairment, mentally disabled persons, and economically and educationally disadvantaged persons, etc. must also be considered as well as emergency situations.

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Finally, Annette Magnin referred to the revision of ICH E6 and the upcoming revision of the Swiss Human Research Act.

Ivo Schauwecker, President EUPATI Switzerland, and Barbara Peters, Clinical Research Department, University of Basel, Switzerland, together gave the presentation "Enabling Patients to Get Involved".

Ivo Schauwecker talked about his own background when he was a study patient, how he became involved with patient engagement through EUPATI and then also became an activist.
Barbara Peters took over from Ivo Schauwecker and addressed first EUPATI in general but then focused on the Swiss EUPATI association and how country-specific material to educate patients was developed. The first Swiss patient expert course was initiated in 2023, a blended learning course, both online and in the classroom. Participants were and are highly motivated and open to become involved. The 2024 course is already fully booked.
Funding and support have been secured by the Swiss National Science Foundation, the Swiss Academy of Medical Sciences, through donations of fees by the Department of Clinical Research Basel (DKF), Hoffmann-La Roche, the Swiss Clinical Trial Organisation (SCTO), EUPATI CH, and the Swiss Group of Clinical Cancer Research (SAKK).

Christine Aeschlimann, Program Manager SAKK Patient Advisory Board, Switzerland, spoke next about "The SAKK Patient Advisory Board – Lessons Learned".

The SAKK (1), a non-profit organisation, was founded in 1965 by oncologists, 22 hospitals are members. There are 21 research groups and 80 % of all cancer patients in Switzerland are reachable for multicentric investigator-initiated clinical trials. The SAKK patient advisory board started in 2015 as a pilot project and has been a regular organ since 2017. There are five women and five men, three below and seven above the age of 50. Their background lies in a relation to a patient organisation or is in research or medicine or they are EUPATI Fellows or willing to get a formal education. Continuous education is offered (500 CHF/year).
There is coordination by a SAKK employee with 5-6 meetings per year, also 1-2 educational sessions. Support is provided by SERI (Swiss State Secretariat for Education, Research and Innovation), the Swiss Cancer Research and the Rising Tide Foundation for Clinical Cancer Research. A foundation of mutual trust and respect has been established and there are regular exchanges with PPI (2) groups in Switzerland and abroad. The SAKK patient advisory board is part of the working group of SCTO (3) on PPI.
The «out of the box» thinking of patient experts for a contact and competence centre such as SAKK is very valuable for an expert organisation like SAKK. Patient involvement is a cultural change. Best is to involve the patient experts at the beginning of a project, when there is still room for manoeuvre. Young oncologists will be educated on how to include patient views in their research and politicians need to be approached together with patient organisations.

1 SAKK: Schweizerische Arbeitsgemeinschaft für Klinische Krebsforschung (Swiss working group on clinical cancer research)
2 PPI: Patient and Public Involvement
3 SCTO: Swiss Clinical Trial Organisation

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(Source: C. Aeschlimann and LinkedIn)

Kerstin Breithaupt-Groegler, -kbr- clinical pharmacology services, Frankfurt/Main, Germany, then spoke about "Good Lay Summary Practice (GLSP) – How to clearly communicate research results".

Lay summaries address the general public, patients, trial participants and people without prior knowledge of a trial, medical terminology or clinical research. The EU Clinical Trials Regulation (EU-CTR) 536/2014 calls for a "summary of clinical trials results in a format understandable for lay persons", the EU CTR Annex V sets out 10 elements that must be addressed in a lay summary, and it is mandatory for all clinical trials falling under the EU-CTR, i.e., trials that received the Clinical Trial Authorisation after 31 Jan 2023.
The EU Expert Group (2018) developed recommendations regarding the content of the 10 elements as well as literacy/numeracy principles. There is a Questions and Answers document for EU CTR 536/2014. The Good Lay Summary Practice (endorsed by EMA in 2022) was developed by a multistakeholder group including EU and US pharmaceutical companies, CROs, academic institutions, patient organisations, and not-for-profit organisations.
The lay language principles outline the use of short words, sentences, and paragraphs, the use of active rather than passive voice. Technical or scientific language must not be used. Present medical terms should be in brackets. Furthermore, neutral, non-promotional language should be used, and statistical terms must be avoided. One should be respectful in language and apply cultural sensitivity. Latin expressions must not be used.
The patients' native language is an important element of fair access to information. As a minimum, the lay summary should be provided in the languages of the countries where the trials took place, matching the languages used in the Informed Consent Form.
Sponsors must upload the Lay Summary to the EU Database via the EU Portal Clinical Trials Information System (CTIS). There must also be access to the Lay Summaries via sponsor-hosted websites. Lay Summaries may increase the visibility of research in the general public, may help to build public trust in researchers and their work. GLSP und EU-Expert Group Recommendations provide important practical guidance. The take-home message is to enable users to understand texts in plain language the first time they are read or heard of.

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Thomas Wiese, F. Hoffmann-La Roche, Basel, Switzerland, gave the following presentation on "Decentralised Clinical Trials – Adapting to Patients' Needs".

Decentralised Clinical Trials (DCTs) mean a shift of clinical trial activities closer to the patients which is enabled by a constellation of evolving technologies such as electronic consent, tele-healthcare, remote patient monitoring and data capture, electronic clinical outcomes, etc. It allows investigators to maintain links to trial participants without in-person visits.

The COVID-19 pandemic catalysed the adoption of decentralised clinical trials as patients' access to trial sites was reduced by 80 percent and because about 70 percent of potential participants live more than two hours from trial sites.

DCTs increase the flexibility and adaptability of recruiting patients which is echoed in recent FDA/ICH E6 R3 guidelines and the Swissmedic position paper to enable greater diversity in clinical trials through changes to eligibility criteria, enrolment practice, and trial design. There will be less frequent study visits and shorter visit durations. Expert telemedicine raters can perform clinical interviews and assessments.

The application of DCTs must be considered on a case-by-case basis. Early and in-depth collaboration with regulators, investigators as well as patient representatives is mandatory.

The level of decentralisation is due to a country's legal or healthcare operating model, the therapeutic area, the stage of development (Phase I-IV) and the molecule's benefit /risk profile.

Lembit Rago, Council for International Organizations of Medical Sciences (CIOMS), Geneva, Switzerland, then spoke about "Patient Involvement in the Development, Regulation and Safe Use of Medicines (CIOMS WG XI Report).

CIOMS was founded in 1949 by WHO and UNESCO, is in official relations with WHO and an associate partner of UNESCO and has been an ICH Observer since 2016. The main areas of work lie in Bioethics, Pharmacovigilance and Product Development. CIOMS has many ongoing working groups and the working group (WG) on patient involvement started in 2018 and published their report in 2022.

Its objective is to discuss the benefits of patient involvement during the whole life cycle of a medicine, from early development through regulatory processes and post-marketing use until (potential) retirement. The WG's composition is International, with involvement of patient representatives, regulators (including EMA, US FDA), industry, academia and various international/national organisations including WHO. All full WG meeting minutes are made public, public meetings are organised for input, and there is public consultation of the final text with a structured analysis and use of comments.

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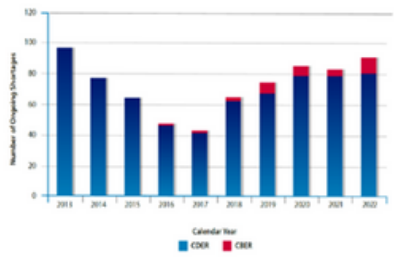
The publication is a 'public good' – an open access online publication. The patient voice offers a valuable perspective throughout the development of a medicine. It should be fully incorporated into the decision-making process. Patients have expert knowledge and understanding of their diseases and conditions. This means they have equal credibility as those who are scientific and medical experts. The CIOMS WG report is unique in several ways. With its 11 chapters it is very comprehensive, has used the medicine life-cycle approach and contains several case studies.

Stefan Muehlebach, University of Basel, Switzerland, gave a presentation on **"Coping with Drug Shortages: A Swiss Perspective."**

Drug shortage is a global trend and refers to all forms of medicines. The drug shortage trend has been long-lasting for several years, both in the USA (example Figure 3) as well as in Europe and other countries.

Figure 3. Number of Annual Ongoing Drug Shortages Per Calendar Year (from CY 2013 to CY 2022).



FDA: Report to the congress July 2023
https://www.fda.gov/.

Elements that determine the impact of medicine shortages on the patients are clinical outcomes, humanistic outcomes and economic outcomes. Involved international organisations are the WHO, the EMA and the FDA. Involved national organisations are the Swiss Federal Office of National Supply (Health Care Products), FONES, which fosters the supply of essential goods, and the Swiss Federal Office of Public Health, FOPH. which provides the legal basis, sets the priorities, and coordinates.

In particular, antibiotics, vaccines and analgesics are concerned by the shortage, which is why the 'Swiss Roundtable for Antibiotics' has been launched. For example, in 2021 and 2022 a total of 50 medicinal products have been withdrawn of which 19 were antibiotics and antimycotics.

Medicine shortages are global but affect nationally. The number and severity for medicine shortages are increasing. The security of supply is jeopardised by withdrawals (vaccines, antibiotics, and basic (old) cancer drugs. The national database for systematic overview needs to be expanded (monitoring, comparison, analyses, international exchange). Compulsory stockpiling assists and must evolve.

Francis P. Crawley, Good Clinical Practice Alliance - Europe (GCPA), Leuven, Belgium gave the final talk on **Developing Situationally Adaptive Approaches for Clinical Research in Addressing Crisis Situations, e.g. COVID-19, the Ukraine Conflict.**

COVID-19 provided a new context for clinical trials. The pandemic was the first crisis affecting clinical trials globally. It was a shock to how clinical trials were conducted, data collected and shared, and to how pharmacovigilance and results were reported.

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The Ukraine Clinical Research Support Initiative (UCRSI) developed the following objectives: Development of a structured ongoing situational analysis of the current clinical trials in Ukraine; establishment of reliable communication and information channels; provision of support information for displaced clinical trial participants, personnel, and scholars; development of specific guidance for addressing clinical trials during and following wartime: Good Clinical Practice Guidance; Ethics Review Guidance; planning for the reconstruction of Ukraine's and the region's clinical trial infrastructure/enterprise following the ending of the war.

To increase awareness of the importance of and need for continuity of the clinical research enterprise in Ukraine outcomes were formulated, i.e., building tools for the clinical trials community in disruptive situations, working directly with patients, academics, industry, regulatory authorities, and data/ tissue banks to provide a voice for clinical trials, a voice for patients, a voice for researchers.

Francis Crawley pointed out the method of "Adaptive Design" for clinical trials, a design that allows modifications to the trial and/or statistical procedures of the trial after its initiation without undermining its validity and integrity. "Adaptive design" models for clinical trials need to be redesigned such that they are also fit for purpose for war, crisis, and disaster situations, sometimes including go/no-go decision algorithms in extremely difficult situations. In cases where study protocols are fundamentally disrupted, adaptive design should mean adapting to the needs of the study participants, not abandoning the participants, not abandoning the health intervention, not abandoning the science.

There are two important documents that have recently been generated: 1 'Clinical Study Report Considerations for Studies Disrupted by the COVID-19 Pandemic' (TransCelerate) and 'Points to consider when developing a Clinical Study Report for a clinical trial that has been disrupted due to unforeseen circumstances' (ACRO and TransCelerate).

Here you can find a short video giving a brief overview on all the speakers.

Authors: **Dr Brigitte Franke-Bray***, **Dr Raoul-Dominique Giger***, **Dr Annette Mollet****, **Dr Martin Traber*** (*SGPM/**SwAPP), 2023 Swiss Annual Symposium Organising Committee

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Successful Completion of the First EUPATI CH Course on Patient Involvement in Clinical Research

Twenty-three graduates completed the eight-month training course on 1st December 2023.

The Department of Clinical Research at the University of Basel developed and implemented this course for patients and relatives who wished to participate in clinical research in collaboration with EUPATI CH.

The course can undoubtedly be considered a success. Over the past few months, the participants have acquired specific knowledge about how the research process works and where they can make an effective contribution. Great emphasis was placed on practical relevance. In addition to pure knowledge transfer, a number of best practice examples from various institutions were presented - mostly by patient representatives.

Just as important was the exchange within the group and with the researchers. The opportunity to meet and discuss regularly was seen as enriching. The project was funded by the Swiss National Science Foundation (SNSF) and the Swiss Academy of Medical Sciences (SAMS).

We congratulate the participants of the first course, and we are proud to welcome 23 new patient experts to EUPATI CH 👏.

Expansion of the course offer

The experience gained from the first round of courses and participants' feedback is being incorporated into the plans for 2024. The next round of courses will start in the first half of the year. To provide even more people with a low-threshold offer, the online courses will also be available as stand-alone courses in a slightly modified form. This means that interested parties can first explore the topic independently and then join the entire course if they are interested. These stand-alone courses will also be offered in French and Italian.

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AMIFE Talks about Precision Medicine on its Congress

The XV National Congress of AMIFE entitled “Collaboration as the Engine of Innovation” was held in Madrid on 22 and 23 November and it gathered around 150 experts.
The Medical Director of the Oncology Division of Palex Medical and coordinator of the Precision Medicine Working Group of the Pharmaceutical Industry Medicine Association (AMIFE), Dr Carlos Hagen, highlighted the need to create a stable framework for public-private collaboration to be able to face the challenges of Precision Medicine during this decade.

"Precision Medicine has entered a phase of exponential growth and, presumably, by the end of the decade, this type of medicine will generate a global value of between 150,000 and 200,000 million dollars. We cannot afford to miss this train ", indicated Dr Hagen.

"The professionals gathered at the congress want to highlight the importance of joint work between the pharmaceutical industry, public administrations, regulatory bodies, universities and research centres and patients for the development of innovative solutions that address present and future diseases, as is precisely the challenge of Precision Medicine. It is very important to work in a coordinated manner with the group of agents that we participate in to face these disruptive changes and not to lose competitiveness compared to other markets such as the United States or Asia," indicated Dr Susana Gomez-Lus, Medical Director at Lundbeck and President of AMIFE.

In this sense, Dr Hagen assured that Europe lost 25 % of investment in R&D since 2001 with respect to the United States. "In that same period of time we have gone from an investment gap in R&D of 2,000 million in 2001 to more than 20,000 million," indicated Dr Hagen, who added that "we do not have an optimised environment for the effective incorporation of the new technologies that are already being made available to health systems. Nor do we have a context that allows us the standardised review of the evidence or agile access to medications, advanced therapies or cutting-edge technologies such as liquid biopsy, artificial intelligence or clinical genomics".
For this reason, the expert considers that the reference framework must be updated and replaced with a new, more integrated model in which the private innovative sector can participate from the beginning, in a similar way to what the Nordic countries are doing.

THE CHALLENGES OF GENERATIVE AI

Dr Julio Mayol, Head of Surgery Department, Hospital San Carlos (Madrid) explained in his presentation 'Is generative AI going to leave us out of work?' that there is a before and

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after of Generative Artificial Intelligence (AI) in health. "Until now, Artificial Intelligence was predictive, responding to patterns, however, Generative Artificial Intelligence is designed to create new results. In this way, AI will help create a healthcare model based on the '5 Ps': Predictive, preventive, participatory, personalised, and population-based. It is necessary to build a new model of collaboration between political leaders and those responsible for technology to design the health services of the future."

Likewise, Dr Mayol highlighted the need that in this new model to be built, the agents also create control bodies for the application of AI in health and wonders if there is currently leadership in the society to prepare it for these disruptive changes. "Generative Artificial Intelligence is like atomic energy; depending on how it is used, it can be beneficial for the society or destructive," he concluded.

Author: Anna Jurczynska, PhD, IFAPP General Secretary

AI in Pharmacovigilance - Report from the IFAPP Webinar on 30 November 2023

Sriram Venkateswaran, Senior Safety Data Scientist (Safety Data Science || Safety Analytics and Reporting Safety and Risk Management, Product Development F. Hoffmann-La Roche Ltd) gave an excellent and lively presentation on the topic 'AI in Pharmacovigilance, Empowerment through Automation'.

He opened his presentation by giving an overview of different kinds of topics which have to be taken into account when talking about AI.

	Intake	Case Management	Submissions & Periodics	Signal Management	Safety Surveillance
AI & Machine Learning	• ML based AE Detection • Machine translation • NLP based case extraction • Speech to text AE detection	• Touchless case processing • AI Based causality • AI based MedDRA and product coding	• NLG based Periodics report generation	• Neural signal detection (Predictive signalling) • Deep learning to identify safety signals	• AI based literature article classification • Social media screening
Engineered Algorithms	• Fuzzy & deterministic Duplicate search • Process mining	• AEs for Special situations • Process mining	• Smart Periodics schedules	• Reduce False positives and Signal leaks with enhanced detection algorithms	
Smart Automation	• ICR • Bot assisted Follow-ups • Bot assisted CTV • Bot assisted Contact test	• Case processing rules engine	• Rules based submission • Reconciliation • Smart Periodics schedules	• Smart signal tracking & alerts	• Automated literature searches

He highlighted the importance of Large Language Models as the central tool in the new approaches.

He also mentioned and reflected on the 'Large Language Models'.
What are they? How are they trained?
Large Language models are neural networks trained on large quantities of unlabelled text. LLMs are general purpose which excel at a wide range of tasks, as opposed to being trained for one specific task (such as sentiment analysis, named entity recognition, or mathematical reasoning).

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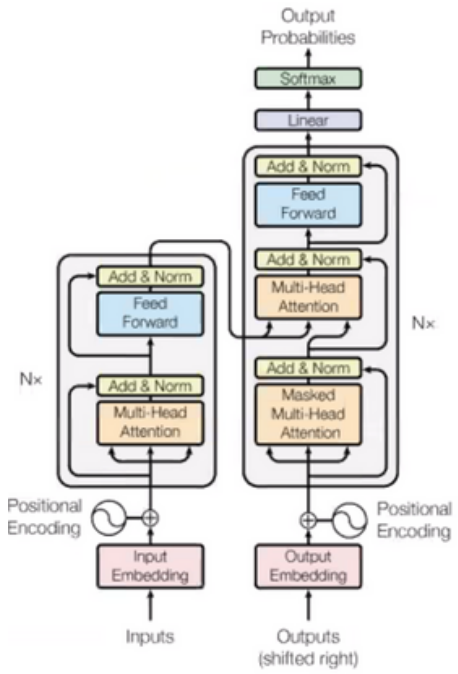
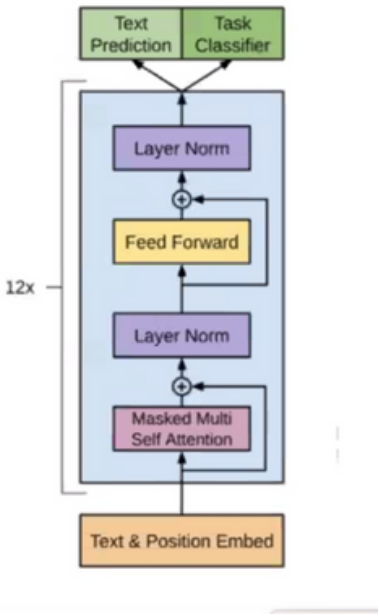
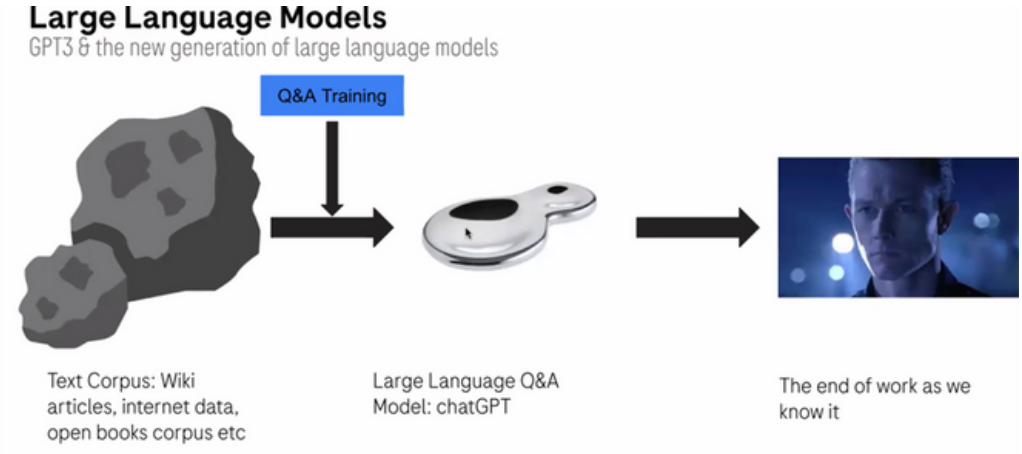
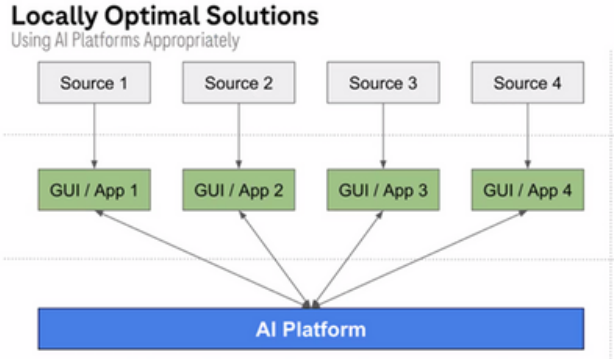




The questions or issues addressed to the systems are depending on the text corps, the quality of the Large Language Model to receive an optimal outcome.



He encouraged and highly recommended to the audience that it is important to use different AI platforms to come to an optimal solution.



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He closed by presenting challenges still ahead in using AI in Pharmacovigilance.

Author:
Birka Lehmann, MD PhD, GFMD, IFAPP Education and Certification Working Group Chair, Senior Expert Drug Regulatory Affairs

Symposium on Antibiotic Resistance

On the 21st of November 2023, Public Health Switzerland and Global Antibiotic Research and Development Partnership (GARDP) commemorated the World AMR (Antimicrobial Resistance) Awareness Week with a symposium at the Kulturcasino Bern. The agenda covered measures to combat AMR in Switzerland and worldwide, achievements thus far, and the persistent challenges.

Insights

The symposium commenced with Carlos Quinto's presentation (Member Board of Directors, Foederatio Medicorum, Helveticorum, FMH), shedding light on the "current situation and practical experience". Quinto underscored Switzerland's relatively low antibiotic consumption and emphasised the critical role of rapid diagnostics labs. He addressed the risks associated with medical tourism in the presence of the strained resource situation in hospitals. Additionally, he highlighted the continued imperative for developing new antibiotics.

Barbara Grützmacher (Cantonal Medical Officer Bern and Vice President of Swiss Association of Cantonal Officers of Health) conveyed the perspective of cantonal doctors, revealing significant heterogeneity in the way how preventive measures are implemented on the cantonal level. Official recommendations exist, but a legal framework on the national level is missing. As the benefits of preventive measures are often not apparent in the short-term, securing funds for prevention remains challenging.

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Providing insights into everyday hospital life, Stephan Harbarth (Director, Department of Infection Prevention and Control, Geneva University Hospitals, HUG) discussed the elevated morbidity, mortality, and costs associated with AMR infections in hospitals. AMR renders the maintenance of "high-quality care standards" difficult and can cause catastrophic outbreaks. Harbarth stressed the value of AMR prevention for both patients and society.

Aligning with Harbarth, Esther Künzli (Swiss TPH) highlighted the increased morbidity, mortality, and substantial costs implied by AMR. Pointing to the multifactorial nature of AMR she advocated for a “One Health” (1) perspective. Künzli underscored the need for improved training, enhanced surveillance, clearer guidelines, and advanced diagnostics on a global scale in human medicine.

Round Table Discussion

The round table discussion was moderated by Andrea Kucera from the NZZ (Neue Zürcher Zeitung), and convened Nora Kronig (Vice Director, Head of the International Affairs Department, FOPH), Peter Beyer (Vice Director GARDP) and Kathrin Huber (Secretary General, Schweizerische Gesundheitsdirektorenkonferenz, GDK; Swiss health directors’ conference).

They discussed the cooperation of the cantons and the FOPH in tackling AMR, with Huber confirming the cantons’ motivation to engage in joint measures. Beyer mentioned the eminent role of prevention in the containment of AMR. However, despite the benefits that prevention measures offer to society, they continue to be met with little enthusiasm. Kronig doubted the chances of success for a new law on prevention measures.

The discussion also covered the challenges posed by AMR in long-term care facilities and the limited resources allocated to care. To address them awareness raising was identified as a key action, with the World AMR Awareness Week considered a smart approach to education.

The observed lack of an adequate stream of new antibiotics led to a debate about the cost of research and insufficient profitability prospects of antibiotic projects. Government support of the pharmaceutical industry was discussed, with Kronig emphasising the need for international collaboration.

Finally, enhanced and novel reward systems incentivising research and development as well as the placing of antibiotics on the market were discussed. The discussion concluded with a call for international agreement of targets and action to reduce AMR, analogous to the blueprint to control the climate crisis.

(1) “One Health” is an integrated, unifying approach to balance and optimise the health of people, animals and the environment (WHO).

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An illustration of the round table discussion with [from left to right] Peter Beyer (Vice Director GARDP), Andrea Kucera (NZZ), Kathrin Huber (Secretary General, GDK) and Nora Kronig (Vice Director, Head of the International Affairs Department, FOPH).

1): https://public-health.ch/de/versteckte-artikel/Antiobiotikaresistenz/)

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GARDP
Global Antibiotic Research & Development Partnership

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"THE FUTURE OF CLINICAL TRIALS, THE PROMISE OF AI AND KEY TRENDS"

Webinar

JANUARY | 30th | 2024 | 2:00 PM CET*

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Webinar

IFAPP Pharmaceutical Medicine

The Future of Clinical Trials, the Promise of AI and Key Trends

Future key trends in clinical trials promise to optimise the performance of drug development. The emerging use of generative AI, increased integration of real-world evidence, enhanced patient advocacy, DCT delivery models and a renewed commitment to structured inclusivity, diversity and equity in trial recruitment will be critical to clinical research and cutting-edge technologies that could redefine care for diseases and conditions where treatment options are limited or non-existent.

Speaker:

Dr Varvara (Barbara) Baroutsou
Consultant in Internal Medicine
Pharmaceutical Medicine Consultant
Research & Experimental Development in Medical Sciences Expert
IFAPP President

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*
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